THURSDAY CONCURRENT SESSION #1

S-1.

Effects of risk-reducing oophorectomy for hereditary breast and ovarian cancer syndrome: Depression and anxiety findings from the PROSper study

Carolyn Gibson, PhD, MPH[1,2], John Boscardin[2], Michael Schembri[1], Lee-may Chen[2], Mindy Goldman[2], Leslie Chan[2], Victoria Bae-Jump[3], Rebecca Kaltman[4], Vanessa Jacoby[2]. [1]San Francisco VA Health Care System, San Francisco, CA; [2]University of California San Francisco, San Francisco, CA; [3]University of North Carolina School of Medicine, Chapel Hill, NC; [4]Inova, Falls Church, VA

Objective: Individuals with an identified pathogenic variant in BRCA-1 or -2 (BRCA) are advised to undergo risk-reducing bilateral salpingo-oophorectomy (RRSO) by age 40-45, or after childbearing plans are complete to prevent ovarian cancer. In largely cross-sectional studies, depressive symptoms have been associated with history of oophorectomy. However, mood symptoms and disorders have not been well-examined in patients receiving RRSO following BRCA diagnosis, and limited longitudinal data exists to examine changes before and after RRSO. To address this gap, we sought to determine if RRSO is associated with changes in depressive symptoms and cancer-related anxiety among reproductive-aged individuals with BRCA, compared to those who choose not to undergo surgery. **Design:** Data were drawn from a longitudinal cohort study of premenopausal women with a BRCA diagnosis who do and do not choose to undergo RRSO within one large, urban healthcare system. Depressive symptoms (Beck Depression Inventory [BDI]) and cancer-related anxiety (Multidimensional Impact of Cancer Risk Assessment [MICRA]) were measured at baseline and every 6 months over a 5-year observed period. Adjusted mean BDI and MICRA scores at each study visit were produced with marginal effects models. Mixed-effects multi-level linear regression models were used to examine associations between RRSO and depressive symptoms and cancer-related anxiety over the five-year observed period. Associations between RRSO and each outcome were assessed in separate models. All models were adjusted for age, race/ethnicity, relationship status, history of depression, history of anxiety, baseline scores (BDI or MICRA), and hormone therapy (time-varying covariate). **Results:** In this study sample of 99 participants with a BRCA diagnosis followed over 5 years (mean age 40.56 [SE 4.3] at baseline), 42 chose to undergo RRSO during the study period. Comparison of mean change from baseline at each 6-month interval showed significantly higher BDI scores in those with RRSO relative to those without RRSO at 12, 30, and 36 months after baseline, and no significant differences in MICRA at any individual timepoint. Overall, individuals who chose to undergo RRSO had increased depressive symptoms (Beck β 1.66, 95% CI 0.80-2.51) and decreased cancer-related anxiety (MICRA β -.05, 95% CI -.09 - -.004) over the 5-year period relative to those who did not undergo RRSO, adjusted for age, race/ethnicity, partner status, and menopausal hormone therapy use. **Conclusion:** Among premenopausal individuals with BRCA, undergoing RRSO may be associated with a small increase in depressive symptoms that was not likely to be clinically meaningful. There was also a small overall decrease in cancer-related anxiety. These findings may be beneficial for surgical decision-making in this patient population.

Sources of Funding: This work was supported by the American Cancer Society (VJ). Work was also supported in part by a VA Health Services Research & Delivery Career Development Award (IK2 HX002402) to CJG.

S-2.

Impact of Estrogen Dosing on Cardiovascular Disease Risk Parameters in Women Experiencing Early Menopause due to Bilateral Oophorectomy

Ronee E. Harvey, MD/PhD[1], Sarah E. Baker, PhD[1], Stephanie Faubion, MD, MBA[2,3], Ekta Kapoor[3,4]. [1]Department of Anesthesiology, Mayo Clinic Minnesota, Rochester, MN; [2]Division of General Internal Medicine, Mayo Clinic in Florida, Jacksonville, FL; [3]Center for Women's Health, Mayo Clinic Minnesota, Rochester, MN; [4]Division of General Internal Medicine, Mayo Clinic Minnesota, Rochester, MN

Objective: Women who undergo early menopause (prior to age 46 years) secondary to bilateral oophorectomy experience an abrupt decrease in estrogen and other ovarian hormones, which is associated with an increased risk of cardiovascular disease (CVD). Administration of estrogen therapy (ET) given until the average age of natural menopause partially mitigates this risk. However, it is unclear whether standard dose ET, which is typically titrated to relieve vasomotor symptoms, is adequate to protect against development of CVD. It is not known whether ET titrated to a goal estradiol level characteristic of premenopausal women, performs better with respect to CVD risk reduction. The goal of this study was to compare the effect of standard dose ET versus ET titrated to premenopausal estradiol levels on blood pressure and subclinical CVD risk parameters in women experiencing early menopause due to bilateral oophorectomy. **Design:** We conducted a randomized, open-label trial to study 15 women who underwent bilateral oophorectomy prior to age 46 years. Eight women were treated with standard dose ET that was adjusted to manage their vasomotor symptoms (typically 2 mg oral estradiol or 100 mcg estradiol patch daily); and the other 7 were treated with titrated ET with a goal estradiol of 80-120 pg/ml (the average estradiol level in a premenopausal woman), irrespective of their symptoms. All participants were studied at baseline, and then at 6 and 12 months after the bilateral oophorectomy. At each time point, we assessed peripheral blood pressure and subclinical parameters of CVD (arterial stiffness and blood pressure reactivity to isometric handgrip and cold stress). **Results:** Women who were treated with standard dose ET and women treated with titrated ET did not differ in age (39±5 vs. 39±5 years, respectively; p=0.89). Serum estradiol levels did not change across time (baseline, 6-months, and 12-months); however, serum estradiol levels were lower in women receiving standard dose ET (69.3±46.7, 52.9±32.5, and 81.6±16.4 pg/mL, across time respectively) compared to women receiving titrated ET (98.0±45.0, 179.4±81.1, and 146.9±105.1 pg/mL, across time respectively; group effect p=0.005, time effect p=0.20, interaction p=0.058). Systolic blood pressure did not differ across time or between the two groups: standard group: 120±10, 115±8, and 114±14 mmHg; titrated group: 127±15, 122±19, and 133±18 mmHg (group effect p=0.09, time effect p=0.35, interaction p=0.17). Diastolic blood pressure also did not differ: standard group: 77±5, 71±5, and 71±8 mmHg; titrated group: 80±8, 76±12, and 84±16 mmHg (group effect p=0.12, time effect p=0.07, interaction p=0.07). Arterial stiffness (group effect p=0.54, time effect p=0.29, interaction p=0.94), blood pressure reactivity to isometric handgrip (group effect p=0.47, time effect p=0.86, interaction p=0.20), and blood pressure reactivity to cold stress (group effect p=0.68, time effect p=0.57, interaction p=0.50) did not differ across time or between groups. **Conclusion:** In women experiencing early menopause due to bilateral oophorectomy prior to the age of 46 years, standard dose ET, adjusted to manage vasomotor symptoms, resulted in lower estradiol levels than titrated ET, which resulted in estradiol levels characteristic of the premenopausal stage. Despite the differences in estradiol levels, blood pressure, arterial stiffness, and blood pressure reactivity to isometric handgrip and cold stress were not different in the two ET groups. This could either signify a lack of effect of estradiol dose and level on these parameters, or this could be a result of the short duration of study. Differences in the CVD risk parameters may become apparent in the standard dose ET versus titrated ET group with a longer duration of comparison.

Sources of Funding: AHA 898649, NIH T32 DK07352, K01 HL148144, U54 AG044170 SCORE, and Mayo Clinic Foundation

S-3.

The long-term effects of bilateral oophorectomy on progression of subclinical atherosclerosis in healthy postmenopausal women

Irene J. Chen, Epidemiology[1], Donna Shoupe[2], Naoko Kono[1], Roksana Karim[1,3], Intira Sriprasert[2], Howard N. Hodis[1,3], Wendy J. Mack[1,3]. [1]Population and Public Health Sciences, University of Southern California, Los Angeles, CA; [2]Department of Obstetrics and Gynecology, University of Southern California, Los Angeles, CA; [3]Medicine, Atherosclerosis Research Unit, University of Southern California, Los Angeles, CA

Objective: Multiple cohort studies have reported the deleterious effects of surgical menopause following bilateral oophorectomy on incidence of cardiovascular disease and mortality. However, little is known concerning the effects of bilateral oophorectomy on progression of subclinical atherosclerosis. In this post-trial analysis, we investigated the effects of concurrent hysterectomy and bilateral oophorectomy on the progression of subclinical atherosclerosis measured a median of 14.3 years following the procedure. **Design:** We obtained data from a reproductive history questionnaire at baseline on 590 healthy postmenopausal women who participated in the Early vs. Late Intervention Trial with Estradiol (ELITE). Subclinical atherosclerosis progression, measured as rate of change in carotid artery intima-media thickness (CIMT) was determined at baseline and every 6 months over a median trial follow-up of 4.8 years following randomization to hormone therapy (HT) or placebo. We used mixed-effects linear models to assess whether postmenopausal women who had undergone hysterectomy and bilateral oophorectomy had a different CIMT progression than postmenopausal women who experienced natural menopause after adjusting for age and treatment assignment (HT, placebo). We also evaluated whether the effects of bilateral oophorectomy on CIMT progression differed by age at oophorectomy or number of years since oophorectomy. **Results:** Among 590 postmenopausal women included in the analyses, 79 (13.4%) underwent concurrent hysterectomy and bilateral oophorectomy with a median (range) of 14.3 (0.5, 38.8) years prior to randomization to the trial. Compared with women with intact ovaries, women who underwent bilateral oophorectomy had significantly higher plasma total triglyceride levels (p=0.003) and lower plasma testosterone levels (p=0.009). The CIMT progression rate in bilaterally oophorectomized women was 2.2 μm per year greater than in postmenopausal women who experienced natural menopause, but the difference was not statistically significant (p=0.08). The CIMT progression rate was significantly greater in postmenopausal women who were more than 50 years old at the time of bilateral oophorectomy (p=0.014) and in postmenopausal women who underwent bilateral oophorectomy more than 15 years prior to randomization (p=0.015) compared with postmenopausal women who had intact uterus and ovaries. **Conclusion:** Consistent with increased incidence of cardiovascular disease and mortality, hysterectomy with bilateral oophorectomy was associated with increased rate of subclinical atherosclerosis progression relative to natural menopause. The association of subclinical atherosclerosis with bilateral oophorectomy was specifically identified in relation to age and time of oophorectomy in this cohort of healthy postmenopausal women. Further research should continue to examine long-term atherosclerosis outcomes related to oophorectomy.

Sources of Funding: This work was supported by the National Institute on Aging, National Institutes of Health (R01-AG024154 and R01-AG059690).

Estimates of CIMT Progression Rate (μm/year, N=590)

Model 1			Model 2			Model 3		
Variables	Beta (SE)	P	Variables	Beta (SE)	P	Variables	Beta (SE)	P
CIMT progression rate (μm/y)								
Natural menopause	7.5 (0.5)		Natural menopause	7.5 (0.5)		Natural menopause	7.5 (0.5)	
Oophorectomy	9.7 (1.2)	0.08	Oophorectomy ≤50 years old	8.5 (1.4)	0.48	Oophorectomy ≤15 years	7.7 (1.7)	0.86
			Oophorectomy >50 years old	13.4 (2.4)	0.014	Oophorectomy >15 years	11.7 (1.7)	0.015

Beta estimates, standard errors in brackets, are from mixed-effects linear models, adjusted for age and treatment assignment.
P values from the Wald test compare the CIMT progression rate between women with bilateral oophorectomy vs. natural menopause.

S-4.

Circulating lipid response to an experimental model of menopause that involves induction of sleep fragmentation and hypoestrogenism in women

Leilah K. Grant, PhD[1,2], Aviva Cohn[1,2], Sybil Crawford[3], Jessica Harder[1,2], Margo D. Nathan[1,2], Irene Gonsalvez[1,2], Tianyu Luo[1,2], Ellexa Menezes[1,2], Anna Joseph[1,2], Mathena Abramson[1,2], Ancella Roy[1,2], Aleta Wiley[1,2], Frank F. Scheer[1,2], Elizabeth B. Klerman[4,2], Ursula B. Kaiser[1,2], Shadab A. Rahman[1,2], Hadine Joffe[1,2]. [1]Brigham and Women's Hospital, Boston, MA; [2]Harvard Medical School, Boston, MA; [3]University of Massachusetts Chan Medical School, Worcester, MA; [4]Massachusetts General Hospital, Boston, MA

Objective: Across the menopause transition, there is a sharp increase in circulating lipids including total cholesterol (TC), high-density lipoprotein-cholesterol (HDL-C), low-density lipoprotein-cholesterol (LDL-C) and triglyceride (TG). While the decline of estradiol (E2) has been implicated in the adverse lipid changes in midlife women, it remains difficult to isolate the effects of the parallel changes in the endocrine milieu, chronological age, and other potential contributing factors such as vasomotor symptoms (VMS) and sleep. As the primary predictor of menopause-related sleep interruption, VMS have been independently associated with dyslipidemia, but menopause-pattern sleep fragmentation (increased awakenings but no change in overall sleep duration) has not been investigated in relation to lipid changes. We therefore investigated whether sleep fragmentation and estradiol (E2) withdrawal via pharmacological E2 suppression contribute independently to adverse changes in circulating lipids using an experimental model of menopause in premenopausal women to remove the confound of age. **Design:** We studied 27 premenopausal women (age mean±SD = 28.4±5.6 years; BMI = 25.3±4.2 kg/m^2) during two 6-day inpatient stays done in the mid-to-late follicular phase (estrogenized; E2 = 48.7±29.5 pg/mL) and following leuprolide-induced hypo-estrogenism (E2 = 7.5±5.9 pg/mL). Each admission involved two nights of unfragmented sleep [8-h time-in-bed (TIB)] followed by three nights of sleep fragmented by auditory stimuli distributed across the night, producing 1 hour of wake after sleep onset while maintaining equal sleep opportunity (9-h TIB). Fasting lipids were assessed after 2 nights of unfragmented sleep and again after 3 nights of sleep fragmentation during both inpatient stays. The effect of sleep fragmentation, E2 state and their interaction was assessed using linear mixed models. The within-person changes from the estrogenized to hypo-estrogenized state were compared between unfragmented and fragmented sleep using paired t-tests. **Results:** Fasting levels of TC (p<0.001), HDL-C (p<0.01), LDL-C (p<0.05) and TG (p<0.01) were significantly higher when women were hypo-estrogenized compared to the estrogenized state. Combining the data from unfragmented and fragmented sleep, values of TC, HDL-C, LDL-C and TG were 156.7, 59.2, 82.0 and 79.0 mg/dL, respectively, in the estrogenized state, and 167.6, 63.0, 87.4 and 88.1 mg/dL, respectively, in the hypo-estrogenized state. Analysis of within-person change between the estrogenized and hypo-estrogenized states showed a percentage increase in lipid levels of 7%, 7%, 6% and 13% for TC, HDL-C, LDL-C and TG, respectively. There was no effect of sleep fragmentation or an interaction between E2 state and sleep fragmentation on any of the lipids. Consistent with the mixed effects analysis, the within-person change in lipids levels between E2 states did not differ by sleep condition. **Conclusion:** Recapitulating menopause-related E2 withdrawal using pharmacological E2 suppression significantly increased circulating lipids. The magnitude of these changes in premenopausal women was similar to that observed in midlife women during the menopause transition suggesting that menopause-related hyperlipidemia is at least in part due to hypoestrogenism. While there was no effect of sleep fragmentation, future analyses will examine the role of the presence and severity of VMS following E2 suppression on circulating lipid levels.
Sources of Funding: This work was supported by the NIH 5R01 AG053838 (HJ).

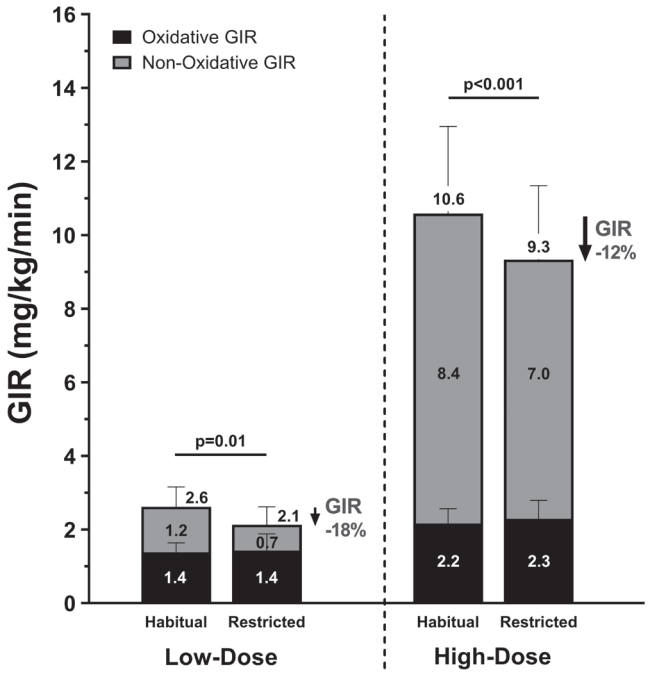
S-5.

Effect of sleep restriction on insulin sensitivity and energy metabolism in postmenopausal women

Prachi Singh[2], Robbie Beyl[2], Jacqueline M. Stephens[1], Robert C. Noland[2], Allison J. Richard[2], Anik Boudreau[2], Josiane L. Broussard[3], Marie-Pierre St-Onge[4], Kara L. Marlatt, PhD, MPH[2]. [1]Basic Science, Pennington Biomedical Research Center, Baton Rouge, LA; [2]Pennington Biomedical Research Center, Baton Rouge, LA; [3]Colorado State University, Fort Collins, CO; [4]Columbia University Irving Medical Center, New York, NY

Objective: Sleep disruption is a primary reason why menopausal women seek medical care. Detrimental changes in metabolism also occur during menopause (e.g., increased abdominal fat, reduced insulin sensitivity). Yet, few studies have investigated how sleep disruption contributes to these unfavorable changes in metabolism. Our study investigated the effect of sleep restriction on insulin sensitivity and energy metabolism in postmenopausal women. **Design:** Postmenopausal women (BMI 25-35 kg/m^2) with ≥7 h of habitual nightly sleep were randomized to a crossover of 4 nights of *habitual sleep* (100% normal sleep) and *sleep restriction* (60% normal sleep) with a 3-week washout. Eucaloric meals were consumed. Assessments after each sleep period included: (1) insulin sensitivity by hyperinsulinemic-euglycemic clamp, defined as the glucose infusion rate (GIR) at low-dose (10 mIU/min/m^2) and high-dose (80 mIU/min/m^2) insulin infusions; and (2) resting energy expenditure (REE), respiratory exchange ratio (RER), and substate oxidation by indirect calorimetry. **Results:** Ten postmenopausal women (ages 58±5 y, BMI 27.9±2.4 kg/m^2) completed the study. Women slept 446±41 min during habitual *vs* 280±22 min during restricted sleep. Compared to habitual sleep, sleep restriction significantly reduced low-dose GIR by 18% (p=0.01) and high-dose GIR by 12% (p<0.001) (**Fig 1**). Non-oxidative GIR was also significantly reduced with sleep restriction by 37% at low-dose and 16% at high-dose insulin infusions (p<0.01). No differences in substrate oxidation, REE, or RER were observed. **Conclusion:** Four nights of sleep restriction reduced insulin sensitivity and non-oxidative GIR in postmenopausal women. Future studies are needed to uncover how sleep disruption alters metabolism during menopause.
Sources of Funding: R01DK125653; R35HL155670; K01DK128227; U54GM104940; P30DK072476.

Fig 1. Difference in Insulin Sensitivity with Sleep Restriction



S-6.

The association between diabetes type, age of onset, and age at natural menopause: a retrospective cohort study using the Canadian Longitudinal Study on Aging

Vrati Mehra, MD[1,2], Christy Costanian, PhD[4], Hugh McCague[3], Michael Riddell, PhD[2], Hala Tamim, PhD[2]. [1]Faculty of Medicine, University of Toronto Temerty Faculty of Medicine, Toronto, ON, Canada; [2]Faculty of Health, York University, Toronto, ON, Canada; [3]Institute for Social Research, York University, Toronto, ON, Canada; [4]School of Medicine, Lebanese American University, Beirut, Lebanon

Objective: Over the past few decades, the incidence of type 1 diabetes (T1D), type 2 diabetes (T2D) and gestational diabetes (GD) has grown steadily across the globe among all age groups. As a result, more women than ever before are expected to spend a larger proportion of their reproductive years living with a diabetes diagnosis. While most studies have looked at the association between ANM and diabetes cross-sectionally or have studied the risk of developing diabetes post menopause, few studies have examined the inverse - the role of pre-menopausal diabetes and its association with ANM. The aim of the present study was to understand the long-term implications of premenopausal diabetes on women's reproductive health including their age at natural menopause (ANM). **Design:** Baseline data from the comprehensive cohort of the Canadian Longitudinal Study on Aging (CLSA) was used for this analysis. Females who reported having a premenopausal diagnosis of T1D, T2D or GD were considered exposed. The main outcome variable was ANM. Kaplan-Meier cumulative survivorship estimates were used to calculate the median ANM by different diabetes types. Multivariable Cox regression models were used to assess the association between different types of diabetes and ANM while adjusting for various socio-demographic, lifestyle and premenopausal clinical factors. Hazard Ratios (HRs) and 95% confidence intervals were reported.

Interaction between diabetes and hypertension as well as diabetes and BMI were also tested. Finally, a sensitivity analysis was conducted to ensure that those with premature menopause were not skewing the HRs towards early menopause. **Results:** The sample comprised of 11,436 participants, weighted to represent 1,474,412 Canadian females aged 45-85 years. The median ANM was 52 years. After adjusting for ethnicity, education, smoking, and premenopausal factors including gravidity among other covariates, early age of diagnosis of both T1D (<30 years) and T2D (30-39 years) were associated with earlier menopause (T1D<30: HR = 1.55, 95% CI 1.05-2.29 and T2D 30-39: (HR=1.82; 95% CI: 1.12- 2.95), as compared with non-diabetics. Additionally, later age of diagnosis of T2D diabetes (>50 years) was associated with later age at natural menopause (T2D: HR= 0.39, 95% CI 0.27-0.56). No significant association between GD and ANM was noted. **Conclusion:** Our results point to accelerated ovarian aging and early menopause among young women living with a diabetes diagnosis. These findings should allow for more focused research geared towards understanding the long-term health implications of diabetes on women's reproductive health and aging.

Sources of Funding: VM has received the CIHR Canada Graduate Scholarship and Ontario Graduate Scholarship.

THURSDAY CONCURRENT SESSION #2

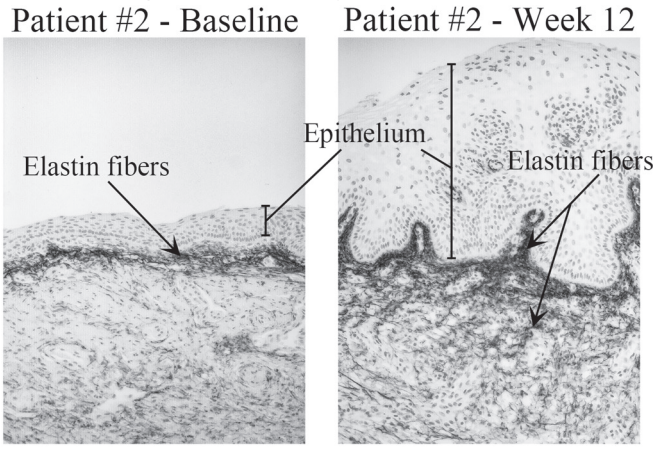
S-7.

Beneficial Effects of Vaginal Prasterone (DHEA) on the Vaginal Histology of Women with VVA Treated or not with Aromatase Inhibitors: A Breakthrough in the Understanding of the Role of Androgens in Vaginal Health.

Céline Bouchard, MD[2], Johanne Ouellet[1], Marie-Christine Dumas[1], Isabelle Côté[1], Alain Dury, PhD[1]. [1]Endoceutics, Québec, QC, Canada; [2]Clinique de recherche en santé des femmes, Quebec City, QC, Canada

Objective: The vaginal mucosa relies on the constant renewal of its epithelium to remain healthy. Epithelial parabasal cells divide and fill up with glycogen as they get pushed towards the vaginal lumen. They end up desquamating and releasing glycogen for the resident lactobacilli to feed on and acidify the medium. The stimulation required for this quintessential mechanism to go on has historically been attributed to estrogens, however, growing clinical evidence supports that androgens may play a role. Aromatase inhibitors (AI) are used in breast cancer survivors to inhibit the synthesis of estrogens. Administering a steroid precursor such as prasterone (DHEA) to patients suffering from vulvovaginal atrophy (VVA) and taking AI will therefore only results in local synthesis of androgens, but no estrogens. We set out to compare the histological changes an atrophic vaginal mucosa goes through with prasterone treatment, with and without exclusion of the estrogenic benefits by AI. **Design:** A Wittner punch was used to collect biopsies both before and after 12 weeks of treatment with 6.5 mg intravaginal prasterone daily (Intrarosa®). Upon collection, samples were formalin fixed and paraffin embedded for further processing with various stainings. Six menopausal women suffering from VVA and meeting the inclusion criteria were recruited, as well as two breast cancer survivors on AI. High resolution digital pictures of the vestibule were also taken before and after treatment. **Results:** The degree of epithelial atrophy visible at baseline histology for VVA patients was variable, but all six patients had the histological characteristics of a thick, healthy epithelium by the end of the study. At baseline, both patients on aromatase inhibitors had a very thin, flattened epithelium. Following treatment with prasterone and despite the aromatase inhibitors, the epithelium showed striking histological improvements, regaining thickness, ridges and glycogen synthesis. Elastin staining was mostly limited to a thin subepithelial layer in atrophied vaginal mucosa specimen, whereas it appeared to qualitatively thicken following treatment, with high elastin contents in Rete pegs. **Conclusion:** Data presented here are believed to be the first demonstration of profound beneficial effects of androgens on VVA, independently from estrogens. While further studies are warranted to better understand the respective contributions of androgens and estrogens to the benefits observed with prasterone in the treatment of GSM, the data presented here strongly suggests that androgens play a significant role in the physiopathology of VVA.

Sources of Funding: This trial was funded by Endoceutics.



S-8.

Change in serum estrogens in postmenopausal women using a vaginal estradiol tablet

Caroline M. Mitchell[6,4], Joseph Larson[2], Carolyn Crandall[3], Shalender Bhasin[5,4], Andrea Z. LaCroix[7], Kris Ensrud[8,9], Katherine A. Guthrie[2], Susan Reed, MD, MPH[1]. [1]Obstetrics and Gynecology, University of Washington, Seattle, WA; [2]Public Health Sciences Division, Fred Hutchinson Cancer Research Center, Seattle, WA; [3]Medicine, University of California Los Angeles, Los Angeles, CA; [4]Harvard Medical School, Boston, MA; [5]Medicine, Brigham and Women's Hospital, Boston, MA; [6]Massachusetts General Hospital Vincent Center for Reproductive Biology, Boston, MA; [7]Herbert Wertheim School of Public Health, University of California San Diego, La Jolla, CA; [8]Medicine and Epidemiology and Community Health, Regents of the University of Minnesota, Minneapolis, MN; [9]Center for Care Delivery and Outcomes Research, Minneapolis VA Health Care System, Minneapolis, MN

Objective: Compare the impact of a low dose vaginal estrogen tablet vs. placebo on serum estrogen concentrations in women enrolled in a randomized trial of treatment for genitourinary syndrome of menopause. **Design:** Secondary analysis from the vaginal estradiol tablet + placebo gel or dual placebo arms of the MsFLASH Vaginal Health randomized trial used serum samples from enrollment and week-12 to measure estradiol, estrone and sex hormone binding globulin (SHBG) concentrations by liquid chromatography-tandem mass spectrometry. We compared baseline participant characteristics by tertiles of week-12 values of the three analytes and by those with week-12 estradiol above and below 2.7 pg/mL. **Results:** Participants from estrogen (n = 90) and placebo (n = 87) groups with complete samples were included. Those in the estrogen group were more likely to have higher week-12 serum estradiol (p=0.003). Adjusted for pre-treatment hormone concentrations, age, clinical site and BMI, assignment to the estrogen vs. placebo treatment group was significantly associated with week-12 estradiol in the highest tertile (aOR 2.2, 95% CI 1.06, 4.54). Of note, 121/177 (68%) participants had enrollment serum estradiol values >2.7 pg/mL. Of those starting <2.7 pg/mL, 38.1% (8/21) in the estrogen group and 34.4% (11/32) in the placebo group had estradiol concentrations >2.7 pg/mL after 12 weeks of study participation (p = 0.78). There was no association of treatment assignment with Week 12 estrone or SHBG concentrations. **Conclusion:** Our analysis demonstrates a significant, though small, increase in serum estradiol after 12 weeks of using vaginal estrogen.

Sources of Funding: This study was supported by NIH/NIA (5R01AG048209).

S-9.

Changes in serum endogenous estrogen concentrations are mediators of the effect of low-dose estradiol on vasomotor symptoms

Kris Ensrud[2,3], Joseph Larson[4], Katherine A. Guthrie, PhD[4], Carolyn Crandall[5], Andrea Z. LaCroix[6], Susan Reed, MD, MPH[1], Shalender Bhasin[7,8], Caroline M. Mitchell[9,8], Hadine Joffe[10,8]. [1]Obstetrics and Gynecology, University of Washington, Seattle, WA; [2]Medicine and Division of Epidemiology & Community Health, University of Minnesota Medical School Twin Cities, Minneapolis, MN; [3]Center for Care Delivery & Outcomes Research, Minneapolis VA Health Care System, Minneapolis, MN; [4]Public Health Sciences Division, Fred Hutchinson Cancer Research Center, Seattle, WA; [5]Medicine, University of California Los Angeles, Los Angeles, CA; [6]Family Medicine and Public Health, University of California San Diego, La Jolla, CA; [7]Medicine, Brigham and Women's Hospital, Boston, MA; [8]Harvard Medical School, Boston, MA; [9]Obstetrics and Gynecology, Massachusetts General Hospital, Boston, MA; [10]Psychiatry, Brigham and Women's Hospital, Boston, MA

Objective: To quantify changes in serum total estradiol (E2) and estrone (E1) concentrationswith initiation of low-dose oral estradiol treatment and evaluate whether changes in these concentrations mediate the effect of treatment in reducing vasomotor symptom (VMS) frequency. **Design:** We analyzed baseline and Week 8 (W8) data from 171 perimenopausal and postmenopausal women with VMS enrolled in low-dose 17β estradiol (n=72) and placebo (n=99) groups of a randomized clinical trial. **Results:** From baseline to W8, women in the low-dose estradiol group had a 4-fold increase in E2 resulting in a W8 E2 of 23 pg/mL and a 5-fold increase in E1 resulting in a W8 E1 of 110.7 pg/mL. In contrast, E2 and E1 among women in the placebo group were essentially unchanged from baseline to W8. Changes in E2 and E1 from baseline to W8 met criteria for mediating the effect of low-dose estradiol treatment on VMS frequency. In multiple linear regression analysis performed with treatment assignment and with change in estrogen concentration added to treatment assignment in a regression model predicting W8 VMS frequency, the total effect of treatment with low-dose estradiol vs. placebo was attenuated, with change in E2 representing a 44.1% reduction (p-value 0.03) and change in E1 representing a 69.5% reduction (p-value 0.02) in total intervention effect. **Conclusion:** Among perimenopausal and postmenopausal women with VMS, treatment with low-dose oral estradiol vs. placebo results in 4 to 5-fold increases in serum E2 and E1. The increases in serum E2 and E1 with low-dose oral estradiol treatment appear to mediate in part the effect of treatment in reducing VMS frequency.

Sources of Funding: MsFLASH 03 was supported by a cooperative agreement issued by the National Institute of Aging (NIA), in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD), the National Center for Complementary and Alternative Medicine (NCCAM) and the Office of Research and Women's Health (ORWH), and NIA grants U01AG032656, U01AG032659, U01AG032669, U01AG032682, U01AG032699, and U01AG032700. A funding renewal was provided by NIA grant 5R01AG048209. At the Indiana University site, the project was funded in part with support from the Indiana Clinical and Translational Sciences Institute, funded in part by grant UL1RR025761 from the National Institutes of Health, National Center for Research Resources, Clinical and Translational Sciences Award. Escitalopram and matching placebo pills were provided by Forest Research Institute.

S-10.

Difference in Venous Thromboembolism Risk between Combination 17β-Estradiol/Progesterone (E2/P4) and Conjugated Equine Estrogen/ Medroxyprogesterone Acetate (CEE/MPA) as Assessed by US Claims Data

David F. Archer[2], Mitra Boolell[3], Brian Bernick[1], Shelli Graham, PhD[1]. [1]TherapeuticsMD, Boca Raton, FL; [2]Eastern Virginia Medical School, Norfolk, VA; [3]Theramex HQ UK Limited, London, United Kingdom

Objective: In the Women's Health Initiative study, there was an increased risk of venous thromboembolism (VTE) reported among women treated with CEE/MPA vs placebo[1]. A review of the literature suggests that the use of E2 and P4, in contrast to CEE and MPA, is not associated with an increased risk of VTE and may be associated with a lower risk[2]. The objective of this analysis was to compare VTE risk in menopausal women using two different oral hormone therapy products approved to treat moderate to severe vasomotor symptoms: combination E2/P4 vs CEE/MPA. **Design:** Retrospective analysis of data from women aged ≥ 40 years who initiated either 1 mg E2/100 mg P4 or CEE/MPA between October 2018 to June 2021, and who did not have a VTE diagnosis in the prior 6 months, were selected from a large US claims database. Treatment was prescribed by a healthcare professional in a real-world setting and observed through pharmacy dispensing records (retrospective non-interventional study). VTE risk was assessed from the first E2/ P4 or CEE/MPA dispensing (index date) until switch to the comparator treatment or end of follow-up (defined as end of any clinical activity observed in the data for a patient or end of data availability). Confounding control was achieved via inverse probability of treatment weighting (IPTW). VTE risk was compared between the E2/P4 and CEE/MPA cohorts using IPT-weighted Kaplan-Meier plots and IPT-weighted regression models. The primary outcome measure was the first diagnosis of VTE observed post-index. **Results:** The study included 6,526 women initiated on E2/P4 and 29,535 on CEE/MPA (mean follow-up: 1.2- and 1.4-years post-index, respectively). Pre-IPTW at baseline, women initiated on E2/P4 were younger (mean age: 54 vs 56 for CEE/MPA), had less cardiovascular disease (34 vs 44%), less hypercholesterolemia (24 vs 31%), and higher prior utilization of other oral HT (estrogen/estradiol-based: 20 vs 12%; progesterone/ progestogen only: 18 vs 5%; oral contraceptives: 9 vs 5%). All covariates were balanced post-IPTW. The VTE incidence per 10,000 women years was 37 and 53 for E2/P4 and CEE/MPA after IPTW (post-IPTW incidence rate ratio 0.70, 95% confidence interval [CI] 0.53-0.92, P < 0.05). Hazard ratio from the IPTW analyses of time to first VTE was 0.70, 95% CI 0.53-0.92, P < 0.05 for E2/P4 vs CEE/MPA (see Table). **Conclusion:** After controlling for confounders, results from these exploratory analyses indicate that the VTE risk may be lower among women initiated on E2/P4 compared to CEE/MPA. Further research is warranted to confirm this finding.

Sources of Funding: Theramex References: 1. Writing Group for the Women's Health Initiative Investigators. *JAMA*. 2002;288(3):321-33. 2. Graham S, et al. *Menopause*. 2021;28(12):1449.

	Post-IPT Weighting		
	1 mg E2/100 mg P4 cohort [1]	CEE/MPA cohort [1]	1 mg E2/100 mg P4 vs CEE/MPA
Time from Index Date (all women)	Rates of VTE (KM-based)	Rates of VTE (KM-based)	HR (95% CI)
3 months	0.09% (0.03-0.30)	0.13% (0.10-0.18)	0.70 (0.53-0.92)*
6 months	0.20% (0.09-0.44)	0.25% (0.20-0.31)	
1 year	0.34% (0.17-0.65)	0.48% (0.40-0.57)	
2 years	0.80% (0.37-1.73)	1.06% (0.91-1.23)	
Time from Index Date to End of Observation [2]	VTE Events / 10,000 WY	VTE Events / 10,000 WY	IRR (95% CI)
All women	36.8	52.8	0.70 (0.53-0.92)*

Abbreviations: IPT = inverse probability of treatment weighting; E2 = 17-β estradiol; P4 = progesterone; CEE = conjugated equine estrogens; MPA = medroxyprogesterone acetate; VTE = venous thromboembolism; KM = Kaplan-Meier; HR = Hazard Ratio; WY = women-years; IRR = incidence rate ratio
[1] women with both medical-based and pharmacy-based clinical activity in the observation period and without pre-index diagnosis of VTE
[2] observation period ends at the earliest between treatment switch (from 1 mg E2/100 mg P4 to CEE/MPA or from CEE/MPA to 1 mg E2/100 mg P4), data cut-off date or end of medical or pharmacy-based clinical activity
*** Statistically significant at P < 0.05**

S-11.

A phase 3, randomized, placebo-controlled, double-blind study to investigate the long-term safety and tolerability of fezolinetant in women seeking treatment for vasomotor symptoms associated with menopause (SKYLIGHT 4)

Genevieve Neal-Perry[1], Antonio Cano[2], Samuel Lederman[3], Rossella E. Nappi[4], Nanette F. Santoro, MD[5], Wendy Wolfman[6], Marci English[7], Catherine Franklin[7], Jun Zhao[7], Faith D. Ottery[7]. [1]UNC School of Medicine, Chapel Hill, NC; [2]University of Valencia, Valencia, Spain; [3]Altus Research, Lake Worth, FL; [4]University of Pavia, Fondazione Policlinico IRCCS S. Matteo, Pavia, Italy; [5]University of Colorado School of Medicine, Aurora, CO; [6]University of Toronto, Toronto, ON, Canada; [7]Astellas Pharma Global Development Inc, Northbrook, IL

Objective: The primary objectives of SKYLIGHT 4 (NCT04003389) were to evaluate the long-term safety and tolerability of fezolinetant and its effect on endometrial health over 52 weeks. These data will complement results from two phase 3, randomized, placebo-controlled efficacy and safety studies, SKYLIGHT 1 and SKYLIGHT 2 (NCT04003155 and NCT04003142). In both studies the four co-primary efficacy endpoints were met, demonstrating that fezolinetant was efficacious for the treatment of moderate-to-severe vasomotor symptoms (VMS) associated with menopause. **Design:** SKYLIGHT 4 was a randomized, placebo-controlled, double-blind, phase 3, 52-week long-term safety study of fezolinetant 45 mg, fezolinetant 30 mg or placebo once daily (1:1:1) in women aged ≥40 and ≤65 years seeking treatment for VMS associated with menopause. Primary endpoints were percentage of women with endometrial hyperplasia, percentage of women with endometrial cancer, and frequency and severity of treatment-emergent adverse events (TEAEs). Endometrial biopsies taken at baseline and week 52/end of study treatment were read by 3 independent pathologists who were blinded to participant treatment allocation. Participants had to meet prespecified criteria for endometrial safety to be included in the primary endometrial biopsy data analysis (Endometrial Health set). Criteria were consistent with the appropriate FDA Draft Guidance to Industry. To meet the primary endpoints, the rates of hyperplasia or malignancy were to be ≤1% with an upper bound of the one-sided 95% confidence interval ≤4%. **Results:** 1830 women were randomized and took ≥1 dose of medication (fezolinetant 45 mg n=609, fezolinetant 30 mg n=611, placebo n=610). A total of 599 met the criteria for the Endometrial Health set (fezolinetant 45 mg n=203, fezolinetant 30 mg n=210, placebo n=186). Endometrial biopsy findings met the prespecified criteria (Table). The incidences of TEAEs and TEAEs leading to discontinuation were similar across groups, and there was a low incidence of serious TEAEs (Table). There was one death in the study (fezolinetant 30 mg group), which was reported as unrelated to treatment. The most common TEAEs (≥5%) were headache and COVID-19. The frequency of transaminase elevations was low, and these TEAEs were generally isolated, transient, and resolved on treatment or with discontinuation. **Conclusion:** These data demonstrate the 52-week long-term safety and tolerability of fezolinetant as studied and support its continued development for the treatment of VMS associated with menopause.

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Becky Ayles of Excel Scientific Solutions and funded by Astellas Pharma Inc.

Endometrial Health	Fezolinetant 45 mg (N=203)	Fezolinetant 30 mg (N=210)	Placebo (N=186)
Hyperplasia, No. (%) [upper limit of one-sided 95% confidence interval]	1 (0.5) [2.3%]	0 [1.4%]	0 [1.6%]
Malignancy, No. (%) [upper limit of one-sided 95% confidence interval]	0 [1.5%]	1 (0.5) [2.2%]	0 [1.6%]
TEAE, No. (%)	Fezolinetant 45 mg (N=609)	Fezolinetant 30 mg (N=611)	Placebo (N=610)
TEAE	389 (63.9)	415 (67.9)	391 (64.1)
Drug-related TEAE	110 (18.1)	94 (15.4)	106 (17.4)
Serious TEAE	23 (3.8)	20 (3.3)	14 (2.3)
Drug-related serious TEAE	3 (0.5)	0	1 (0.2)
TEAE leading to permanent discontinuation of study drug	28 (4.6)	34 (5.6)	26 (4.3)
Drug-related TEAE leading to permanent discontinuation of study drug	17 (2.8)	16 (2.6)	16 (2.6)
Deaths	0	1 (0.2)	0
TEAEs occurring in ≥5% of the total fezolinetant group by preferred term			
Headache	55 (9.0)	52 (8.5)	56 (9.2)
COVID-19	32 (5.3)	38 (6.2)	38 (6.2)
TEAE=treatment-emergent adverse event			

S-12.

Brain Function and Verbal Memory Positively Associated with Endogenous Estradiol in Postmenopause

Rachel A. Schroeder, BS[4], Rebecca C. Thurston, PhD[2], Minjie Wu[2], Howard Aizenstein[2], Carol Derby[1], Pauline Maki, PhD[3]. [1]Albert Einstein College of Medicine, Bronx, NY; [2]UPMC, Pittsburgh, PA; [3]Psychiatry, University of Illinois Chicago, Chicago, IL; [4]Psychology, University of Illinois Chicago, Chicago, IL

Objective: Although levels of estradiol (E2), secreted by the ovary, and estrone (E1), secreted by peripheral tissues, are lower in the postmenopause, a number of health outcomes including depressive symptoms, bone health, and cardiovascular health have been shown to associate with endogenous estrogens in postmenopause. It is unknown whether brain function also varies with endogenous estrogens in the postmenopause, especially estrone, which is less widely studied in relation to brain health. Verbal memory is the cognitive domain shown to change most reliably in the menopause transition, and neuroimaging studies show changes in memory circuitry with estrogen supplementation and depletion. In this study we examined how brain function during performance of a memory task varies with endogenous estrogen levels in postmenopausal women. **Design:** We examined data from 199 postmenopausal women enrolled in the MsBrain cohort of women (mean age 59.3 +/- 3.9 years, 83.9% white). Serum E1 and E2 were assessed using liquid chromatography-tandem mass spectrometry (LC/MS-MS). Participants underwent functional magnetic resonance imaging (fMRI) scans during performance of verbal encoding and recognition tasks. E1 and E2 levels were separately regressed on patterns of brain activation, controlling for age, BMI, and education. To determine the clinical significance of patterns of brain activation showing associations with estrogen, we associated the magnitude of activation in those areas with performance on the California Verbal Learning Test (CVLT), a validated assessment of verbal learning **Results:** During encoding, E2 levels were positively associated with activation in the right inferior temporal gyrus, left inferior frontal gyrus, left superior temporal gyrus, left superior frontal gyrus, and bilateral middle frontal gyrus. Activation in the

left inferior frontal gyrus and left middle frontal gyrus were positively associated with CVLT-assessed verbal learning, supporting the importance of activation in these areas to verbal learning. During recognition, E2 was negatively associated with activation in the right superior frontal gyrus. E1 was negatively associated with activation in the bilateral superior temporal gyrus, left insula, left precentral gyrus, bilateral postcentral gyrus, and the right superior frontal gyrus during encoding; these regions were not significantly associated with verbal learning. All results corrected $p < 0.05$. **Conclusion:** Our results suggest that high endogenous levels of E2, but not E1, promote the function of frontal brain areas to support verbal encoding.
Sources of Funding: RF1AG053504 (Thurston & Maki)

TOP-SCORING ABSTRACT PRESENTATIONS

S-13.

Efficacy and Safety of Estetrol (E4), a Promising New Treatment for Menopausal Vasomotor Symptoms: Results of Two Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial

Wulf Utian[1], Mélanie Taziaux[2], Amanda Black[3], Ulysse Gaspard[4], Rogiero A. Lobo[5], Jean-Michel Foidart[2,4]. [1]Case Western Reserve University School of Medicine, Cleveland, OH; [2]Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Liege, Belgium; [3]University of Ottawa, Ottawa, ON, Canada; [4]Universite de Liege, Liege, Belgium; [5]Columbia University Irving Medical Center, New York, NY

Objective: Estetrol (E4) is a native estrogen produced by the human fetal liver. Like other estrogens, E4 binds and activates the nuclear estrogen receptor α (ERα) and recruits the same coregulators. Unlike other estrogens, E4 induces limited activity on membrane ERα in several tissues including the breast and antagonizes this pathway in the presence of estradiol. E4 and selective estrogen receptor modulators (SERMs) do not recruit the same coregulators and therefore E4 is considered the first Native Estrogen with Selective Tissue activity (NEST). Data in pre- and postmenopausal women has shown that E4 alone or in combination with a progestin has minimal stimulatory effects on triglycerides, sex hormone binding globulin, and angiotensinogen. E4 also had minimal effects on clinically relevant hemostasis markers that are used as markers of risk of venous thromboembolism. A multicenter, randomized, placebo-controlled, double-blinded, dose-finding phase 2 study including 257 postmenopausal women aged 40 to 65 years found that E4 was effective for the treatment of menopausal vasomotor symptoms (VMS), genitourinary symptoms, and quality of life, with a favorable safety profile. Here, we present the first top line efficacy results from two Phase 3 trials on the use of E4 for the treatment of moderate to severe VMS in postmenopausal women. The trials were conducted in Europe, Latin America, Russia, and North America (USA and Canada) (E4Comfort I and II studies). **Design:** The E4Comfort studies were two placebo-controlled, double-blind, multicenter, randomized trials that evaluated the efficacy and safety of E4 for the treatment of moderate to severe VMS in postmenopausal women age 40 to 65 years. Included were hysterectomized (H) or non-hysterectomized (NH) subjects with ≥7 daily or ≥50 moderate to severe bothersome VMS in the week before randomization. Subjects were randomized to one of three arms (E4 15 mg, E4 20 mg, or placebo) in a 1:1:1 ratio and received study drug for 12 weeks (efficacy part; n=200 per arm). Efficacy was measured by the mean change from baseline in the frequency and severity of moderate to severe VMS at week 4 and week 12 compared to placebo based on the daily diary reports (co-primary endpoints). The studies were designed to assess the general and endometrial safety with up to 12 months of treatment with E4 15 and 20 mg (H and NH women; E4Comfort II) or with E4 20 mg in combination with progesterone 100 mg (NH women; E4 Comfort I). **Results:** Both studies met all four co-primary endpoints. Compared to placebo, there was a significant reduction in the frequency (up to 80%) and severity (up to 56%) of moderate to severe VMS at week 4 and week 12 ($p<0.05$). At week 12, E4 had a positive effect on quality of life (mood swings, anxiety, sleep, joint pain, libido, skin and hair quality) based on a secondary endpoint evaluation in the E4Comfort I study. **Conclusion:** E4 is effective at decreasing vasomotor symptoms in postmenopausal women. With the expectation that E4's good safety profile will be confirmed in the E4Comfort I and II studies, E4 will offer a novel treatment option for symptomatic postmenopausal women.

Sources of Funding: This research was funded by Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Liège, Belgium

S-14.

The Progesterone Challenge Test (PCT) to Identify Populations at High Risk for Endometrial Cancer: a Systematic Review and Meta-analysis

Elise Abi-khalil, PhD[1], Derek Chiu[1], Rachel J. Woima[1], Laurence Bernard[2], Jessica McAlpine[1], Aline Talhouk[1]. [1]Obstetrics and Gynecology, The University of British Columbia Faculty of Medicine, Vancouver, BC, Canada; [2]Department of Gynecologic Oncology and Reproductive Medicine, MD Anderson Cancer Center, Houston, TX

Objective: Most endometrial cancers (EC) evolve from endometrial proliferation, triggered by excess estrogen with low progesterone. This proliferation can cause thickening of the endometrial lining and gland crowding, and eventually progress to endometrial hyperplasia and cancer. Risk-reducing interventions (surgical, hormonal and lifestyle) may not be cost-effective in the general population due to low disease prevalence. The progesterone challenge test (PCT) is a short course, low dose progesterone regimen that can determine whether estrogens are present in sufficient quantity to cause endometrial proliferation, prompting a withdrawal bleed (+PCT). We hypothesize that this non-invasive test can be used in tandem with risk modeling to identify populations at high-risk to whom risk-reducing interventions can be targeted. This systematic review and meta-analysis aimed to report sensitivity and specificity of the PCT to evaluate its utility as a screening tool for risk-reducing interventions. **Design:** We searched PubMed, MEDLINE (Ovid), EMBASE and Web of Science to identify studies, published in English or French, prior to January 2022, using the following keywords: endometrial cancer, endometrial neoplasm, adenocarcinoma, progesterone challenge test, and menopause. We included reports that enable the computation of positivity rate, sensitivity, and specificity of the PCT to detect endometrial proliferation, hyperplasia (with or without atypia), or cancer. The proportion of +PCT was pooled using a random effects model, and the sensitivity and specificity were pooled using a Bayesian hierarchical summary receiver operating characteristic (HSROC) model and compared across and within specific populations. Specificity calculations excluded studies where participants with negative PCT tests were not biopsied. Pooled estimates of sensitivity and specificity were used to compute positive predicted values (PPV). **Results:** After removing duplicates, our search identified 83 articles. Screening of abstracts excluded 46 studies, and that of full text screening an additional 17 articles. Four review articles were identified but were excluded from the meta-analysis portion of the study. The 16 remaining studies that met our inclusion criteria had a total of 21 datasets reporting on 5585 post-menopausal women who underwent the PCT. Seven datasets (n=323) were from a population with risk factors, and 3 datasets (n=45) from a population with atypical adenomatous hyperplasia. Positivity rate of the PCT was higher in populations with EC risk factors (36% vs 24%). The pooled overall sensitivity and specificity were 0.96 (95% Confidence Interval (CI): 0.89-1.0) and 0.92 (95% CI: 0.82-1.00), respectively. We estimate PPV to be 0.39 (95% CI: 0.2-1) if prevalence is at 5%, and 0.57 (95% CI: 0.35-1) if prevalence is at 10%. **Conclusion:** The PCT is sensitive and specific. The positive predictive value of PCT can be significantly improved by focusing testing on populations with risk factors, and likely higher prevalence of disease. This supports using the PCT together with a risk prediction model.

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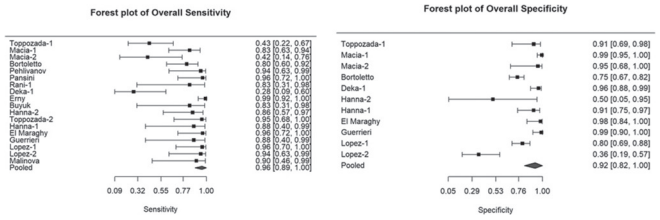


S-15.

Prospective associations of midlife HDL metrics and their changes since midlife with future cognitive performance: The Study of Women's Health Across the Nation (SWAN) HDL Ancillary Study

Meiyuzhen Qi[1], Jeff Billheimer[2], Maria Brooks, PhD[1], Emma Barinas-Mitchell, PhD[1], Carol Derby[3], Imke Janssen[4], Sybil Crawford, PhD[5], Trevor Orchard[1], Dan McConnell[6], Chung-Chou H. Chang[1], Arun S. Karlamangla[7], Samar R. El Khoudary[1]. [1]University of Pittsburgh, Pittsburgh, PA; [2]University of Pennsylvania, Philadelphia, PA; [3]Albert Einstein College of Medicine, Bronx, NY; [4]Rush University, Chicago, IL; [5]University of Massachusetts Chan Medical School, Worcester, MA; [6]University of Michigan, Ann Arbor, MI; [7]University of California Los Angeles David Geffen School of Medicine, Los Angeles, CA

Objective: The brain is the most cholesterol rich organ in the human body. Impaired brain cholesterol metabolism and elevated peripheral cholesterol may contribute to the development of dementia through neurodegenerative and vascular pathology. As the only lipoprotein involved in reverse cholesterol transport from cells, high-density lipoprotein (HDL) may participate in the pathological pathways of dementia. HDL particles (HDL-P) possess numerous features impacting cardiovascular and metabolic health. SWAN previously demonstrated that midlife women may experience HDL dysfunctionality, and that the conventional metric, HDL cholesterol (HDL-C) is a poor measure of HDL function in midlife and older women. Therefore, we aimed to assess the associations of novel HDL metrics (midlife and changes since midlife) with future cognitive performance in women, for whom dementia is disproportionately prevalent. **Design:** Midlife women traversing menopause were evaluated over time with repeated measures of a comprehensive set of HDL metrics [HDL lipid contents (HDL-C, HDL phospholipid (HDL-PL), and HDL triglyceride (HDL-TG)); HDL subclass (total, large, medium, and small HDL-P, and HDL size); and HDL cholesterol efflux capacity (HDL-CEC)] as well as of cognitive measures [processing speed (symbol digit modality test); and episodic memory immediate and delayed recall (East Boston memory test)]. Prospective associations of midlife HDL metrics and their changes since midlife with future cognitive performance measure were assessed using mixed effect models. Final models were adjusted for learning effects due to repeated exposure to the same cognitive test, retention effects reflecting the timing of drop out, time-varying age at cognitive test, as well as time-fixed study site, education level, race, menopause status, body mass index, and total HDL-P (for models of HDL lipid contents) or HDL-C (for the remaining models) measured at baseline HDL. **Results:** We included 305 midlife women (706 observations) with mean age of 51 (SD=3) and 72% of them being premenopausal at baseline. In final models, a higher midlife medium HDL-P was associated with better future processing speed and immediate recall levels over time. Larger increases in medium HDL-P since midlife were associated with better subsequent immediate and delayed recall. Higher

midlife total HDL-P was associated with better future immediate recall over time. In addition, greater increase in total HDL-P and HDL-PL since midlife were associated with better future immediate recall (**TABLE**). **Conclusion:** Among women, higher midlife medium HDL-P was associated with better future processing speed, while increases in total HDL-P, medium HDL-P and HDL-PL since midlife were associated with better episodic memory. The current study suggests that HDL metrics are novel markers that may be targeted in women for maintaining cognitive performance later in life.

Sources of Funding: SWAN has granted support from NIH, DHHS, through the NIA, the NINR and the NIH ORWH (U01NR004061 U01AG012505 U01AG012535 U01AG012531 U01AG012539 U01AG012546 U01AG012553 U01AG012554 U01AG012495 U19AG063720) and SWAN repository (U01AG017719). SWAN HDL has granted support from NIA (AG058690).

The prospective associations of midlife HDL metrics and their changes since midlife with future cognitive performance

	HDL-C	HDL-PL	HDL-TG	HDL-CEC	Total HDL-P	Large HDL-P	Medium HDL-P	Small HDL-P	HDL size											
Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	Midlife	Change	
Processing speed	β (SE)	-0.40 (0.59)	-0.05 (0.34)	0.14 (0.63)	0.04 (0.32)	0.21 (0.49)	-0.01 (0.33)	0.76 (0.62)	-0.02 (0.33)	0.73 (0.61)	-0.12 (0.33)	-0.58 (0.95)	-0.18 (0.33)	1.19 (0.51)	-0.55 (0.32)	-0.48 (0.53)	0.63 (0.32)	-0.33 (0.68)	-0.13 (0.32)	
p-value	0.499	0.894	0.820	0.895	0.672	0.972	0.223	0.958	0.232	0.729	0.540	0.584	0.02	0.085	0.362	0.051	0.628	0.687		
Reversely coded test scores	Immediate recall	β (SE)	0.07 (0.06)	-0.10 (0.06)	0.05 (0.06)	-0.17 (0.06)	-0.03 (0.05)	0.05 (0.06)	-0.04 (0.07)	-0.10 (0.06)	-0.13 (0.06)	-0.14 (0.06)	-0.15 (0.10)	-0.07 (0.06)	-0.14 (0.06)	0.18 (0.06)	0.03 (0.06)	0.07 (0.06)	-0.02 (0.07)	0.001 (0.06)
p-value	0.269	0.101	0.432	0.005	0.554	0.441	0.551	0.086	0.043	0.018	0.143	0.207	0.018	0.002	0.538	0.205	0.744	0.988		
Delayed recall	β (SE)	0.04 (0.06)	-0.02 (0.06)	0.08 (0.06)	-0.10 (0.05)	-0.02 (0.05)	0.01 (0.06)	-0.01 (0.06)	0.01 (0.06)	-0.07 (0.06)	-0.10 (0.05)	-0.08 (0.10)	-0.01 (0.05)	-0.09 (0.05)	-0.13 (0.06)	0.03 (0.05)	0.04 (0.05)	-0.03 (0.07)	0.03 (0.05)	
p-value	0.503	0.687	0.225	0.069	0.664	0.838	0.909	0.879	0.251	0.084	0.393	0.835	0.100	0.018	0.564	0.419	0.664	0.616		

β indicates changes in processing speed (number of correct responses) or reversely coded immediate and delayed recall (number of incorrect responses) per SD higher midlife HDL metrics or increase in HDL metrics since midlife.

S-16.

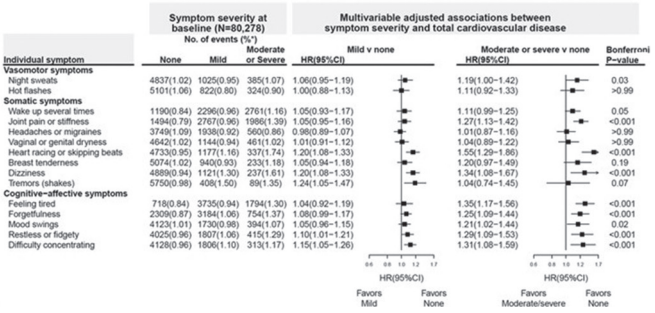
The Severity of Individual Menopausal Symptoms, Cardiovascular Disease, and All-Cause Mortality in the Women's Health Initiative Observational Cohort

Matthew S. Nudy, MD[1], Aaron K. Aragaki, MS[2], Xuezhi Jiang, MD/PhD[3], JoAnn E. Manson, MD, DrPH[4], Matthew A. Allison, MD, MPH[5], Aladdin H. Shadyab, PhD, MS, MPH[5], Howard N. Hodis[6], Robert A. Wild, MD, MPH, PhD[7], John A. Robbins[8], Simin Liu, MD, ScD[9], Michelle J. Naughton, PhD, MPH[10], Sarah Dreibelbis, DO[3], Margery Gass, MD[11], Marcia L. Stefanick, PhD[12], Carolina Valdiviezo, MD[13], Peter Schnatz, MD[3]. [1]Penn State University, Hershey, PA; [2]Fred Hutchinson Cancer Research Center, Seattle, WA; [3]Reading Hospital, West Reading, PA; [4]Brigham and Women's Hospital, Boston, MA; [5]University of California San Diego, La Jolla, CA; [6]University of Southern California, Los Angeles, CA; [7]The University of Oklahoma, Norman, OK; [8]University of California Davis, Davis, CA; [9]Brown University, Providence, RI; [10]The Ohio State University, Columbus, OH; [11]NAMS, Cleveland, OH; [12]Stanford University, Stanford, CA; [13]Cardiology, Georgetown University, Washington, DC

Objective: To examine the association between common menopausal symptoms (MS), cardiovascular disease (CVD) and all-cause mortality. **Design:** In an observational cohort of 80,278 postmenopausal women with no known CVD at baseline from the Women's Health Initiative (WHI), we assessed individual MS severity for night sweats, hot flashes, waking up several times at night, joint pain or stiffness, headaches or migraines, vaginal or genital dryness, heart racing or skipping beats, breast tenderness, dizziness, tremors (shakes), feeling tired, forgetfulness, mood swings, restless or fidgety, and difficulty concentrating. Outcomes included CVD events and all-cause mortality. Associations between MS severity and outcomes were assessed during a median of 8.2 years of follow-up. All results were multivariable-adjusted and individual associations were Bonferroni corrected to adjust for multiple comparisons. A machine learning approach (least absolute shrinkage and selection operator (LASSO)) was used to select the most parsimonious set of MS most predictive of each outcome. **Results:** The severity of night sweats, waking up several times at night, joint pain or stiffness, heart racing or skipping beats, dizziness, feeling tired, forgetfulness, mood swings, restless or fidgety, and difficulty concentrating were each significantly associated with CVD (Figure 1). The individual severities of heart racing or skipping beats, dizziness, tremors (shakes), feeling tired, forgetfulness, mood swings, restless or fidgety and difficulty concentrating were associated with all-cause mortality. Moderate or severe dizziness had the largest hazard ratio (1.58; 95% confidence interval 1.35 to 1.86). LASSO selected dizziness, heart racing, feeling tired and joint pain as most predictive of CVD, while dizziness, tremors and feeling tired were most predictive of all-cause mortality. **Conclusion:** Among women with no known CVD at baseline, the severity of specific MS was significantly associated with CVD and mortality. Consideration of severe MS may enhance sex specific CVD risk predication in future cohorts, but caution should be applied as severe MS could also indicate other health conditions.

Sources of Funding: None

Figure 1. Hazard ratios associating the severity of individual menopausal symptoms to total cardiovascular disease (composite of coronary heart disease, stroke, congestive heart failure, angina, peripheral vascular disease, carotid artery disease, and coronary revascularization) during the study period. Summary statistics were from a Cox proportional hazards model where baseline hazard functions were stratified by age group and hysterectomy status with covariate adjustment for race, ethnicity, education, smoking, bilateral oophorectomy, menopausal HT use (never/past/current; main effect and interaction term with hysterectomy status), sleep duration, statin use, history of high cholesterol, aspirin use, use of antihypertensive medication, treated diabetes, family history of MI and continuous (linear) covariates: age, age at menopause, BMI, systolic BP, diastolic BP and physical activity (log-transformed). P-values corresponded to a test for trend. P-values and 95%CI used a Bonferroni corrected α = 0.05/15 to control for multiple comparisons so that type I error across all 15 symptoms was ≤ 0.05.



FRIDAY CONCURRENT SESSION #1

S-17.

Menopausal Vasomotor Symptoms and White Matter Hyperintensities in Midlife Women

Rebecca C. Thurston, PhD[1,3], Minjie Wu[1], Yuefang Chang, PhD[4], Howard Aizenstein, MD, PhD[1], Carol Derby, PhD[5], Emma Barinas-Mitchell, PhD[3], Pauline Maki, PhD[2]. [1]Psychiatry, University of Pittsburgh, Pittsburgh, PA; [2]Psychiatry, University of Illinois at Chicago, Chicago, IL; [3]Epidemiology, University of Pittsburgh, Pittsburgh, PA; [4]Neurosurgery, University of Pittsburgh, Pittsburgh, PA; [5]Epidemiology and Population Health, Albert Einstein College of Medicine, Bronx, NY

Objective: The menopause transition is increasingly recognized as a time of importance for women's brain health. A growing body of work indicates that the classic menopausal symptom, vasomotor symptoms (VMS), may be associated with poorer cardiovascular health. Other work links VMS to poorer cognition. We investigate whether VMS, when rigorously assessed using physiologic measures, are associated with greater white matter hyperintensity volume (WMHV) among midlife women. White matter hyperintensities are a marker of cerebral small vessel damage linked to later cognitive decline, dementia, and mortality. We consider a range of potential explanatory factors in any VMS-WMHV associations and explore whether VMS are associated with the spatial distribution of WMHV. **Design:** As participants in the MsBrain Study, 225 women aged 45-67 and free of hormone therapy underwent ambulatory VMS monitoring (physiologic, electronic diary), actigraphy assessment of sleep, physical measures (height, weight, blood pressure), phlebotomy (glucose, insulin, lipids), and 3 Tesla neuroimaging. Associations between VMS (24-hour, wake, sleep) and whole brain WMHV were considered in linear regression models adjusted for age, race, education, smoking, body mass index, blood pressure, insulin resistance, and lipids. Secondary models considered WMHV in specific brain regions (deep, periventricular, frontal, temporal, parietal, occipital) and additional covariates including wake after sleep onset (WASO). **Results:** Physiologically-assessed VMS were associated with greater whole brain WMHV in multivariable models, with the strongest associations observed for sleep VMS [24-hour VMS, B(SE)=.095 (.045), p=.032; Wake VMS, B(SE)=.078 (.046), p=.092, Sleep VMS, B(SE)=.174 (.060), p=.004]. Associations were not accounted for by additional covariates including actigraphy-assessed WASO. When considering the spatial distribution of WMHV, sleep VMS were associated with both deep WMHV and periventricular WMHV, as well as with frontal lobe WMHV. **Conclusion:** VMS, particularly VMS occurring during sleep, were associated with greater WMHV. Identification of female-specific midlife markers of poor brain health later in life is critical to identify women who warrant early intervention and prevention. VMS have the potential to serve as female-specific midlife markers of brain health in women.

Sources of Funding: Funded by NIH Grants RF1AG053504 (Thurston & Maki), R01HL105647 (Thurston), and 2K24HL123565 (Thurston)

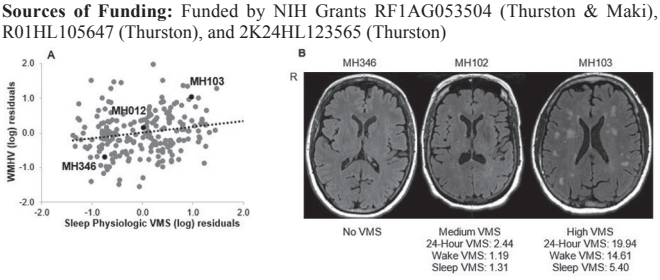


Figure. Scatterplots of associations between sleep VMS and WMHV (A) and MRI scans of white matter hyperintensities in representative women with no, medium, and high frequency VMS (B).

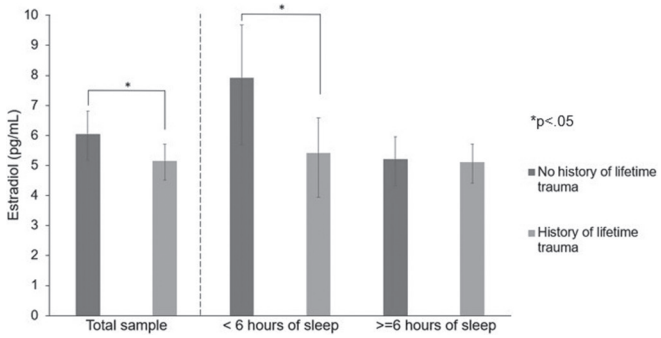
S-18.

Traumatic experiences and hormone concentrations among midlife women

Mary Y. Carson, PhD[1], Rebecca C. Thurston, PhD[3], Pauline Maki, PhD[2]. [1]Psychology, University of Pittsburgh, Pittsburgh, PA; [2]Psychiatry, University of Illinois at Chicago, Chicago, IL; [3]Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA

Objective: Traumatic experiences are associated with adverse mental and physical health outcomes. However, less is known about how traumatic experiences relate to the hypothalamic pituitary gonadal axis. Psychological trauma has the potential to suppress ovarian function and reduce ovarian estrogen secretion. However, the relationship between trauma and sex hormones among midlife women is not well understood. Further, it is unknown how mitigating factors may impact this association. For example, prior work has found that associations between trauma and health were most pronounced in the context of short sleep. We tested whether traumatic experiences are associated with endogenous sex hormones (estradiol, estrone, follicle stimulating hormone; FSH) in midlife women. We additionally investigated whether these associations vary by sleep duration. **Design:** Participants were 260 postmenopausal women free of hormone therapy (79% white, 17% black, 4% other ethnicity; Mean age=59 years). Women completed questionnaires (Brief Trauma Questionnaire, Center for Epidemiological Studies Depression, PTSD Checklist-Civilian Version, demographics), a blood draw, and ambulatory monitoring of sleep (actigraphy) as well as vasomotor symptoms (sternal skin conductance). Estradiol and estrone were assessed via liquid chromatography-mass spectrometry and FSH was assessed via immunoassay. Associations between traumatic events and sex hormones were tested via separate linear regression models. Covariates included age, race/ethnicity, body mass index, and smoking history. Depressive and post-traumatic stress symptoms, physiologic vasomotor symptoms, and time since the final menstrual period were considered in additional models. Sleep duration was evaluated as a moderator of associations between trauma and hormones. **Results:** Of the 260 women, 165 women (64%) reported a lifetime traumatic event. Women with a trauma history had lower levels of estradiol [b(SE)=-.16 (.08), p=.04; Figure 1] as well as estrone [b(SE)=-.14 (.06), p=.01; Figure 1] compared to women without this history in models adjusted for age, race/ethnicity, body mass index, and smoking history. Trauma was not associated with FSH [b(SE)=.05 (.07), p=.49; multivariable]. Findings were not accounted for by depressive or post-traumatic stress symptoms, vasomotor symptoms, or years since the final menstrual period. Sleep duration was a significant moderator of the association between trauma history and estradiol, such that the relationship between trauma history and lower estradiol was observed mainly in women sleeping less than 6 hours/night (p=.01; Figure 1). **Conclusion:** Among these midlife postmenopausal women, trauma history was associated with lower concentrations of estrone and estradiol. Associations between trauma history and lower estradiol were seen primarily in women with short sleep. This work underscores the importance of considering trauma in relation to endogenous estrogens, which have implications for women's midlife health.

Sources of Funding: RF1AG053504, R01HL105647, K24HL123565, UL1TR000005.



Adjusted values of estradiol by trauma history, stratified by sleep duration.

S-19.

Sociocultural, behavioral, and cardiovascular disease risk factors related to vasomotor symptoms among midlife Latinas

Yamnia I. Cortes, PhD, MPH, FNP-BC, FAHA[4], Jamie Crandell, PhD[1,2], Krista M. Perreira[3]. [1]School of Nursing, University of North Carolina System, Chapel Hill, NC; [2]Biostatistics, University of North Carolina at Chapel Hill Gillings School of Global Public Health, Chapel Hill, NC; [3]Social Medicine, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC; [4]School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC

Objective: Nearly 70% of Latinas report vasomotor symptoms (VMS), or hot flashes and night sweats, during the menopause transition. Latinas experience a greater prevalence and longer duration of VMS than non-Latina White women. Although studies suggest that depressive symptoms, sleep disturbances, and cardiovascular disease (CVD) risk are associated with VMS, Latinas remain underrepresented in menopause research. The purpose of the current analysis was to identify sociocultural, behavioral, and CVD risk factors related to VMS in midlife Latinas. **Design:** This is a cross-sectional analysis using baseline data from 44 participants enrolled in *Menopausia, Salud, Corazón*, an experimental study designed to reduce cardiovascular disease (CVD) risk in Latinas during the menopause transition. Eligible participants are Latinas aged 40-60 years living in North Carolina, who are perimenopausal or early postmenopausal, and free of CVD. Bilingual (English, Spanish) research assistants and community health workers recruited women from community settings including businesses, churches, clinics, health fairs, and community-based organizations. Sociocultural and behavioral factors such as age, education, years residing in the United States, perceived stress, everyday discrimination, sleep, and religiosity/spirituality were collected using interviewer-administered questionnaires in Spanish or English. CVD risk factors including weight, waist circumference, body mass index, blood pressure, and lipid profile were assessed during an in-person clinical exam. Participants were asked how many days in the past two weeks they experienced hot flashes or night sweats (0 days, 1-5 days, 6+ days). Student's t-test or Mann-Whitney U test and chi-square or Fisher's exact test were performed to compare factors across VMS reporting groups (any versus none). Tests were two-sided, α=0.1. **Results:** Participants were on average 47.5 ± 4.8 years of age, 98% were born outside of the United States and completed the survey in Spanish, 62% reported difficulty paying for basics, and 59% reported VMS in the past two weeks. Women reporting VMS were more likely to have a high school degree or greater (67% vs 39%, p=0.08) and to report having social support in their religious/spiritual community (91% vs. 39%, p=0.0005). Women reporting no VMS in the past two weeks had a better overall sleep score (4.9 vs 8.2, p=0.02) and lower systolic blood pressure (116.0 vs. 123.9, p=0.08). There were no group differences in terms of age, financial strain, perceived stress, or everyday discrimination. **Conclusion:** Latinas are disproportionately affected by VMS, but there is limited research on factors related to VMS in this population. This pilot study found that educational attainment, spiritual support, sleep, and blood pressure may be associated with VMS among Latinas. Since findings may vary based on national origin and cultural contexts, future research in larger sample sizes is necessary to further examine risk and protective factors for VMS among Latinas.

Sources of Funding: This study is funded by the National Institutes of Health and the National Institute of Minority Health and Health Disparities (K23MD014767, PI: Cortés) and the University of North Carolina Provost's Office Junior Faculty Development Award. Additional support was provided by the NC TraCS Inclusive Science Program (ISP) UL1TR002489 (Perreira).

S-20.

Psychosocial factors and menopause symptoms are associated with hair cortisol levels in midlife Latinas

Yamnia I. Cortes, PhD, MPH, FNP-BC, FAHA[1], Christian Long[1], Chongben Zhan[1], Jamie Crandell, PhD[1], Krista M. Perreira[2]. [1]School of Nursing, University of North Carolina at Chapel Hill, Chapel Hill, NC; [2]Social Medicine, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC

Objective: Cortisol, an indicator of psychobiological stress, increases during the menopause transition. Increased urinary cortisol during the menopause transition has been related to more severe vasomotor symptoms. However, cortisol measures in saliva, urine, and blood represent acute and not chronic activation of the hypothalamic-pituitary-adrenal (HPA) axis. Hair cortisol is an emerging measure of cumulative HPA axis activity over the preceding three months. This analysis aimed to examine psychosocial factors, menopause symptoms, and cardiometabolic factors associated with hair cortisol levels in midlife Latinas. **Design:** We conducted a cross-sectional analysis using baseline data from 23 participants with hair cortisol measures in *Menopausia, Salud, Corazón* – a pilot study designed to reduce cardiovascular disease (CVD) risk in midlife Latinas. Participants were Latinas aged 40-60 years living in North Carolina, who were perimenopausal or early postmenopausal, free of CVD, with no hormone therapy use in the prior three months. Bilingual (English, Spanish) research assistants and community health workers recruited women from community settings including businesses, churches, clinics, health fairs, and community-based organizations. Cortisol was extracted from hair samples (1-3 cm in length) using Salimetrics kit 1-3002 and run in duplicates, with results reported as the average of the duplicates (pg/mg). Psychosocial factors (e.g., financial strain, perceived stress, everyday discrimination, resiliency) and menopause symptoms were collected using interviewer-administered questionnaires. Cardiometabolic factors including weight, waist circumference, body mass index, blood pressure, and lipid profile were assessed during an in-person clinical exam. Separate bivariate linear regression analyses were conducted to assess factors associated with hair cortisol. Tests were two-sided, α=0.1. **Results:** Women were on average age 47.7 ± 4.6 years, 48% had a high school education or higher, 52% were Spanish-speaking only, and 57% reported difficulty paying for basics. The mean cortisol level was 3.04 ± 1.5 pg/mg. Perceived stress was positively associated with cortisol levels (ß [SE]= 0.21 [0.10], p=0.06). Older age at menarche (ß [SE]= 0.45 [0.20], p=0.04), feeling down/depressed (ß [SE]= 1.33 [0.58], p=0.03), and reporting any vasomotor symptoms (ß [SE]= 1.77 [0.52], p=0.003) were also associated with higher cortisol levels. In terms of sleep habits, we found that reports of restless sleep (ß [SE]= 2.03 [0.86], p=0.03), waking up earlier than planned (ß [SE]= 1.37 [0.64], p=0.05), and waking up several times at night (ß [SE]= 1.20 [0.69], p=0.09) were associated with higher concentrations of hair cortisol. We did not find any associations between cardiometabolic factors and hair cortisol. **Conclusion:** Hair cortisol is an emerging biomarker of psychobiological stress. However, few studies have assessed hair cortisol in midlife women, particularly Latinas. This pilot study found that perceived stress, older age at menarche, feeling down/depressed, reports of vasomotor symptoms, and sleep disturbances are related to higher concentrations of hair cortisol. Future research in larger sample sizes is necessary to confirm these findings and explore the use of hair cortisol in menopause research.

Sources of Funding: This study is funded by the National Institutes of Health and the National Institute of Minority Health and Health Disparities (K23MD014767, PI: Cortés), and the University of North Carolina Provost's Office Junior Faculty Development Award. Additional support was provided by the NC TraCS Inclusive Science Program (ISP) UL1TR002489 (Perreira).

S-21.

Persistent gap in menopause care 20 years after the WHI in France: a population-based study of menopause-related symptoms and their management

Florence A. TREMOLLIERES, MD, PhD[1], Gabriel André, MD[2], Brigitte Letombe, MD[3], Luc Barthelemy, MSc[4], Amélie Pichard, MSc[4], Bertrand Gelas, MD[5], Patrice Lopes, MD[6]. [1]Hôpital Paule de Viguier, Toulouse Menopause Center, Toulouse, France; [2]Dr. André, Private Practice, Strasbourg, France; [3]Dr.Letombe, Private Practice, Paris, France; [4]Stethos, Paris, France; [5]Laboratoire Theramex SAS, Pars La Défense, France; [6]UNiversity of Nantes, Medical School, Nantes, France

Objective: To assess the current management of menopause in France with regard to menopause-related and genitourinary symptoms, with a focus on menopause hormone therapy (MHT) use **Design:** The ELISA Study is a population-based survey of 5,004 French representative women aged 50 to 65 years. From July to August 2020, the participating women answered an online computer assisted web interview on menopause-related and genitourinary symptoms and their management, including use of MHT. **Results:** Among the 5,004 selected women, 4,041 whose postmenopausal status was confirmed were included in the final analyses. Of the untreated 3,685 women, 87% reported at least 1 menopausal symptom, with a significantly higher percentage of symptomatic women in the 50-54 age group (92%, p<0.05) than in the other two age groups (55-59 years: 89% and 60-64 years: 82%). 68% of the surveyed women experienced on average 2.5 symptoms of the genitourinary syndrome of menopause (GSM). Using a visual analogue scale (VAS) from 0 (no impact) to 10 (high impact) to evaluate the impact of menopausal/GSM symptoms on their quality of life, mean VAS score was 5.9 (SD: 2.2), with 25% of the women aged 55-59 years rating their quality of life between 8 and 10. 61% of the surveyed women reported being regularly followed by a health care professional. 44% of women reported never having discussed their menopausal/GSM symptoms with a health care provider. The main reasons were because menopause is "a normal part of women's lives", because it was not "necessary to do so", or their symptoms were "not serious enough". Only 242 women (6%) were current MHT users, of whom 49% were using estrogen-alone therapy and 71% were using transdermal estrogens. Fear of hormones (35%) and MHT side effects (25%) were the main reasons given for not using MHT. 62% of the women reported that the decision not to take MHT was supported by their physician's opinion. **Conclusion:** This large population-based survey confirmed not only the high prevalence of menopause-related and GSM symptoms in postmenopausal women within the first 10-15 years after menopause, but also the very low percentage of MHT users in France. Twenty years after the publication of the initial Women's Health Initiative (WHI) results, management of postmenopausal women is still characterized by unmet needs in menopausal care. Therefore, there is a strong need to educate the public and health care providers about menopause-related problems and possible solutions, including MHT through dedicated educational programs.

Sources of Funding: Theramex France SAS

FRIDAY CONCURRENT SESSION #2

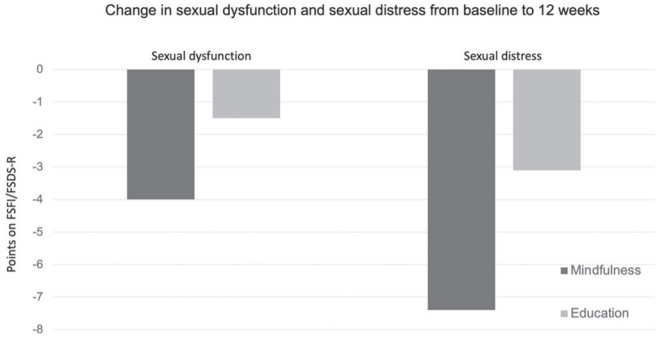
S-22.

A pilot trial of a virtually-delivered group mindfulness intervention for midlife and older women with low libido

Holly N. Thomas, MD MS[1], Jonathan Yabes[1], Lori Brotto[2], Sonya Borrero[1], Rebecca C. Thurston, PhD[3]. [1]Medicine, University of Pittsburgh, Pittsburgh, PA; [2]The University of British Columbia, Vancouver, BC, Canada; [3]Psychiatry, University of Pittsburgh, Pittsburgh, PA

Objective: Low libido is common among women and is associated with significant distress. Mindfulness meditation is effective for low libido in women, but existing interventions are not tailored by age. We conducted a pilot randomized controlled trial of a virtually delivered, mindfulness-based group intervention for midlife and older women with low libido compared to an active control group. We assessed feasibility, acceptability, and explored preliminary outcomes of sexual dysfunction and distress. **Design:** Women aged 45 and older who had bothersome low libido were randomized to the intervention or an educational control group. Women in both groups met weekly six times for 90 minutes over videoconference with either a physician and a mindfulness instructor (intervention) or a physician alone (control). Women in the intervention group received mindfulness meditation training and sexual psychoeducation. Women in the control group received general menopause health education without a focus on sexuality. We assessed satisfaction and likelihood of recommending the group to another woman with low libido at group conclusion on 5-point Likert scales (primary outcomes). We assessed sexual function [Female Sexual Function Index (FSFI)] and sexual distress [Female Sexual Distress Scale-Revised (FSDS-R)] at baseline and at 12 weeks (exploratory outcomes). Lower scores on the FSFI and FSDS-R denote better sexual function and lower sexual distress. We used chi squared tests to examine differences in primary outcomes between groups. We fitted linear regression models to compare changes in FSFI and FSDS-R from baseline to 12 weeks for each group. **Results:** Of 81 women screened, 61 were randomized, 41 attended at least one session, and 37 had follow-up data available (N=15 intervention, N=22 control). Mean age was 57 (range 47-76), and 19% were pre- or perimenopausal, 54% were post-menopausal, and 26% had hysterectomy or oopherectomy. Satisfaction was high in both groups. In the mindfulness group, 13% were extremely satisfied, 60% very, 20% moderately, 7% a little, and 0% not at all (education group: 5%, 41%, 41%, 9%, 5%, chi2=2.82, p=0.244). Women in the mindfulness group were more likely to recommend it to another woman with low libido. In the mindfulness group, 67% would definitely or probably recommend, 33% maybe, and 0% a little or not at all (education group: 41%, 23%, 36%, chi2=6.98, p=0.031). Women randomized to mindfulness had greater improvements in sexual function (mean FSFI change: -4.0 intervention v. -1.5 control, p=0.001) and sexual distress (mean FSDS-R change: -7.4 intervention v. -3.2 control, p=0.001) compared to women in the education group. **Conclusion:** A virtually-delivered, mindfulness-based group intervention for midlife and older women with low libido is feasible and acceptable and results in greater improvements in sexual function and sexual distress compared to active control.

Sources of Funding: NIH's National Institute on Aging (K23AG052628) and National Heart Lung and Blood Institute (K24HL123565).



S-23.

Sexual functioning of peri- and postmenopausal women Veterans may differ by sexual orientation

Anna E. Blanken, PhD[1,2], Laura Muratore, MA[1,2], Alison J. Huang[1,2], Carolyn Gibson, PhD, MPH[2]. [1]Mental Health, San Francisco VA Health Care System, San Francisco, CA; [2]Psychiatry and Behavioral Sciences, University of California San Francisco, San Francisco, CA

Objective: Sexual function is a dynamic process that reflects an interaction of vascular, neurological, hormonal, and psychosocial factors. An estimated 25-85% of postmenopausal women report challenges with sexual function. Evidence suggests that sexual minority women (SMW; a term encompassing a range of sexual orientations for women with same-sex attractions and/or partners) may have increased risk of adverse mental and physical health outcomes in and after the menopause transition, including more severe menopause symptoms. However, research also suggests that SMW may demonstrate unique pathways of resilience during the menopause transition. Overall, little is known about SMWs' experiences of menopause. To address this gap, we examined whether indices of sexual functioning differed between SMW and heterosexual women in a sample of peri- and postmenopausal women Veterans. We further explored associations of sexual functioning with psychosocial factors among women by self-identified sexual orientation. **Design:** We analyzed cross-sectional survey data from midlife and older (45-64 years old) women Veterans who receive Veteran's Health Administration (VHA) health care. There is a higher percentage of SMW among women Veterans relative to the general population. Self-reported sexual orientation was used to categorize women as heterosexual vs. SMW, which included lesbian, bisexual, and pansexual women. Participants completed the Day-to-Day Impact of Vaginal Aging Questionnaire (DIVA) Sexual Functioning 5-item subscale, and self-reported genitourinary symptoms related to sexual function (vaginal irritation, vaginal dryness, pain during sexual activity) in the past 2 weeks. Depression, anxiety, and trauma symptoms were assessed with the Patient Health Questionnaire 9-item (PHQ-9), General Anxiety Disorder 7-item (GAD-7) and PTSD Check List (PCL). We used independent sample t-tests (continuous variables) and chi-square tests (categorical variables) to examine differences in sexual function and genitourinary symptoms by sexual orientation. We further investigated these relationships using logistic and linear regression models adjusting for age, education, race, and body mass index. We used Pearson's correlation to explore associations with psychosocial factors that may contribute to sexual functioning among each sexual orientation identity. **Results:** In the analytic sample of 198 women, 52 (26%) self-identified as SMW. A greater proportion of SMW (65%) reported engagement with any type of sexual activity (e.g., solo or partnered) in the past month than heterosexual women (40%), X2 (2, N=198) = 10.6, p<0.01, which remained significant after controlling for covariates (OR 1.21, 95% CI: 1.32-8.55). In fully adjusted models, SMW reported better sexual functioning as indicated by lower DIVA scores (B=-0.59, p=0.02) and were less likely to report pain during sexual activity (B=-1.9, p =0.02). SMW were also less likely to report vaginal dryness (B=-1.15, p=0.02), but did not significantly differ from heterosexual women in reporting vaginal irritation. Exploratory correlational analyses revealed that experience of military sexual assault was associated with lower sexual function (r = 0.19, p = 0.03) in heterosexual women, but not SMW. Greater depression (r=0.34, p<0.001), anxiety (r=0.26, p<0.01), and trauma-related (r=0.24, p<0.01) symptoms were related to poorer sexual functioning in heterosexual women, but not SMW. **Conclusion:** Midlife and older SMW Veterans were more likely to be sexually active and reported better sexual functioning and less pain during sexual activity, compared to their heterosexual peers. SMW were also less likely to report some vaginal symptoms. Although untested, past work has posited that SMW with same-sex partners may have more favorable sexual function outcomes during the menopause transition due to greater variation in sexual behaviors, compared to heterosexual women who are more likely to engage in

penetrative sex with men. Additionally, our data suggests that psychosocial factors such as depression, anxiety and trauma, may have greater impact on sexual function of heterosexual women, compared to SMW.
Sources of Funding: VA Career Development Award CDA IK2 HX002402 National Institute On Aging NIA K24AG068601

S-24.

Association Between Vasomotor Symptom Frequency and Weight Gain in the Study of Women's Health Across the Nation (SWAN)

Carolyn J. Gibson[1], Aki Shiozawa, DrPH, MBA[2], Andrew J. Epstein, PhD[3], Wei Han, PhD[2], Shayna Mancuso, DO, FACOG[2]. [1]Department of Psychiatry and Behavioral Sciences, University of California San Francisco, San Francisco, CA; [2]Astellas Pharma US Inc, Northbrook, IL; [3]Medicus Economics, Philadelphia, PA

Objective: The primary objective of this analysis was to quantify the extent to which changes in VMS frequency are associated with subsequent weight gain in midlife women. This analysis also aimed to assess possible mediation of weight gain by sleep problems and potential moderation by menopause stage, and to examine the extent to which cumulative exposure to VMS is associated with long-term weight gain. **Design:** Longitudinal data from the multi-site Study of Women's Health Across the Nation (SWAN), a large, multi-ethnic cohort of women in midlife (n=3302, age 42–52 years at baseline), were analyzed retrospectively. SWAN data were collected from annual assessments at baseline and at up to 10 follow-up visits from 1995 through 2008. The current sample included participants with a visit (t) who had 2 lagged visits (t–1 and t–2). Self-reported VMS frequency (number of days in past 2 weeks with hot flashes and night sweats [0, 1–5, 6–8, 9–13, and 14 days; high frequency categorized as ≥6 days]), self-reported sleep problems (binary indicators of 3+ times in past 2 weeks), and weight (kg, body mass index [BMI], and waist circumference) were measured at each annual SWAN study visit. To isolate the impact of VMS frequency on weight gain, linear regression was used to assess the associations between changes in VMS frequency from visits t–2 to t–1 and changes in weight measures from visits t–1 to t. Associations between cumulative exposure to VMS (10 consecutive visits with ≥6 days or with any days of VMS in past 2 weeks) and overall changes in weight were also examined by linear regression. Associations between lagged changes in VMS frequency and changes in weight measures were calculated overall and by menopause stage. Proportional and absolute changes in weight measures were calculated over visits. Mediation of VMS weight gain associations by sleep problems and moderation by menopause stage were explored. **Results:** The main analytic sample included data from 2361 participants (12,030 visits; at baseline, mean age 51.1 [SD: 3.7], 45.5% late perimenopausal or postmenopausal, 47.5% White). Cumulative exposure to VMS included data from by 1743 participants (12,182 visits). Increases in VMS frequency from visit t–2 to visit t–1 were associated with significant increases from visit t–1 to visit t in weight (0.31 percentage points [ppt]; 0.24 kg; $P<.01$), BMI (0.29 ppt; 0.08 kg/m^2; $P<.01$), and waist circumference (0.20 ppt; 0.20 cm; $P=.04$) compared with visits in which VMS frequency did not change. Onset of high VMS frequency (≥6 days in the past 2 weeks) from visit t–2 to visit t–1 was significantly associated with proportional increases from visit t–1 to visit t in weight (0.35 ppt; $P=.03$), BMI (0.33 ppt; $P=.04$), and waist circumference (0.30 ppt; $P=.04$) compared with visits for which VMS frequency was <6 days at both visits t–2 and t–1. In fully adjusted models, having 10 consecutive visits with high VMS frequency was associated with relative increases in waist circumference of 3.5 ppt and 3.0 cm, and having 10 consecutive visits with any VMS (≥1 day) was associated with relative increases in waist circumference of 2.6 ppt and 2.1 cm. Concurrent sleep problems contributed no more than a quarter of the observed effect. Evidence for moderation by menopause stage in the association between VMS frequency and weight gain was inconsistent. **Conclusion:** This study provides the first evidence that VMS, including increases in VMS, onset of high-frequency VMS, and persistent VMS, may be independently associated with weight gain among midlife women. These findings highlight the need for research to clarify potential mechanisms linking VMS to subsequent weight gain in midlife and may inform appropriate counseling about health risks and potential interventions for women with VMS.
Sources of Funding: Astellas Pharma. Writing support provided by Rachel Delinger, MPH, of Echelon Brand Communications, LLC, an OPEN Health company, funded by Astellas.

S-25.

Migraine and Sleep: What is the Association in Midlife Women?

Stephanie Faubion, MD, MBA[2], Summer Ghaith[1], Juliana M. Kling, MD, MPH[3], Kristin Mara[5], Felicity Enders, PhD[5], Amal J. Starling, MD[4], Ekta Kapoor[6]. [1]Mayo Clinic School of Medicine - Scottsdale Campus, Phoenix, AZ; [2]Division of General Internal Medicine, Mayo Clinic in Florida, Jacksonville, FL; [3]Division of Women's Health Internal Medicine, Mayo Clinic Arizona, Scottsdale, AZ; [4]Department of Neurology, Mayo Clinic Arizona, Scottsdale, AZ; [5]Department of Quantitative Health Sciences, Mayo Clinic Minnesota, Rochester, MN; [6]Division of General Internal Medicine, Mayo Clinic Minnesota, Rochester, MN

Objective: Poor sleep costs the US economy approximately $411B annually. The prevalence of poor sleep quality is higher among women compared to men and increases significantly after the age of 50-55 years. Similarly, migraine is a common, chronic condition, affecting 1 in 5 women or more than 21 million women in the US. Migraine tends to worsen during the menopause transition and improves after menopause. A relationship between poor sleep quality and migraine has been previously identified. However, the association of poor sleep and migraine in the menopausal transition, specifically, remains unclear. The objective of this study was to evaluate the association of migraine and sleep quality in pre-compared to perimenopausal women taking into account potential confounding variables. **Design:** A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause and Sexuality (DREAMS) was conducted using questionnaires completed by pre- and peri-menopausal women who presented to women's health clinics at Mayo Clinic in Minnesota, Arizona, and Florida, from May 2015 - May 2021. History of migraine was obtained by self-report at the time of the visit. Sleep quality and duration were assessed with the Pittsburgh Sleep Quality Index (PSQI). Associations between poor sleep quality (PSQI >5) and migraine history (Y/N) were evaluated using a multivariable logistic regression model, that adjusted for body mass index (BMI), anxiety, depression and severity of hot flashes. **Results:** A total of 2,067 women were included in the analysis, 594 (28.7%) of whom reported a history of migraine. Women were of mean age 43.2 years, white (92.2%), partnered (75.1%), educated (86% with at least some college), 53.5% were perimenopausal, and 71.2% met the criteria for poor sleep. In univariate analysis, a history of migraine predicted poor sleep in both pre- and perimenopausal women (OR 1.56, 95% CI 1.14-2.12, p=0.005 and OR 1.60, 95% CI 1.17-2.20, p=0.004 respectively). In multivariable analysis, a history of migraine remained a predictor of poor sleep in premenopausal women (OR 1.43, 95% CI 1.01-2.02, p=0.042), but not in perimenopausal women (OR=1.15, 95% CI 0.81-1.65, p=0.43). The c-statistic for the multivariable models predicting poor sleep was 0.74 for pre-menopausal women and 0.78 for peri-menopausal women, suggesting that the model for predicting poor sleep has good discrimination in both groups. There was not a statistically significant association between migraine history and sleep duration (≤ 7 hours vs >7 hours) in either pre- or perimenopausal women. **Conclusion:** This cross-sectional study confirms an association between a history of migraine and poor sleep in pre- and perimenopausal women. However, in contrast to the relationship in premenopausal women, the relationship appears to be explained by other factors known to affect sleep in the menopause transition, such as BMI, anxiety, depression, and the presence of hot flashes in perimenopausal women. Clinicians caring for women should query patients with migraine about sleep, irrespective of menopause status. Management strategies to address poor sleep in migraineurs may differ depending on menopause status.
Sources of Funding: None

S-26.

Experience of Menopause in the Workplace: Data from the Mayo Clinic Registry of Midlife Women

Ekta Kapoor, MBBS[1], Mary Hedges, MD[2], Rajeev Chaudhry, MBBS, MPH[1], Juliana M. Kling, MD, MPH[3], Chrisandra Shufelt, MD[6], Mariam Saadedine, Doctor of Medicine[4], Kristin Mara[1], Felicity Enders, PhD[1], Stephanie Faubion, MD, MBA[5]. [1]Mayo Clinic Minnesota, Rochester, MN; [2]Mayo Clinic Department of Internal Medicine, Jacksonville, FL; [3]Mayo Clinic Department of Internal Medicine, Scottsdale, AZ; [4]American University of Beirut, Faculty of Medicine, Beirut, Lebanon, Beirut, Lebanon; [5]Mayo Clinic Florida, Jacksonville, FL; [6]Barbra Streisand Women's Heart Center, Los Angeles, CA

Objective: Previous research, conducted mainly outside the U.S., has shown that menopause symptoms may adversely impact a woman's performance, motivation, and relationships in the workplace, ultimately reducing her overall engagement at work. Given that midlife women constitute a significant proportion of the global workforce, the potential economic impact of menopause symptoms in the workplace and the lost work productivity are staggering. The current study's aim was to evaluate the impact of menopause symptoms in the workplace among women receiving primary care at a U.S. tertiary care center. **Design:** This was a cross-sectional study conducted among women in the Mayo Clinic Registry of Midlife Women (Hormones and ExpeRiences of Aging, HERA). Women aged 45-60 years, who receive primary care at four Mayo Clinic sites- Rochester, MN; Scottsdale, AZ; Jacksonville, FL; and Mayo Clinic Health System, northwest WI, received a survey between March and June 2021. The questionnaire assessed menopause symptoms (with the Menopause Rating Scale, MRS) and the impact of these symptoms on work. The total MRS score and the domain scores in the somatic, psychological, and urogenital subscales were included in the analysis. An adverse work outcome was defined by an affirmative response to any of the following: "missed days from work in the past 12 months; hours cut back at work in the last 6 months; laid-off or fired from work in the last 6 months; and quit/retired/changed jobs in the last 6 months," specifically due to menopause symptoms. **Results:** Of the 5219 respondents, 4440 (85%) reported current employment, and qualified for the study. The mean age of the participants was 53.9±4.5 years; majority were white (95%), married (77%) and educated (59% college graduate or higher). The mean total MRS score was 23.1, signifying severe symptom burden. Overall, 13% of the women reported at least one adverse work outcome due to menopause symptoms; 480 (11%) women reported missing work in the preceding 12 months (mean number of days missed=3), 250 (6%) reported cutting back on hours in the preceding 6 months, 12 (0.3%) reported being laid off in the preceding 6 months, and 45 (1%) reported quitting/retiring/changing jobs in the preceding 6 months. Women with higher MRS scores were more likely to report an adverse work outcome, as compared to those with lower scores, a pattern that was consistent across all menopause symptom domains. The odds for reporting an adverse outcome in the workplace increased monotonically with increasing severity of menopause symptoms, with women scoring in the fourth quartile of total MRS scores being 15.6 (95% CI 10.7-22.7; p<0.001) times more likely to have an adverse work outcome compared to those in the first quartile. The association between menopause symptoms and an adverse work outcome was strongest in the psychological domain [21 times increased odds (95% CI 13.20-33.99; p<0.001) in women with symptoms in the fourth quartile versus those in the first quartile]. **Conclusion:** In this large U.S. study on the impact of menopause symptoms on women in the workplace, women reported a negative impact of their menopause symptoms on work. Furthermore, the severity of menopause symptoms correlated with the probability of an adverse work

outcome. The findings highlight the opportunity to improve the treatment of menopause symptoms in working women. They also draw attention to the potential economic impact of menopause symptoms, and the need for creation of workplace policies that include education of employers, managers, and supervisors in order to support midlife women during this universal life stage transition.
Sources of Funding: None

FRIDAY CONCURRENT SESSION #3

A Decade of MsFLASH Findings – Time to Get the Word Out

Susan D. Reed[1], Andrea Z. LaCroix, PhD[2], Katherine A. Guthrie[3], Garnet Anderson[3], Kristine Ensrud[4], Bette Caan[5], Janet S. Carpenter[6], Lee Cohen[7], Susan Diem[4], Ellen Freeman[8], Hadine Joffe[9], Joseph Larson[3], Susan McCurry[10], Caroline Mitchell[11], Katherine Newton[12], Leslie Snyder[13], Barbara Sternfield[14]. [1]Obstetrics and Gynecology/ Epidemiology, University of Washington, Seattle, WA; [2]Herbert Wertheim School of Public Health, University of California, San Diego, CA; [3]Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA; [4]Epidemiology/Medicine, University in Minnesota, Minneapolis, MN; [5]Research, Kaiser Permanente, Oakland, CA; [6]School of Nursing, Indiana University, Indianapolis, IN; [7]Reproductive Psychiatry Resource & Information Center, Massachusetts General Hospital/Harvard Medical School, Boston, MA; [8]Obstetrics and Gynecology/Psychiatry, Perlman School of Medicine, University of Pennsylvania, Philadelphia, PA; [9]Psychiatry Research, Brigham and Women's Hospital, Boston, MA; [10]Psychosocial and Community Health, University of Washington, Seattle, WA; [11]Obstetrics and Gynecology, Massachusetts General Hospital/Harvard Medical School, Boston, MA; [12]Kaiser Permanente Washington Health Research Institute, Seattle, WA; [13]Communication, University of Connecticut, Storrs, CT; [14]Research, Kaiser Permanente, Oakland, CA

Objective: The Menopause Strategies: Finding Lasting Answers for Symptoms and Health network was created to conduct randomized clinical trials of diverse interventions for common, bothersome menopausal symptoms. The final aim was dissemination of study findings. **Methods:** Study sites included Boston, Indianapolis, Minneapolis, Oakland, Philadelphia, and Seattle. All trials shared standardized eligibility criteria and endpoints. Primary outcomes included vasomotor symptoms (VMS), sleep quality, insomnia symptoms, and vaginal symptoms. Secondary outcomes included quality of life, sexual function, and mood. An interactive website that presents evidence-based information on menopause symptoms and treatments was created. **Results:** We completed 5 randomized clinical trials and 6 ancillary studies, testing 9 interventions in over 1,300 women and collecting nearly 16,000 bio-specimens. Escitalopram, venlafaxine XR, and low dose estradiol diminished VMS frequency by approximately 50% vs. 30% in the placebo groups. No VMS benefits were observed with yoga or exercise compared to usual activity, nor with omega-3 supplementation compared to placebo. Cognitive behavioral therapy for insomnia reduced self-reported insomnia symptoms and improved overall sleep quality compared to menopause education control. We did not find significant benefit from a vaginal estradiol tablet nor a vaginal moisturizer, compared to placebo tablet and gel, in diminishing severity of vaginal symptoms. Treatment with low dose vaginal estradiol, but not vaginal moisturizer, modestly improved overall menopause-related quality of life and sexual function domain scores, but not other domain scores. Our website, https//mymenoplan.org has 6 sections: About Menopause, Symptoms, Treatments, Women's Stories, Who We Are, and a Toolbox (containing create My Menoplan, interactive assessments and symptom diaries). Data from the MsFLASH studies and other rigorous clinical trials, evidence reviews, meta-analyses, and midlife women's cohort studies (e.g., SWAN) informed website content. Using the Menoplan feature, women can choose symptoms of interest and view a table of possible treatments, filtered by personal preference (e.g., treatments they can do on their own, safe treatments for breast cancer survivors, or treatments to discuss with their health care provider). **Conclusions:** The MsFLASH trials contributed substantially to our understanding of menopausal symptom treatment. It is important that clinicians counseling women about available treatment options consider all therapies – both nonhormonal and hormonal. Our evidence-based interactive website will provide midlife women and their providers the tools necessary to develop an individualized, evidence-based management plan.
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POSTER PRESENTATIONS

P-1.
Impact of a nurse-led digital menopause service on menopause symptoms, evaluated through Menopause Rating Scale and satisfaction score

Kathy Abernethy, MClinSci RN, Thea Sofie Schei, PhD. Peppy Health, London, United Kingdom

Objective: Traditionally, menopause care has been delivered in clinics via scheduled short appointments by medical doctors. However, individuals often say it is difficult to have a discussion around evidence-based information that is clinically relevant to them as well as understanding all options open to them for managing symptoms and future health. People want to make choices in this area of their health, yet accessing personalised, evidence-based information in order to do so, can be hard. Peppy has been designed for people to digitally access whole-person care, including advice, signposting and personalised one-to-one support led by a British Menopause Society specialist nurse, as well as nutritional, emotional and lifestyle support from a team of nurses, nutritional therapists, psychotherapist and counsellors. Peppy, a digital nurse-led menopause service was offered to individuals through an employee benefit program paid for through UK employers. Open to all staff and their partners, the aim was to assess overall service satisfaction and changes in menopause symptoms after using the service for 90 days. **Design:** 3260 individuals aged 45-55 joined the service and completed the Menopause Rating Scale over a 12-month period. Of these, 55% self-reported as perimenopausal, 12% as postmenopausal, 7% as premenopausal, 3% as 'induced' and 22% as 'not sure'. 23% reported taking HRT. 17% had taken time off work due to menopausal symptoms. To assess menopausal symptoms over time, 895 participants completed the Menopause Rating Scale (MRS) both at baseline and after 90 days. 103 of the users also completed the Net Promoter Score (NPS) at day 90 to measure service satisfaction. **Intervention:** The intervention offered ongoing 1:1 personalised messenger support, unlimited remote video consultations with menopause practitioner, extensive library of evidence-based resources and broadcasts covering menopause, therapy choices, health topics and life-related topics. All evidence was in line with NICE Guidance, British Menopause Society Guidelines and current UK best practice. **Outcome measures:** The MRS is a validated psychometric tool to evaluate severity of menopausal symptoms in relation to health-related quality of life. MRS enables comparison of symptom severity over time and to measure pre and post intervention across three symptom domains: somato-vegetative, psychological and urogenital. NPS is a customer loyalty and satisfaction measurement asking clients how likely they are to recommend the service to others on a scale of 1-10. A result between -100 to 100 is obtained. A score above 0 is good, above 20 favourable and above 80, world class. **Results:** At baseline, 69% of users reported severe MRS scores, with higher MRS scores associated with taking more time off in the 12 months prior to using Peppy ($R2 = 0.03$, $\beta = 0.35$, 95% CI[0.283, 0.418], $p < 0.001$). After 90 days there was a 23.65% reduction in MRS score (-4.46 ± 95% CI[-4.989, -3.939], $p < 0.001$), with individual comparisons showing greater reductions for users who reported being peri- (-4.46 95% CI[-3.78, -5.41], $p < 0.001$) or post-menopausal (-6.44 95% CI[-5.08, -7.79], $p < 0.001$), induced (-5.06, 95% CI[-2.41,-7.72], $p < 0.001$) or not sure (-4.46, 95% CI[-3.35, -5.57], $p < 0.001$), in comparison to premenopausal users (-2.52, 95% CI[-0.45, -.4.58], $p = 0.02$). Of the users with severe MRS scores at baseline, 49% of users reported no, mild or moderate symptoms after using Peppy. Additionally, the more users had engaged with the app, the larger the reduction in MRS scores they reported ($R2 = 0.03$, $\beta = -0.008$, 95% CI[-0.01, -0.005], $p < 0.001$). NPS was 77, indicating excellent customer experience. **Conclusion:** The majority of women reported severe menopause symptoms upon joining the service, often resulting in needing to take time off work. The intervention was associated with a very high level of satisfaction amongst participants and a significant reduction in the severity of symptoms after 90 days. The level of app engagement was also associated with the reduction in symptom severity. The results indicate that a nurse-led, digitally-accessed menopause programme is a promising new approach to managing menopause symptoms.
Sources of Funding: None

P-2.
Pelvic Floor Disorders Amongst Midlife and Older Female Veterans

Khadija Alshowaikh, MD, Ngozi Anaemejeh, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD. OBGYN, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Women are the fastest-growing group in the Veteran population. Since Operation Desert Storm, women have encountered greater exposure to trauma, injury, and many environmental hazards that present new and unique health risks. Female veterans' may have unique risk factors for pelvic floor disorders directly related to their military service. Pelvic floor disorders (PFD), including urinary incontinence, pelvic organ prolapse, lower urinary tract symptoms, and fecal incontinence, present a challenge to the quality of life and are associated with significant mental health comorbidities as women advance through the midlife years and beyond. The Department of Defense recognizes a knowledge gap regarding women's health requirements and has advocated for more research on health issues that affect female service members. We aim to focus on the urogenital health needs of women Veterans and the unique management issues faced by clinicians. **Design:** A Literature review via Pubmed/Medline and Google Scholar was conducted. Keywords included "pelvic floor disorder," "urinary incontinence," "pelvic organ prolapse," "lower urinary tract symptoms," "fecal incontinence," "aging," and "veteran women." **Results:** Limited data note that urinary conditions are the second most common diagnoses amongst women Veterans, especially those aged 65 years and older. Approximately 50% of Veteran women exhibit some loss of pelvic support leading to pelvic organ prolapse and are twice as likely as men to present with bladder pain syndrome. Military-specific factors associated with increased PFD include strenuous exercise during basic and paratrooper training, psychological stress, and harmful urinary habits during active duty, such as decreased access to care and bathrooms, postponed urination, and fluid restriction. Lower ranked, never deployed, and those who have served for more than ten years may also be at notably higher risk for PFD. Moreover, mental health disorders such as depression, sexual trauma, and post-traumatic stress disorder were 10% higher amongst female Veterans with urinary conditions. The pelvic floor is involved in emotional processing, and repeated stress exposure increases activity in pelvic floor muscles. Mental health comorbidities present a unique challenge to clinicians assessing urogenital health as women with a history of PTSD, and sexual violence find pelvic examinations distressing, embarrassing, and frightening. Other delays in treatment can be attributed to older veteran females more prevalently living in rural areas with lower access to specialized care. Addressing female veterans' specific urogenital health needs, mental health comorbidities, and access to health care allows for increased coordination of care and reduces treatment delays. **Conclusion:** The increased involvement of women

in the military has contributed to significant new and unique gender health care disparities contributing to female Veterans' vulnerabilities. Additionally, female Veterans' clinical and sociodemographic characteristics vary by age group. Further research to understand the midlife and older age women and their gender-specific urogenital health needs in a timely manner is imperative to alleviate morbidities and ensure quality care.
Sources of Funding: None.

P-3.
Efficacy Outcomes with Relugolix Combination Therapy in Perimenopausal Women with Uterine Fibroids: LIBERTY Studies

David F. Archer[3], James A. Simon[4], Rachel McLean[1], Xin Zhao[1], Andrea S. Lukes[2]. [1]Myovant Sciences Ltd, Brisbane, CA; [2]Carolina Women's Research and Wellness Center, Durham, NC; [3]Obstetrics and Gynecology, Eastern Virginia Medical School, Norfolk, VA; [4]The George Washington University, Washington, DC

Objective: In the 24-week, Phase 3 LIBERTY 1 and 2 studies, relugolix combination therapy (Rel-CT; relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) significantly reduced menstrual blood loss (MBL) in women with uterine fibroids (UF) and heavy menstrual bleeding. Here, the efficacy and safety of Rel-CT through 24 weeks is reported in a subgroup of potentially perimenopausal women (defined as age ≥ 45 years) compared with the overall study population (age 18–50 years). **Design:** Premenopausal women with ultrasound-confirmed UF and MBL ≥80 mL per cycle were randomized 1:1:1 to Rel-CT or placebo for 24 weeks, or Delayed Rel-CT (relugolix 40 mg monotherapy for 12 weeks, followed by Rel-CT for 12 weeks). Primary efficacy endpoint: proportion of treatment responders, defined as MBL volume <80 mL and at least a 50% reduction from baseline MBL volume over the last 35 days of treatment, measured by the alkaline hematin method. Key secondary efficacy endpoints: 1) amenorrhea rate; 2) mean percent reduction in MBL volume; 3) reduction in distress from bleeding, passing of blood clots, and tightness/pressure in the pelvic area, as measured by the Bleeding and Pelvic Discomfort (BPD) scale; 4) proportion of women with moderate-to-severe pain at baseline (Numerical Rating Score [NRS] ≥4) achieving minimal-to-no fibroid-associated pain; 5) proportion of women with anemia (hemoglobin ≤10.5g/dL) at baseline who achieved an increase in hemoglobin levels of >2 g/dL; 6) percent change in largest UF volume; and 7) percent change in uterine volume. Analyses comparing the Rel-CT group vs placebo group were performed on the modified intent-to-treat population using pooled data from LIBERTY 1 and 2. Proportions were compared using Cochran–Mantel–Haenszel tests, and changes or percent changes from baseline to Week 24 were tested with mixed-effects or ANCOVA models, with treatment, visit, baseline MBL and treatment by visit interaction included as fixed effects. All reported P values are two-sided, and 95% confidence intervals (CIs) for treatment differences are provided. **Results:** Potentially perimenopausal women included 282/768 (36.7%) women from LIBERTY 1 and 2 (95 randomized to Rel-CT; 94 to placebo). Mean [standard deviation] baseline characteristics were similar (except for age) between potentially perimenopausal women and the overall pooled population: age (47.4 [1.7] vs 42.5 [5.2] years, respectively), body mass index (31.1 [6.4] vs 31.2 [7.1] kg/m^2), MBL volume (228.6 [146.4] vs 243.0 [182.2] mL). Efficacy results are reported in Table 1. Adverse events for potentially perimenopausal women were consistent with those for the overall population. **Conclusion:** In potentially perimenopausal women from the LIBERTY studies, Rel-CT demonstrated a significant reduction of MBL volume; achievement of amenorrhea; improvements in hemoglobin levels, UF-associated pain and quality of life; and reductions in UF volume vs placebo, and was generally well-tolerated through 24 weeks. Results were consistent with the overall study population.
Sources of Funding: Myovant Sciences GmbH

Table 1. Efficacy Results for Potentially Perimenopausal Women and the Overall Study Population

Efficacy endpoints	Potentially Perimenopausal Women				Overall Study Population			
	Placebo (N=94)	Rel-CT (N=95)	Difference (95 CI), %	P	Placebo (N=256)	Rel-CT (N=253)	Difference (95 CI), %	P
Proportion of women with <80mL and ≥50% reduction in MBL, n (%)	19 (20.21)	79 (83.16)	62.95 (51.43, 73.90)	<0.001	43 (16.80)	183 (72.33)	55.54 (48.37, 62.70)	<0.001
Women who achieved amenorrhea over last 35 days of treatment, n (%)	8 (8.51)	59 (62.11)	53.59 (42.33, 64.86)	<0.001	11 (4.30)	130 (51.38)	47.09 (40.45, 53.73)	<0.001
Percent change from baseline to Week 24 in MBL volume, LS mean (standard error [SE])	−15.5 (7.27)	−89.0 (6.89)	−73.5 (−92.7, −54.3)	<0.001	−19.5 (3.53)	−84.7 (3.58)	−65.2 (−74.8, −55.6)	<0.001
Change from baseline to Week 24 in Uterine Fibroid Symptom and Quality of Life BPD scale score, LS mean (SE)	−19.0 (3.50)	−50.9 (3.43)	−31.9 (−41.0, −22.7)	<0.001	−17.4 (2.03)	−48.4 (2.04)	−31.1 (−36.4, −25.7)	<0.001
Women with a NRS score ≥4 during the 35 days prior to randomization who achieved a max. NRS score ≤1 for UF-associated pain over last 35 days of treatment, n (%)	13 (18.57)	29 (46.03)	27.46 (12.15, 42.77)	<0.001	21 (13.91)	57 (45.24)	31.33 (21.04, 41.63)	<0.001
Women with anemia at baseline who achieved an increase in hemoglobin levels of >2 g/dL from baseline at Week 24, LS mean (SE)	4 (21.05)	13 (61.90)	40.85 (13.15, 68.55)	0.0111	7 (11.67)	34 (55.74)	44.07 (29.19, 58.95)	<0.001
Percent change from baseline to Week 24 in primary UF volume, LS mean (SE)	−7.2 (7.81)	−11.4 (7.67)	−4.1 (−24.4, 16.1)	0.6867	−4.2 (3.98)	−15.4 (4.06)	−11.2 (−21.7, −0.7)	0.0374
Percent change from baseline to Week 24 in uterine volume, LS mean (SE)	−2.2 (3.67)	−17.5 (3.59)	−15.2 (−24.7, −5.8)	<0.001	0.2 (2.24)	−13.6 (2.28)	−13.8 (−19.7, −7.9)	<0.001

P-4.
The Psychosocial Impact of Body Image in Peri- and Post-menopausal Women

Hassiet Asberom, Lucy Guan, MPH, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD. Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Body changes during the peri- and post-menopausal period may positively or negatively influence a woman's self-body image. Symptoms and signs can include flushing, vaginal dryness, breast changes, sexual dysfunction, wrinkles, and weight gain. Psychosocial symptoms include mood changes or age-related anxiety. A negative attitude towards menopausal changes can manifest in a negative body image, which can enhance body dissatisfaction, low self-esteem, and sexual dysfunction. This review explores the relationship between menopausal symptoms and body esteem. **Design:** A literature review using PubMed to find peer reviewed journal articles examining the relationship between body image and peri- or post-menopausal symptoms. **Results:** One study found a correlation between a higher mean BMI and negative body image in post-menopausal women of multiple racial/ethnic groups. Women who gained weight or had multiple weight fluctuations reported higher levels of a negative body image. Another study assessed the relationship between the severity of post-menopausal symptoms and body image, additionally affected by socio-demographic factors. Significant positive correlations were found between body image and the education level of the wife ($p < 0.001$, $r = 0.20$), education level of the husband, ($p < 0.001$, $r = 0.26$), and adequacy of monthly household income ($p < 0.001$, $r = 0.32$). Overall, increasing severity of menopausal symptoms correlated with decreasing body image. However, women with higher monthly incomes appeared to have less risk of a negative body image. A qualitative study reported that a negative body image related to physical symptoms such as weight gain or sagging breasts had an adverse impact on sexual satisfaction. Participants who reported higher sexual satisfaction noted the importance of having a supportive partner to boost their self-acceptance and self-confidence. Other studies showed an elevated severity of menopause symptoms was correlated to a greater prevalence of eating and body image disorders. Data from another study noted that appearance-related menopausal attitudes were negatively related to body surveillance ($p < 0.05$) and positively related to body esteem ($p < 0.05$). Body surveillance was defined as women viewing their own bodies as an outside observer, with cultural context influencing how they interpret changes in their bodies. Appearance-related aging anxiety was positively related to body surveillance ($p < 0.05$), but unrelated to body esteem. Another study found supporting evidence that women dissatisfied with their body image, compared to cultural standards, had greater negative attitudes toward menopause. Many women tied menopause to anxiety about the aging process, considering old age to be unattractive and linked to feeling invisible in society. However, this study also found women who felt more freedom and confidence during this period of their life despite the physical changes to their bodies. They reported that accepting menopause as a natural and inevitable process while caring less about cultural standards of beauty contributed to their positive attitude. **Conclusion:** These data suggest that severity of menopause symptoms may be influenced by insecurity regarding body image. However, several studies included in this review have limited generalizability since all participants were from similar geographic regions. Cultural constructs of femineity and body attractiveness may influence a woman's body image in different ways. These studies also found multifaceted responses, suggesting some women may view menopause as a new and exciting period of their life, highlighting the importance of studying diverse samples when evaluating the psychosocial impact of menopause. Given the connection between menopause and appearance, it would be beneficial for health care providers to incorporate "body-positive" counseling to women experiencing menopause. These interventions should not only focus on weight loss but should encompass broader health behavior transformations, helping women accept the physical and psychological changes that occur during menopause. This can boost feelings of attractiveness, creating a positive impact on a woman's self-acceptance, self-confidence, and self-perceived body image.
Sources of Funding: None

P-5.
Culture: An Influence on the menopausal experience.

Etphane D. Barthelus, Eesha Vijayakumar, Gloria Bachmann, MD, Juana Hutchinson-Colas, MD. Robert Wood Johnson Women's Health Institute, Rutgers The State University of New Jersey, New Brunswick, NJ

Objective: Menopause, which marks the end of a woman's natural fertility is a transition that all women experience. However, a woman's culture, values, and even individual attitudes can influence how she views, experiences, and manages this period of time in her life. Menopause is not widely spoken about or understood in several cultures and can often be kept secret or considered a taboo topic, whereas, in other cultures, this event is seen as a positive and a natural change. These positive experiences tend to relate to an increased role in the family and religion. A woman's positive experience with menopause appears to also affect the reporting of symptoms; that is, fewer symptoms are associated with a positive experience. In this review, the peer-reviewed literature on the implications of cultural determinants on the menopause experience was explored. **Design:** A Literature review via Pubmed/Medline and Google Scholar was conducted. Keywords included "cultural aspects of menopause," "menopause and culture," "positive menopause experience," "cultural influence on menopause," and "lower reporting of menopause symptoms and culture." **Results:** The available data suggest that culture can influence the menopause experience. In several cultures, such as the Mayan culture, women view menopause as a positive experience that brings about the end of menstruation, the end of contraception use, and sexual freedom. Menopause also

signifies the end of strict gender roles for women in Islamic cultures. In Indigenous cultures, women who undergo menopause tend to have an increased role in both the family and religion as they are often seen as wise women. These women have an elevated social status in their communities, leading to a positive menopausal experience. Among European and North American White women, however, menopause is usually associated with aging. In addition to culture, lifestyle choices that include nutrition and exercise may positively impact the menopause experience as well. For example, Japanese women tend to have fewer vasomotor symptoms than Western women probably due to a higher consumption of soy and phytoestrogens. Among all women, data support the fact that exercise may also reduce menopausal symptoms such as depression and improve vasomotor symptoms. **Conclusion:** In several non-Western cultures, menstruation leads to increased participation in religion or family life for many women. As such, as they go through menopause, these women tend to embrace the freedom that comes with the menopause transition. That transition can be viewed as a rebirth, a time when they can do things they may have been restricted to before. A positive menopause experience also may lead to lower symptom reporting. The commonality between the cultures and a positive experience appears to be an increased societal status for the woman. However, the menopausal experience is not homogeneous; therefore, more research is needed to determine how culture affects menopause.

Sources of Funding: None

P-6.

Women's Experience with Menopause: A Second National Survey

Devon Bernsley, BA, Alyssa Dweck, MS, MD, James Komorowski, MS. Bonafide Health, LLC, Harrison, NY

Objective: In 2021, an inaugural menopause survey of over 1,000 women (40-65 yrs) was published. This survey focused on women's awareness, confidants, and treatments associated with menopause. A second, similar survey emphasizing perimenopause, aging, intimacy, and male understanding was conducted in 2022 to expand the female participant number and engage women in various stages of menopause. **Design:** A national survey was conducted on a random sample of menopausal women. Women (40-65 yrs) who were experiencing perimenopausal or menopausal symptoms were permitted to participate and were sent an online survey focusing on five topics: 1) Overall Knowledge of Perimenopause/Menopause, 2) Experience with Menopause, 3) Sex During Menopause, 4) Male Knowledge & Experience, and 5) Aging as a Woman. **Results:** 2,005 women responded to the national survey. *Overall Knowledge of Perimenopause/Menopause*. Regarding perimenopausal awareness: 30% were not aware what perimenopause is, 27% were not aware of the common signs or symptoms, 34% were not aware when perimenopause typically starts, and 39% were not aware of treatment options for menopause symptoms. Women want to know the following about perimenopause: 71% want to learn how to manage symptoms, 69% the signs and symptoms to look out for, 64% what is "normal" and what should be escalated to a healthcare provider, 59% when symptoms can start, 47% how to talk to people without being embarrassed, and 41% how to ask others for support. *Experience with Menopause.* When asked what would help them feel more supported in aging: 54% responded mental health support, 45% open conversations with loved ones, and 34% open conversations in the media. *Sex During Menopause*. The following were symptoms that make intimacy during menopause less enjoyable: 43% reported low libido, 33% less confidence, and 29% painful intercourse. In 71% of these cases, women reported that their partner is understanding about their symptoms during intercourse. With menopause, 25% of women reported the inability to orgasm, and 22% reported weaker orgasms. *Male Knowledge & Experience.* When asked about male support, 76% of women felt support from romantic partners, 68% from male friends, and 70% from male family members. Also, 65% reported that their partner understands their symptoms of menopause well, and 28% said they understand extremely well. When asked what would make them feel more supported by men, 41% answered more menopausal education, 38% general discussions about women's health, 28% research done by men in their lives, and 25% answered men opening up discussions. Of these women, 77% talk openly with men in their life about menopause and 47% speak very openly. Women found that talking openly about menopause leads to positive outcomes: 50% found it educates men, 45% reported it helps men be more supportive, 40% reported feeling relieved, 34% felt less alone, and 30% reported that it builds empathy in men. *Aging as a Woman*. When asked how they feel about aging: 44% don't feel old, 36% feel anxious, 27% feel sad, and 26% feel content. Women were twice as likely to feel anxious about aging versus happy (36% vs. 16%). When asked about embracing aging, women responded: 27% were very confident, 43% were somewhat confident, and 30% were not confident. Of these women, 60% felt that more pro-aging content is needed. Regarding the negative stereotypes of aging: 44% feel the negative stigmas associated with age affect how menopause is addressed in the media, 34% would feel more supported as they age if more conversations were represented in the media, and 32% think there is stereotyping and prejudice shown towards older women compared to previous years. **Conclusion:** A major finding of this national survey is that women desire more information and knowledge of perimenopause/menopause. Education on the symptoms of menopause, the timing of symptoms, and how to support women with menopause-related symptoms appears vitally important to women. With 73% of respondents feeling less than very confident about aging, reducing stigma and increasing education related to aging is a priority. Overall, this broad, national survey conveys the drastic need for increased education and social awareness as it relates to menopause so that women feel more supported.

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P-7.

Coping with menopause: the long journey of women from symptoms to relief

Diana Bitner[1], Lisa Halvorson[2], Cecilia Caetano, MD[3], Cecile Janssenswillen[3], Stephanie Brown[4]. [1]True. Women's Health, Grand Rapids, MI; [2]Bayer US LLC, Whippany, NJ; [3]Bayer CC AG, Basel, Switzerland; [4]Ipsos, New York, NY

Objective: Many women feel unprepared for menopause & are unaware that symptoms may be severe and last up to 10 years. Furthermore, women may not be aware that treatment is available, lack knowledge of available options, or not wish to use current options due to safety concerns or personal preference. Vasomotor symptoms (VMS), as well as sleep disturbances & mood changes, are some of the most bothersome symptoms associated with menopause & are common reasons why women seek help from their healthcare professional (HCP). There is often an emphasis on strategies for coping with symptoms rather than treatment, and in many cases the journey to receiving effective treatment is long, lasting up to several years. We conducted research to understand the VMS patient journey from origination and awareness through diagnosis, treatment, and maintenance. We aimed to identify the timeline associated with steps of the typical journey, decision-points, decision influencers (the woman herself; friends, family, colleagues; HCP or others), and drivers of decisions (both evidence-based and emotional) as well as identify triggers during the journey that lead to seeking advice/treatment & which could act as opportunities for earlier HCP intervention to optimize care. **Design:** The study consisted of 3 phases including group & individual interviews & an ethnographic interview with video assignments (Table). **Results:** Women in this study typically learned about VMS gradually through observing them in others or through stories shared by other women. Women may not associate VMS with menopause when they occur in the absence of menstrual changes. In this sample, at the onset of VMS, women lacked comprehensive information about what occurs in the menopausal transition or when changes may occur & felt unprepared to advocate for their health & well-being or to make informed decisions. When looking for self-directed relief, the group found that credible online information about VMS & options for relief was limited, difficult to locate, or forgettable. Furthermore, they reported that online content relating to VMS and menopause is dominated by advertisements & information about OTC supplements. Some women reported taking months or even years to conclude that symptoms like VMS & lack of sleep persist despite OTC therapy, or that the convergence of several symptoms could no longer be tolerated. There was no one specific trigger that prompted women to discuss VMS with an HCP. When seeking HCP-directed relief, the group felt they were unprepared to have comprehensive discussions about VMS & options for treatment. They also reported that not all HCPs offer a full range of treatment options and do not always follow up about menopause progress. The women questioned had modest expectations for the efficacy of products for VMS relief. Given the persistence of VMS experienced by the group during treatment, they were receptive to learning about new options. These women were keen to hear from peers about their experiences and choices & were interested to know "what other women do" about VMS. **Conclusion:** Based on those interviewed in this study, there is a need to increase recognition of VMS associated with menopause & the availability of treatment options. This may empower women to seek advice for symptoms earlier rather than feeling like they should 'cope' with them & increase confidence to proactively raise the topic with their HCP. There are opportunities to provide further information on the management of symptoms through all types of media and/or in conversations with HCPs. HCPs have the opportunity to empower women by bringing menopause into the conversation earlier, raising awareness of what a woman may expect during the menopausal transition, and discussing the potential impact of VMS and other symptoms which can be associated with this life stage. HCPs could also follow up with women after the initial discussion to enable earlier intervention if symptoms become bothersome. This may also facilitate improved conversations and informed decision-making regarding individualized treatment options.

Sources of Funding: Study conducted by IPSOS and funded by Bayer CC AG.

Qualitative interviews – Phase 1A 3x group interviews with n=3 participants in each group (total N=9)	90-minute webcam session 'Lead' respondent plus 2 family/friends, all of whom have experienced hot flashes and discussed them together Each lead was receiving a different therapy for VMS – either hormone therapy, prescription therapy or an ingested/topical over-the-counter (OTC) product
Qualitative interviews – Phase 1B One-to-one webcam interviews with n=24 participants	60-minute webcam session 4 women who had not spoken with an HCP about VMS 20 women who had spoken with an HCP about VMS 8 women were using hormone therapy, 7 using non-hormonal prescription therapy and 5 using OTC treatment (but may have used prescription therapy in the past) for VMS
Ethnographic interviews – Phase 2 One-to-one webcam interviews with n=10 participants	75-minute webcam session In the two-week period following quantitative interviews 10 participants who were involved in the qualitative interview stage (Phase 1B) One webcam interview and 7 video assignments delivered via smartphone app

P-8.

A Guide to Accessing and Utilizing SWAN Data and Biospecimens

Maria Brooks, PhD[2], Nanette F. Santoro, MD[1], Sioban Harlow, PhD[3], Rebecca C. Thurston, PhD[2], Alicia Colvin, PhD[2], Samar El Khoudary, PhD[2], Robin Green, PsyD[4], Rachel Hess, PhD[5], Howard Kravitz, DO, MPH[6], Genevieve Neal-Perry, MD PhD[7], Leslie Swanson, PhD[3], Albert Shieh, MD[9], Elaine Yu, MD[8]. [1]Obstetrics and Gynecology, University of Colorado Denver School of Medicine, Aurora, CO; [2]University of Pittsburgh, Pittsburgh, PA; [3]University of Michigan, Ann Arbor, MI; [4]Albert Einstein College of Medicine, Bronx, NY; [5]University of Utah Health, Salt Lake City, UT; [6]Rush University Medical Center, Chicago, IL; [7]University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC; [8]Massachusetts General Hospital, Boston, MA; [9]University of California Los Angeles, Los Angeles, CA

Objective: To provide an overview of the study design and wealth of data and biological specimens available from the Study of Women's Health Across the Nation (SWAN) cohort. Processes for obtaining SWAN data resources and specimens are housed at the National Institute of Aging's AgingResearchBiobank (https://agingresearchbiobank.nia.nih.gov/). Data are archived at the National Archive of Computerized Data on Aging (NACDA) (https://www.icpsr.umich.edu/web/NACDA/series/253). **Design:** Sharing scientific resources is a critical component of large-scale contemporary research and has potential to fuel scientific breakthroughs. Research sharing allows investigators external to the research study opportunities to access data collected from such studies. Yet many external researchers may find it challenging to identify available resources and navigate the steps required for access. **Results:** The Study of Women's Health Across the Nation (SWAN) is a longitudinal multi-racial and ethnic cohort of women studied over 17 waves of data collection between 1996 and 2016 as they transitioned through menopause and into early old age. SWAN initially conducted a 15-minute cross-sectional screening survey of 16,065 women aged 40-55 years at 7 sites in the United States to identify 3302 eligible women who consented to participate in the longitudinal cohort study. At study entry, women were 42-52 years old, had an intact uterus and at least one ovary, were not taking exogenous hormones, were not pregnant or lactating, and had had at least one menstrual period within the past 3 months. Each site enrolled White women and women from one other self-identified racial/ethnic group (Black, Hispanic, Japanese and Chinese). SWAN aimed to characterize biological and psychosocial antecedents of the menopause transition and their relationship to midlife women's health, including the experience of multiple racial and ethnic groups. Repeated measures of reproductive hormones, menopausal symptoms, sleep, genitourinary and sexual function, physical and cognitive function, cardiometabolic and bone health, psychological well-being and quality of life were performed. Serum, plasma, and urine specimens collected at clinic visits are stored in the SWAN Repository, including daily urinary samples (for hormone analysis) and symptom diaries collected for ≤50 days annually for ≤10 years in a subset. Datasets and specimens are housed at the NIA's AgingResearchBiobank along with essential study documents, protocols, data collection forms, codebooks and bibliography. The Biobank's process for requesting archived resources includes documented IRB approval, a scientifically rigorous study proposal and funding information. Data and/or material transfer agreements are created by the Biobank for recipients for use in research projects. Datasets and study documents available to the general public are housed at the NACDA. **Conclusion:** An expansive collection of SWAN biospecimens and datasets are available to investigators and trainees. These resources can be used for pilot studies, research projects, and manuscripts. Understanding the existing resources and the process required to access them provides a broad group of researchers the opportunity to advance academic research.

Sources of Funding: The Study of Women's Health Across the Nation (SWAN) has grant support from the National Institutes of Health (NIH), DHHS, through the National Institute on Aging (NIA), the National Institute of Nursing Research (NINR) and the NIH Office of Research on Women's Health (ORWH). (Grants U01NR004061; U01AG012505, U01AG012535, U01AG012531, U01AG012539, U01AG012546, U01AG012553, U01AG012554, U01AG012495, and U19AG063720). The content of this abstract is solely the responsibility of the authors and does not necessarily represent the official views of the NIA, NINR, ORWH or the NIH.

P-9.

The Lived Experience of Perceived Changes in Sexual Desire and Responses

Sonya O. Carothers, PhD. Nursing, Wilkes University, Wilkes-Barre, PA

Objective: Sexual desire and responses may change due to natural menopause and could potentially negatively impact a once-healthy sexual relationship between a heterosexual couple. The objective of this study was to describe the lived experience of perceived changes in sexual desire and responses from a menopausal female or a male partner of a menopausal female during or after menopause. **Design:** A descriptive phenomenological approach was used to reveal the true essence of a participant's lived experience of perceived changes in sexual desire and responses which highlighted perceptions, feelings, and personal reactions. The theoretical framework used for this study was Meleis' (2010) transitions theory defined as "a passage from one fairly stable state to another fairly stable state" (Chick & Meleis, 1986). In transitions theory, a clinician considers inhibitors of successful transitions along with factors that facilitate successful transitions while considering, the recipient's personal meaning and attitude. In-depth interviews were used for data collection and research took place at a family practice clinic located in southeast Texas, and via ZOOM because of the COVID-19 pandemic. **Results:** Participant's ages ranged from 43 years to 68 years. 95% were married. 75% had 20 or more marriage years with the same partner. 75% were African American, 5% Asian, 10% Caucasian, and 10% Hispanic. 5% had a high school education completing through grade 12, 35% had some college, 20% had a 4-year degree, and 40% had beyond a 4-year degree. **Results** are presented as developed themes. **Theme 1**: An uncomfortable experience with decreased desire. 84% of females experienced a decreased or non-existant sexual desire because of pain due mostly to vaginal dryness. 100% of males sexual desire remained the same. **Theme 2**: Conflicting messages of desire. 75% of females gave a conflicting message saying she had no sexual desire yet voiced she enjoyed sex. All males were consistent with their responses.**Theme 3**: Physical and mental metamorphosis. 83% of females explained a disconnect between her mind thinking she achieved vaginal moisture but her body had not responded as such. 25% of males perceived a strong erection but in essence he lacked rigidity. **Theme 4:** A sense of duty 92% of females felt obligated to perform her "wifely duty". 87.5% of males did not feel obligated. **Theme 5**: The disappearance of spontaneity. 90% of all participants described the inability to no longer be spontaneous with sex resulted in decreased sexual desire because of preperation needed beforehand. Females because of having to apply a vaginal lubricant and males because of the need to use erectile dysfunction medication. **Theme 6**: A natural part of aging. 31% of females described age affects her physical appearance and perceived this influenced her male partner's desire. 62.5% of males said age correlated with other life-obligations affecting sexual desire, but not because of his partner's menopausel state. **Theme 7**: Love conquers all. 81% of females stressed her decrease in sexual desire was not reflective of her love for her partner. 75% of males emphasized changes in his partner's sexual desire or response did not negatively affect his love for his partner. **Conclusion:** This phenomenological inquiry subsidized a gap in the literature by creating new data that provided insight into lived experiences of perceived changes in sexual desire and responses during the menopause transition or after menopause from the perspective of both females and males which is scarcely acknowledged in current literature. A new data finding in this research uncovered participant's living an experience described as a disappearance of spontaneity that decreased sexual desire. Also, this research uncovered a lived experience described by participant as having engaged and exciting sexual thoughts and seemingly being physically prepared for sexual intercourse but resulted in physical unresponsiveness. It is the recommendation of this researcher that health care providers who attend to perimenopausal or menopausal aged patients take advantage of screening and educational opportunities. Continued research on this unique population of menopause aged females and males would help define evidenced-based care that positively and accurately reflect patient needs.

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P-10.

Changes in Female Sexual Function Index scores in postmenopausal women with hypoactive sexual desire disorder treated with flibanserin at a specialty clinic

Somi Javaid, MD, Jerome Chelliah, MD, MPH, Louise Brown, Doctorate of Pharmacy. HerMD, Clayton, NC

Objective: The primary study objective was to evaluate flibanserin's real-world clinical effectiveness. In the U.S, flibanserin is approved to treat hypoactive sexual desire disorder (HSDD) in premenopausal women and in Canada to treat premenopausal and naturally postmenopausal women ≤60 years of age. However, data on treatment effectiveness outside of the research setting are limited. Therefore, this retrospective chart review study was conducted to bridge this knowledge gap. **Design:** Structured data (partner and menopausal status, medications, medical history, and weight) were extracted from predefined fields in the clinic's electronic health record (EHR) system using on-demand reports. Free-text encounter notes served as the data source for subjective unstructured data (benefits and tolerability), and Female Sexual Function Index (FSFI) scores were used as an objective measure of clinical effectiveness. Patients with low libido (R68.82 or F52.0) and ≥1 flibanserin prescription submitted through the clinic's EHR system (Flibanserin Patient [FP]), seen between September 1, 2015, and August 31, 2020, are included in this analysis. FPs were further categorized as either FP Users or FP Non- Users based on verified flibanserin usage. FSFI scores were captured via one of two methods. Hard copies of the questionnaire were initially completed, scanned, and saved as a PDF in the patient's EHR, and later scores were captured electronically using an iPad. FSFI scores obtained using hard copies were calculated manually, and scores captured electronically were automatically calculated. FSFI scores for FP Users were recorded on an excel spreadsheet using a unique patient identifier and FSFI completion dates. Completed FSFI score dates were reviewed to ensure they coincided with documented flibanserin usage in the encounter notes and the dates listed under the RxPlan section of the patient's EHR. For an FSFI score change to be considered valid, it must have occurred during documented flibanserin usage with a baseline score before initiating flibanserin and at least one on-treatment follow-up score. **Results:** FPs accounted for 256 (6%) of clinic patients seen during the study period. Among FP Users (n=147), 47 (32%) had valid FSFI score changes: 24 postmenopausal and 23 premenopausal women. The average time between baseline and follow-up FSFI score was approximately 4 months (range 1 – 15 months), with 2 months the most frequent. Valid FSFI score changes in postmenopausal FP Users are shown in the table. Subjective HSDD benefits were documented in the encounter notes of 18 (75%) of these women. The most frequently prescribed concomitant medications were testosterone in 16 (67%) and IntraRosa 10 (42%) in postmenopausal FP Users. **Conclusion:** The treatment of HSDD is multifaceted, and flibanserin is just one component of care. Therefore, the benefits reported here may or may not be related to flibanserin alone. However, our findings suggest that improvements in FSFI scores observed during clinical trials in premenopausal women may also be observed in certain postmenopausal women in clinical practice. More extensive studies are needed to verify these findings.

Sources of Funding: Sprout Pharmaceuticals

Overview of valid FSFI score changes in postmenopausal Flibanserin Patient Users

FSFI Score Change*	Average	Median	Minimum	Maximum
Total	9	7.25	-3.2	28.3
Desire	1	1	0	2.4
Arousal	1.4	1.2	-2.4	6
Lubrication	1.5	1.2	-1.2	6
Orgasm	1.7	1.0	-0.4	6
Satisfaction	1.6	1.6	-0.8	6
Pain	1.5	0.4	-0.8	6

***Higher scores indicate greater levels of sexual functioning**

P-11.

Telehealth-focused EducAtional Curriculum and Sessions for Health Center Care Teams on Post Menopause: TEACH-PM

Monica M. Christmas, MD[1], Lisa Masinter, MD[3], Elizabeth Adetoro[3], Madison Weigand[2], Isra M. Hasnain[2], Katherine Brito[2], Jennifer Morrison[3]. [1]Obstetrics & Gynecology, University of Chicago Division of the Biological Sciences, Chicago, IL; [2]University of Chicago Pritzker School of Medicine, Chicago, IL; [3]AllianceChicago, Chicago, IL

Objective: 1. To educate community health center (CHC) primary care providers, within the AllianceChicago and Health Choice Networks (HCN), on best practices to deliver care and counseling to patients around menopause symptom management with an emphasis on utilizing telehealth to optimize access to care. 2. To obtain baseline knowledge, knowledge gained and perceived value and outreach of the program through pre- and post- assessment of participants at each session. **Design:** Four webinars took place from July 2021 to February 2022. Dr. Monica Christmas MD, FACOG, NCMP, director of Menopause Program and Center for Integrated Women's Health at UChicago Medicine, served as the content expert, and led the development of the TEACH-PM curriculum. The TEACH-PM curriculum included topics such as best practices for delivering virtual care around menopause and strategies for managing menopause symptoms. Primary care providers within the AllianceChicago and Health Choice Networks who previously registered to receive notifications on upcoming network webinars were invited to participate through email notifications. The dates of all 4 lectures were provided in the notification along with registration instructions. The lectures were recorded and made available to network providers who were not able to join during the live lectures. Individuals registered for the sessions were asked to complete a general survey capturing demographics pertaining to their clinical background, patient population and knowledge base around menopause care. We evaluated knowledge gained and perceived value, and outreach of the program through pre- and post- assessment of participants at each session. **Results:** Over 100 participants from CHCs in the HCN and AllianceChicago network attended the four live sessions. Of those that completed the baseline survey, their specialty background was as follows: 11% Internal Medicine, 33% Family Medicine, 22% OB/GYN and 33% other specialties. Of those that completed the CE evaluation, 88% "Strongly Agree" that they intend to apply the knowledge and/or skills acquired to their practice team and are better able to collaborate with a multidisciplinary care team. For those that took the post series survey, we asked them to identify areas where they plan to implement changes in their practice because of info from the sessions. 78% of respondents plan to implement changes in patient education, 44% in treatment plan, and 33% in patient diagnosis. **Conclusion:** Data on menopause care in underserved populations is scare. This project updated CHC providers with the most current practices involving menopause management and telehealth and revealed deficits in current menopause care in CHC networks. The menopause transition is a pivotal point where intervention and treatment may improve quality of life and decrease overall morbidity and mortality.

Sources of Funding: Funding provided through grant obtained through the Pfizer Global Medical Grants Independent Medical Education Program.

Webinar	Title	Learning Objectives
July 14, 2021	Menopause basics: what, when, why?	• Discuss menopause basics • Explain the implications of menopause on overall health and wellbeing • Identify differences in menopause symptoms based on race/ethnicity • Recognize the attitudes and perceptions of menopause • Apply knowledge about the menopause experience to improve care in underserved populations • Discuss benefits and barriers to utilizing telehealth to manage menopause in the CHC environment
October 13, 2021	Menopause Hormone Therapy (MHT): the good, the bad, the treatment	• Identify types of MHT • Explain the indications for MHT • Discuss use of MHT in medically complex patients • Describe racial/ethnic differences in the uptake of MHT • Recognize tools to enhance the patient-provider experience
December 8, 2021	Non-hormonal Menopause Treatment Options an Evidence Based Approach: From Prescription Therapy to Complementary Alternative Medicine	• Review evidence-based non-hormonal treatment options for management for VMS and GSM • Discuss new treatments for management of VMS on the horizon • Explore complementary alternative medicine approach to menopause care • Develop framework for patient-centered midlife care utilizing telemedicine
February 9, 2021	Menopause is More than Hot Flashes and Vaginal Dryness: Strategies for managing sexual dysfunction, physical changes, mental changes and sleep disturbances	• Understand mental and physical changes related to menopause • Recognize sexual dysfunction and sleep disturbance in the context of menopause • Explain treatment options for managing menopausal symptoms outside of VMS and GSM • Outline strategy for integrating menopause care into workflow

P-12.

What is the association between menopause and urinary symptoms? A Systematic Review

Monica M. Christmas, MD[2], Shilpa Iyer, MD[2], Juraj Letko, MD[2], Cassandra Daisy, BS[1], Sumiko Maristany[1]. [1]University of Chicago Pritzker School of Medicine, Chicago, IL; [2]University of Chicago Department of Obstetrics and Gynecology, Chicago, IL

Objective: The term genitourinary symptoms of menopause (GSM) has been coined to better encompass the variety of symptoms experienced during menopause. It is unclear, however, if the included urinary symptoms of dysuria, urinary urgency and frequency, recurrent urinary tract infections (UTI), and urge and stress incontinence (UUI, SUI) are attributable to menopause, age, or a combination of other risk factors. Our objectives were to define the association between menopause and urinary symptoms, and to systematically review the effects of systemic or vaginal menopausal hormone therapy for urinary symptoms. **Design:** This systematic review included randomized controlled trials (RCTs) that enrolled menopausal women with primary or secondary outcomes of dysuria, frequent UTI, urgency, frequency, or incontinence. Non-English language, animal, cancer, pharmacokinetic, observation and pilot studies as well as secondary analyses and conference abstracts were excluded. Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and PubMed were searched through October 2020. **Results:** 5,265 papers were identified, of which 29 RCTs were included (Table 1-2.). We found that systemic estrogen therapy (ET) did not improve urinary symptoms over placebo. However, vaginal estrogen therapy improved a wide array of urinary symptoms in postmenopausal women including dysuria, urinary frequency, UUI, SUI, and reduced the risk of recurrent UTIs. **Conclusion:** The relationship between menopause and lower urinary tract symptoms (LUTS) is unclear; however, treatment with local estrogen therapy appears to have some benefits. Future prospective trials assessing urinary symptoms in those with primary ovarian insufficiency, premature menopause, and perimenopause may help determine if there is an association between decreased estrogen levels and LUTS.

Sources of Funding: Internal funds from the Department of Obstetrics and Gynecology University of Chicago.

Table 1. Characteristics and main findings of included systemic estrogen trials

Study Title	Author	Year	Country of Origin	Treatment	N	Treatment Duration	Findings	Jadad Score
Urinary incontinence in postmenopausal women treated with estrogens: A double-blind clinical trial	Walter	1978	Denmark	Oral estrogen v. placebo	29	20 days	Significant decrease in self-reported frequency, urgency, and urge incontinence in treatment group (oral estradiol) compared to placebo in women who had no DO on urodynamics (sensory OAB) ($p<0.05$). No change in urethral pressure in either group.	2
Oestriol in the prophylactic treatment of recurrent urinary tract infections in postmenopausal women	Kirkengen	1992	Norway	Oral estradiol v. placebo	40	3 weeks	Both groups had reduced UTI frequency but no statistical significance between groups. pH in the treatment group decreased from 6.5 to 5.5 ($p < 0.01$).	5
Efficacy of estrogen supplementation in the treatment of urinary incontinence. The Continence Program for Women Research Group	Fantl	1996	United States	Oral conjugated equine estrogen and medroxyprogesterone cyclically v. placebo	83	3 months	No change in incontinence episodes, nocturia, frequency, or patient perception of improvement in the treatment group.	5
Low dose oestrogen prophylaxis for recurrent urinary tract infections in elderly women	Cardozo	1998	United Kingdom	Oral estradiol v. placebo	72	6 months	No statistical significance between groups.	5
The effect of oestrogen supplementation on post-menopausal urinary stress incontinence: a double-blind placebo-controlled trial	Jackson	1999	United Kingdom	Oral estradiol valerate v. placebo	67	6 months	No significant effect of estrogen on SUI. Also no change in frequency, nocturia, or maximum urethral closure pressure.	3
Effects of oral estrogen and progestin on the lower urinary tract among female nursing home residents	Ouslander	2001	United States	Oral estrogen and progestin v. placebo	32	6 months	There was no significant difference in wetness rate, incontinence, and bladder capacity between the treatment and placebo groups.	3

Table 2. Characteristics and main findings of included vaginal estrogen trials

Study Title	Author	Year	Country of Origin	Treatment	N	Treatment Duration	Findings	Jadad Score
Local estrogen treatment in patients with urogenital symptoms	Simunić	2003	Croatia	Estradiol vaginal tablets v. placebo	1612	12 months	Urinary (dysuria, atrophy) symptoms in estrogen group decreased from 51.9% to 15.5%, vs placebo 47.6% to 35.9% ($p=0.028$). The following symptoms improved in the estrogen group compared with placebo: incontinence, 31.3% vs 13.5% ($p=0.002$), UTI 23.7% vs 6.2% $p=0.034$, frequency/nocturia 47.4% vs 9.4% ($p=0.001$).	5
Vaginal oestradiol for the treatment of lower urinary tract symptoms in postmenopausal women - A double-blind placebo-controlled study	Cardozo	2001	United Kingdom	Vaginal estradiol v. placebo	110	3 months	Vaginal estradiol had no effect on frequency and nocturia. Subjects with urinary urgency at baseline saw improvement in urgency. There was no improvement in incontinence for subjects with detrusor instability at baseline. No other urodynamic variables showed improvement with estradiol compared to placebo.	3
A randomized, open, parallel-group study on the preventive effect of an estradiol-releasing vaginal ring (Estring) on recurrent urinary tract infections in postmenopausal women	Eriksen	1999	Norway	Estradiol-releasing vaginal ring v. no ring	108	9 months	Proportion of subjects with ring that remained UTI free was significantly higher than those who did not. The cumulative likelihood of remaining UTI free was 45% in the estrogen ring group vs 20% in the placebo group. There was significant improvement in urge ($p=0.03$) and stress incontinence ($p=0.003$) in the estrogen ring group. There was no change in dysuria, frequency, or urgency.	4

P-13.

Inflammatory Cytokines are Associated with Lower Trabecular Bone Score at the Lumbar Spine in Postmenopausal Women

JANHAVI DAMANI, Integrative and Biomedical Physiology[1,2], Mary Jane De Souza, PhD[3], Connie J. Rogers[4,2]. [1]Integrative and Biomedical Physiology Program, The Pennsylvania State University - University Park Campus, University Park, PA; [2]Huck Institutes for the Life Sciences, The Pennsylvania State University - University Park Campus, University Park, PA; [3]Department of Kinesiology, The Pennsylvania State University - University Park Campus, University Park, PA; [4]Department of Nutritional Sciences, Penn State University Park, The Pennsylvania State University - University Park Campus, University Park, PA, US, academic, University Park, PA

Objective: Osteoporosis is characterized by reduced bone mineral density (BMD) and is estimated to affect over 200 million women worldwide. Due to the adverse effects associated with pharmacological drugs for osteoporosis, there is increasing interest in the potential of nutritional interventions to mitigate postmenopausal bone loss. Prunes (dried plums) are rich in bioactive phenolic compounds that may target inflammatory pathways, which are upregulated in a hypoestrogenic environment and consequently promote bone loss. The overarching goal of the study was to evaluate the effects of one year of prune consumption as a dietary supplement (two doses: 50g/day and 100g/day) on BMD (primary outcome) and inflammatory mediators (secondary outcome) in postmenopausal women. The goal of the current analyses was to explore the relationship between inflammatory mediators and bone outcomes in postmenopausal women at baseline prior to prune supplementation to better understand which inflammatory cytokines may be most important in bone health in this population. **Design:** Postmenopausal women (n=235, 55-75 years old) with BMD T-score of <0.0 and >-3.0 at any site were recruited for a single-center, parallel-arm, 12-month randomized controlled trial (RCT; NCT02822378) to evaluate the effects of 50g and 100g prunes/day compared to a control group. All participants received 1200mg calcium and 800 IU vitamin D_3 as standard of care. BMD was measured every 6 months using dual-energy X-ray absorptiometry. Blood was collected at baseline and after 12 months of prune consumption. Inflammatory mediators included serum C-reactive protein (CRP) and plasma pro-inflammatory cytokines (TNF-α, IL-1β, IL-6, IL-8, MCP-1). **Results:** 235 women (age 62.1 ± 5.0yr) were randomized into Control (n=78), 50g Prune (n=79), or 100g Prune (n=78) groups with a compliance of 90.2 ± 1.8% and 87.1 ± 2.1% in the 50g and 100g Prune groups, respectively. At baseline, age at menopause was positively correlated with plasma IL-1β ($p<0.05$), and time since menopause showed significant negative correlations with BMD and bone strength measurements. At baseline, plasma TNF-α, IL-1β, IL-6, and IL-8 were negatively correlated with trabecular bone score at the lumbar spine ($p<0.05$). Furthermore, multiple regression analysis indicated that at baseline, in combination with BMI and dietary calcium intake, plasma TNF-α accounted for 27.1% of the variability in total hip BMD ($p<0.05$). **Conclusion:** At baseline, inflammatory markers and time since menopause were inversely associated with bone health parameters in postmenopausal women, suggesting that inflammatory markers may be an important mediator for postmenopausal bone loss. Thus, dietary factors such as prunes may represent a promising non-pharmacological intervention to attenuate inflammatory mediators that can contribute to bone loss in postmenopausal women.

Sources of Funding: California Prune Board

P-14.

Prunes preserve cortical bone density and estimated strength in a 12-month randomized controlled trial in postmenopausal women: The Prune Study

Mary Jane De Souza[1], Kristen J. Koltun[1], Nicole C.A. Strock[1], Hang Lee[2], JANHAVI DAMANI, Integrative and Biomedical Physiology[1], Connie J. Rogers[1], Nancy I. Williams[1], Mario Ferruzzi[3], Cindy H. Nakatsu[4], Connie Weaver[5]. [1]The Pennsylvania State University, University Park, PA; [2]Massachusetts General Hospital, Boston, MA; [3]University of Arkansas for Medical Sciences, Little Rock, AR; [4]Purdue University, West Lafayette, IN; [5]San Diego State University, San Diego, CA

Objective: Dietary consumption of prunes has favorable impacts on areal bone mineral density (BMD); however, more research is necessary to understand the influence on volumetric BMD (vBMD), bone geometry, and estimated bone strength. The purpose of this investigation was to evaluate the effects of prunes (50g or 100g/day) on vBMD, geometry, and strength in postmenopausal women during a 12-month dietary intervention. **Design:** Single center, parallel arm 12-month randomized controlled trial (RCT; NCT02822378) to test effects of 50g and 100g prunes vs. a Control group on vBMD, bone geometry, and strength at the 4%, 14%, 38% and 66% tibial sites via peripheral quantitative computed tomography (pQCT). Generalized linear mixed effects modeling (GLMM) was used to assess changes over time among groups ($p<0.05$). **Results:** 235 women (age 62.1±5.0yr) were randomized into Control (n=78), 50g Prune (n=79), or 100g Prune (n=78) groups. Compliance was 90.2±1.8% and 87.1±2.1% in the 50g and 100g Prune groups. Dropout was 22%; however, the dropout rate was 41% for the 100g Prune group (compared to other groups 10% Control; 15% 50g Prune; ($p<0.001$)). A group×time interaction for cortical vBMD was observed in Control vs 100g Prune groups ($p=0.009$), but not in Control vs 50g Prune groups ($p=0.226$) at the 14% diaphyseal tibia. Cortical vBMD decreased in the Control group from Baseline (1073.5±5.0 mg/cm^3) to 12 months (1068.0±5.0 mg/cm^3; $p<0.001$) but did not change in the 100g Group (Baseline: 1078.7±5.5 mg/cm^3; 12 months: 1078.3±5.6 mg/cm^3; $p=0.798$). A group×time interaction for estimated strength (SSI) was also observed at the 14% diaphyseal tibia for Control vs. Pooled groups ($p=0.024$) such that strength decreased in the Control group from Baseline (1186.3±18.1 mm^3) to 12 months (1167.6±18.2 mm^3; $p<0.001$) but not the combined Prune group (1171.4±1171.4 mm^3; 1166.4±13.6 mm^3; $p=0.275$). At the 38% diaphyseal tibia, a group×time interaction for total vBMD was observed for the Control

vs 100g Prune group (p=0.046), but not in Control vs 50g Prune group (p=0.462). Total vBMD decreased in the Control group from Baseline (829.9±9.8 mg/cm^3) to 12 months (824.5±9.8 mg/cm^3; p<0.001) but not in the 100g Group (Baseline: 827.6±10.8 mg/cm^3; 12 Months: 825.3±10.8 mg/cm^3; p=0.145). No significant interaction effects were observed for measures of bone geometry at any site. **Conclusion:** Prune consumption preserves vBMD and strength at weight-bearing, predominantly cortical sites.
Sources of Funding: California Prune Board Award Number 180215

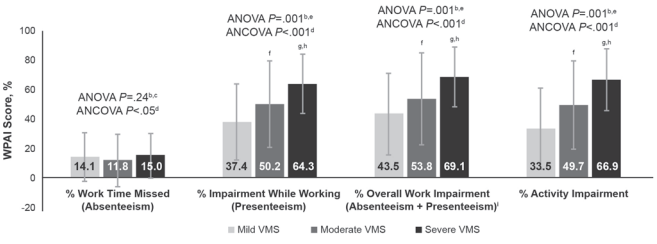
P-15.

Association Between Severity of Vasomotor Symptoms of Menopause and Work Productivity in a Survey of US Women

Barbara DePree, MD, NCMP, MMM[1], Aki Shiozawa, DrPH, MBA[2], Deanna King, MS, PhD[2], Arianne Schild, MS[2], Mo Zhou, PhD[3], Hongbo Yang, PhD[3], Shayna Mancuso, DO, FACOG[2]. [1]Women's Specialty Hospital, Holland Hospital, Holland, MN; [2]Astellas Pharma US Inc, Northbrook, IL; [3]Analysis Group Inc Boston, Boston, MA

Objective: To evaluate the association between vasomotor symptom (VMS) severity and work productivity in a real-world population of women with symptoms of menopause (secondary objective; primary objective reported separately). **Design:** For this online survey, US women aged 40–65 y in peri- or post-menopause experiencing VMS ≥14 times/wk for ≥1 week in the month before the survey were enrolled. Women were classified by VMS severity (mild/moderate/severe) based on self-rated response on the Menopause Rating Scale. The impact of VMS on daily activities and work productivity was assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire and reported according to VMS severity. The impact of VMS-induced sleep disturbance on productivity was also evaluated according to VMS severity. **Results:** Among 619 respondents (mean age 53.0 y; mean 5.7 y since last menstruation), VMS severity was mild in 88 (14.2%), moderate in 266 (43.0%), and severe in 265 (42.8%). A majority were employed, including 64.8% of women with mild VMS, 49.6% with moderate VMS, and 64.2% with severe VMS. Presenteeism (impairment at work), overall work impairment (absenteeism + presenteeism), and impairment in general activities varied significantly by VMS severity with and without adjusting for confounding factors; absenteeism differed significantly by VMS severity after adjusting for confounding factors (**Figure**). Most women (overall: 90.8%; mild: 81.8%; moderate: 86.8%; severe VMS: 97.7%) reported that VMS impacts their sleep, and most of these women (83.1%, 75.0%, 73.2%, and 94.2%, respectively) reported that the sleep changes affect their productivity. **Conclusion:** VMS severity is positively associated with degree of impairment in daytime activities and work productivity. VMS associated with menopause commonly disrupt sleep, which in turn affects daytime productivity.
Sources of Funding: Astellas Pharma, Inc. Writing support by Traci Stuve, MA, of Echelon Brand Communications, LLC, an OPEN Health company, funded by Astellas.

Figure. VMS-Related Work Productivity and Activity Impairment (WPAI)[a] in the Past Week



[a]WPAI outcomes are expressed as percentages of impairment, with higher values indicating greater impairment. Questions assessed impairment in the past 7 days. Absenteeism and presenteeism were assessed only in employed participants; activity impairment was assessed in all participants. [b]*P* values calculated using 1-way ANOVA. [c]Pairwise tests were not conducted for absenteeism since the null hypothesis of the 1-way ANOVA was rejected. [d]With mild VMS serving as the reference category, *P* values were calculated using ANCOVA adjusting for age, race/ethnicity, education, marital status, time since VMS onset, menopause stage, smoking status, caffeine use, body mass index, comorbidities, current use of pharmacologic treatment, and current use of nonpharmacologic treatment for VMS. [e]Pairwise comparisons were conducted using *t*-tests with adjustments (Bonferroni correction) made for multiple comparisons since the null hypothesis of the 1-way ANOVA was rejected. [f]Pairwise comparison of moderate vs mild was significant (presenteeism *P*<.01; overall work impairment *P*<.05; activity impairment *P*<.001). [g]Pairwise comparison of severe vs mild VMS was significant (all *P*<.001). [h]Pairwise comparison of severe vs moderate VMS was significant (all *P*<.001). [i]Percent overall work impairment due to VMS was calculated as (absenteeism + [1-absenteeism]*presenteeism).

ANOVA, analysis of variance; ANCOVA, analysis of covariance; VMS, vasomotor symptoms; WPAI, Work Productivity and Activity Impairment questionnaire.

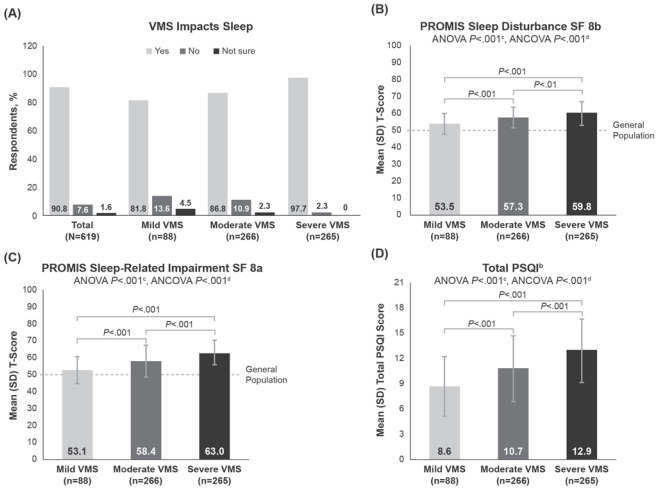
P-16.

Association Between Vasomotor Symptom Severity and Sleep Outcomes in a Survey of US Women With Symptoms of Menopause

Barbara DePree, MD, NCMP, MMM[1], Aki Shiozawa, DrPH, MBA[2], Deanna King, MS, PhD[2], Arianne Schild, MS[2], Mo Zhou, PhD[3], Hongbo Yang, PhD[3], Shayna Mancuso, DO, FACOG[2]. [1]Women's Specialty Hospital, Holland Hospital, Holland, MN; [2]Astellas Pharma US Inc, Northbrook, IL; [3]Analysis Group Inc Boston, Boston, MA

Objective: Vasomotor symptoms (VMS) associated with menopause can cause sleep disturbances and awakenings. This online survey evaluated the association between self-reported VMS severity and sleep quality. **Design:** US women aged 40–65 y in peri- or post-menopause experiencing ≥14 VMS/wk for ≥1 wk in the month before the survey were enrolled. Women were classified by VMS severity (mild/moderate/severe) based on their response on the Menopause Rating Scale. They were asked about VMS effects on sleep and completed the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance (SD) Short Form (SF) 8b (primary endpoint), PROMIS Sleep-Related Impairment (SRI) SF 8a, and Pittsburgh Sleep Quality Index (PSQI). PROMIS measure scores were converted to T-scores (standardized so 50=mean of general population and standard deviation=10). **Results:** Among 619 respondents (mean age 53 y, median 2.3 y since VMS onset, median 22.0 VMS/wk), VMS severity was mild in 88, moderate in 266, and severe in 265. Overall, 356 (57.5%) women had never been treated for VMS; of 256 ever treated for VMS, 38 (14.8%), 35 (13.7%), and 78 (30.5%) were currently using hormone therapy, nonhormonal therapy, and nonprescription therapy, respectively. Most women (90.8%)—including 81.8%, 86.8%, and 97.7% of those with mild, moderate, and severe VMS—reported that VMS impacts sleep (**Fig A**). Overall PROMIS SD SF 8b mean T-scores were >50, indicating more sleep disturbance than in the general population; sleep disturbance significantly increased with greater VMS severity (**Fig B**). Responses were similar on the PROMIS SRI SF 8a (**Fig C**). Mean PSQI total scores (**Fig D**) and all 7 domain scores (not shown) were positively associated with VMS severity. **Conclusion:** The vast majority of women and almost all those with severe VMS said VMS had a detrimental impact on sleep. As VMS severity increased, sleep disturbance and sleep-related impairment rose and sleep quality worsened.
Sources of Funding: Astellas Pharma. Writing support provided by Traci Stuve, MA, of Echelon Brand Communications, LLC, an OPEN Health company, funded by Astellas.

Figure. Impact of VMS on Sleep. (A) Self-reported impact on sleep. (B) PROMIS Sleep Disturbance SF 8b T-scores.[a] (C) PROMIS Sleep-Related Impairment SF 8a T-scores.[a] (D) PSQI total score.[b]



[a]Standardized T-scores were calculated such that 50 (10) [dashed line] represents the mean (SD) for the US general population. [b]PSQI total score was calculated by summing the 7 domain scores (range: 0–21), with a higher score indicating worse sleep quality. [c]*P* values were calculated using 1-way ANOVA; pairwise tests were conducted using t tests with adjustments (Bonferroni correction) for multiple comparisons since the null hypothesis of the 1-way ANOVA was rejected. [d]With mild VMS serving as the reference category, *P* values were calculated using ANCOVA, adjusting for age, race/ethnicity, education, marital status, employment status, time since VMS onset, menopause stage, smoking status, caffeine use, body mass index, comorbidities, current use of pharmacologic treatment, and current use of nonpharmacologic treatment for VMS.

ANOVA, analysis of variance; ANCOVA, analysis of covariance; PROMIS, Patient-Reported Outcomes Measures Information System; PSQI, Pittsburgh Sleep Quality Index; SD, standard deviation; SF, short form; VMS, vasomotor symptoms.

P-17.

Enhancing Diet and Exercise Counseling for Menopausal Women

Eshani Dixit, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD. Rutgers Robert Wood Johnson Medical School, Piscataway, NJ

Objective: While menopausal counseling often focuses on ameliorating the symptoms associated with estrogen loss, this stage of life also increases a woman's risk of cardiovascular disease, breast and gynecologic cancers, and osteoporosis. Although diet and exercise counseling is part of routine care, perhaps consideration should be given for clinicians to schedule a separate encounter for this discussion. **Design:** A literature search was conducted of peer-reviewed journal article published from 1995 to 2022, including the key words "nutrition," "menopause," "counseling," and "diet." **Results:** The scant data available suggest that high fiber diets that include an abundance of fruits and vegetables may alter the circulating levels of sex hormones, possibly ameliorating vasomotor symptoms Among other benefits, the recently completed FLAMENCO trial provides evidence that multicomponent physical exercise programs can provide benefit to menopause-related symptoms, particularly vasomotor symptoms. Diet related risk factors for cardiovascular disease are also more pronounced in menopause. Postmenopausal individuals have a higher total plasma level of LDL cholesterol, with overall denser LDL molecules. AHA Phase 2 and Phase 3 diets are recommended to individuals at elevated risk of cardiovascular disease, and evidence shows that postmenopausal individuals may experience a greater HDL increase response to exercise than premenopausal individuals. Osteoporosis is another significant concern for the menopausal population, with postmenopausal individuals experiencing a greater annual change and rate of change in bone density than their premenopausal counterparts. Exercise has been shown to be beneficial in osteoporosis prevention and possibly reversal as well, in combination with increased dietary intake of calcium and vitamin D. In one study, the majority of menopausal individuals reported interest in structured lifestyle change programs to alleviate their symptoms and specifically desire targeted strategies for managing their diet and exercise. Further, counseling in a group setting has been shown to improve diet, exercise, and foot care behaviors among menopausal diabetics. **Conclusion:** Diet and exercise management are important considerations for the menopausal patient. Structured counseling around lifestyle modifications appears to bedesired by menopausal individuals and has been shown to improve self-care behaviors. Peri-menopausal gynecologic visits present an opportunity to begin and continue this conversation. Perhaps consideration should be given to a template of gynecological care that includes a separate visit for this type of counseling.
Sources of Funding: None.

P-18.

Impact of Attending a Menopause Clinic on Symptom Management and Quality of Life

Erin Duralde, MD, Heather D. Hirsch, MD. Medicine, Division of Women's Health, Brigham and Women's Hospital, Boston, MA

Objective: We sought to assess the impact of attending this single institution midlife and menopause clinic via patient surveys issued before all new and returning visits on symptoms and quality of life. **Design:** In September 2021, we instituted a pre-visit survey for new and returning patients regarding their symptoms, past medical history, treatment use, and included six validated survey instruments: PHQ-9, GAD-7, Menopause Rating Scale, PROMIS Sleep Disturbance Scale, Hot Flash Related Daily Interference Scale, and the Female Sexual Function Index. To assess for differences between those new to clinic and those engaging with the practice, we cohorted patients into new and return patients. To respect the assumption of independence, we included only one observation per person, selecting the most recent observation for each person to maximize average follow-up time. We used STATA 17 for descriptive statistics and t-tests for significance. **Results:** All patients received the pre-visit survey; 390 completed surveys. After selecting only the most recent survey for each person, there were 176 new patient surveys and 214 returning patient surveys. The majority of patients were postmenopausal with about a quarter in perimenopause, with no difference between the groups. Approximately 10% had breast cancer, 5% chemotherapy, and 8% antiestrogen therapy. Few had history of other cancers, deep venous thrombosis, heart disease, stroke, or osteoporosis, and none had a pulmonary embolism. The majority (59%) had never tried any local or systemic hormonal therapy for their symptoms. We found statistically significant differences in outcomes on 4 out of 6 of pre-validated survey instruments between new and returning patients (Table 1). There was a significant reduction in Menopause Rating Scale symptoms (15.2 to 11.2, p= 0.000), the Hot Flash Related Daily Interference Scale (25.9 to 13.8, p 0.000), anxiety by GAD-7 score (10.3 to 7.7, p= 0.021), and an increase in Female sexual Function Index (13.4 to 17.1, p=0.002). There were non-significant trends toward improvement in depression on the PHQ-9 and sleep with the PROMIS Sleep Disturbance Scale **Conclusion:** Attending a dedicated midlife clinic is associated with reduced menopause symptoms, decreased interference of hot flashes in daily life, less anxiety, and improved sexual function. Such a clinic addresses symptoms that often go untreated and strongly impact women's quality of life.

Sources of Funding: None

Survey Instrument Scores, Comparing New to Return Patients

Scale	Score Reference Range	New patients Mean Score (SD)	Return patients Mean Score (SD)	p-value
Menopause Rating Scale	0 best – 44 worst	15.2 (6.8)	11.2 (6.3)	0.000*
PROMIS Sleep Disturbance Scale	8 best - 40 worst	20.1 (5.7)	18.8 (5.8)	0.066
Hot Flash Related Daily Interference Scale	0 best -100 worst	25.9 (22.7)	13.8 (18.2)	0.000*
Female Sexual Function Index	2 worst – 36 best	13.4 (9.1)	17.1 (9.9)	0.002*
PHQ-9	0 best – 27 worst	8.7 (5.6)	7.1 (5.8)	0.107
GAD-7	0 best- 21 worst	10.3 (6.6)	7.7 (6.5)	0.021*

*** p<= 0.05**

P-19.

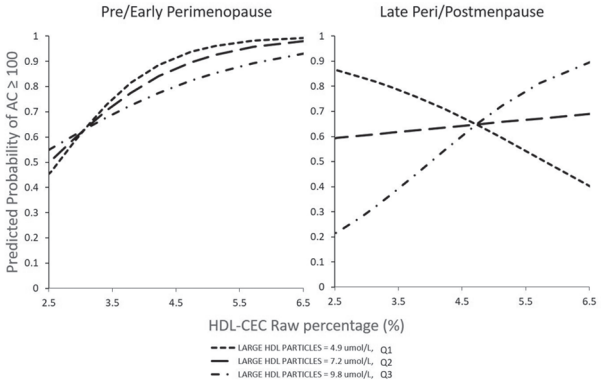
The Contribution of HDL Subclasses to the Associations of HDL Function with Aortic Calcification in Pre- vs. Postmenopausal Women: The SWAN Heart and HDL Ancillary Studies

Samar El Khoudary, PhD[1], Xirun Chen[1], Sybil Crawford[2], Trevor Orchard[1], Jeff Billheimer[3], Imke Janssen[4], Maria Brooks, PhD[1]. [1]University of Pittsburgh, Pittsburgh, PA; [2]UMass Chan Medical School, Worcester, MA; [3]University of Pennsylvania Perelman School of Medicine, Philadelphia, PA; [4]Rush University Medical Center, Chicago, PA

Objective: The ability of high-density lipoprotein subclasses, mainly large HDL particles (HDL-P), to promote cholesterol efflux capacity (CEC) from macrophages is weaker after than before menopause. This suggests that CEC associations with cardiovascular risk may vary by HDL subclasses in pre vs. postmenopausal stages. Our objectives were to assess associations of CEC with aortic artery calcification (AC), an early marker of atherosclerosis, and test whether these associations vary by level of HDL subclasses in pre- vs. postmenopausal women. **Design:** The Study of Women's Health Across the Nation (SWAN) Heart and HDL ancillary studies measured AC, CEC and nuclear magnetic resonance spectroscopy of HDL subclasses (total, large, medium and small HDL-P) at the same time point. Using logistic regressions associations of CEC with AC (AC score ≥100) presence were assessed at different stages of the menopause transition. Three-way interactions of CEC, HDL subclasses and menopause stage were tested. Final models were adjusted for age, study site, race, body mass index, systolic blood pressure, smoking status, physical activity, anti-lipid medication use and hormone therapy use. **Results:** The study included 262 women (mean age ± SD: 50.9 ± 2.8 years; 163 pre/early perimenopause vs. 99 late peri/postmenpause) who had data available on CEC, HDL subclasses and menopause stage. In unadjusted analysis and only in late peri/postmenopause women, higher CEC was marginally associated with lower prevalence of AC [0.47 (0.21, 1.02)]. Adjusting for covariates abolished this association. In final models, effect modification of large HDL subclasses on association of CEC with AC presence vary by menopause stage (P value for three-way interaction=0.01). In late peri/postmenopausal women, CEC was more strongly positively associated with higher prevalence of AC at higher levels of large HDL particles, while in pre/early perimenopause it was more strongly positively associated with higher prevalence of AC at lower levels of large HDL particles (**Figure**). No other three-way interactions were observed. **Conclusion:** In late peri/postmenopause stages, higher level of large HDL subclasses may detrimentally modify the expected cardioprotective associations of CEC with aortic calcification. Our results support the notion that large HDL particles may become dysfunctional during the menopause transition.

Sources of Funding: The SWAN has grant support from: NR004061; AG012505, AG012535, AG012531, AG012539, AG012546, AG012553, AG012554, AG012495. The SWAN Repository: U01AG017719. SWAN Heart was supported by HL065581, HL065591, HL089862. SWAN HDL ancillary study has grant support from NIA: AG058690.

Figure. Effect modification of large HDL subclasses on association of CEC with AC presence by menopause stage



P-20.

Menopause Stage Progression and Risk of Incident Cardiovascular Events: The SWAN Study

Samar El Khoudary, PhD[1], Saad Samargandy[2], Xirun Chen[1], Rebecca C. Thurston, PhD[1], Maria Brooks, PhD[1], Sybil Crawford[3], Yamnia I. Cortes, PhD, MPH, FNP-BC, FAHA[4], Elizabeth Jackson[5], Carol Derby[6]. [1]University of Pittsburgh, Pittsburgh, PA; [2]King Abdulaziz University, Jeddah, Saudi Arabia; [3]University of Massachusetts, Worcester, MA; [4]The University of North Carolina at Chapel Hill, Chapel Hill, NC; [5]University of Alabama at Birmingham, Birmingham, AL; [6]Albert Einstein College of Medicine, Bronx, NY

Objective: An earlier age at the onset of menopause is associated with higher risk of incident cardiovascular events postmenopause. However, multiple adverse cardiometabolic and vascular health alterations occur across stages of the menopause transition. Yet, the risk of CVD events across stages of the menopause transition has not been examined. With its prospective design and precise longitudinal assessment of menopause related factors (menopausal stage, age at menopause), the Study of Women's Health Across the Nation (SWAN) is uniquely positioned to provide one of the most robust evaluations of the relation of menopause stage to incident CVD risk. We hypothesize that risk of CVD events increases as women transition over the menopause in a dose-response fashion. **Design:** A total of 3302 women (47.0% White), aged 42 to 52 years at baseline, underwent up to 16 in-person follow up visits. Visits at which women were pregnant or on hormone therapy were dropped. Menopause stages were characterized over time based on bleeding patterns and hormone therapy use. The combined outcome of incident CVD events was defined as myocardial infarction, stroke, heart failure, revascularization and CVD deaths. The relationship between time-varying menopause stage and combined incident CVD was tested in a left truncated Cox proportional hazards model with chronologic age as the time scale. Data were censored at visit preceding bilateral oophorectomy and/or hysterectomy. Models were adjusted for demographics, and baseline behavioral, and CVD risk factors. Missing time points of the longitudinal menopause stage variable were imputed conditioning on the previous observed stage using the fully conditional specification method leveraging the wealth of demographic and longitudinal characteristics in SWAN. **Results:** Participants experienced 198 CVD events (incidence rate per 1000 person year=4.73) over 22 years of follow-up. In unadjusted models, the risk of CVD events increased in a dose-response manner with menopause stage. Specifically, compared with the premenopause, the HRs(95%) associated with each advanced menopause stage were: early peri: 1.89(0.72, 4.97), late peri/early post: 3.00(1.03, 8.79), and late post: 4.63(1.54, 13.91), trend P value=0.001. Although findings were attenuated, a trend remained significant after adjusting for race/ethnicity, financial strain, education, and baseline smoking, physical activity, low-density lipoprotein cholesterol, body mass index, systolic blood pressure, C-reactive protein, and ever being diabetic [HR(95% CI) early peri: 1.68(0.64, 4.43), late peri/early post: 2.16(0.74, 6.27), late post: 3.25(1.09, 9.71), trend P value=0.01]. Results were similar without data imputation and after adjusting for time varying – as opposed to baseline – behavioral and CVD risk factors. **Conclusion:** Risk of CVD events progresses over the menopause transition beyond the increase in risk from chronologic aging, supporting the need to monitor women's cardiovascular health as they traverse menopause to apply preventive interventions before CVD manifests.

Sources of Funding: The Study of Women's Health Across the Nation (SWAN) has grant support from the National Institutes of Health (NIH), DHHS, through the National Institute on Aging (NIA), the National Institute of Nursing Research (NINR) and the NIH Office of Research on Women's Health (ORWH) (Grants U01NR004061;

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P-21.

Hysterectomy in BRCA carriers: What are the differences between patients who have hysterectomy at the time of risk reducing BSO and those that opt for RRSO without hysterectomy?

Alexa N. Fiffick, DO[1], Tara K. Iyer, MD[1], Holly L. Thacker, MD[1], Mariam M. AlHilli, MD[2,5], Holly J. Pederson, MD[3,4]. [1]Specialized Women's Health, Cleveland Clinic, Cleveland, OH; [2]Subspecialty Women's Health, Cleveland Clinic, Cleveland, OH; [3]Breast Services, Cleveland Clinic, Cleveland, OH; [4]Genomic Medicine Institute, Cleveland Clinic, Cleveland, OH; [5]Cardiovascular and Metabolic Sciences, Cleveland Clinic, Cleveland, OH

Objective: Risk-reducing bilateral salpingo-oophorectomy is recommended for women with high-risk pathogenic genetic variants, namely *BRCA1* and *BRCA2*, due to their increased risk of breast and ovarian cancers. *BRCA1*, particularly, is also associated with a slightly elevated risk of endometrial cancer. Thus, some women undergo hysterectomy at time of RRSO for risk-reduction, while others have hysterectomy to limit progestational exposure with anticipated hormone replacement therapy. However, there are no formal guidelines to perform risk-reducing hysterectomy in *BRCA1/2* positive patients. Despite this, hormone replacement therapy until the time of natural menopause is guideline recommended not only for the treatment of symptoms that may occur due to surgical menopause, but for overall health and well-being. If a patient does not undergo hysterectomy with RRSO and requires HRT, they may experience postmenopausal bleeding either as a side effect of the therapy, or due to other underlying causes. Postmenopausal bleeding will then lead to an obligatory investigation to determine the cause of bleeding, which can lead to further financial, physical, and emotional burden to the patient. It is possible that consequently women may then undergo a subsequent hysterectomy. We will conduct a retrospective cohort study utilizing a database of *BRCA* positive patients followed at Cleveland Clinic to investigate the adherence to NCCN guidelines for RRSO, incidence of concurrent hysterectomy, adherence to NCCN guidelines for HRT, adherence to guidelines for osteoporosis screening, incidence of postmenopausal bleeding and treatments for bleeding, and incidence of subsequent hysterectomy. **Design:** Retrospective cohort of BRCA 1/2 carriers from Cleveland Clinic **Results:** Pending **Conclusion:** Pending

Sources of Funding: None

P-22.

Is Hormone Replacement Therapy Associated with Reduced Risk of Adhesive Capsulitis in Menopausal Women? A Single Center Analysis

Eliana Saltzman, MD[2], Emily K. Reinke, PhD[2], Elizabeth P. Wahl, MD[2], Anne C. Ford, MD[1], June Kennedy, PT,DPT[2], Jocelyn Wittstein, MD[2]. [1]Obstetrics and Gynecology, Duke University Medical Center, Durham, NC; [2]Orthopedics, Duke University School of Medicine, Durham, NC

Objective: Adhesive capsulitis (AC) is a common orthopaedic disorder, characterized by spontaneous onset of shoulder pain and gradual loss of active and passive shoulder range of motion.[1] Nearly a century since AC was first described, the etiology and pathophysiology remain unknown. It is recognized that AC mostly affects women aged 40 to 60 years old.[1] There are several associated medical conditions including: thyroid dysfunction[2], diabetes[3], and breast cancer treatment. Given the demographic most commonly affected by AC, it is interesting that the role of estrogen in the pathophysiology has not been described. Estrogen is known to play an important role in MSK; stimulating new bone formation, promoting muscle growth and repair, maintain connective tissue integrity, and reducing inflammation. As such, the purpose of this study was to determine if hormone replacement therapy (HRT) is protective against adhesive capsulitis in menopausal women. **LIST OF REFERENCES:** 1. Hsu JE, Anakwenze OA, Warrender WJ, Abboud JA. Current review of adhesive capsulitis. *J Shoulder Elb Surg*. 2011;20(3):502-514. doi:10.1016/j.jse.2010.08.023. 2. Wohlgethan JR. Brief Report Frozen Shoulder in Hyperthyroidism. :936-939. 3. Juel NG, Brox JI, Brunborg C, Holte KB, Berg TJ. Very High Prevalence of Frozen Shoulder in Patients With Type 1 Diabetes of ≥45 Years' Duration: The Dialong Shoulder Study. *Arch Phys Med Rehabil*. 2017;98(8):1551-1559. doi:10.1016/j.apmr.2017.01.020. **Design:** A single institution electronic medical record system was queried to retrospectively review menopausal women between the ages of 45 and 60. Subjects included were those enrolled in a single healthcare system coverage model to minimize inaccessibility to external episodes of care. Only data in existence as of November 1st 2018 was reviewed. Patients were identified using ICD-10 codes for perimenopausal/menopausal symptoms, menopause, estrogen replacement therapy, shoulder pain, shoulder stiffness and AC. A REDCap database was then built, allowing the authors to review medical records and verify the variables and diagnoses. The diagnosis of AC on chart review was confirmed by a sports medicine fellowship-trained orthopaedic surgeon and shoulder-specialized physical therapist. Patients identified with AC were further reviewed for rotator cuff tears, if corticosteroid injections were received, and lastly if surgery was required. Both groups were assessed for associated endocrine disorders. Odds ratio for diagnosis of AC was determined for subjects with and without HRT. All statistical analysis were conducted in SAS 9.4 (Cary, NC). Statistical significance was assessed at $p < 0.05$. **Results:** A total of 1,952 patients were included in the study, with 152 patients receiving HRT. The distribution of thyroid disorder and diabetes were similar between the two groups with no statistically significant difference. In the HRT cohort 11.2% were identified with thyroid disorder and 9.2% with diabetes; in the no HRT 12.4% were identified with a thyroid disorder and 14.3% with diabetes. Additionally, 4.0% of patients with HRT and 7.7% of those without HRT had AC. Those not receiving HRT had 99% greater odds of adhesive capsulitis compared to those receiving HRT; however, this association did not reach statistical significance (OR: 1.99; 95% CI 0.86, 4.58; $p = 0.11$). **Conclusion:** This is the first known study to evaluate the role of HRT in the development of AC amongst menopausal women in a single center. We concluded from our preliminary study that women not receiving HRT had greater odds of AC, however the study is limited by the available sample size. While the analysis is underpowered, the 95% confidence interval for the odds ratio contains values that support the hypothesis that HRT may be protective against AC. This preliminary data will serve as a basis for larger multi-center and prospective studies to further evaluation this association.

Sources of Funding: None

P-23.

Toward a continuous passive automatic detection of physiological hot flashes via wearable technology

Massimiliano de Zambotti, PhD[1,2], Andreas Tsiartas[1], Nicole Arra[1], Alison Polkinhorne[1], Ann Garnier, BA[2], Fiona Baker[1]. [1]SRI International, Menlo Park, CA; [2]Lisa Health Inc., Oakland, CA

Objective: The most common and disruptive symptom of menopause is hot flashes (HFs), affecting about 80% of women, with a median duration of 7 years. A HF is a heat dissipation response, characterized by sweating and peripheral vasodilation, as well as sensations of heat, flashing, anxiety, and chills. The physiological changes can be detected from measures of a sudden increase in sternum skin conductance (SC, hallmark of the phenomenon), reduction in blood pressure, and increased heart rate. HFs typically last a few minutes and vary in frequency between women, occurring several times per hour in some. No current commercially available solutions exist to automatically and longitudinally track physiological HFs. Following the advancement in sensor technology, computational power, and scientific knowledge about menopause and HFs, we developed and pilot-tested a novel consumer-oriented artificial intelligence (AI)-based algorithm for real-time HF detection via commercially available, multi-sensor, wrist-based wearable technology. **Design:** The algorithm was trained and tested on a dataset of 366 physiological HFs recorded from eleven midlife women (51-64 y) tracked with both an ambulatory research-grade HF monitor (UFI Biolog) and an Empatica E4 wrist device across ~48 hours in free-living conditions. Additional sensors were used to measure environmental temperature and humidity (iButton), activity levels and sleep (Fitbit Charge 4). None of the women had severe mental or medical conditions and were not taking current medications known to affect sleep and/or the cardiovascular system, including hormone therapy. An expert manually evaluated sudden increases in sternal SC (defined as 1.5 uS/30s) measured with the research-grade HF monitor, which was used as the gold-standard. The AI-based HF classifier used a combination of features derived from E4 signals. A binary decision tree classifier was used to predict the presence or absence of HFs. The algorithm was trained and evaluated to choose the optimal parameters using a leave-one-subject-out cross-validation approach (4 subjects, 126 HFs) and then evaluated on a held-out dataset (7 subjects, 240 HFs). The algorithm performance was evaluated in terms of accuracy (averaged sensitivity and specificity) relative to the gold-standard. **Results:** The AI-based real-time HF tracking algorithm achieved an overall accuracy of >90% on the testing dataset (correctly detected 227 HFs out of a total of 240 HFs), and had an average of <2 false alarms per hour of recording (detecting a HF when not present) largely due to HF misdetection during periods of sweating (no features were implemented in the current algorithm to limit the time lag between consecutive HFs). Accuracy was also partially dependent (up to 15% in absolute differences) on additional factors like signal noise (determined by augmenting the training dataset with 0-to-25% synthetically randomly generated signal drops and spikes), time of day, environmental temperature and humidity, sleep/wake state, physical activity level. **Conclusion:** HFs in women have a negative effect on quality of life and are associated with increased cardiovascular risk. Longitudinal, passive tracking of HFs can ultimately advance our understanding of their effects on women's health and wellness, and can be applied to improve clinical evaluation and management of menopause symptomatology. Among future directions, the algorithm's performance needs to be tuned toward precision, and evaluated longitudinally on a large scale, considering factors known to affect signal quality and accuracy of measurement of HF physiology, including skin tone, body mass index, and age.

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P-24.

Women, Work and Menopause: Findings from the Elektra Health Menopause in the Workplace Survey 2022

Jacqueline Giannelli[1], Anna Barbieri[1,2], Jannine Versi[1], Alessandra Henderson[1], Ioana Calcev[1]. [1]Elektra Health, Ridgefield, CT; [2]Mount Sinai Health System, New York, NY

Objective: Elektra Health is a digital health platform that supports women throughout their 10-year menopause journey via evidence-based education, on-demand virtual care, and community support. Although there are over 50M women currently or soon to be navigating the menopause transition, adequate community and educational support is generally lacking in the workplace. In June 2022, Elektra Health collected survey data from 2003 US-based female professionals ages 40-55, with the aim of analyzing how employees are navigating menopause in the workplace, including impact of symptoms, assessment of workplace and employer support, and potential need for additional menopause resources. **Design:** In June 2022, Elektra Health performed an analysis using

aggregated, anonymized data from 2003 female employees between the ages of 40-55 in the US, to identify menopause and workplace trends. A third-party platform called Census Wide was used to ensure all employees polled were reflective of the reported samples discussed in the report. Respondents self-identified as working professionals ranging from from managers to C-suite professionals and provided their menopause status. The respondents were asked about their menopause symptoms and specifically, the experience of those symptoms in the workplace, as well as what support they would like from their employers, if any. Respondents answered the question, "Generally, how much more or less support would you like in managing menopause from your employer?" on a scale from "a lot more support" to "a bit more support"; "neither more nor less support"; "a bit less support"; or "a lot less support". The responses "a lot more support" and "a bit more support" were combined into a new category, "more support wanted", which was then analyzed by both age group and racial identity. Statistical analysis used a two proportion z-test. Analyses were conducted in R. **Results:** Out of 2003 respondents, 923 women were aged 40-45 (46%), 554 aged 46-50 (27.7%) and 526 aged 51-55 (26.3%). 1,555 women self-identified as White (77.6%), and 285 women self-identified as Black or African American (14.2%). Of the surveyed group, 32.6% reported that menopause impacted their work performance and 19.5% reported having left or considered leaving a job because of symptoms. The need for additional employer support for menopause was expressed by 876, or 43.7%, of the respondents. The proportion of 40-45 year old women wanting more menopause support from their employers was found to be significantly greater than the proportion of 46-50 year old women who wanted more support ($z = 2.34$; $p < .05$ ($p=.0097$); (sig: alpha =.05)) and 51-55 year old women ($z = 4.00$; $p < .05$ ($p=.00003$); (sig: alpha=.05)) who wanted more support. A secondary finding was that the proportion of Black and African American women wanting more menopause support from their employers was significantly greater than the proportion of White women wanting more support ($z=2.21$; $p < .05$ ($p=.0134$); (sig: alpha=.05)). **Conclusion:** The Elektra survey shows a significant impact of menopause on women in the workplace. There is clearly a strong interest for menopause support from employers, with a greater number of women in the younger age cohort expressing the need for additional help. We postulate that this difference represents a currently unmet need for education and intervention in the earlier phases of the menopause transition and/or demonstrates increased comfort of younger respondents in discussing this issue. The results of the survey have implications for forward-thinking employers who are interested in the well-being of their employees. Education and menopause related resources may reduce absenteeism, encourage retention of female managers, and reduce health costs. Additionally, support for menopause in the workplace has the potential for company cost-savings by minimizing employee turnover and maximizing brand reputation and company loyalty. More research is required to understand the nuanced preferences of working women experiencing menopause, as well as the types of support that are most effective in the workplace, and how to deliver high quality services while also respecting employees' privacy.

Sources of Funding: Elektra Health

P-25.

Performance of Endometrial Cancer Case Finding Algorithms Among Women with Select Comorbidities in US Claims Data

Djeneba Djibo[2], Andrea V. Margulis, MD, ScD[3], Cheryl N. McMahill-Walraven[2], Catherine Saltus[4], Patricia Shuminski[2], James Kaye[5], Catherine Johannes[5], Brian Calingaert[5], Mark Libertin[2], Shelli Graham, PhD[1]. [1]TherapeuticsMD, Boca Raton, FL; [2]CVSHealth, Blue Bell, PA; [3]RTI Health Solutions Barcelona, Barcelona, Spain; [4]RTI Health Solutions Waltham, Waltham, MA; [5]RTI Health Solutions Research Triangle Park, Research Triangle Park, NC

Objective: Although an algorithm to identify cases of endometrial cancer in insurance claims using International Classification of Disease version 9 Clinical Modification (ICD-9-CM) codes has been published, no such algorithm has been ascertained for ICD-10-CM codes. The objective of this stidy was to determine the overall positive predictive value (PPV) of an endometrial cancer case identification algorithm using ICD-10-CM diagnosis codes and among women having type 1 or type 2 diabetes mellitus (DM), obesity, or endometrial hyperplasia. **Design:** Study population consisted of women aged ≥ 50 years without prior hysterectomy or endometrial ablation, with at least 12 months enrollment in a health plan prior to diagnosis of endometrial cancer from 2016 through 2020. The algorithm variant A used diagnostic codes for malignant neoplasms of uterine sites (C54.x), excluding C54.2 (malignant neoplasm of myometrium), the algorithm variant B used C54.1 (malignant neoplasm of endometrium) only. Both variants require at least 1 inpatient or 2 outpatient diagnoses (on different dates, separated by any interval). A random subsample of provisional cases was adjudicated via review of medical records as confirmed, probable, possible cases, or non-cases. Agreement in case determination among adjudicators was measured using the kappa coefficient (κ). We estimated the PPV of each variant of the case finding algorithm with exact 95% confidence intervals (CI). **Results:** Of 3,143 provisional cases identified by algorithm variant A, medical records for 294 unique provisional cases were obtained and adjudicated; 288 of the 294 also were provisional cases per algorithm variant B. Among the women with a provisional case (n=294), the median age was 69.0 years (25th and 75th percentiles: 63.0, 74.0) years. Among those, 49.0% were obese, 42.5% had type 1 or type 2 DM, and 27.6% had endometrial hyperplasia. Both variants identified the same confirmed cases (n=223), but differed in identification of non-cases, and possible cases. There was high level of agreement between adjudicators, κ=0.78. The overall PPV (95% CI) was 84.2% (79.2%-88.3%) for variant A and 85.8% (80.9%-89.8%) for variant B. Among obese women, PPV was 90.9% (84.7%, 95.2%) for both algorithm variants. Among women with DM, PPV was 85.7% (77.8%, 91.6%) for variant A and 87.3% (79.6%, 92.9%) for variant B. Predictive values were highest among those with endometrial hyperplasia: PPV was 96.1% (88.8%, 99.2%) for variant A and 96.0% (88.9%, 99.2%) for variant B. **Conclusion:** Based on these results, both variants of the ICD-10-CM case finding algorithm were successful in the identification of true endometrial cancer cases. Algorithm variant B identified fewer provisional cases not determined to be true positive cases than variant A.

Sources of Funding: TherapeuticsMD

P-26.

The Role of Intimate Partners in the Wellness of Menopausal Women

Lucy Guan, MPH, Hassiet Asberom, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD. Obstetrics and Gynecology, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Menopause can be associated with physical and emotional changes that can functionally affect and be influenced by intimate relationships with partners. Menopausal symptoms, such as vasomotor symptoms, vaginal dryness and adverse changes in sexual function may often occur due to aging and to the progressive decline of female hormones. These changes in sexual function may impact the menopausal woman's intimate relationship. As social support can positively influence the experience of menopause, partners' awareness of symptoms, knowledge of treatment, and their understanding and expectations of menopause may serve as a potential educational avenue to further support women as they navigate this transition. This review examines current attitudes and awareness of the partners of midlife and older women and explores the role partners play in their physical and psychosocial challenges. **Design:** A literature review of peer-reviewed articles was conducted through PubMed and Google Scholar. **Results:** Data suggest that social support from family, friends and intimate partners is associated with less isolation, improved quality of life, and decreased severity of menopausal symptoms. Qualitative studies explore how the relative abruptness of menopause symptoms can be profoundly distressing, manifesting in a decreased quality of life. Menopausal women often describe mood changes as a major source of distress, as these changes may be negatively perceived by their partners and family members. The complex experience of menopause is also shaped by societal norms and negative cultural views towards aging. One study reported that menopausal women are seen negatively by premenopausal women and men, with men having more negative attitudes. One qualitative study suggested that partners may have an influence on whether a woman seeks treatment for symptoms they may not have viewed as worrisome, as menopausal symptoms can vary widely from individual to individual. Others often avoided discussing their symptoms with partners or seeking treatment due to their partners not believing these symptoms were actually present. Other studies suggest that a partner's perceptions and attitudes towards menopause may be related to the severity of women's menopausal symptoms, their own attitudes towards menopause, as well as their intimate relationships; however, the causal relationship remains unclear. The limited data that exists regarding partners' attitudes towards menopause focuses on male partners. The Men's Attitudes Toward mEnopause survey study explored the awareness and attitudes of male partners, highlighting the need for education and awareness of symptoms. This study found that men often misattributed common menopause symptoms to other causes, including feeling emotionally down or depressed, being overweight, or another health issue unrelated to menopause. A randomized controlled trial conducted in Iran assigned the intervention group to a 3-month educational training program for husbands of women aged 45 to 55. The educational content included symptoms and complications of menopause, management options, and spouse support during perimenopause. The results revealed a significant difference between the men's knowledge scores about menopause before and after the educational program in the intervention group, as well as significant differences in total satisfaction scores and scales of marital communication, conflict resolution, leisure activities, and marriage and children between women in the intervention group. **Conclusion:** The results of this review underscore the importance of partner education and awareness in providing social support to menopausal women, through their medical challenges as well as the social and relational difficulties. Further research that expands upon the role of partners' attitudes toward menopause is warranted, especially to broaden the scope beyond heteronormative relationships. Possible interventions include comprehensive menopause education for partners on recognizing the signs and symptoms, treatment and management options, and the supporting role of the partner during the menopausal transition. Furthermore, it is imperative to acknowledge relational challenges and encourage open partner communication in the individualized counseling and treatment of menopausal women.

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P-27.

Use of Probiotics in the Menopause: Is there a Role?

Lucy Guan, MPH, Juana Hutchinson-Colas, MD, Gloria Bachmann, MD. Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Menopausal health-related symptoms due to estrogen decline are typically managed with hormonal therapy. Alternative therapeutic strategies that are utilized by some women include dietary supplements, such as probiotics. There are data that suggest gut microbiota and estrogen decline may increase the risk of these adverse symptoms. However, the health benefits and safety of probiotics are generally less defined, as most dietary supplements are neither reviewed nor approved by the FDA. This review explores whether the use of oral probiotics in peri- and post-menopausal women may be of benefit in the relief of menopausal symptoms. **Design:** A literature review was conducted for peer-reviewed journal articles of randomized control trials from PubMed published from inception to April 2022, examining whether use of probiotics in peri- and post-menopausal women led to improvements in various menopause-related health outcomes. **Results:** Literature search yielded six double-blind, randomized control

trials. A summary of these trials is as follows. An increase in FSH levels following probiotic administration was suggested in one study; however, the baseline levels for the therapy group were significantly higher than the baseline of the placebo group, in which an increase in FSH was also observed. Another study reported that administration of milk fermented with *Lactobacillus helveticus* yielded increased serum calcium levels ($P<0.05$) and reduced serum PTH ($P<0.01$) compared to control milk, suggesting the possibility of improved calcium metabolism. Data that reported on the effect of combining administration of isoflavones with probiotics suggested that there were no benefits to alleviating VMS, such as vaginal dryness and sexual complaints. Another study with isoflavones and probiotics showed statistically significant decreases in physiological ($P<0.01$) and self-reported hot flash frequency ($P<0.05$) and physiological hot flash intensity ($P<0.01$), but no significant differences between systolic and diastolic BP, LDL, HDL, TC and triglyceride concentrations. Two studies using the same participant sample of obese postmenopausal women examined the effects of varying doses of supplemented multispecies probiotics. One found a higher dosing regimen was associated with significant decreases in lipopolysaccharide levels ($P<0.001$), fat mass ($P<0.05$), subcutaneous fat ($P<0.0002$), TC ($P<0.002$), and triglyceride ($P<0.01$) and glucose levels ($P<0.0001$). The second study found no statistically significant differences in endothelial and vascular dysfunction, except for increased VEGF levels ($P<0.001$). These studies suggest potential cardioprotective effects among obese postmenopausal women. **Conclusion:** There are few randomized control trials on whether probiotics can alleviate menopausal symptoms and health complications. Additionally, the results of the available few are difficult to generalize as studies used probiotics with different species and combinations with other supplements or alternative therapies, followed varying dosing regimens and with small cohort sizes. Despite a growing interest in alternative therapies, benefits of probiotics on peri- and post-menopausal health are not well-defined.
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P-28.

Reported practice patterns for use of hormone therapy in healthy patients and gynecologic cancer survivors

Chelsey A. Harris, MD, Christina E. Dancz, MD MPH, Kaitlin Doody, MD, Sharon Winer, MD MPH, Donna Shoupe, Intira Sriprasert, MD PHD. Obstetrics and Gynecology, University of Southern California Keck School of Medicine, Los Angeles, CA

Objective: Use of hormone therapy (HT) sharply declined after reports of increased cardiovascular and breast cancer risk from the Women's Health Initiative study in 2002. Current clinical guidelines state it is best practice or clinicians to assess benefits and risks of HT use for each individual menopausal patient. This study aims to evaluate knowledge and practice patterns for HT use in clinicians treating healthy menopausal patients who are healthy, and those with history of gynecologic cancers. Secondary aims were: 1) to compare knowledge, attitudes and practice patterns between in-training and practicing clinicians and 2) to assess perceptions of training and preparation required to competently manage menopausal patients. **Design:** A web-based survey invitation was distributed to medical students, residents, fellows, and practicing clinicians in the department of Obstetrics and Gynecology, Family Medicine, and Internal Medicine at a large academic institution. The 30-question survey assessed basic demographics, provider knowledge of diagnosis and management of menopause. Questions also evaluated reported training experience and feelings of preparedness to manage menopausal patients. Descriptive analysis was used to summarize and report of survey results. **Results:** Sixty-six clinicians completed the survey. Most (74%) were female under 40 years old. Two-third of respondents are in-training and one-third are practicing. A majority of responders correctly answered questions about the diagnosis, evaluation and initial HT treatment for menopausal women. Regarding duration of treatment, 54.6% of respondents indicated they would prescribe HT in premature menopause patients until at least the natural age of menopause. Only 23.4% of respondents correctly selected the recommendation of national guidelines to prescribe HT in menopausal patients with menopausal symptoms as long as possible with considerations of benefits versus risks. For cancer survivors, reporting clinicians describe willingness to prescribe systemic HT for 18.8%, 17.2% and 44.4% for patients with high grade serous ovarian cancer, early-stage endometrial cancer and cervical cancer, respectively. Reporting clinicians were much more likely to recommend vaginal HT in cancer survivors (46.9%, 37.5% and 60.9%, for each cancer, respectively). Among in-training students, residents, and fellows, 56.8% reported having 0 to 1 lecture or didactics on menopause management. Among practicing clinicians, where most were 5+ years out of training, 54.4% reported attending to 0 to 1 continuing medical education sessions dedicated to management of menopause. Most responding clinicians (73.9%) agreed it is important to be trained to manage menopausal patients, however, 43.2% of trainees and 13.6% of practicing clinicians feel "not at all prepared" to manage menopausal patients. Reported trusted sources for information were: ACOG (63.6%), USPSTF (50.0%), AAFP (31.9%) and NAMS (15.2%). All results are similar between in-training and practicing clinicians. **Conclusion:** Most respondents correctly answered questions about diagnosis and evaluation of menopause and initial HT treatment. Reported duration of HT use was highly variable. Variations in use of HT in menopausal patients with a history of gynecologic cancer was pronounced, with more uptake of vaginal compared to systemic HT. Amongst the diverse population of survey participants, most felt inadequately prepared to manage menopausal patients. Reported exposure to training on menopause management is limited among clinicians who routinely care for menopausal patients. Professional organizations are important sources of information regarding menopause management for clinicians.
Sources of Funding: None

P-29.

Patient Characteristics and Menopause Symptoms Recorded during Intake at a Boston Menopause Specialty Clinic

Heather D. Hirsch, MD[1,3], Erin Durdale[2]. [1]Internal Medicine, Brigham and Women's Hospital, Boston, MA; [2]Mass General Brigham Inc, Boston, MA; [3]Harvard Medical School, Boston, MA

Objective: To gather information on the patient characteristics of women presenting to a dedicated menopause clinic in Boston Massachusetts in a large academic medical center, and to identify self-reported bothersome symptoms motivating a new patient visit. **Design:** We performed a cross-sectional study of patients seeking consultation for menopause or sexual health-related midlife concerns at the Brigham and Women's Hospital's specialty menopause clinic between September 2021 and June 2022. Patients completed a structured response survey including questions about the symptoms motivating their visit. We used STATA 17 to calculate descriptive statistics on frequency and percentages of non-mutually exclusive symptoms on interest. **Results:** Of the 208 patients who completed intake surveys, the average age of presentation was 52.3 years, with most women self-reporting post-menopausal status (53.1%), while 24.6% reported perimenopause, and 13.7% were unsure of their status. The top three reasons selected out of thirteen options for the visit were sleep problems (64.5%), hot flashes (60.2%), and memory and/or concentration problems at (53.6%). Out of this cohort, 59.7% reported never trialing any kind of hormone therapy, while 38.4% had tried a local and/or systemic method in the past. **Conclusion:** This study of patients attending a dedicated menopause clinic in a densely populated northeast metropolitan area highlights several important gaps in the care for women in midlife. The most frequently bothersome symptoms, affecting more than half of all patients, were sleep disturbances, hot flashes, and brain fog. Meanwhile, vaginal dryness and loss of sexual desire affected nearly half of all patients. This suggests these symptoms were not yet alleviated by primary and/or specialty care. There may be regional differences in symptoms and patient motivation to disclose them, requiring further study.
Sources of Funding: None

Table 1. Symptoms Motivating First Visit

Patients selected all that applied

Symptom	Frequency (%) N= 211
Hot flashes	127 (60.2)
Memory/concentration problems	113(53.6)
Headaches	60 (28.4)
Mood swings	83 (39.3)
Sleep problems	136 (64.5)
Loss of sexual desire	102 (48.3)
Arousal/orgasm problems	58 (27.5)
Reduced genital sensation	40 (19.0)
Vaginal dryness	101 (47.9)
Painful intercourse	64 (30.3)
Genital pain	12 (5.7)
Pelvic pain	19 (9.0)
Other	21 (10.0)

Table 1. Symptoms Motivating First Visit

P-30.

Biopsychosocial Factors for Opioid Use Disorders Among Midlife and Aging Women

Caitlyn A. Horton. Women's Health Institute, Robert Wood Johnson University Hospital, New Brunswick, NJ

Objective: Opioid overdose deaths are steeply rising for every population with midlife women seeing the greatest percent increase.[1,2] Midlife women currently receive the greatest number of opioid prescriptions at a rate almost twice that of midlife men.[2] The CDC recommends physicians adopt a biopsychosocial approach to pain management to prevent and treat Opioid Use Disorders (OUDs).[1] A more holistic approach would consider the unique biopsychosocial factors experienced by midlife women that set them apart from other members of their sex and age group. Of those prescribed opioids, back and joint pain make up nearly 40% of prescriptions.[3] Midlife and older women are also more likely to report mental health issues compared to younger women, and those with OUDs are more likely to have psychiatric comorbidity than adult men.[3] Instability in one's community contributes to an increased risk of developing an OUD, with decreased financial stability and the death of a loved one being factors impacting midlife and older women at increased rates.[4] As a result of their age and sex, midlife women experience increased stigma for OUDs. The stigma midlife women with OUDs face can be a potential barrier to seeking out treatment and isolate them further from their community. Disruption in care and community can contribute to the rapidly rising opioid overdose death rates amongst this population. **Design:** A review of existing research on OUDs and midlife and aging women was conducted. **Results:** Available literature are sparse regarding the biopsychosocial factors associated with OUDs by age and sex, especially for midlife and older women. OUD treatment and prevention practices that consider biopsychosocial factors have been shown to aid midlife women. Women-centered treatment programs are designed to specifically cater to the needs of midlife women and encourage a

stigma-free space.[1,5] These programs may offer child care, domestic counseling, and mental health screenings. As midlife women receive the greatest number of prescription opioids, state drug monitoring programs can prevent multiple prescriptions from being filled and prevent overprescription.[4] **Conclusion:** While understanding the unique OUD risks for midlife and older women, prescribing physicians should refer to CDC and Medicare pain management guidelines. Harm reduction practices to prevent overdose, like naloxone education and accessibility can be adapted to highlight this population. For those with chronic pain conditions that need this intervention, co-prescribed naloxone alongside their opioid prescriptions should be considered. Further research should be done to measure the correlation of each biopsychosocial factor for midlife and older women and OUDs, as well as researching the general impact of OUDs by age and sex.

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P-31.

A Randomized Trial of Continuous Transdermal Nitroglycerin to Suppress Hot Flashes by Inducing Nitrate Cross-Tolerance in Perimenopausal and Postmenopausal Women

Alison J. Huang, MD, MAS, Peter Ganz, Steven Cummings, Carolyn Gibson, PhD, MPH, Michael Schembri, Harini Raghunathan, Eric Vittinghoff, PhD, Deborah Grady. University of California San Francisco, San Francisco, CA

Objective: Physiologic studies indicate that nitric oxide (NO) plays a key role in mediating hot flash-related vasodilation, with local blockade of NO synthase appearing to suppress cutaneous vasodilation during hot flash episodes. Nitroglycerin (NTG) is an organic nitrate medication that is converted to NO in the vascular wall and initially triggers vasodilation; however, continuous use of NTG for more than 24 hours results in rapid development of nitrate tolerance, including cross-tolerance to endogenous nitrates such as NO. We sought to determine whether continuous administration of transdermal NTG could decrease the frequency or severity of hot flashes by inducing nitrate cross-tolerance in peri- and postmenopausal women. **Design:** The Flushing Reduction Associated with Nitroglycerin (FRAN) trial was a randomized, double-blinded, placebo-controlled trial in women aged 40 to 62 years who were postmenopausal or in the late menopausal transition, reported an average of at least 7 hot flashes per day, and did not have coronary disease or multiple risk factors for coronary disease. Women were recruited from the San Francisco Bay area from 2017-2022 and randomly assigned in equal ratios to uninterrupted daily use of transdermal NTG patches (participant-directed dose escalation from 0.2 to 0.6 mg/hour) or identical-appearing placebo patches for 12 weeks. Validated symptom diaries assessed change in the daily frequency of any hot flashes (primary outcome) from baseline to 5 and 12 weeks of treatment. Secondary outcomes included changes in the daily frequency of moderate-to-severe hot flashes and daily hot flash severity score (calculated as the total number of hot flashes weighted by hot flash severity) by diary over these time periods. **Results:** Among the 141 women randomized (70 to NTG, 71 to placebo), mean (SD) age was 54.6 (3.9) years, 20.6% were in the late menopausal transition, 6.4% had undergone bilateral oophorectomy, and 73.0% were naturally postmenopausal or had undergone hysterectomy. At baseline, participants reported an average (SD) of 10.8 (3.5) hot flashes per day, including 8.4 (3.6) moderate-to-severe hot flashes per day. Sixty-five (92.9%) of women in the NTG group and 69 (97.2%) in the placebo group completed follow-up at 5 and 12 weeks. Over 5 weeks, the average daily frequency of any reported hot flashes decreased by 41.7% in the NTG versus 32.7% in the placebo group (P=.10, Table figure); the average daily frequency of moderate-to-severe hot flashes decreased by 44.7% in the NTG group versus 35.1% the placebo group (P=.06, Table figure). By 12 weeks, however, the average frequency and severity of hot flashes had decreased by more than 40% in both groups and did not differ substantially between groups (P≥.50 for all, Table figure). Over two thirds of women assigned to NTG initially reported headache, compared to 5.6% assigned to placebo (P<.01), but only one participant in each group continued to report headache at 12 weeks (P=1.0). **Conclusion:** Although continuous use of NTG may induce cross-tolerance to NO as a mediator of hot flash-related vasodilation, it did not result in greater sustained improvements in hot flash frequency or severity over 12 weeks in peri- or postmenopausal women relative to placebo.

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Table: Change in frequency and severity of hot flashes over 5 and 12 weeks, by treatment group

	Nitroglycerin	Placebo	Between-Group Difference	
	Mean (95% CI)	Mean (95% CI)	Mean (95% CI)	P
Change from baseline to 5 weeks				
Any hot flashes per day	-4.5 (-5.3, -3.7)	-3.6 (-4.3, -2.8)	-0.9 (-2.0, 0.2)	.10
Moderate-to-severe hot flashes per day	-3.9 (-4.7, -3.1)	-2.8 (-3.6, -2.1)	-1.0 (-2.1, 0.0)	.06
Daily to flash severity score	-9.1 (-10.8, -7.3)	-6.9 (-8.6, -5.3)	-2.1 (-4.6, 0.3)	.08
Change from baseline to 12 weeks				
Any hot flashes per day	-4.6 (-5.5, -3.7)	-4.6 (-5.0, -3.8)	0.1 (-1.2, 1.3)	.92
Moderate-to-severe hot flashes per day	-3.8 (-4.7, -3.0)	-3.5 (-4.3, -2.7)	-0.4 (-1.5, 08)	.50
Daily hot flash severity score	-9.2 (-11.0, -7.3)	-8.9 (-10.7, -7.1)	-0.3 (-2.8, 2.3)	.84

Mean estimates and 95% confidence intervals derived from linear mixed models with adjustment for baseline values.

P-32.

Post-Traumatic Stress Symptoms and Inflammation Among Midlife Women

Karen P. Jakubowski, PhD[2], Pauline Maki, PhD[1], Mary Y. Carson, PhD[2], Yuefang Chang, PhD[2], Rebecca C. Thurston, PhD[2]. [1]University of Illinois Chicago, Chicago, IL; [2]University of Pittsburgh, Pittsburgh, PA

Objective: Trauma is common and related to poor health among midlife women. Post-traumatic stress disorder (PTSD) symptoms following traumatic or extremely stressful experiences are related to adverse physical health outcomes, including chronic pain and obesity. However, limited work has examined relations between PTSD symptoms and inflammatory markers among midlife women. Inflammation plays a critical role in the pathophysiology of numerous chronic diseases. We tested whether PTSD symptom severity was associated with elevated markers of inflammation among midlife women after accounting for potentially confounding factors. **Design:** Participants were 272 women aged 45-67 years old free of cardiovascular disease, stroke, or dementia. Women completed a validated survey for past-month PTSD symptom severity (PTSD Checklist-Civilian Version; total score range: 17-85); reported medical history and medication use via interview; and provided body mass index (BMI) and a fasting blood draw for interleukin-6 (IL-6) and high sensitivity C-reactive protein (hsCRP). Women were excluded from analyses if they had an autoimmune disorder (N=13) or were taking immunosuppressive medications (N=2), and for hsCRP analyses, had values of hsCRP>10 mg/L (suggestive of acute infection; N=26). Relations between PTSD scores and IL-6 (log) and hsCRP (log) were assessed in linear regression models, adjusting for age, race/ethnicity, education, BMI (log), and other anti-inflammatory medication use (e.g., NSAIDs). **Results:** The analytic sample included N=257 and N=232 women in IL-6 and hsCRP analyses, respectively. Women were on average 59 years old; 2% identified as Asian or Pacific Islander, 17% Black, 2% Multiracial, and 79% White. On average, women reported low to moderate severity of PTSD symptoms (*M*=24.7, *SD*=8.5). Women who reported greater PTSD symptoms had higher IL-6 [B(SE)=.19 (.09), p=.03, multivariable; Figure]. There was no significant association between PTSD symptoms and hsCRP [B(SE)= -.03 (.11), p=.78, multivariable]. **Conclusion:** PTSD symptoms were related to elevated IL-6 after adjusting for confounders. Results are consistent with prior work that suggests associations between trauma and IL-6, but not hsCRP. Results underscore the importance of assessing trauma and PTSD among midlife women in routine clinical care. There is potential value in treatment of PTSD symptoms to promote the health and wellbeing of aging women.

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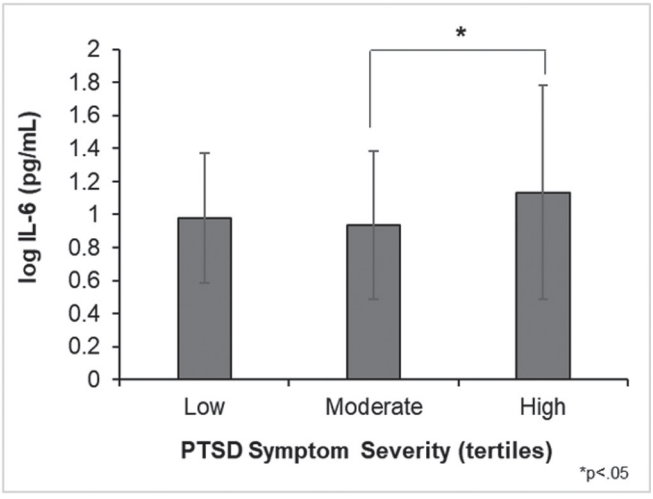

Figure 1. PTSD symptom severity and IL-6 (raw means). PTSD displayed as tertiles for illustrative purposes.

P-33.

Burden of Insomnia Among Osteoporosis Patients: A US Retrospective Claims Database Analysis

Emerson M. Wickwire[2], Timothy R. Juday, PhD, MPA[1], Feride H. Frech, PhD, MPH[1], Mona Kelkar[3], Jihaeng Heo, PhD, MS[3], Caroline Margiotta, MA[3], Manoj H. Malhotra, MD[1]. [1]NBG Medical Affairs, Eisai Inc, Woodcliff Lake, NJ; [2]University of Maryland School of Medicine, Baltimore, MD; [3]Genesis Research LLC, Hoboken, NJ

Objective: Chronic insomnia has been associated with accelerated bone loss, a greater likelihood of osteoporosis, and an increased risk of bone fractures. This study sought to determine the incremental all-cause healthcare resource utilization (HCRU) and costs associated with insomnia in a cohort of patients with osteoporosis. **Design:** This retrospective study used the IBM MarketScan Commercial and Medicare Supplemental Databases (Jan 2014-Dec 2019) to identify patients: (1) age ≥18 years; (2) with ≥1 ICD-9/ICD-10 codes for insomnia OR with ≥2 prescriptions for zolpidem immediate release (IR) OR trazodone ≤150mg OR benzodiazepine; (3) with ≥12 months of continuous enrollment pre-/post-index date (earliest diagnosis or medication fill date); and (4) with ≥2 ICD-9/ICD-10 codes for osteoporosis. Patients with sleep disorders other than insomnia were excluded. The resulting patients ("insomnia cohort") were 1:1 matched on age, sex and Elixhauser Comorbidity Index (ECI) score to osteoporosis patients without insomnia or other sleep disorders ("control cohort"). HCRU and costs were reported per patient per month (PPPM) over the 12-month follow-up period. Generalized linear models were used to compare adjusted outcomes between cohorts controlling for covariates including sex, age, ECI, geographic region, antidepressant use, antihypertensive use and anti-hyperglycemic use. **Results:** For each cohort, 5,194 osteoporosis patients (mean age 67.5 years, 98.5% female, 7.1 ECI score) were identified. In adjusted analyses, significantly more patients in the insomnia cohort had at least one inpatient admission per month ($p<0.0001$), inpatient stays were significantly longer ($p<0.001$), had at least one ED visit per month ($p<0.0001$) and mean outpatient visits were significantly higher ($p<0.0001$) relative to the control cohort. However, mean number of inpatient admissions and mean number of ED visits were not significantly different between cohorts. After adjusting for covariates, mean total PPPM costs were significantly higher in the insomnia cohort than in the control cohort ($2,030 and $1,490, respectively; mean ratio [MR] = 1.36; $p<0.0001$). Mean PPPM costs for inpatient visits (MR = 1.05; p=not significant), ED visits (MR = 1.13; $p<0.05$), and outpatient costs (MR = 1.38; $p<0.0001$) were also higher for the insomnia cohort. **Conclusion:** In patients with osteoporosis, comorbid insomnia was associated with more intensive HCRU and higher costs relative to those without insomnia. These results suggest that insomnia has a meaningful impact on the health and related health care resource utilization of patients with osteoporosis.

Sources of Funding: Eisai Inc.

P-34.

Burden of Insomnia Among Peri-/Post-Menopausal Women Undergoing Hormone Replacement Therapy: A Retrospective Claims Database Analysis

Emerson M. Wickwire[2], Timothy R. Juday, PhD, MPA[1], Feride H. Frech, PhD, MPH[1], Mona Kelkar[3], Jihaeng Heo, PhD, MS[3], Caroline Margiotta, MA[3], Manoj H. Malhotra, MD[1]. [1]NBG Medical Affairs, Eisai Inc, Woodcliff Lake, NJ; [2]University of Maryland School of Medicine, Baltimore, MD; [3]Genesis Research LLC, Hoboken, NJ

Objective: One in four menopausal women experience insomnia, often due to vasomotor symptoms such as night sweats, hot flashes, and flushing. Insomnia is also very common in post-menopausal women, in part due to decreasing levels of estrogen. At the same time, insomnia is associated with increased economic costs in the general population. The purpose of this study was to evaluate the impact of insomnia on all-cause healthcare resource utilization (HCRU) and costs in peri/post-menopausal women undergoing hormone replacement therapy (HRT). **Design:** This retrospective study used the IBM MarketScan Commercial and Medicare Supplemental Databases (Jan 2014-Dec 2019) to identify patients: (1) age ≥18 years; (2) with ≥1 ICD-9/ICD-10 codes for insomnia OR with ≥2 prescriptions for zolpidem immediate release (IR) OR trazodone ≤150mg OR benzodiazepine; (3) with ≥12 months of continuous enrollment pre-/post-index date (earliest diagnosis or medication fill date); (4) with ≥2 ICD-9/ICD-10 codes for menopause; and (5) evidence of HRT. Patients with sleep disorders other than insomnia were excluded. The resulting patients ("insomnia cohort") were 1:1 matched on age, sex and Elixhauser Comorbidity Index (ECI) score to peri-/post-menopausal patients undergoing HRT but without insomnia or other sleep disorders ("control cohort"). HCRU and costs were reported per patient per month (PPPM) over the 12 month follow-up period. Generalized linear models were used to compare adjusted outcomes between cohorts controlling for covariates including sex, age, ECI, geographic region, antidepressant use, antihypertensive use and anti-hyperglycemic use. **Results:** For each cohort, 3,634 peri-/post-menopausal patients (mean age 54.2 years, 100% female, 1.1 ECI score) were identified. In adjusted analyses, significantly more patients in the insomnia cohort had at least one inpatient admission per month ($p<0.05$), inpatient stays were significantly longer ($p<0.05$), and mean outpatient visits were significantly higher ($p<0.0001$) relative to the control cohort. However, there were no significant differences between the insomnia cohort and the control cohort in mean number of inpatient admissions (0.10 versus 0.09, respectively) and mean number of ED visits (0.12 versus 0.1, respectively). Adjusted analyses also showed significantly higher mean total PPPM costs for the insomnia cohort than the control cohort ($1,188 and $1,029, respectively; mean ratio [MR] = 1.16; $p<0.0001$). Mean PPPM costs for inpatient visits were lower (MR = 0.95; p=not significant), ED visits were higher (MR = 1.19; $p<0.01$), and outpatient costs were higher (MR = 1.17; $p<0.0001$) for the insomnia cohort. **Conclusion:** Among peri-/post-menopausal women undergoing HRT and relative to non-insomnia controls, insomnia patients had higher HCRU and costs. These results suggest that insomnia adds to the economic burden in peri-/post-menopausal women undergoing HRT.

Sources of Funding: Eisai Inc.

P-35.

Effects of Clairvee® oral probiotic supplementation on women's vaginal odor in an open-label experience trial

Susan Kellogg Spadt, PhD, CRNP[1], Brooke Faught, DNP[2], Michael Krychman, MD[3], Devon Bernsley, BA[4], Sarah Sylla, BS[4], Alyssa Dweck, MS, MD[4], James Komorowski, MS[4]. [1]Center for Pelvic Medicine, Academic Urology of PA, LLC., Bryn Mawr, PA; [2]Women's Institute for Sexual Health (WISH), Urology Associates, Nashville, TN; [3]Southern California Center for Sexual Health and Survivorship Medicine, Newport Beach, CA; [4]Bonafide Health, LLC, Harrison, NY

Objective: Hormonal fluctuations during menopause can cause an imbalance in the vaginal microbiome, leading to symptoms like malodor, vulvovaginal irritation, and discomfort. Clairvee® is an evidence-based oral probiotic formulation shown to balance the vaginal microbiome and provide relief from vaginal itching and discharge. The purpose of this open-label experience trial was to assess Clairvee's impact on self-reported vaginal odor. **Design:** This study nationally enrolled women from 3 different medical centers. To enroll, women visited their health care provider, verbally confirmed they did not have a vaginal infection, and responded yes to the following question: During the past week, have you experienced odor from your vulva or vagina? Trial enrollment did not control for menopausal status nor use of concomitant local or systemic hormones or vaginal moisturizers. Women (age 24-70) who were enrolled in the study and reported vaginal odor at baseline were included in the present analysis (n=33). Each Clairvee capsule contained 400 mcg dietary folate equivalent (DFE), 5 billion CFU Clairvee vaginal blend comprised of *Lactobacillus acidophilus* (BLA-14) and *Lactobacillus rhamnosus* (BHN001), and 50 mg lactoferrin. Participants were instructed to take one capsule daily for 15 consecutive days each month. Participants reported on their experience via online questionnaires at baseline, after taking the product for two weeks, and every two weeks thereafter. The following efficacy endpoints were measured: Vulvovaginal Symptoms Questionnaire (VSQ); rating of the severity of vaginal symptoms, including itching, discharge, burning, and odor, using a four-level scale (absent; mild; moderate; severe); and product satisfaction/experience questions. VSQ is 21 yes (1) or no (0) questions with four scales: Symptoms, Emotions, Life-impact, and Sexual impact. The total score was the sum of the first 17 questions if non-sexually active or the 21 questions if sexually active. A higher score indicates greater severity of symptoms. Subjects were compensated for their participation in the study. Wilcoxson sign rank tests were run for non-parametric symptom severity four-level scale data and paired t-tests were run for the VSQ-21 combined scores. Data are reported as percent change and mean and standard deviation where applicable. **Results:** Thirty-three women completed 4 weeks of supplementation. After two weeks, 63% of women reported an improvement in odor, and after four weeks, 75% of women reported an improvement. The improvements in odor were statistically significant at both weeks 2 and 4 ($p < 0.01$). In addition, 30% of the women reported an absence of odor at weeks 2 and 4. Of the women that were sexually active, VSQ-21 combined scores improved significantly after 4 weeks (13.33 ± 4.9 baseline vs. 5.75 ± 3.8, $^{**}p < 0.01$, n=20). VSQ-21 also improved significant after 2 weeks (7.11 ± 4.9, $^{*}p < 0.01$, n=19). All women (100%) experienced improvement in one or more symptoms including itching, discharge, burning, dryness, odor, irritation, and painful urination within 4 weeks (n=31). When asked about the 15-day on and 15-day off regimen of Clairvee, 84% of women reported that the dosing regimen was convenient. Additionally, over half of the women were satisfied with Clairvee after 2 weeks. **Conclusion:** The results of this open-label experience trial demonstrated that Clairvee improved vaginal odor in a population specifically experiencing vaginal odor at baseline. Furthermore, these results revealed general satisfaction with the product and dosing regimen.

Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonafide Health, LLC.

P-36.

Effects of Clairvee® oral probiotic supplementation on women's vaginal symptoms in an open-label experience trial

Susan Kellogg Spadt, PhD, CRNP[1], Brooke Faught, DNP[2], Michael Krychman, MD[3], Devon Bernsley, BA[4], Sarah Sylla, BS[4], Alyssa Dweck, MS, MD[4], James Komorowski, MS[4]. [1]Center for Pelvic Medicine, Academic Urology of PA, LLC., Bryn Mawr, PA; [2]Women's Institute for Sexual Health (WISH), Urology Associates, Nashville, TN; [3]Southern California Center for Sexual Health and Survivorship Medicine, Newport Beach, CA; [4]Bonafide Health, LLC, Harrison, NY

Objective: Hormonal fluctuations during menopause can cause an imbalance in the vaginal microbiome, leading to symptoms such as malodor, vulvovaginal irritation, and discomfort. Clairvee® is an evidence-based oral probiotic formulation shown to balance the vaginal microbiome and provide relief from vaginal itching and discharge. The purpose of this open-label experience trial was to explore the effects of Clairvee on vaginal symptoms in healthy women. **Design:** This study nationally enrolled women from 3 medical centers. Women (age 24-82) visited their health care provider, confirmed they did not have a vaginal infection, and responded yes to the following question: During the past week, have you experienced odor from your vulva or vagina? Trial enrollment did not control for menopausal status nor use of concomitant local or systemic hormones or vaginal moisturizers. Each Clairvee capsule contained 400 mcg dietary folate equivalent (DFE), 5 billion CFU Clairvee vaginal blend comprised of

Lactobacillus acidophilus (BLA-14) and *Lactobacillus rhamnosus* (BHN001), and 50 mg lactoferrin. Participants were instructed to take one capsule daily for 15 consecutive days each month. Participants reported on their experience via online questionnaires at baseline and each two weeks thereafter. The following efficacy endpoints were measured: Vulvovaginal Symptoms Questionnaire (VSQ); rating of the severity of vaginal symptoms, including itching, discharge, burning, and odor, using a four-level scale (absent; mild; moderate; severe); and product satisfaction/experience questions. VSQ is 21 yes (1) or no (0) questions in 4 scales: Symptoms, Emotions, Life-impact, Sexual impact. Total score was the sum of the first 17 questions if non-sexually active or the 21 questions if sexually active. A higher score indicates greater severity of symptoms. Wilcoxson sign rank tests were run for non-parametric symptom severity four-level scale data, and paired t-tests were run for the VSQ-21 combined scores. **Results:** The number of women reporting an improvement in vaginal burning, itching, irritation, dryness, odor, and painful urination improved significantly at week 2 ($p<0.05$). The number of women reporting an improvement in symptom severity improved significantly at week 4 for all vaginal symptom severity questions ($p<0.05$) (Table 1). Additionally, the sexual health endpoints of the VSQ were analyzed specifically and the findings after four weeks include: 40% of women saw an improvement in desire (n=42), 41% of women saw an improvement in sexual relationships (n=29), 41% of women saw a reduction in pain during sexual activity (n=29), 48% of women saw a reduction in dryness with sexual activity (n=29), 24% of women saw a decline in bleeding (e.g. spotting) with sexual activity (n=29), and 39% of women saw an average decrease in vaginal symptoms relating to sexual activity. **Conclusion:** This was an exploratory analysis that demonstrated the areas in which Clairvee can be effective in helping with symptoms related an imbalanced vaginal microbiome. The results of this open-label experience trial demonstrated that Clairvee significantly improved distressing vaginal symptoms including burning, itching, irritation, dryness, odor, painful urination, and discharge in the women who were specifically experiencing those symptoms at baseline.

Sources of Funding: This study was funded by JDS Therapeutics, LLC, the parent company of Bonafide Health, LLC.

Table 1. Week 2 and 4 improvement percentages following Clairvee supplementation for women who experienced the indication at baseline (N = 46). * $p>0.05$ vs. baseline +$p>0.05$ week 2 vs. week 4

Indication	Week 2	Week 4		
	Percentage	n	Percentage	n
Burning	70% *	20	95% *	19
Itching	59% *	29	92% *	25
Irritation	69% *	29	89% *	28
Dryness	52% *	33	74% *+	31
Odor	63% *	32	75% *	31
Painful urination	100% *	10	67% *	9
Discharge	42%	26	60% *	25

P-37.

Effects of Cross-Hormone Therapy in Aging Transgender Women – A Literature Review

Pranali Kerkar, MBBS[1,2], Veda Nambi, BA[1,5], Gloria Bachmann, MD[1,3], Juana Hutchinson-Colas, MD[1,4]. [1]Women's Health Institute, Rutgers The State University of New Jersey, New Brunswick, NJ; [2]LGBTQ Health, Rutgers School of Public Health, Piscataway, NJ; [3]Obstetrics & Gynecology, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ; [4]Obstetrics, Gynecology & Reproductive Sciences, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ; [5]Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Hormonal therapy (HT) has become a mainstay medical treatment option for the management of gender dysphoria in transgender patients of both biological sexes. Adult trans women (birth-assigned males) generally are prescribed a combination of estrogen and an antiandrogen to induce the desired physical (ie, changes in body composition, facial/body hair, breast size, voice, reproductive/sexual function) and psychological effects. However, there is a need to counsel this population on the long-term effects of steroid hormone modulation on the various organ systems. Most of the data available on the effects of long-term HT come from studies of postmenopausal cisgender women. This review examined the effects of long-term hormone therapy on the cardiovascular system, breast tissue, bones, and blood in transgender women and the care received as they age. With the increasing de-stigmatization and acceptance of the transgender community, it is important that guidelines for appropriate and sensitive care be uniformly adapted by all practitioners. **Design:** PubMed/Medline, ScienceDirect, and Google Scholar were utilized with keywords including "elderly", "transgender woman", "transwomen" "transsexual", "aging", "hormone therapy", and "cross hormone therapy". Evidence-based reports and reviews since 2012 were given priority and expert opinions were sought when conflicting information was encountered. Older resources were considered when primary sources were needed. Given the paucity of data, all resources were given careful consideration. **Results:** There is very little literature or investigation relevant to the care of aging transgender women who have been on long-term hormone therapy. Exogenous sex hormones may interact with hormone-dependent metabolic pathways, affect some biochemical assays, and impact some or many clinical outcomes. There seems to be an association between long-term cross hormone therapy in transwomen and the factors influencing diseases in the cardiovascular system, breast tissue, bone, and blood. However, there are only limited data on the effects of long-term hormone therapy in this population. **Conclusion:** With the rising acceptance of the LGBTQ community over the past years, increasing numbers of aging transgender women will be interfacing with health care providers. The current hormone replacement therapy recommendations are based on limited evidence from scant studies. The establishment of large, long-term cohort studies from different regions of the world, where different hormone regimens are used in clinical practice, will assist in advancing the understanding of long-term health benefits and risks in this aging population. Since transgender medicine is a fairly new professional focus, more research is needed in this area. This will help develop and establish evidence-based and concise enunciation of guidelines and standards of care applicable to these aging transgender women and empower them to make more informed decisions.

Sources of Funding: None

P-38.

Association of primary ovarian insufficiency with handgrip strength in US women: a national population-based study

Hoon Kim, MD, PhD, NCMP[1,2], Jiyeon Han[1,2], Sung Woo Kim[1,2], Seung Yup Ku[1,2], Chang Suk Suh, MD, PhD[1,2]. [1]Obstetrics and Gynecology, Seoul National University College of Medicine, Seoul, Korea (the Republic of); [2]Obstetrics and Gynecology, Seoul National University Hospital, Seoul, Korea (the Republic of)

Objective: Postmenopausal women experience a progressive decrease in muscle strength. Handgrip strength (HGS) is a non-invasive measure to evaluate muscle strength or physical function. Although the effect of age at menopause on HGS has been studied, the effect of primary ovarian insufficiency (POI) has not been well recognized. We aimed to investigate the association of POI with HGS. **Design:** This study is based on a Cross-sectional National Health and Nutrition Examination Survey (NHANES) in the United States. We analyzed the national representative data on 1,122 women in the United States aged 19-79 years from the NHANES from 2011 to 2014 when HGS was measured. HGS was determined as the maximum value in kilograms (kg) assessed using either hand. POI was defined when the study participant had experienced the last menstrual period before age 40. HGS was compared between women with and without POI, adjusting for potential confounders using a complex survey analysis. **Results:** A total of 60 women reported POI, representing an estimated population of 1,069,289 postmenopausal women accounting for the complex sampling and weighting methods used. Women with POI were more likely to be younger, obese, non-Hispanic black, less educated, and current smokers compared to those without POI. Women with POI had significantly lower HGS than that of women without POI (25.0 kg vs. 27.4 kg, $P<0.001$). This association did not change after controlling for age, ethnicity, education level, family income, high-risk alcohol intake, smoking status, physical activity, and use of hormone therapy (25.3 kg vs. 27.4 kg, $P=0.04$) **Conclusion:** There was a significant difference in HGS between women with and without POI in this nationally representative study of postmenopausal women. The association was not different after adjustment for potential confounders. More attention should be paid to women with POI.

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P-39.

As the adenomyosis is diagnosed earlier, the menopause comes earlier

Jiyeon Han[1], Eun Joo Lee, Doctor[1], Hye Yun Kim[1], Sung Woo Kim, MD[1,2], Hoon Kim[1,2], Seung Yup Ku[1,2], Chang Suk Suh[1,2]. [1]Obstetrics and Gynecology, Seoul National University Hospital, Jongno-gu, Korea (the Republic of); [2]Obstetrics and Gynecology, Seoul National University College of Medicine, Seoul, Korea (the Republic of)

Objective: Heavy menstrual bleeding, dysmenorrhea and chronic pelvic pain are the typical symptoms of adenomyosis. Although hysterectomy is the definitive treatment for adenomyosis, patients in their 40s usually want conservative treatment, waiting until menopause. Therefore, the timing of menopause is important in determining treatment options for adenomyosis. This study aims to evaluate whether the characteristics of adenomyosis correlates to the age at menopause. **Design:** The medical records of 224 postmenopausal women who were diagnosed with adenomyosis at Seoul National University Hospital from November, 2016 to March, 2022 were retrospectively reviewed. 39 women who received chemotherapy and 92 women with uncertain age at menopause were excluded. 93 women were eligible for analysis. 201 postmenopausal women without history of chemotherapy were eligible for control. Menopause was defined as the absence of menstruation for consecutive 12 months. Adenomyosis was diagnosed by ultrasound, and the anteroposterior diameter(APD) of the uterus was measured. Simple linear regression analysis was performed to analyze the correlation between menopausal age and other factors. **Results:** Patients was diagnosed with adenomyosis at 44.28±6.04 years on average, and the mean APD was 5.75±1.25cm. Adenomyosis group experienced menopause significantly earlier than control group (50.58±4.52 years vs. 51.76±3.26 years, $p = 0.011$). Both APD ($R^2 = 0.072$, $p=0.016$) and the age at diagnosis of

adenomyosis ($R^2 = 0.516$, $p<0.001$) were positively correlated with the age at menopause. **Conclusion:** Women with adenomyosis experienced menopause earlier, and there is a positive correlation between the age at menopause and diagnosis of adenomyosis.
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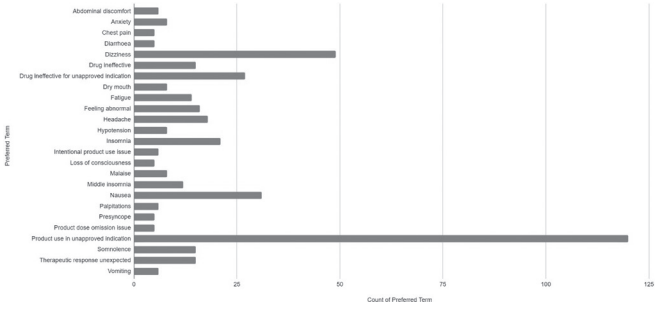
P-40.
Exploratory analysis of flibanserin's postmarketing safety and tolerability among postmenopausal women

Sheryl A. Kingsberg, PhD[2,3], Anthony Faragasso, MD[4], Louise Brown, PharmD[1], Sharon Donatucci[4], Sejal Patel, PharmD[5]. [1]TriangleRxConsult, LLC, Wendell, NC; [2]OBGYN, UH MacDonald Women's Hospital, Cleveland, OH; [3]Case Western Reserve University, Cleveland, OH; [4]Pharmacovigilance, Sprout Pharmaceuticals, Raleigh, NC; [5]Medical Affairs, Sprout Pharmaceuticals, Raleigh, NC
Objective: Flibanserin is approved in the US for premenopausal women and in Canada for pre and naturally postmenopausal women, ≥60 years, to treat hypoactive sexual desire disorder (HSDD). Clinical trials suggest that flibanserin's safety profile is similar among pre-and postmenopausal women. During a Phase 3 postmenopausal study, the most frequently reported adverse events (AEs) were dizziness (10%), somnolence (9%), nausea (8%), and headache (6%). This study explores postmarketing AEs received from postmenopausal women and their clinicians during flibanserin treatment. The primary objective of this safety study is to further characterize flibanserin's safety profile among postmenopausal women treated in a clinical setting. **Design:** This study is a retrospective exploratory analysis of AEs captured in a global safety database (August 15, 2015, to May 12, 2022). The database was queried for US reports of AEs in postmenopausal women using the Medical Dictionary for Regulatory Activities Search Strategy Version 21.1. Preferred Term (PT) "Product use in unapproved indication." This PT was selected as postmenopausal use is an unapproved indication in the US. Reports were filtered to identify and exclude non-postmenopausal unapproved usages, such as use in males and premenopausal women with non-HSDD conditions. All reports stating postmenopausal use are included in this analysis. If reproductive status was not specified, age was used as an indicator. If age was unknown, the report was excluded. The average age for menopause in the US is 51 years, and the age range selected to represent postmenopausal status was 51-75 years. Adverse events were categorized using PTs, and descriptive statistics were used to summarize the results. **Results:** Our search identified 195 unique reports of use in postmenopausal women (by a reported specific term or by age) with at least one AE during the study period. There were 656 reported AEs, 16 (2.4%) were serious, and no fatalities. Adverse events by PT occurring in ≥5 reported events are summarized in the Figure. Dispensing data from one specialty pharmacy found that approximately 18% of flibanserin prescriptions were filled by women >50 years over the past year. No incidence data were calculated as AE reporting is voluntary and true exposure is unknown **Conclusion:** The postmarketing safety profile of flibanserin among postmenopausal women is similar to that observed with premenopausal women and during clinical trials. Excluding general PTs such as unapproved use and drug ineffective, the most frequently reported postmarketing AEs included dizziness, nausea, and insomnia. No safety signals specific to postmenopausal women have been identified to date. Although informative, the lack of information on medical history, concomitant medications, and other potential interacting products limit the ability to make inferences on causality in most reported cases.
Sources of Funding: Sprout Pharmaceuticals, Inc.



P-41.
Global View of Vasomotor Symptoms and Sleep Disturbance in Menopause: A Systematic Review

Sheryl A. Kingsberg, PhD[1], Renate Schulze-Rath, MD, MSc[3], Claire Mulligan, PhD[2], Carsten Moeller, PhD[3], Cecilia Caetano, MD[4], Johannes Bitzer, MD, PhD[5]. [1]University Hospitals Cleveland Medical Center, Cleveland, OH; [2]Beacon Medical Communications, Brighton, United Kingdom; [3]Bayer AG, Berlin, Germany; [4]Bayer AG, Basel, Switzerland; [5]University Hospital, University of Basel, Basel, Switzerland
Objective: To assess the prevalence and incidence, stratified by race/ethnicity, of vasomotor symptoms (VMS) and sleep disturbance (SLD) in menopausal women worldwide. Treatment patterns for menopausal symptoms were also investigated. **Design:** PubMed and Embase were searched on 27 April 2021 for epidemiological/observational studies reporting the prevalence or incidence of menopausal symptoms or treatments in menopausal or middle-aged women, published from 2000 to 2021. Papers focusing only on subpopulations of menopausal women with comorbidities (e.g. diabetes) were excluded. Quality was assessed using the Joanna Briggs Institute Checklist for Prevalence Studies, with scores of 7–9, 4–6 and 0–3 considered to represent good, moderate and poor quality, respectively. **Results:** 3799 records were screened and 27 papers (19 studies) were identified that reported the prevalence of VMS, SLD or treatment stratified by race/ethnicity (no relevant incidence data were found). Quality was rated as good, moderate and poor in 21, 5 and 1 papers, respectively. VMS were reported in 17 papers (hot flushes, 11 papers; night sweats, 5 papers; VMS overall, 7 papers). SLD was reported in 10 papers (difficulty falling asleep, 3 papers; frequent waking, 3 papers; problems with morning waking, 2 papers; SLD overall, 9 papers). For both symptoms, the reported prevalence varied widely (examples shown in Table). Potential sources of variation included not only race/ethnicity and menopausal stage, but also differences in patient questionnaires, symptom definitions and recall periods. Nevertheless, some common patterns emerged. For example, 5 studies compared the prevalence of hot flushes, night sweats or VMS overall between Black women and White, Hispanic, and/or Asian (Japanese or Chinese) women; all showed the highest prevalence in Black women, while Asian women had the lowest prevalence (dependent on menopausal stage in 2 studies). The prevalence of SLD overall was compared between Black, White and Asian women in 2 study populations; both showed the highest prevalence in White women and lowest prevalence in Asian women. SLD overall was more common than VMS overall in Asian women but not in Black women. Treatment patterns were reported in 10 papers (menopausal hormone therapy [HT] or complementary/alternative therapy, 8 papers; sleep medication, 3 papers). The prevalence of treatment use varied widely but showed some common patterns. HT use was compared between White women and Black and/or Asian women in 4 studies, while 3 studies compared sleep medication use between White and Black women; all these studies showed a higher prevalence of treatment use in White women, reflecting prevalence patterns of SLD but not VMS. **Conclusion:** The highly variable prevalence of VMS, SLD and use of HT/sleep medication across studies and races/ethnicities may be related to individual and cultural factors as well as differences in study design. Black women had a higher prevalence of VMS and a lower prevalence of HT use than White women. SLD was more common than VMS in Asian women. These results highlight the need for standardized measures of menopausal symptoms, individualized counselling and treatment approaches, and a focus on under-served minorities.
Sources of Funding: Bayer AG
Table. Prevalence of VMS and sleep disturbance overall by race/ethnicity and menopausal status

	Prevalence (as reported in included studies) by menopausal status, %						
	Mixed/ unclear*	Pre-menopause	Peri-menopause	Pre- to early peri-menopause transition	Early to late peri-menopause transition	Late peri- to post-menopause transition	Post-menopause
VMS overall							
Black	45.6	38, 61.4	–	57	83	81	53.6
White	31.2	28, 58.3	–	41	68	73	28.4
Hispanic	35.4	42, 41.7	–	39	68	50	42.1
Japanese	17.6	28, 35.9	–	32	59	43	–
Chinese	20.5	23, 29.0	–	30	58	67	–
Sleep disturbance overall							
Black	24.8–82.8	26.4–37	36.0–46	–	–	–	35.6–56 (Surgical: 42.6)
White	24.7–86.3	20.3–39	41.2–61.2	–	–	–	27.2–65.5 (Surgical: 55.3)
Hispanic	35.4–66.4	29.8, 30.4	44.8, 41.2	–	–	–	39.8, 50.3 (Surgical: 46.9)
Japanese	28.2, 74.9	20.7	31.6, 42.2	–	–	–	25.8 (Surgical: 73.7)
Chinese	31.6, 77.9	27.3	41.4, 34.7	–	–	–	38.9 (Surgical: 19.9)

***Prevalence data for pre-, peri- and post-menopausal women combined, or for middle-aged women with unspecified menopausal status**

P-42.
Gender-Based Preferences on Telemedicine

Saira Khan, MD[1], Juliana M. Kling, MD, MPH[2,3], Suneela Vegunta, MD[2], Paru David, MD[2], Mina Al-Badri, MBChB, MD[2]. [1]Internal Medicine, Mayo Clinic Arizona, Scottsdale, AZ; [2]Women's Health Internal Medicine, Mayo Clinic Arizona, Scottsdale, AZ; [3]Center for Women's Health, Mayo Clinic Minnesota, Rochester, MN
Objective: Vasomotor symptoms (VMS) affect up to 80% of menopausal women, yet 73% of women reported their symptoms are not treated.[1,2] Although likely multifactorial in cause, known gender-based disparities in healthcare may also play a role. For example, women are more likely to report delays in healthcare access.[3] This was likely exacerbated by the Coronavirus (COVID-19) pandemic when an estimated 30-40% of U.S. adults reported delaying or avoiding medical care.[4] To improve access to care, telemedicine forged a new path for healthcare. The objective of this study was to further examine potential gender-based differences in telemedicine preference to expand medical care. **Design:** Patients seen in the outpatient setting of Mayo Clinic (Minnesota, Arizona, and Florida) were given surveys at random following their medical appointment. A total of 476,777 outpatient surveys from all sites were obtained between 6/2020 and 11/2021. The survey utilized a scale of 1 (least) to 5 (most favorable) to assess characteristics of visits, such as ease of scheduling. Results were presented as type 3 sums of squares and least squares for the model-adjusted probability at each combination of gender and visit type. **Results:** Of the 476,777 responses, 409,496 visits were in-person compared

to 12,159 via telephone and 55,122 by video. Women made up 47.5% of the survey respondents compared to 37.3% men. The average age of respondents was 63 years of age for in-person visits, 66 years of age for phone visits, and 59 years of age for video visits. Compared to men, women found telehealth appointments easier to schedule (77.3% women rated 5/5 versus 75.6% men). Telehealth did not impact quality of care (87.1% women rated 5/5 versus 87.8% men), or shared decision-making (85.0% women rated 5/5 versus 86.3% men). Overall, women were just as likely to recommend their telehealth practitioner to others (87.4% women rated 5/5 versus 88.7% men). **Conclusion:** Given the pervasiveness of VMS in menopause, and the opportunity to correct a widening gap of care access caused by COVID-19, telemedicine allows practitioners to individualize care for women in the outpatient setting.

Sources of Funding: None

Patient Demographics

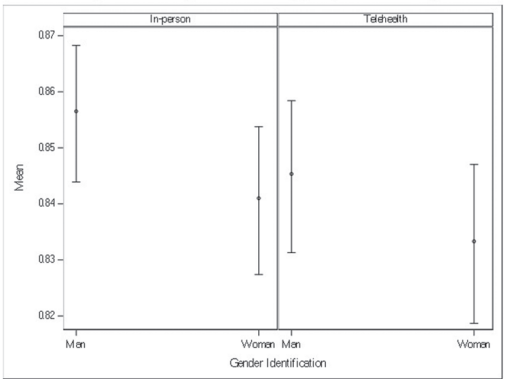
	In-person (N=409496)	Phone (N=12159)	Video (N=55122)	Total (N=476777)
Age (years)	63.6	66.3	59.2	63.1
Gender Identification				
Woman	192742 (47.1%)	5202 (42.8%)	28477 (51.7%)	226421 (47.5%)
Man	151215 (36.9%)	5089 (41.9%)	21753 (39.5%)	178057 (37.3%)
Other/Choose Not to Disclose	65290 (15.9%)	1861 (15.3%)	4824 (8.7%)	71975 (15.1%)

Patients Satisfaction of Telemedicine Visits

	Woman (N=33679)	Man (N=26842)	Other (N=6760)
Ease of Scheduling	25824 (77.3%)	20122 (75.6%)	4741 (70.2%)
Concern Demonstrated by Practitioner	29127 (87.1%)	23390 (87.8%)	5559 (82.2%)
Explanations Provided by Practitioner	28345 (85%)	22986 (86.3%)	5398 (79.8%)
Shared-Decision Making	28655 (86.3%)	22997 (86.8%)	5403 (79.9%)

Patients that responded 5/5 satisfaction for telemedicine visits (video, phone).

Figure: Percent of Respondents Fully Recommending (5/5) Practitioner by Gender and Visit Type



P-43.

The Brave New World of Sexual Lubricants: The Heterosexual Women's Perspective in a Community Based Sexual Medicine Center

Michael Krychman. So Cal Center for Sexual Health, Newport Beach, CA

Objective: There is a plethora of emerging data concerning lubricant osmolality, additives and potentially caustic ingredients that are in sexual lubricants. For the woman who suffers from genitourinary syndrome of menopause (GSM) moisturizers and lubricants are considered the initial self-directed primary choice of intervention. The marketing of lubricants makes choice and product selection is often confusing, cumbersome, and time-consuming. Silicone based lubricants offer many advances comparatively to their water-based counter parts. They are long lasting, do not evaporate and are the top choice for anal and or aqua sex. Silicone lubricants are inert, anhydrous and do not affect the vaginal ph. We conducted an in-office survey to assess women's perceptions of silicone-based lubricant. **Design:** An in-office survey was conducted in a random sampling of self-identified heterosexual women who attended a community and or academic based sexual medicine/ gynaecology clinic. A total 30 women completed the survey. Surveys were completed and participants were not financially compensated. Demographic, sexual health and impact of silicone lubricant use was collected. All answers were anonymous **Results:** Thirty women with a mean age of 46 (range 25-67) who were all users of silicone lubricant were surveyed. Ninety-six (96%) of subjects reported improved comfort during coitus, and 87% report improved sexual enhancement whereas 97% reported improved overall sexual pleasure with the use of a silicone lubricant. No adverse effects were reported. Most (75%) preferred silicone over water-based products. Most women (63%) had another available lubricant that was water based indicating that they used specific lubricants for specific sexual behaviour. Most reported the slickness, long lasting qualities, and little amount per use as beneficial qualities for a lubricant. On a Likert scale of 1-10 where (1 was completely dissatisfied with silicone as a lubricant and 10 most satisfied), participants rated silicone lubricant on average tat 9.1/10. Fifty percent of this sample engage in anal sex whereas 70% engage in sexual intimacy in the bath/ hot tub, swimming pool or shower and used silicone lubricant for these sexual events. **Conclusion:** Silicone based lubricant remains an important option for specific sexual play. As well are gaining popularity due to their inert characteristics and their ability not to impact mucosa or vaginal ph. The incidence of anal and aqua sex is not insignificant in a heterosexual population, and professionals should inquire not only about if their patients are sexually active but query about the specific nature of sexual activity. Lubricant recommendations should mirror behaviour and one lubricant is not ideal for all situations. Specific lubricant use may also change throughout the lifespan. Silicone lubricant offers an excellent choice for a variety of sexual situations, and has high patient acceptability, with noted improved sexual enhancement, pleasure, and overall satisfaction.

Sources of Funding: None

P-44.

Menopause age and time from menopause completion are associated with handgrip strength and endurance in older females

Emma J. Lee, PhD[1], Chowdhury Tasnova Tahsin[2], William Stokes[2], Nisha Panigrahy[1], Miguel Anselmo[2,3], Aline Glazos[1,4], Tanya Melnik[5,6], Marnie Vanden Noven[7], Jason R. Carter[8,9], Dawn A. Lowe[1,2], Manda L. Keller-Ross[1,2]. [1]Div. of Physical Therapy, Dept. of Rehabilitation Medicine, University of Minnesota Twin Cities, Minneapolis, MN; [2]Div. of Rehabilitation Science, Dept. of Rehabilitation Medicine, University of Minnesota Twin Cities, Minneapolis, MN; [3]College of Continuing Education, University of Minnesota Twin Cities, Minneapolis, MN; [4]Doctor of Physical Therapy Program, St. Catherine University, Saint Paul, MN; [5]Div. of General Internal Medicine, Dept. of Medicine, University of Minnesota Twin Cities, Minneapolis, MN; [6]University of Minnesota Physicians, Minneapolis, MN; [7]Dept. of Sport Science, Belmont University, Nashville, TN; [8]Dept. of Health and Human Development, Montana State University, Bozeman, MT; [9]Office of Research and Economic Development, Montana State University, Bozeman, MT

Objective: Lower strength during a muscle-fatiguing exercise corresponds to a longer time to fatigue. Furthermore, older adults demonstrate a longer time to fatigue in submaximal isometric exercise than younger adults. In postmenopausal females, aging and the loss of estrogens contribute to diminished muscular strength. However, whether age at menopause completion affects strength and time to fatigue has not been explored, and it is clinically relevant to understand the complex relations between the timing of estrogen loss, aging, and muscular performance. Our purpose was to determine whether menopause age and/or time elapsed since completing menopause influence time to fatigue during an isometric handgrip exercise in postmenopausal females. **Design:** Participants completed two visits. Inclusion criteria: Female; postmenopausal; aged 50-70 yrs. Exclusion criteria: Autonomic/cardiometabolic disorder; cardiovascular disease; use of medications that affect autonomic function; nicotine/tobacco use; body mass index (BMI) ≥ 35 kg m^{-2}. Visit 1: Written informed consent; questionnaires (medical history, physical activity). Visit 2: Measurement of height/mass; assessment of isometric handgrip maximum voluntary contraction force (MVC); handgrip at 30% of MVC to voluntary fatigue; blood draw (estrone, estradiol). **Results:** Thirty-two participants completed all procedures (age: 62±4 yrs. [mean±SD]; BMI: 25.5±4.2 kg m^{-2}). Mean age at menopause was 50±4 yrs. (range: 40-56 yrs.), while time from menopause was 12±6 yrs. (range: 1-27 yrs.) Time to fatigue was significantly correlated with menopause age ($r=-0.486$, $p=0.005$) and time from menopause completion ($r=0.583$, $p<0.001$). In addition, time to fatigue was significantly associated with MVC ($r=-0.684$, $p<0.001$), current age ($r=0.385$, $p=0.030$), and estrone ($r=-0.374$, $p=0.038$), suggesting that aging and menopause-related losses of sex hormones also contribute to muscular performance in older females. Estradiol was not significantly correlated with time to fatigue or MVC ($p\geq0.230$). Maximum voluntary contraction force was significantly related to time from menopause completion ($r=-0.385$, $p=0.029$) and to physical activity level ($r=0.449$, $p=0.010$). **Conclusion:** Menopause age and time since completing menopause contribute to time to fatigue for a submaximal fatiguing handgrip exercise in postmenopausal females. Although these findings may be associated with the reduction in strength that occurs with aging, the timing of menopause—and thus the duration of estrogen deficiency—appears to be implicated in submaximal isometric muscular endurance performance. The role of menopause age in mediating age-related strength losses merits further investigation. Because physical strength is vital for carrying out activities of daily living, these results may be relevant for developing interventions to preserve strength in aging females.

Sources of Funding: EL: F32HL160012; MKR: K01 AG064038-01A1

P-45.

Preclinical Alzheimer's Disease Biomarker Risk Profile for Postmenopausal Women: An Exploratory Multimodal Neuroimaging Study

Genna Losinski, Masters of Art[1], Jeff Burns[2], Jill Morris[2], Eric Vidoni[2], Jon Clutton[2], Amber Watts, PhD[1,2]. [1]Psychology, University of Kansas College of Liberal Arts and Sciences, Lawrence, KS; [2]University of Kansas Alzheimer's Disease Research Center, Fairway, KS

Objective: Two-thirds of Alzheimer's Disease (AD) patients are women. A variety of AD risk factors (e.g., genetic, medical, and hormonal) affect postmenopausal women more negatively. The Estrogen Hypothesis is the leading theory for these gender and sex differences. It underscores the neuroprotective effect of estrogen and how estrogen dysfunction may exacerbate or precipitate AD development. Very few studies have examined sex-specific AD risk factor differences between postmenopausal women and age-matched men during the preclincal stage. This exploratory multimodal neuroimaging study aimed to examine sex differences in cognitively normal older adults on: (1) Amyloid-β on 18F-AV-45 Florbetapir PET imaging (2) neurodegeneration via T1 weighted MRI volumetrics, (3) cerebral blood flow via ASL-MRI. We identified genetic,

medical, and hormonal AD risk factors associated with the neuroimaging outcomes with observed sex differences. **Design:** Sedentary older adults (N = 112, age 65+) without evidence of cognitive decline and with elevated and sub-threshold levels of cerebral amyloid were included in the analysis. All participants received 18F-AV-45 Florbetapir Amyloid PET scans and T1- and T2- weighted MRI scans. We selected brain regions of interest based on known AD pathology trajectory patterns and the Estrogen Hypothesis. We assessed demographic (age, education), genetic (*APOE* genotype status), and medical risk factors (fasting glucose, mean arterial pressure, waist to hip ratio, and android and gynoid body fat percentages). We conducted an exploratory analysis in a subset of women (n = 23) with reproductive health history examining AD biomarker differences by hysterectomy status and HRT use. **Results:** Multivariate analysis of covariance models demonstrated differences between men and women among the hypothesized brain regions as measured by T1 weighted MRI analyses (F (5, 103) = 13.56, p = <0.001) and ASL-MRI analyses (F (7, 102) = 2.58, p = 0.017). Adjusting for age, education, and intracranial volume, women exhibited lower volume in the hippocampus, amygdala, parahippomcampal gyrus, insula, and caudate compared to men. Women showed higher blood flow compared to men in several brain regions, including the amygdala, temporal lobe, anterior cingulate cortex, precuneus, superior parietal lobe, parahippocampal gyrus, and hippocampus. There was a sex difference in beta amyloid levels among hypothesized brain regions overall as measured by 18F-AV-45 PET imaging (F (5, 104) = 2.63, p = 0.028), however univariate analyses revealed no significant group differences for individual brain regions. For women, LASSO regressions selected non-optimal fasting glucose, higher android fat percentage, and *APOE* ε4 carrier status as the most consistent and uniquely informative predictors for lower volume and higher blood flow among brain regions with observed sex differences in brain biomarkers. Age, education, and non-optimal waist to hip ratio were associated with the observed differences in brain volume and cerebral blood flow for both sexes. Underpowered exploratory analysis of reproductive health history revealed no differences for HRT use (1-β = 0.19) or hysterectomy status (1-β = 0.16) among brain regions examined. However, group differences by hysterectomy status was approaching significance (F (7, 13) = 2.44, p = 0.08) and non-hysterectomized women showed higher blood flow in the amygdala (p = 0.003) and temporal lobe (p = 0.010) compared to hysterectomized women. **Conclusion:** Our findings suggest genetic and cardiovascular risk factors uniquely predict lower brain volume and higher blood flow in AD-related brain regions in postmenopausal women compared to age-matched men. Findings support the development of sex-specific strategies for modifiable risk factors during the AD preclinical stage. Future studies with larger sample sizes may be better able to examine the relationship between menopausal history characteristics and hormonal risk factors and AD biomarkers during the preclinical stage.

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P-46.

Identifying factors that predict menopause symptoms to support personalised care pathways

Rebecca Love, Alex Handy. Vira Health Ltd, London, United Kingdom

Objective: Menopausal symptoms vary across women for factors such as ethnicity, socio-economic position and lifestyle habits. However, there is limited understanding of which factors are most important for predicting individual symptom severity and trajectories; identifying these factors is a key step towards designing more personalised care pathways for women with symptoms of menopause. Therefore, the objective of this study was to identify baseline factors that predict women's future symptom experiences using data from the Study of Women's Health Across the Nation (SWAN). **Design:** SWAN is a longitudinal study which enrolled 3302 women in America at baseline in 1996-7 who were between 42–53 years (median age 46) with an intact uterus, had at least one menstrual period in the three months prior to baseline and were not taking sex steroid hormones. We selected 10 baseline variables with prior evidence for potential association with menopause symptoms; age, body mass index (BMI), serum levels of estradiol, follicle stimulating hormone (FSH), testosterone, chronic illness *(yes or no)*, ethnicity *(Black, Chinese, Japanese, Causcasian, Hispanic)*, gross family annual income *($ <19999, 20000-49999, 50000-99999, >=100000)*, relative physical activity *(much less, somewhat less, the same, somewhat more, much more)* and smoking status *(never, previous, current)*. Reported symptom severity scores for the prior 2 weeks *(1=not at all, 5=every day)* were used to construct a total symptom score for each visit and sub-categories for psychological *(feeling depressed, mood changes, feeling fearful, feeling nervous, irritability)*, physical *(dizzy spells, forgetfulness, headache, stiffness)*, vasomotor *(heart racing, cold sweats, night sweats, hot flushes)* and urogenital *(vaginal dryness)* symptoms. An analysis cohort with available data for all the baseline predictors and symptom scores for 9 annual visits after baseline was created. Multivariable linear mixed models were used to test associations between baseline predictors and longitudinal symptom scores (p<0.05 threshold). The cohort was split into train and test subsets to review predictive performance and was assessed across 5 runs for mean squared error (MSE) and the coefficient of determination (r2) with 95% confidence intervals. **Results:** The analysis cohort included 1278 women (median age 46, mean BMI 27) with reported ethnicities of 22% Black, 10% Chinese, 12% Japanese, 56% Causasian and no Hispanic participants, illustrating that selection bias is challenging to mitigate in multi-year analyses which require continuous follow-up data. There were, however, multiple associations with total symptom scores including BMI (β 0.51, p $1.06x10^{-3}$), testosterone (β -0.71, p 0.01), chronic illness (β 1.24, p $5.73x10^{-6}$), income ($*<19999* reference, *20000-49999* β -2.37, p $1.58x10^{-5}$, *50000-99999* β -2.64, p $1.72x10^{-6}$, *>=100000* β -3.23, p $1.49x10^{-7}$), physical activity (*much less* reference, *somewhat less* β -0.96, p 0.03, *the same* β -1.87, p $3.58x10^{-5}$, *somewhat more* β -1.98, p $2.34x10^{-5}$, *much more* β -1.66, p 0.01) and smoking status (*never* reference, *current* β 1.51, p 4.45x10-4). There were notable sub-category associations with all ethnicities reporting lower vasomotor scores compared to Black participants (*Chinese* β -0.91, p $3.84x10^{-7}$, *Japanese* β -0.69, p $5.45x10^{-5}$, *Caucasian* β -0.56, p $1.35x10^{-6}$), higher FSH (β 0.24, p $9.02x10^{-4}$) and estradiol (β 0.14, p 0.04) associated with higher vasomotor scores and older women at baseline reporting less severe psychological symptoms (β -0.16, p 0.02). The 10 baseline predictor mixed model explained 5% of the variance for total symptom scores (r2 0.05 (0.03-0.07)) and was, on average, +/-5.86 points from the true reported score (MSE 34.33 (30.85-37.80)). **Conclusion:** All 10 baseline factors were associated with reported overall or sub-category menopause symptoms for up to 9 years in the future. Whilst the prediction performance in this sample was moderate, there is potential for significant improvement through building larger samples, integrating more variables and developing more sophisticated models.

Sources of Funding: Vira Health Ltd, Innovate UK health aging challenge

P-47.

Bone Mineral Density Changes over 52 Weeks in Perimenopausal Women with Uterine Fibroids Treated with Relugolix Combination Therapy vs Untreated Cohort

Ayman Al-Hendy[1], Rachel McLean[2], Dongmei Zhai[2], Michael R. McClung[3]. [1]Obstetrics and Gynecology, University of Chicago Department of Medicine, Chicago, IL; [2]Myovant Sciences Ltd, Brisbane, CA; [3]Oregon Osteoperosis Center, Portland, OR

Objective: Relugolix combination therapy (Rel-CT; relugolix 40 mg, estradiol 1 mg, norethindrone acetate 0.5 mg) is approved for the treatment of heavy menstrual bleeding (HMB) in premenopausal women with uterine fibroids (UF). This present analysis aimed to characterize longitudinal bone mineral density (BMD) changes over 52 weeks in potentially perimenopausal women (defined as age ≥ 45 years) with UF who were treated with Rel-CT in the Phase 3 LIBERTY Long-term Extension (LTE) study. As a reference, BMD changes from an age-matched independent cohort of women with UF from the Natural History Study (NHS) who were not exposed to Rel-CT are also presented. **Design:** This prospective, observational NHS enrolled premenopausal women (18–50 years of age) with UF, to characterize longitudinal BMD changes over 52 weeks. The NHS was conducted in parallel with the pivotal Phase 3, 24-week, placebo-controlled LIBERTY 1 and 2 studies, and the subsequent LTE study in which eligible women were treated with open-label Rel-CT for up to an additional 28 weeks. BMD was measured by dual-energy X-ray absorptiometry at screening and Weeks 24 and 52 in both the NHS and LIBERTY studies. Analysis of BMD changes over 52 weeks was performed in the subpopulations of these potentially perimenopausal women who were exposed to Rel-CT in the pivotal LIBERTY studies and LTE, and in untreated women in the UF cohort of the NHS. For the LTE study, only women who were treated continuously with Rel-CT for up to 52 weeks were included; women with pre-existing osteoporosis or other metabolic bone disorders were excluded. **Results:** In total, 95/262 (36.3%) women in the NHS UF cohort and 63/163 (38.7%) women in the Rel-CT group of the LIBERTY LTE were potentially perimenopausal. Baseline demographics were generally similar between subgroups of potentially perimenopausal women in the NHS vs LIBERTY LTE: mean [standard deviation, SD] age (47.1 [1.58] vs 47.5 [1.78] years, respectively), mean [SD] body mass index (30.7 [7.15] vs 30.9 [5.00] kg/m^2), and a history of never smoking (83.2% vs 74.6%). Results for BMD at baseline and Week 52 are reported alongside percent change from baseline data in Table 1. **Conclusion:** In potentially perimenopausal women with UF, minimal BMD changes were observed over 52 weeks of Rel-CT treatment in the LIBERTY LTE study. BMD changes with Rel-CT were consistent with changes observed in age-matched, untreated women with UF in the NHS, highlighting the preservation of BMD with Rel-CT through 52 weeks.

Sources of Funding: Myovant Sciences GmbH

Table 1. BMD Results in Potentially Perimenopausal Women in the NHS (untreated UF cohort) and LIBERTY LTE (Rel-CT group)

	L1–L4 lumbar spine		Total hip	
	NHS (untreated UF cohort)	LIBERTY LTE (Rel-CT group)	NHS (untreated UF cohort)	LIBERTY LTE (Rel-CT group)
Baseline BMD, n; mean (SD) g/cm2	92; 1.20 (0.201)	63; 1.18 (0.145)	92; 1.03 (0.150)	63; 1.03 (0.122)
Week 52 BMD, n; mean (SD) g/cm2	72; 1.21 (0.210)	49; 1.16 (0.146)	74; 1.04 (0.153)	47; 1.03 (0.103)
Percent change from baseline at Week 52, n; mean (SD)	72; –0.25 (2.623)	49; –0.75 (3.056)	74; 0.04 (1.945)	47; –0.19 (2.220)

P-48.

Chemotherapy history and its association with menopausal symptoms and impaired quality of life in middle-aged or older postmenopausal women who are breast cancer survivors

ALVARO MONTERROSA-CASTRO, MARIA MERCADO-LARA. Grupo de Investigación Salud de la Mujer, Universidad de Cartagena, Cartagena, Colombia

Objective: to estimate the association between the history of chemotherapy with the presence of menopausal symptoms and the deterioration of the quality of life in postmenopausal women of middle age or older adults, survivors of breast cancer. **Design:** cross-sectional study that is part of the CAVICSEN project (Quality of Life in Breast Cancer Survivors), approved by the ethics committee of the University of Cartagena, Colombia and endorsed by the Colombian Ministry of Science. The participants were postmenopausal women, with one or more years since the diagnosis of breast cancer and residents of Cartagena, Colombia. A form was applied that explored sociodemographic characteristics, data from the clinical history and the Menopause Rating Scale items (a tool that identifies the presence and severity of eleven menopausal symptoms and

allows knowing about somatic, psychological, urogenital deterioration and quality of life, be generally as severe). Statistical analysis was performed with EPI-INFO-7. Nineteen unadjusted logistic regressions were performed: dependent variable (each of the menopausal symptoms, presence of somatic, psychological, urogenital, or quality of life impairment, as well as severe impairment) and independent variable (history of chemotherapy). OR [95%CI] was calculated, p<0.05 value was statistically significant. **Results:** Results: 291 women aged between 37-90 years were studied, 176 (60.5%) aged 60 or less and 115 (39.5%) older than that age. 255 (87.6%) received chemotherapy and 36 (12.3%) did not receive chemotherapy, as part of their breast cancer treatment. The former was 58.1±9.4 years old, BMI 26.8±4.5, on average 69.9±60.2 months since the diagnosis of breast cancer, 12.5±7.7 years since the last menstruation and the 34.1% had presented early menopause. The second, 59.5±8.2 years, 27.4±3.8 BMI, on average 74.3±83.8 months since breast cancer diagnosis, 11.9±9.7 years since last menstruation and 30.5% had had early menopause (p=0.5). There were also no statistical differences in terms of marital status, family history of breast cancer, nutritional status, history of surgery or radiotherapy, sexual activity, or participation in social support groups, when compared according to history of chemotherapy. Hot flashes and joint muscle pain were the most frequent menopausal symptoms, affecting more than 60% of those studied. Half of the participants reported vaginal dryness, sleep disturbances, or physical-mental tiredness. The third part manifested irritability, anxiety, or depressive mood disorder. 20% reported sexual or bladder problems. Somatic impairment was identified in 59.1%, psychological impairment in 53.6%, urogenital impairment in 55.6%, and quality of life impairment in 61.1%. In turn, severe somatic impairment in 7.5%, severe psychological impairment in 3.4%, severe urogenital impairment in 15.8%, and severe impairment of quality of life in 12.7%. In both groups, according to the history of chemotherapy, the order of frequency of symptoms was the same. No differences were observed in the frequency of menopausal symptoms, in general deterioration or in severe somatic, psychological, urogenital, or quality of life deterioration, when comparing the two groups (p>0.05). In addition, history of chemotherapy for breast cancer was not associated with any of the menopausal symptoms or impairments in the quality of life domains that were assessed (p>0.05). OR: 0.55 [95% CI: 0.2-1.3] was estimated in the association between a history of chemotherapy and severe deterioration in quality of life. **Conclusion:** In a group of middle-aged or older Colombian postmenopausal women who were breast cancer survivors, a history of chemotherapy was not associated with the presence of menopausal symptoms or with somatic, psychological, urogenital, or quality of life impairment

Sources of Funding: None

P-49.

Factors Associated with Sexual Disorders in Colombian Climacteric Women: A cross-sectional Study

ALVARO MONTERROSA-CASTRO[1,2], Angelica Monterrosa-Blanco[1,2]. [1]Grupo de Investigación Salud de la Mujer, Universidad de Cartagena Facultad de Medicina, Cartagena de Indias, Colombia; [2]Universidad de Cartagena, Cartagena, Colombia

Objective: Objective: to identify factors associated with sexual disorders in Colombian climacteric women using The Female Sexual Function Index, abbreviated version [FSFI-6] **Design:** Cross-sectional study that is part of the CAVIMEC project [Quality of life in menopause and Colombian ethnic groups]. Healthy women, aged between 40-59 years, residing in urban or rural areas of the Colombian Caribbean, were invited to participate and were surveyed in 2019, face to face in their own residences by nursing assistants. They filled out a form that questioned sociodemographic characteristics and applied the FSFI-6 scale to identify sexual dysfunction and disorders of desire, arousal, satisfaction, coital pain, lubrication, and orgasm. The lower the score for each item and the scale, the worse sexuality. Anonymous, confidential and voluntary participation. For data analysis, EPIINFO 7 was used. Unadjusted logistic regression was performed: dependent variable sexual dysfunction and each of the sexual disorders, independent variables sociodemographic characteristics. a value of p<0.05 was considered significant. Study approved by the ethics committee of the University of Cartagena, Colombia. **Results:** 1445 women were studied, mean age 47.5±15.5 years, 39.5% premenopausal, 26.9% in transition to menopause and a third postmenopausal. The IFSF-6 scale score was 15.4+9.5. Dysfunction was identified in 37.7%. The age range 55-59 compared to 40-44 was associated with a higher probability of sexual dysfunction and the six sexuality disorders explored by FSFI-6 <0.001). The same was observed with daily coffee intake, smoking, post menopause and lack of a stable sexual partner (p<0.001). The lack of studies was associated with sexual dysfunction OR: 1.87 [95%CI:1.1-3.0], p=0.011. Overweight and abnormal weight status were associated with a greater presence of desire and lubrication disorders (p<0.001). Performing activity outside the home was associated with a lower frequency of all disorders (p<0.01)Being mestizo with respect to Afro-descendant was associated with a greater presence of all sexual disorders (p<0.0001), except orgasmic disorders **Conclusion:** Several factors: educational, ethnic, nutritional, work and habits, were associated with dysfunction or with other disorders of sexuality. It is recommended that, during the climacteric, sexuality disorders be addressed, and sociodemographic and personal factors be considered.

Sources of Funding: None.

FACTORS ASSOCIATED WITH SEXUAL DYSFUNCTION

Workers	OR:3.90 [95%CI:1.6-9.4]
Widow	OR:5.71 [95%CI:2.0-15.9]
Mestiza	OR:1.88 [95%CI:1.4-2.4]
Without a stable partner	or:4.45 [95%CI:2.7-7.3]
Coffee consumption	OR:1.33 [OR:95%CI:1.0-1.6]
Current smoking	OR:2.65 [95%CI:1.6-4.2]
Post menopause	OR:3.63 [95% CI:2.8-4.7]

Frecuency of disordes sexual female

Desire	307 (21.2%) [95%CI:19-2-23.4]
Arousal	282 (19.5%) [95%CI:17.5-21.6]
Lubrication	429 (29.6%) [95%CI:27.3-32.1]
Orgasm	373 (25.8%) [95%CI:23.6-28.1]
Satisfaction	206 (14.2%) [95%CI:12.5-16.1]
Pain	270 (18.6%) [95%CI:16-7-20.7]

P-50.

Prevalence and association between possible eating disorder with subclinical hypothyroidism in postmenopausal women living in Colombia

JORGE CONTRERAS-SALDARRIAGA, ALVARO MONTERROSA-CASTRO, VERONICA ABAD-LONDOÑO, Angelica Monterrosa-Blanco. Grupo de Investigación Salud de la Mujer, Universidad de Cartagena Facultad de Medicina, Cartagena de Indias, Colombia

Objective: To identify the prevalence and association of symptoms and possible eating disorder with subclinical hypothyroidism in postmenopausal women living in two Colombian cities. **Design:** Cross-sectional study that is part of the Thyroid Project and Colombian Menopausal Women, approved by the ethics committee and endorsed by the University of Cartagena. Colombia. Postmenopausal women residents of the cities of Cartagena and Medellín, Colombia, were recruited in their own residences and participated anonymously and voluntarily by filling out a form after signing informed consent. A physician applied the format that explored sociodemographic characteristics, clinical history data and applied the items of the SCOFF scale (Sick, Control, One, Fat, Food). Tool that allows identifying symptoms related to eating disorders with dichotomous responses and establishing a possible eating behavior disorder. A nursing assistant took a peripheral venous blood sample to measure TSH and free T-4 with an ultrasensitive third generation chemiluminescence technique. Subclinical hypothyroidism was defined as TSH greater than 4.5µIU/mL with free T-4 between 0.7-1.9ng/dL. Statistical analysis was performed with EPI-INFO-7. Adjusted and unadjusted logistic regression was performed to establish association, OR [95%CI]. Dependent variable (subclinical hypothyroidism) and independent variable the SCOFF scale items and possible eating disorder. p value <0.05 was considered statistically significant. **Results:** 303 postmenopausal women were included. Age 54.6±5.6 years,.69.9% residents in the city of Cartagena and 30.1% in Medellín. Hysterectomy: 26.7%, oophorectomy: 11.8%, diabetics: 9.5%, dyslipidemia: 31.6%, anxiety: 15.1%, depression: 12.2%, family history of thyroid disorder: 19.4%, thyroid nodule: 3.9% and thyroid surgery 1.3 %. Subclinical hypothyroidism was found in 4% of those studied. With the SCOFF scale, it was found that 31% reported feeling sick because they considered their stomach uncomfortably full. 20% reported being worried about asking for control over how much they eat, believing they are fat when others say they are too thin, or having lost more than 6 kg in the last three months. 15% considered that food dominated their life. It was estimated that 98 (32%) of the participants had a possible eating disorder. In unadjusted logistic regression, considering that food dominated your life and having lost more than six kg in the last three months were associated with subclinical hypothyroidism (p<0.05). In the adjusted regression, neither the symptoms nor the possible eating disorder was associated with subclinical hypothyroidism (p>0.05). **Conclusion:** In a group of Colombian postmenopausal women, it was found that more than 20% had symptoms and 32% had a possible eating disorder, while 4% had subclinical hypothyroidism. No significant association was observed between the eating disorder assessment and subclinical hypothyroidism.

Sources of Funding: None

Symptoms and possible eating disorders, n (%)

	All 303	With subclinical hypothyroidism 13 (4.3)	Without subclinical hypothyroidism 290 (95.7)	p
Do you make yourself Sick because you feel uncomfortably full?	96 (31.6)	5 (38.4)	91 (31.3)	0.39
Do you worry you have lost Control over how much you eat?	73 (24.0)	5 (38.4)	68 (23.4)	0.17
Have you recently lost One stone in a 3-month period?	64 (21.1)	6 (46.1)	58 (20.0)	0.03
Do you believe yourself to be Fat when others say you are too thin?	69 (22.7)	3 (23.0)	66 (22.7)	0.60
Would you say the Food dominates your life?	47 (15.5)	5 (38.4)	42 (14.4)	0.03
Possible eating disorder	98 (32.3)	7 (53.8)	91 (31.3)	0.08

Association with subclinical hypothyroidism, OR [95%CI], p

	Unadjusted	Adjusted
Do you make yourself Sick because you feel uncomfortably full?	1.36 [0.43-4.29], 0.59	0.73 [0.16-3.32], 0.69
Do you worry you have lost Control over how much you eat?	2.04 [0.64-6.44], 0.22	1.36 [0.28-6.61], 0.69
Have you recently lost One stone in a 3-month period?	3.43 [1.11-10.59], 0.03	2.90 [0.81-10.37], 0.10
Do you believe yourself to be Fat when others say you are too thin?	1.01 [0.27-3.80], 0.97	0.43 [0.07-2.44], 0.34
Would you say the Food dominates your life?	3.69 [1.15-11.82], 0.02	4.06 [0.74-22.19], 0.10
Possible eating disorder	2.55 [0.83-7.80], 0.10	1,21 [0.10-13.84], 0.87

P-51.

Prevalence of Sexual Problems According to Perception of Loneliness in Colombian Climacteric Women in the COVID-19 Pandemic: A Cross-sectional Study

ALVARO MONTERROSA-CASTRO[1,2], Angelica Monterrosa-Blanco[1,2]. [1]Grupo de Investigación Salud de la Mujer, Universidad de Cartagena Facultad de Medicina, Cartagena de Indias, Colombia; [2]Universidad de Cartagena, Cartagena, Colombia

Objective: Objective: to estimate the prevalence of sexual problems according to the perception of loneliness in Colombian climacteric women at the beginning of the COVID-19 pandemic. **Design:** cross-sectional study that is part of the CAVIMEC+COVID STUDY research project (quality of life in the menopausal and Colombian ethnicities under pandemic conditions). Climacteric women (40-59 y) residing in Colombia participated between June 1 and 5, 2020 by filling out an electronic form. Participants were asked to apply their responses according to their perceptions between May 1 and May 30, 2020. In that period, because of COVID-19, confinements and curfews were decreed by the national government in some Colombian cities. In addition, infection and death curves were rising daily. The women participated voluntarily, anonymously, and confidentially, filling out an electronic form that asked about sociodemographic characteristics and applied the Jong Gierveld Loneliness Scale (JGLS) and Menopause Rating Scale (MRS) items. With JGLS, emotional loneliness, social loneliness and general loneliness were identified. With item eight of the MRS, sexual problems (changes in sexual desire, in sexual activity and satisfaction) were explored. Sample size calculation was performed with data from the Colombian population census of 2005 that established a projection of 25,772,783 women for 2020; of these, 2,859,309 were aged 40 to 59 years old. A sample size of 664 women was calculated in the Epidemiological Analysis from Tabulated Data 3.1 (EPIDAT) software: 99% confidence level, 50% expected proportion, 1% significance and 5% absolute precision. Statistical analysis was performed with Stata-16. The research project has the institutional endorsement of the Universidad de Cartagena, Colombia. **Results:** 984 women filled out the form. The median age of the total sample was 48.0 years old (IQR:42.0-53.5). A total of 84.5% of surveyed women were Hispanic, 13.7% Afro-descendant, and 1.7% indigenous; 39.2% were postmenopausal. Emotional loneliness was identified in 433 participants (44.0%) [95%CI:40.9-47.1], social loneliness in 415 (42.2%) [95%CI:39.1-45.3] and general loneliness in 438 (44.5%) [95% CI:41.4-47.6). Sexual problems were reported by 53.1% of participants [95%CI:48.4-57.7] with emotional loneliness and 33.7% [95%CI:29-9-37.8] of women without emotional loneliness (p<0.001). Sexual problems were reported by 51.3% [95%CI:46.5-56.1] of women with social loneliness and 35.6% [95%CI:31.8-39.7] without social loneliness (p<0.001). Sexual problems were reported by 53.6% [95%CI:48.4-57.7] of women with general loneliness and 33.1% [95%CI:29.9-37.8] without general loneliness (p<0.001). **Conclusion:** sexual problems were significantly more frequent among women with emotional, social, and general loneliness than among those who did not have this perception

Sources of Funding: None

P-52.

Endometrial Pathology: Comparison Between Peri- and Post-Menopausal Women Undergoing Ultrasound-Guided Biopsy

Jennifer H. Fang, B.A.[1], Akhil C. Bandi, B.A., M.S.[2], Veda Nambi, B.A.[1], Gloria Bachmann, MD[1], Adrian Balica, M.D.[1]. [1]Rutgers Robert Wood Johnson Medical School, Piscataway, NJ; [2]Carnegie Mellon University, Pittsburgh, PA

Objective: The objective of this study was to compare the pathology as well as the presenting indications for biopsy between peri- and post-menopausal women undergoing ultrasound-guided endometrial biopsy. **Design:** A total of 195 subjects (mean age 54.7 ± 9.19 years) who underwent ultrasound-guided endometrial biopsy at Rutgers Robert Wood Johnson Medical School between July 2018 - October 2021 were identified. Approval was obtained from the Rutgers Institutional Review Board (IRB). Subjects under the age of 40 (n=8) were excluded from the study. The remaining subjects were stratified into two age groups: 40-51 (n=89) and over 51 (n=98), as 51 years is the average age of menopause and also the median age of these women. **Results:** Indications for ultrasound-guided endometrial biopsy in subjects ages 40-51 were abnormal uterine bleeding (AUB; 55.8%), fibroids (27.9%), post-menopausal bleeding (PMB; 3.8%), and endometrial thickening (4.49%); while indications in women over the age of 51 were PMB (46.6%), fibroids (19.8%), endometrial thickening (19.8%), and AUB (10.3%). Pelvic ultrasound showed similar distributions of detecting fibroids (41.1% vs 44.5%), adenomyosis (20.2% vs 9.2%), and endometrial thickening (0.8% vs 2.5%) for both age groups, respectively. In subjects with a known history of fibroids, the endometrium was not well-visualized on ultrasound in 13.2% of 40- to 51-year-olds and 18.9% of women over the age of 51. Endometrial pathology in women ages 40-51 were 53.3% benign, 16.2% endometrial polyps, and 4.8% disordered proliferation, and 0% malignancy. This distribution was similar in women over the age of 51: 50.5% were benign, 15.2% had polyps, 1.9% had disordered proliferation, but 1.9% had malignancy. Both patients that were diagnosed with malignancy were over the age of 51. There was no significant difference in BMI between the two groups. **Conclusion:** This study is limited by its retrospective nature and small sample size, but suggests that there is no significant difference in prevalence of non-benign pathology between peri- and post-menopausal women undergoing ultrasound-guided endometrial biopsy. Although fibroids and polyps usually affect women of reproductive age, these benign structural disorders may explain bleeding even in post-menopausal women. In women with fibroids, ultrasound guidance may not be as helpful for measuring endometrial thickness and an endometrial biopsy alone should be considered for diagnosis.

Sources of Funding: None

	Indication				Ultrasound Findings			Pathology Findings			
Age	AUB	Fibroids	PMB	Endometrial Thickening	Fibroids	Adenomyosis	Endometrial Thickening	Benign	Polyps	Disordered Proliferation	Malignancy
40-51 (n=89)	58	29	4	4	53	26	1	58	17	5	0
>51 (n=98)	12	23	54	22	53	11	3	53	16	2	2

P-53.

Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause: efficacy in women stratified by race using pooled data from two Phase 3 studies

Genevieve Neal-Perry[1], Petra Stute[2], Marci English[3], Deanna King, MS, PhD[3], Misun Lee[3], Antonia Morga[4], Emad Siddiqui[4], Faith D. Ottery[3]. [1]UNC School of Medicine, Chapel Hill, NC; [2]Inselspital, Bern, Switzerland; [3]Astellas Pharma Global Development Inc, Northbrook, IL; [4]Astellas Pharma Europe Ltd, Addlestone, United Kingdom

Objective: The burden of vasomotor symptoms (VMS) is known to be higher in Black or African American women than White women. This pre-specified analysis investigated the efficacy of fezolinetant in Black and non-Black subgroups (as self-identified) using pooled data from two Phase 3 studies, SKYLIGHT 1 and SKYLIGHT 2 (NCT04003155; NCT04003142). In both studies the four co-primary efficacy endpoints were met and fezolinetant was well tolerated. **Design:** SKYLIGHT 1 and 2 were double-blind, placebo-controlled Phase 3 studies with an identical design. Women ≥40–65 y with moderate-to-severe VMS (average ≥7 hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. The four co-primary efficacy endpoints were mean change from baseline to week 4 and 12 in the frequency and severity of moderate-to-severe VMS. **Results:** The pooled group comprised 1022 women who were randomized and took ≥1 dose of medication. At baseline, VMS frequency was numerically higher for Black than non-Black women (Table). Fezolinetant 30 mg and 45 mg statistically significantly reduced VMS frequency at weeks 4 and 12 vs placebo in the overall population and in both Black and non-Black subgroups. In addition, fezolinetant 45 mg statistically significantly reduced VMS severity at weeks 4 and 12 vs placebo in the overall population and Black and non-Black subgroups. **Conclusion:** These data confirm a higher VMS frequency at baseline in the Black women who participated in this study compared with the non-Black women and overall population. This pooled analysis from SKYLIGHT 1 and SKYLIGHT 2 demonstrates efficacy at week 4 that was maintained through week 12 in both Black and non-Black populations.

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Sue Cooper of Excel Scientific Solutions and funded by Astellas Pharma Inc.

Co-primary endpoint: frequency of moderate-to-severe VMS based on pooled data					
Overall population	Analysis visit	Statistics	Placebo (N=342)	Fezolinetant 30 mg (N=339)	Fezolinetant 45 mg (N=341)
	Baseline	Mean (SD)	11.04 (4.46)	10.94 (4.80)	11.10 (6.45)
	Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	7.64 (5.46) – –	5.57 (5.01) –1.89 (0.32) [>0.001]	5.43 (6.00) –2.28 (0.32) [>0.001]
	Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	6.79 (6.28) – –	4.63 (4.75) –2.15 (0.35) [>0.001]	4.27 (4.68) –2.51 (0.35) [>0.001]
Black subgroup*	Analysis visit	Statistics	Placebo (N=59)	Fezolinetant 30 mg (N=56)	Fezolinetant 45 mg (N=59)
	Baseline	Mean (SD)	11.67 (5.54)	11.18 (4.12)	11.54 (5.23)
	Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	8.30 (7.44) – –	5.71 (4.78) –2.28 (0.78) [0.004]	5.39 (5.68) –2.95 (0.77) [>0.001]
	Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	8.15 (10.24) – –	4.92 (4.85) –3.02 (0.87) [>0.001]	4.29 (5.70) –3.67 (0.85) [>0.001]
Non-Black subgroup*	Analysis visit	Statistics	Placebo (N=283)	Fezolinetant 30 mg (N=282)	Fezolinetant 45 mg (N=282)
	Baseline	Mean (SD)	10.91 (4.20)	10.89 (4.94)	11.01 (6.68)
	Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	7.50 (4.96) – –	5.54 (5.06) –1.81 (0.35) [>0.001]	5.44 (6.08) –2.15 (0.35) [>0.001]
	Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	6.52 (5.12) – –	4.58 (4.74) –1.97 (0.39) [>0.001]	4.27 (4.45) –2.27 (0.39) [>0.001]
Co-primary endpoint: severity of moderate-to-severe VMS based on pooled data					
Overall population	Analysis visit	Statistics	Placebo (N=342)	Fezolinetant 30 mg (N=339)	Fezolinetant 45 mg (N=341)
	Baseline	Mean (SD)	2.42 (0.34)	2.42 (0.34)	2.40 (0.35)
	Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	2.12 (0.57) – –	1.96 (0.63) –0.15 (0.04) [>0.001]	1.88 (0.70) –0.24 (0.04) [>0.001]
	Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	2.01 (0.64) – –	1.82 (0.74) –0.20 (0.06) [>0.001]	1.75 (0.78) –0.24 (0.06) [>0.001]
Black subgroup*	Analysis visit	Statistics	Placebo (N=59)	Fezolinetant 30 mg (N=56)	Fezolinetant 45 mg (N=59)
	Baseline	Mean (SD)	2.42 (0.32)	2.42 (0.36)	2.40 (0.34)
	Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	2.13 (0.62) – –	1.94 (0.68) –0.21 (0.11) [0.053]	1.87 (0.73) –0.25 (0.10) [0.016]
	Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	2.06 (0.73) – –	1.80 (0.83) –0.25 (0.14) [0.068]	1.74 (0.77) –0.29 (0.13) [0.030]

P-54.

S-Equol improves the quality of life for postmenopausal healthy women with complaints from aging.

Kenichi Oe, Yuichi Ukawa, Kazuya Mitsuhashi. Healthcare SBU, Daicel Corporation, Tokyo, Japan

Objective: S-Equol is known as a substance produced from soy isoflavone, daidzein, by intestinal bacteria. It exhibits a higher estrogen-like activity than daidzein (1). The transformation of daidzein to equol by the intestinal microflora widely differs among individuals, depending on their eating and lifestyle habits. Those who have the equol-producing bacteria in their intestinal flora are known to alleviate menopausal symptoms, maintain bone density, reduce the risk of breast, prevent skin aging, and reduce the risk of dementia and lifestyle-related diseases (2, 3). We evaluated the effect of S-Equol on quality of life (QOL) and its safety in postmenopausal healthy women. **Design:** A randomized, double-blind, placebo-controlled, parallel-group comparative study was carried out with 59 postmenopausal healthy Japanese women (40 - 65 years) who experienced discomforts associated with female hormone decline and who did not produce equol. Subjects were divided into two groups, a test food (capsule containing 5 mg of S-equol) group (30 subjects) and a placebo food group (29 subjects). Each group ingested 2 capsules daily for 12 weeks. Quality of life was evaluated using the anti-aging QOL common questionnaire (4) at 0, 4, 8, and 12 weeks. **Results:** The test food group that was studied significantly improved conditions compared to the placebo food group in multiple items of the questionnaire. The items included “Underweight”, “Constipation”, “Cold sensitivity”, “Not motivated”, “Not feeling happy”, “Not enjoying daily life”, “Lost confidence”, “Sociability”, “Self-affirmation”, “Worry”, “Stiff shoulders”, “Dull”, “Loss of appetite”, and “Stomachache”. No significant differences were observed in blood pressure and pulse, body weight, percentage body fat, BMI, hematological test, blood biochemical test, endocrinological test, and general urine test between the two groups after 12 weeks **Conclusion:** It was concluded that daily intake of 10 mg of S-equol for 12 weeks may improve problems associated with aging and contribute to the improvement of QOL. **References:** (1) Modern Physician 2018; 38:393-396 (2) Yoshikata R, Myint KZ, Ohta H. Relationship between equol producer status and metabolic parameters in 743 Japanese women: equol producer status is associated with antiatherosclerotic conditions in women around menopause and early postmenopause. Menopause, 2017; 24:216-224. (3) Pawlowski JW, Martin BR, McCabe GP, et al. Impact of equol-producing capacity and soy-isoflavone profiles of supplements on bone calcium retention in postmenopausal women:A randomized crossover trial Am J Clin Nutr. 2015; 102:695-703. (4) Oguma Y, Iida K, Yonei Y, Satoh T. Significance evaluation of Anti-Aging QOL Common Questionnaire. Glycative Stress Research 3(3):177-185, 2016

Sources of Funding: Daicel Corporation

P-55.

Association between Rest-Activity Rhythms (RARs) and cognitive function in healthy early postmenopausal women

Alexandra Paget-Blanc, BS[2,1], Stephen F. Smagula, PhD[3,4], Rebecca C. Thurston, PhD[3,4], Yuefang Chang, PhD[5], Rachel A. Schroeder, BS[6], Pauline Maki, PhD[2,7]. [1]Graduate Program in Neuroscience, University of Illinois Chicago, Chicago, IL; [2]Psychiatry, University of Illinois Chicago, Chicago, IL; [3]Psychiatry, University of Pittsburgh School of Medicine, Pittsburgh, PA; [4]Epidemiology, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA; [5]Neurosurgery, University of Pittsburgh School of Medicine, Pittsburgh, PA; [6]Psychology, University of Illinois Chicago, Chicago, IL; [7]Obstetrics & Gynecology, University of Illinois Chicago, Chicago, IL

Objective: As women are disproportionally affected by Alzheimer’s disease (AD), it is important to identify modifiable early risk factors. Alterations in circadian rest-activity rhythms (RARs) are common among individuals with AD and may contribute to further progression of the disease. Individuals with AD and mild cognitive impairment exhibit altered actigraphy-assessed RARs characterized by increase rhythm fragmentation and less robust activity patterns compared to healthy individuals. In cognitively unimpaired older women, rhythm fragmentation predicted future cognitive decline. These studies have largely focused on older individuals. Given that the neuropathological disease process begins years before the onset of clinical dementia focusing on midlife women may help identify marker of cognitive health to distinguish normal from abnormal brain aging before the onset of the disease. Here we aim to determine whether disruption in RARs was associated with cognitive performance in cognitively unimpaired postmenopausal women. **Design:** Participants were early postmenopausal women based on STRAW+10 criteria. Exclusion criteria included: stroke/cerebrovascular accident, brain injury, brain tumor, dementia, Parkinson’s disease, use of hormone therapy or SSRI/SNRI antidepressants in past 3 months. Participants completed a 72-hour wrist actigraphy monitoring and neuropsychological assessment including measures of verbal learning and memory (California Verbal Learning Test;CVLT), working memory (Letter Number Sequencing), mental rotation (Card Rotation Test), and processing speed (Symbol Digit Modalities Test;SDMT). Three nonparametric RAR variables were obtained (intra-daily variability, inter-daily stability (IS), and relative amplitude (RA)). Associations between RAR measures and cognitive performance were assessed using linear regression. In separate models, we used each cognitive outcome as dependent variable and each RAR variable as independent variable, adjusting for age, race/ethnicity, and education. Power transformations were applied to IS and RA and the cognitive data were standardized. **Results:** The sample included 224 women (59.16±4.23 years old). In the unadjusted models, IS and RA were each positively associated with CVLT Learning [IS: B(SE)=0.36(0.13), p=0.008; RA:B(SE)=0.45(0.13), p<0.001] and SDMT [IS: B(SE)=0.29(0.13), p=0.034; RA: B(SE)=0.54(0.13), p<0.001]. In the adjusted models, only IS remained a significant predictor of CVLT Learning [B(SE)=0.28(0.13), p=0.026]. For SDMT, there were significant interactions between the RAR variables and race such that the relationships between IS and SDMT, and RA and SDMT, were significantly stronger for women of color than for white women [IS: B(SE)=0.81(0.33), p=0.013; RA:B(SE)=0.58(0.29), p=0.048]. **Conclusion:** In this sample of early postmenopausal women, rhythms stability (IS) and robustness (RA) were related to better verbal learning and processing speed; these association were stronger among women of color than white women. These results suggest that lack of balance and stability of activity patterns across day were markers of worse cognitive function in postmenopausal women of color. Given that RARs are potentially modifiable, increasing stability and balance of activity patterns may provide future preventive approaches for dementia that could benefit women of color particularly. More research investigating other factors contributing to these associations and how they vary over time is needed to further understand the extend of our findings.

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P-56.

Feasibility of a Novel Wrist-Worn Thermal Device for Management of Sleep-Disrupting Hot Flashes During Menopause

Nader Naghavi, PhD[1], Sonja K. Billes, PhD[1], Andrew Vetter, MS[1], Molly Moor, PhD[2], Mary Emma Searles, BSc[3], Nicholas Hathaway, MS[3], Rebecca Spencer, PhD[3], Pamela Peeke, MD[1], Matthew Smith, PhD[1]. [1]Embr Labs, Boston, MA; [2]Bayview Research, Pompano Beach, FL; [3]Institute for Applied Life Sciences, University of Massachusetts Amherst, Amherst, MA

Objective: Menopausal hot flashes contribute to poor sleep and negatively impact quality of life. The Embr Wave is a noninvasive wearable thermal device that applies personalized cooling and warming to thermoreceptors on the inside of the wrist. New modes with cooling and warming sessions specifically for sleep and hot flashes were introduced on the Embr Wave. This study evaluated the feasibility and preliminary efficacy of nighttime use of the Embr Wave for managing hot flashes and sleep during menopause. **Design:** Self-described peri/postmenopausal women experiencing sleep-disrupting hot flashes and insomnia were enrolled. The study consisted of a 1-week baseline and 2-week intervention in which participants were provided the Embr and instructed to use it as needed. Primary outcomes were device use (recorded by the device) and subjective reports of sleep and hot flashes. Sleep was measured with the PROMIS Sleep Disturbance (PROMIS SD, range 0-100) and Sleep Related Impairment (PROMIS SRI, range 0-100) and Insomnia Severity Index (ISI, range 0-28). Hot flashes were assessed with the Hot Flash Related Daily Interference Scale (HFRDIS, range 0-10), daily hot flash number and severity, and control over nighttime hot flashes (range 0-10). Additionally, participants completed the Perceived Stress Scale (PSS, range 0-40). Wilcoxon signed rank tests were used to compare outcome measures for baseline and intervention week 2. Spearman’s rank order correlations were used to evaluate associations between device use and outcomes. Study was conducted remotely due to COVID. **Results:** 31 participants (age: median 53, range 46-61 years) completed the

study between November 2020 to March 2021 in the US; 26 had retrievable use data. Baseline data indicated mild sleep disturbance and impairment, subthreshold insomnia, and moderate stress (Table). Mean±SD baseline frequency of daytime and nighttime hot flashes was 15.5±15.0 and 14.8±9.0 per week. Mean±SD (median) device use per 24 hours was 5.2±4.7 (4.7) sessions and 2.3±2.5 (1.5) hours. PROMIS SD, PROMIS SRI, and ISI improved during the intervention compared to baseline (all $p<0.01$, Table). The intervention also resulted in reduced frequency of nighttime hot flashes, frequency of severe nighttime hot flashes, and increased control over nighttime hot flashes (all $p<0.05$, Table). In participants with greater baseline hot flash interference (HFRDIS score ≥3, n=15), larger improvements in PROMIS SD and SRI, and hot flash control were observed ($p<0.05$) as well as a reduction in PSS (baseline mean±SD 21.7±3.2 vs intervention 17.4±5.7, $p<0.05$). There was a positive correlation between the number of subjective hot flashes and number of sessions logged by the device ($r_s=0.502$, $p<0.01$). No adverse events were reported. **Conclusion:** Results support the feasibility of the Embr Wave for management of sleep-disrupting hot flashes and night sweats in menopausal women. The intervention was associated with improvements in subjective measures of sleep, hot flashes, and perceived stress. The correlation between number of device sessions and number of hot flashes support use of the device for management of hot flashes. Larger longer studies to evaluate the impact of daytime and nighttime use of the Embr Wave on hot flashes and other menopausal symptoms are planned.

Sources of Funding: Embr Labs

Measures (N=31)	Baseline mean±SD	Intervention mean±SD	p-value
PROMIS SD T-score	55.7±6.1	52.2±6.2	0.009
PROMIS SRI T-score	55.6±8.4	51.6±8.3	0.003
ISI	11.8±4.2	9.5±4.1	0.004
HFRDIS	3.2±2.1	2.7±2.0	0.210
Number of nighttime hot flashes (7-day cumulative)	14.8±9.0	12.0±9.2	0.025
Number of severe nighttime hot flashes (7-day cumulative)	3.2±7.9	2.3±6.3	0.011
Control over nighttime hot flashes	2.3±2.8	3.6±3.1	0.034

P-57.

Feasibility of a Novel Wrist-Worn Thermal Device for Managing Bothersome Hot Flashes in Women with Breast Cancer

Andrew Vetter, MS[1], Sonja K. Billes, PhD[1], Nader Naghavi, PhD[1], Molly Moor, PhD[4], Jasmine Sukumar, MD[2], Omar Alfaour, BS[2], Lindsey Stuckey, BS[2], Nicole Williams, MD[2], Mathew Cherian, MD[2], Bhuvaneswari Ramaswamy, MD[2], Robert Wesolowski, MD[2], Matthew Smith, PhD[1], Pamela Peeke, MD[1], Maryam Lustberg, MD MPH[3], Sagar Sardesai, MBBS[2]. [1]Embr Labs, Boston, MA; [2]Comprehensive Cancer Center, The Ohio State University Wexner Medical Center, Columbus, OH; [3]Yale University Yale Cancer Center, New Haven, CT; [4]Bayview Research, Pompano Beach, FL

Objective: Hot flashes are a common side effect of endocrine therapy (ET) in breast cancer survivors. Hot flashes are associated with poor quality of life and treatment nonadherence. The Embr Wave is a noninvasive wearable device that applies cooling and warming to the inside of the wrist and has been associated with decreased hot flash interference and improved sleep in unaffected post-menopausal women. We conducted an exploratory interim analysis of Cohort 1 of a randomized crossover study evaluating the feasibility of the device for managing hot flashes in women with a history of breast cancer. **Design:** Women with a history of breast cancer who reported bothersome hot flashes were enrolled; a stable dose of adjuvant ET was allowed. Participants were allocated to 4 weeks of no device followed by 4 weeks of device (participants were instructed to use the device as needed). Cohort 1 was conducted using the first generation device. The primary outcome was feasibility of the device and the coprimary outcome measures were device use and user satisfaction. Additional outcome measures included Hot Flash Related Daily Interference Scale (HFRDIS, range 0-10) and hot flash number and severity. Assessments were collected remotely due to COVID. We conducted an exploratory interim analysis in participants assigned to no device for the first 4 weeks (baseline) who also had retrievable device use data. Wilcoxon signed rank tests were used to compare mean HFRDIS score for baseline vs intervention week 4; mean daily hot flash number and severity were compared for baseline (weeks 1 and 2) vs intervention week 4. Device use and user satisfaction were evaluated with Kendall's Tau-b correlations. **Results:** Cohort 1 enrolled participants from Nov 2020 to Dec 2021; 10 met inclusion criteria for the interim analysis. Mean±SD age was 44±6 and 80% were on ET. Mean±SD (median) device use per 24 hours was 5±4 (4) sessions and 1.2±1.5 (0.7) hours. User satisfaction was positively correlated with hours of device use ($\tau_b=0.629$, $p<0.05$, n=9). HFRDIS decreased from baseline (mean±SD 4.6±1.6) to intervention week 4 (2.6±1.4, $p<0.01$, n=9). Total number of daily hot flashes decreased from 6.8±3.6 at baseline to 4.9±2.5 at intervention week 4 ($p<0.05$, n=7); the number of daily moderate to severe hot flashes also decreased from 4.8±2.5 vs 2.4±1.3 ($p<0.05$, n=7). No adverse events were reported. **Conclusion:** Results from Cohort 1 support the feasibility of the Embr Wave for management of bothersome hot flashes in women with a history of breast cancer. Preliminary results indicate a positive impact of the device on hot flash interference and frequency and severity of hot flashes. Cohort 2 will evaluate the second generation device. Future studies should evaluate the impact of the Embr Wave on sleep, quality of life, and treatment adherence in breast cancer survivors.

Sources of Funding: Embr Labs

P-58.

Menopause symptoms and eating habits of postmenopause women in times of the SARS-CoV-2 pandemic

Monique G. Nascimento[1,3], Luiza Bayer[1], Bruna Oliveira[1,3], Priscilla R. e Silva Noll[1,2], Matias Noll[2], Ricardo dos Santos Simes[1], Edmund Chada Baracat[1], Isabel C. Esposito Sorpreso[1], José M. Junior[1]. [1]Obstetrics and Gynecology, Universidade de Sao Paulo Hospital das Clinicas, Sao Paulo, Brazil; [2]Department of Public Health, Instituto Federal Goiano, Goiania, Brazil; [3]Universidade de São Paulo, Faculdade de Saúde Pública, São Paulo, Brazil

Objective: This study aimed to compare dietary intake and menopausal symptoms in postmenopausal women before and during the current pandemic scenario. **Design:** Cohort design with 271 integrants and Research participants were asked to complete health questionnaires during the SARS-CoV-2 pandemic. Data on eating habits were collected via telephone interview with the aid of the 24-hour food recall. To relate the data on eating habits, the foods and preparations were classified according to the degree of processing, following the NOVA classification: culinary preparations (sum of natural and minimally processed foods and culinary ingredients), processed foods and ultra-processed foods. The obtained data were typed and tabulated in Excel spreadsheet and analyzed in the Statistical Package for the Social Sciences (SPSS) program version 21.0. **Results:** During the pandemic, 73 (26.6%) of postmenopausal women continued to participate in the study. Of these, 2.7% (2) were diagnosed with COVID-19 and 97.3% (71) were in social isolation. Regarding menopausal symptoms, the intensity of total and vasomotor symptoms during social isolation (17.73 ± 9.99) was lower compared to the pre-pandemic period (22.49 ± 10.55)($p<0.001$). About food intake, the succession of food groups consumed by postmenopausal women followed the pattern of the pre-pandemic period (culinary preparations, ultra-processed and processed foods, respectively), with significant exception of the intake of processed foods from 8.66 to 5.44 calories ($p<0.001$). **Conclusion:** Women showed a decrease in the intensity of menopausal symptoms during social isolation compared to the pre-pandemic period. Also, the food intake of postmenopausal women showed similarities between the pre-pandemic period and during social isolation, with a decrease in the intake of processed foods.

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P-59.

A Overview Of Systematic Reviews In Medicinal Plants And Herbal Formulations For The Treatment Of Climacteric Symptoms: A Lack Of Research On Southern Hemispheric Plants

CAIO FABIO S. PORTELLA[1,2], Igor de Azevedo da Silva[3], Ricardo dos Santos Simes[1], Edmund Chada Baracat[1], José M. Soares Júnior[1], Isabel C. Esposito Sorpreso[1]. [1]Ginecologia e Obstetricia, Universidade de Sao Paulo Hospital das Clinicas, Sao Paulo, Brazil; [2]Brazilian Academic Consortium for Integrative Health, São Paulo, Brazil; [3]Universidade Anhembi Morumbi, Sao Paulo, Brazil

Objective: The purpose of this study is to examine the medicinal plants and phytotherapeutic resources that are used to treat climacteric and menopausal symptoms. **Design:** The method used was a systematic review of the available literature of the overview type. The theme was searched in the following databases: Pubmed, Scielo, Virtual Health Library - PAHO, Scopus, Web of Science, and EMBASE; the search strategy for each database was constructed using the following key terms and their variants: Phytotherapy, herbology, menopause, postmenopause, and perimenopause, menopausal symptoms, and menopausal transition. The following criteria were used to determine eligibility: systematic reviews and meta-analyses; articles written in Portuguese, English, or Spanish; and dates ranging from 11/01/1994 to 11/01/2022. The following criteria were used to determine exclusion: articles with incomplete content; full articles written in English, Spanish, or Portuguese; reviews combining in-vitro and/or animal studies with clinical studies; evidence maps; and reviews of uncontrolled studies. **Results:** Results: We discovered 12.436 records in the searching databases; after removing duplicates, we selected 67 records based on title and abstract. Trifolium pratense, Humulus lupulus, Valeriana officinalis, Actaea racemosa, Linum usitatissimum, Cimicifuga racemosa, Lepidium meyenii, Panax ginseng, Foeniculum vulgare, Trigonella foenum-graecum, Tribulus terrestris, Schisandra chinensis, Nigella sativa, Vitex ag Marijuana sativa, Pueraria Mirifica, Phoenix dactylifera L, Oenothera biennis, and Pimpinella anisum. Kuntai, Xianling Gubao, Danggui liu huang, Kun Tai, Gui lu Er Xian Jiao, Piascledine, and Bai shao were all cited as herbal formulations, as were isolated phytoestrogens such as genistein, glycitein, isoflavones, and the isoflavone derivative daidzein. The majority of reviews identified examine the impacts of Soy, the plant with the most studies in the assessed literature, and its derivative products. **Conclusion:** We observed a wide variety of medicinal plants and phytotherapeutic resources for menopausal/climacteric symptoms, with a particular emphasis on North American, European, and Asian plants. It is highlighted that, despite the fact that South America has the highest plant richness on the earth, no native South American species have been discovered, not even African or Australian, highlighting the critical need for more research in the southern hemisphere continents.

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P-60.

Social Media as Health Education Strategy for Women in The Menopause and Postmenopauseal Transitions and Medical Students

CAIO FABIO S. PORTELLA[1,2], Camila C. Francisquetti[1], Mariana Machado[1], Nayara S. Sousa Santos[1], Adriana S. Hashimoto[1], Caroline da Silva Burch[1], Igor de Azevedo da Silva[3], Ricardo dos Santos Simes[1], Priscilla R. e Silva Noll[1,4], Edmund Chada Baracat[1], José M. Soares Júnior[1], Isabel C. Esposito Sorpreso[1]. [1]Ginecologia e Obstetricia, Universidade de Sao Paulo Hospital das Clinicas, Sao Paulo, Brazil; [2]Brazilian Academic Consortium for Integrative Health, São Paulo, Brazil; [3]Universidade Anhembi Morumbi, Sao Paulo, Brazil; [4]Instituto Federal Goiano, Goiania, Brazil

Objective: Describe a teaching model using social media as a health education strategy for women transitioning to menopause and postmenopause. **Design:** Between May and June 2021, the Gynecology Discipline of the Obstetrics and Gynecology Department of the University of São Paulo Medical School conducted a descriptive, exploratory, qualitative study through the Edital 01/2020–2021-funded project "Health Education for Women in the Transition to Menopause and Postmenopause." The project was initiated by the University of Sao Paulo Undergraduate Pro-Rectorate. During the pre-implementation stage of the media channels, an online form was created using Google Forms and distributed via social communication platforms (Facebook, Instagram, and the researchers' personal Whatsapp networks), where it was filled out by women in the transition to menopause and post-menopause using the "Snowball" sampling technique. Sociodemographic data were collected, as were questions about the period's meaning, recognition, and experience. Additionally, Google Trends provided information on the major trends in search tools for the following search terms: climatic, menopause, pre-menopause, and post-menopause. **Results:** Medical students developed social media channels and a website dedicated to the gynecological field at the University of São Paulo - Faculty of Medicine: 287 women over the age of 40, 83.3 percent white, 9.9 percent brown, 3.7 percent yellow, and 3.1 percent black. Regarding familiarity with the terms "menopause" (95.5 percent), "climacteric" (72.5 percent), "postmenopause" (66 percent), and "perimenopause" (25.5 percent), 78.8 percent expressed interest in a platform with content connected to the topic. The primary terms used to describe the menopausal transition period in the qualitative study were "mood swings," "heat," "loss of libido," "vaginal dryness," "irritation," "tiredness," "discomfort," "aging," "insomnia," "weight changes," and "changes." The research culminated in the creation of a web page, www.menopausando.com.br, as well as pages on the social media platforms Instagram, Facebook, and a SPOTIFY podcast aimed at educating women in the menopause transition and postmenopause about their health. In the first 60 days of the channels' existence, 340 Instagram followers, 70 Facebook followers, and eight podcast episodes aired on the SPOTIFY platform were added, as well as three requests for interviews on television and radio channels due to the channels' social media presence. **Conclusion:** The establishment of channels facilitated communication between undergraduate students and the community. Simple, low-cost, and with a large potential reach, aside from being an effective tool for preventative awareness and health promotion among women in menopause and postmenopause, enhances quality of life and menopausal symptoms in a playful and educational manner. This interest is reinforced by data from Google Trends, which indicates a similar trend in search terms. Thus, the exploratory study helped fund the development of the website "Menopausando" and other social media platforms (Facebook, Instagram, and Spotify) that were made by students with the help of their teachers. This allowed for fun learning, a lot of communication with the community, and the wide spread of knowledge.

Sources of Funding: Edital 01/2020–2021-funded project "Health Education for Women in the Transition to Menopause and Postmenopause"

P-61.

Bioidentical Compounded Hormones. What do the patients know? Cross-Sectional Survey

Cristina A. Ramirez Colunga, Dra., Eva M. Márquez Mata, Selene García-Luna, Ph.D, Arturo Morales-Martínez, Dr.med., Luis H. Sordia-Hernández, Dr.med., Otto Valdés-Martínez, Dr.. Centro Universitario de Medicina Reproductiva, Universidad Autónoma de Nuevo León, Monterrey, Mexico

Objective: To assess the knowledge, perceptions and preferences about the bioidentical hormone therapy in menopausal patients. **Design:** Cross-sectional online surveys about their knowledge and use of BCH were carried out on menopausal women that first-attended the Menopausal clinic at a University Hospital in Monterrey, Mexico. The surveys were applied from May 15 to June 15, 2022 using the Google forms platform. Obtained responses were recorded on an Excel database and analyzed using GraphPad Prism. **Results:** A total of 57 patients agreed to participate in the survey, 5% of whom were excluded for not fully responding to the questionnaire. Of the 54 women surveyed, the mean age was 57 years (SD 6.3). Less than half (42.5%) of the participants had heard or read anything about BCH. Their main source of information was: a health professional (34.7%, 8/23), followed by internet sources (30.4%, 7/23) and a family member or friend (30.4%, 7/23). Importantly, 70.3% (38/54) considered that, because they are bioidentical, they are safer compounds than conventional hormones. Therefore, if they require HRT to attenuate symptoms related to menopause they would prefer to use BCH therapy (OR 555, 95% CI 32.52-5753, p=<0.0001). In addition, 90.7% (49/54) of the participants considered that BCH does not represent a risk for the development of breast cancer and 92.5% (50/54) for endometrial cancer. Regarding age, there was a tendency for older patients (61.27 ± 6.76) to prefer the use of these "natural" therapies, however, was not significant. Finally, 46.2% (25/54) consider that BCH has some type of strict regulation in the US and Mexico. **Conclusion:** Our results indicate that there is a gap of information about BCH therapies. The primary information source was health professionals. Interestingly, they believed the BCH therapy does not pose a risk for the development of breast and endometrium cancer. As expected, the term "bioidentical" was a deceiving and confounder term, since the responders that referred not to have knowledge about the BCH, considered it synonym of "natural" and that does not pose risk to their health therefore would prefer to use BCH over conventional hormonal therapy if needed.

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P-62.

A Sex-based Analysis to Address the Question: Do Reproductive Hormones Associate with Cognitive Performance in Older People Living with HIV (PLWH)?

NANCY K. REAME, PhD, MSN, NCMP[1], Alvin Gordian-Arroyo, MPD[1], Jose Gutierrez-Contrerez, MD, MPH[2], Jianfang Liu, PhD[1], Rebecca Schnall, PhD, MPH[1,3]. [1]School of Nursing, Columbia University Irving Medical Center, New York, NY; [2]Department of Neurology, Columbia University Irving Medical Center, New York, NY; [3]Dept of Population and Family Health, Mailman School of Public Health, Columbia University Irving Medical Center, New York, NY

Objective: In PLWH, even when well-controlled, neurocognitive decline is accelerated with aging. Although sex differences are generally under-studied, women living with HIV (WLWH) versus affected men (MLWH) show cognitive vulnerabilities. Besides psychosocial influences, the role of menopause - when estradiol declines and FSH rises- has emerged as a possible sex-specific factor underlying these differences, but relative hormonal contributions are unclear. To better distinguish the influence of sex hormones on cognitive performance in PLWH, we conducted a sex-based bivariate and multivariate analysis of cognitive domain measures and selected reproductive hormones drawn from a larger community sample of non-white older PLWH previously characterized for cerebrovascular disease features (Guteirrez et al, 2020) and sex differences in white matter hyperintensities (NAMS poster, 2021, manuscript under review). **Design:** In the parent study, 85 participants ages 50-75 and living with HIV participated in the cross-sectional study and completed a neuropsychological assessment, a blood draw, a demographic survey, health questionnaire and a magnetic resonance imaging (MRI) scan. Single plasma hormone measures for estradiol (E2), testosterone (T), dihydroepiandrosterone sulphate (DHEA-S) and follicle stimulating hormone (FSH) were determined via immunoassay. The neuropsychological evaluation consisted of a standard set of tests previously described (Guteirrez et al, 2020) to assess 6 cognitive domains: verbal intelligence, attention, recall, motor processing speed, language, and memory. After excluding exogenous hormone users (n=6), data from 44 women and 35 men were analyzed to compare demographics, cardiovascular, dementia and HIV risk factors, log-transformed sex hormone values and cognitive domain score averages of the study participants. Bivariate and moderation analysis using multivariable general linear regression models were conducted. **Results:** As previously reported (NAMS, 2021), there were no differences in demographics, cardiovascular and dementia risk factors or HIV health status in this sample of PLWH (mean age 59.8±0.6 years, 55.7% female, 72% non-Hispanic black). Reproductive hormone measures differed as expected by sex, menopause status and age. In MLWH, cognitive domain Z scores were higher than in WLWH for language fluency, episodic verbal memory, executive attention but only different for episodic verbal memory (p=0.04). In WLWH, z scores were higher for verbal learning memory and processing speed, but not different than in MLWH. Trends for modestly strong associations between FSH and motor processing speed (r=0.25, p_value>0.05) as well as for DHEAS and verbal learning memory (r=0.31, p_value<0.05) were seen but only in females. After controlling for age, education, cranial size, and white matter hyperintensity volume, there was a significant interaction between sex and FSH for motor processing speed (B=-1.0866, p value=0.0006) as well as for DHEAS and motor processing speed (B=-0.6856, p_value=0.0009). For females, there was a positive relationship between FSH and motor processing speed (B=0.8176, p_value=0.0009), whereas for males, a negative relationship was NS (B=--0.6431, p_value=0.16). Females also showed a positive relationship between DHEAS and motor processing speed (B= 0.2792, p_value=0.04), whereas for males, there was a negative relationship (B= -0.4064, p_value=0.013) **Conclusion:** In PLWH, FSH and DHEAS demonstrate sexually dimorphic associations with motor processing speed - a measure of cognitive performance that has been linked to neurocognitive vulnerabilities in WLWH.

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P-63.

Effects of Bothersome Symptoms during the Late Reproductive Stage and Menopausal Transition: Observations from the Women Living Better Survey

Nancy F. Woods, BSN, PhD, FAAN, FGSA[1], Nina Coslov, MBA[2], Marcie K. Richardson, MD, FACOG[3,4]. [1]Biobehavioral Nursing, University of Washington, Seattle, WA; [2]Women LIving Better, Cambridge, MA; [3]Atrius Health, Newton, MA; [4]OB/GYN, Beth Israel Deaconess Medical Center, Boston, MA

Objective: Bothersome symptoms during the late reproductive stage and menopausal transition sometimes interfere with women's activities of daily living and relationships, yet little is known about the specific effects of different groups of symptoms. Aims of these analyses were to examine the effects of bother related to 5 symptom groups on participant's assessment of 4 outcomes: interference with everyday activities, interference with relationships, "not feeling like myself," and self-ratings of health. **Design:** Participants responded to the online Women Living Better survey during 2020. In addition to rating 61 symptoms as bothersome on a scale from not at all bothered (0) to extremely bothered (6), they also indicated the degree to which their symptoms interfered with their activities and relationships indicating not at all (0) to a great deal (4). They

indicated the extent to which they didn't "feel like myself" choosing none of the time (0) to all of the time (4) and rated their health from poor (1) to excellent (5). Symptoms were grouped using results of principal components analysis. Five symptom groups with the highest bother ratings were analyzed for this report, including: brain fog, volatile mood, fatigue/pain, VMS/sleep onset, and anxiety/vigilance symptoms. Two-stage hierarchical regression analysis was used to examine personal characteristics of the participants such as education, menopause-related factors, roles and stressors (stage 1) and effects of five symptom group bother ratings on interference with daily activities and relationships, "not feeling like myself," and health ratings (stage 2). **Results:** Interference with daily activities was related to difficulty paying for basic items and bother associated with the brain fog, anxiety/vigilance, fatigue/pain, and VMS/sleep onset symptom groups. Interference with relationships was correlated with being in a committed relationship and bother related to all 5 symptom groups. "Not feeling like myself" was related to having completed less education, reporting greater overall stress, brain fog, anxiety/vigilance, volatile mood, and fatigue/pain symptoms. More positive health ratings were related to having completed more education, having responsibility for children or dependents, experiencing greater satisfaction with roles, and less fatigue/pain symptom bother. Bother related all five symptom groups was related to increased interference with relationships, but bother related to interference with daily activities was related to four of the five symptom groups, but not volatile mood symptoms. The phrase "not feeling like myself" was related to more bothersome anxiety/vigilance, volatile mood, brain fog, and fatigue/pain symptoms. Of interest was that VMS/sleep symptoms, often attributed to the menopausal transition, were not related to either "not feeling like myself" or to self-ratings of health. Moreover, self-rated health was related only to fatigue/pain symptom bother. **Conclusion:** These findings suggest that the experience of symptoms that are typically attributed to a developmental event, in this case perimenopause, may be viewed as unrelated to one's health. Further clarification of which symptoms can be attributed to perimenopause rather than other factors such as aging, will improve anticipatory guidance about perimenopause. Similarly additional investigation of the meaning of the phrase "not feeling like myself" could help clarify why bothersome symptoms such as mood, fatigue, and cognitive symptoms, but not vasomotor/insomnia symptoms, are associated with this descriptor. Setting accurate expectations about what is typical can influence anticipation, experiences, and attributions of symptoms. Further investigation on these fronts will contribute to timely, accurate anticipatory guidance and strategic symptom management for patients and providers.

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P-64.

Adverse Childhood Experiences and Female Sexual Dysfunction in Midlife Women: Is There a Link?

Mariam Saadedine, Doctor of Medicine[1], Stephanie Faubion, MD, MBA[3,7], Carol Kuhle, DO, MPH[6], Juliana M. Kling, MD, MPH[7,2], Kristin Mara[4], Felicity Enders, PhD[4], Ekta Kapoor, MBBS[7,5]. [1]Faculty of Medicine, American University of Beirut, Beirut, Lebanon; [2]Division of Women's Health Internal Medicine, Mayo Clinic, Scottsdale, AZ; [3]Division of General Internal Medicine, Mayo Clinic, Jacksonville, FL; [4]Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN; [5]Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Mayo Clinic, Rochester, MN; [6]Division of General Internal Medicine, Mayo Clinic, Rochester, MN; [7]Mayo Clinic Women's Health, Rochester, MN

Objective: Adverse childhood experiences (ACEs) decrease the Quality-Adjusted Life Expectancy (QALE) of victims by 9.5 years. One in three children experiences at least one ACE, and 39% of United States (US) women report experiencing two or more ACEs in their lifetimes. ACEs have previously been linked with self-reported total menopause symptom burden and vasomotor symptoms. However, the association between ACEs and female sexual dysfunction (FSD), defined as the presence of distressing sexual problems, remains unassessed in midlife women. The prevalence of sexual problems in women in the US is 40%, with a steep rise after menopause reaching more than 70%. Female sexual dysfunction (FSD) is the presence of sexual problems combined with sexual distress, affecting about 12% of US women. Child sexual abuse, specifically, has been previously identified to associate with lower female sexual function and sexual satisfaction. The objective of this study was to evaluate the association between ACEs and FSD in midlife women, considering possible confounding factors. **Design:** A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause, and Sexuality (DREAMS) was conducted using questionnaires completed by sexually active women aged 40-65 years who presented to a women's health clinic at Mayo Clinic in Rochester, from May 2015 to December 2016. History of ACEs was obtained with the validated ACE questionnaire. FSD was assessed by the Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale-Revised (FSDS-R). The association between ACEs and FSD (FSFI ≤ 26.55 **and** FSDS-R ≥ 11) was evaluated using a multivariable logistic regression model, adjusting for age, menopause status, hormone therapy use, anxiety, depression, relationship satisfaction, hot flash severity, and history of abuse in the past year. **Results:** A total of 1257 women were included in the analysis, 53.4% of whom had FSD. Women were of mean age of 52.9 years, white (96.2%), partnered (88.9%), educated (93% with at least some college), perimenopausal or postmenopausal (58.5%), and 57% reported having at least one ACE. Women were classified according to the number of ACEs: No ACEs, 1-3 ACEs, and ≥ 4 ACEs. Nearly half (41.8%) reported 1-3 ACEs and 15.4% had ≥ 4 ACEs. The proportion of women with FSD increased sequentially as the number of ACEs increased: 49.4% in the No ACEs group, 54.7% in the 1-3 ACEs group, and 67.4% in the ≥ 4 ACEs group ($p<0.001$). In the univariate analysis, a history of ≥4 ACEs significantly increased the odds of FSD compared to No ACEs (OR 2.12, 95% CI 1.50-2.99, $p<0.001$). The association remained statistically significant in the multivariable analysis after adjusting for all confounders (OR 1.75, 95% CI 1.15-2.68, $p=0.009$). History of 1-3 ACEs compared to No ACEs also increased the odds of FSD in both univariate (OR 1.24, 95% CI 0.97-1.58, $p=0.083$) and multivariable (OR 1.18, 95% CI 0.88-1.58, $p=0.27$) analyses, but the results were not statistically significant. **Conclusion:** This cross-sectional study demonstrates an association between a history of adverse childhood experiences and FSD in midlife women. This association was independent of other factors known to correlate with ACEs that can potentially affect female sexual function, such as anxiety, depression, and severe hot flashes. Given the association of ACEs and many other adverse health outcomes, this association reiterates the need for efforts to protect children. In addition, the findings also highlight an opportunity for clinicians to screen for ACEs in women with FSD and to offer multidisciplinary treatment, including referral for counseling as indicated.

Sources of Funding: None

P-65.

Associations between Childhood Adversity and Age at Natural Menopause

Mariam Saadedine, Doctor of Medicine[1], Stephanie Faubion, MD, MBA[2,3], Ekta Kapoor[3,4], Kristin Mara[5], Felicity Enders, PhD[5], Paru David, MD[6], Juliana M. Kling, MD, MPH[3,6]. [1]Faculty of Medicine, American University of Beirut, Beirut, Lebanon; [2]Division of General Internal Medicine, Mayo Clinic, Jacksonville, FL; [3]Mayo Clinic Women's Health, Rochester, MN; [4]Division of General Internal Medicine, Mayo Clinic, Rochester, MN; [5]Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN; [6]Division of Women's Health Internal Medicine, Mayo Clinic, Scottsdale, AZ

Objective: Women globally continue to experience different forms of adversity including adverse childhood experiences (ACE). More than half of the women in the US have experienced an ACE in their lives. Beyond the immediate harmful impacts of childhood adversity, these life experiences are associated with reduced quality of life and lower life expectancy. ACE have also been associated with more severe menopause symptoms. However, the association between ACE and age at natural menopause has not been examined. One study showed that intergenerational violence exposure (maternal childhood physical abuse and her child's sexual abuse) was associated with an earlier age at natural menopause. While menopause is a natural process, it has been linked with accelerated aging. Similarly, increasing age at menopause has been associated with a reduction in mortality risk. The objective of this study was to evaluate the association between ACE and the age at natural menopause. **Design:** A cross-sectional analysis from the Data Registry on the Experiences of Aging, Menopause, and Sexuality (DREAMS) was conducted using questionnaires completed by postmenopausal women who went through natural menopause (have gone 12 consecutive months without a period), and who presented to a women's health clinic at Mayo Clinic, Rochester, MN from May 2015 to December 2016. History of childhood adversity was obtained with the validated ACE questionnaire. The association between ACE and age at natural menopause was evaluated using a multivariable linear regression model, adjusting for educational level, race/ethnicity, smoking, obesity, marital status, and employment status. **Results:** A total of 350 women were included in the analysis with mean age at menopause of 50.9 years. At the time of the clinical visit, women were of mean age 59.2 years, white (92.9%), partnered (82%), educated (91.3%); 54% reported having at least one ACE. Women were classified according to the number of ACEs: no ACE, 1-3 ACE, and ≥ 4 ACE. Nearly half (41.7%) reported 1-3 ACE and 12.6% had ≥ 4 ACE. The age at natural menopause decreased sequentially as the number of ACE increased: 51.2 years with no ACE, 50.8 years with 1-3 ACE, and 50.3 with ≥ 4 ACE. In the univariate analysis, a history of 1-3 ACE decreased the age of menopause by 0.4 years (95% CI -1.7 to 1.0, $p=0.6$), and a history of ≥ 4 ACE decreased the age at menopause by 0.8 years (95% CI -2.8 to 1.2, $p=0.41$), but the results were statistically insignificant. Similarly, in multivariable analysis, a history of 1-3 ACE decreased the age of menopause by 0.3 years (95% CI -1.6 to 1.0, $p=0.67$), and a history of ≥4 ACE decreased the age of menopause by 1.3 years (95% CI -3.2 to 0.7, $p=0.21$), but the results were statistically insignificant. **Conclusion:** While stressful life experiences like ACE can theoretically influence the age at menopause, this study did not show a significant relationship between adverse childhood experiences and age at natural menopause. More studies on larger scales are needed to confirm these findings, and to assess for other factors that may influence the age at natural menopause.

Sources of Funding: None

P-66.

Approximating Systemic Estrogen Exposure from Vaginal Estrogen Cream Therapy

Mark Newman, MS, Doreen Saltiel, MD, JD, Desmond A. Curran. Precision Analytical, Inc, McMinnville, OR

Objective: It is not clear if vaginal application of estrogen results in clinically significant systemic effects, though this would likely only occur at high doses. Collecting real-world data regarding systemic estrogen exposure from vaginal estrogen use is difficult as serum collection is invasive and no other sampling method has been shown to provide reliable and accurate results. One objective of this study was to determine if high dose vaginal estrogen cream use showed expected dose-dependent increases in urinary estrogen levels. Secondarily, cases with high dose vaginal therapy were examined to test the urine assay's ability to successfully remove any potential contamination for accurate analysis of systemic estrogen exposure. **Design:** This was a retrospective observational study conducted using data from the database of a diagnostic laboratory (Clinical Trials ID: NCT04305093). Results included urinary concentrations of 10 different estrogen metabolites including estrone (E1), estradiol (E2), and estriol (E3). From this database of over 100,000 results, 58 postmenopausal women met inclusion criteria and had both baseline results and results while using a 0.1 mg dose of vaginal estrogen cream, Biest (60% E3, 40% E2; applied to the labia daily). From this group, 30 women had an

additional measurement while using 0.25 mg and 17 women (non-overlapping) had a measurement while using 0.5 mg. The assay method used in this study has previously been shown to systematically remove more than 97% of any free hormone contamination via a methyl tert-butyl ether (MTBE) wash and this removal of contamination was confirmed in each sample. The Jonckeere-Terpstra trend test was used to assess for ordered trends across dose categories. **Results:** The mean age of study participants was 55.7 years. Increasing doses of the vaginal estrogen cream resulted in dose-dependent increases in median urinary concentrations of E1, E2, and E3. All 3 metabolites showed statistically significant ordered trends across dose categories (p<.00001 Jonchkeere-Terpstra trend test). The median E2 concentration increased from 0.36 ng/mg-Cr at baseline to 0.9 ng/mg-Cr at a dose of 0.1 mg, 1.13 ng/mg-Cr at a dose of 0.25 mg and 1.90 ng/mg-Cr at 0.5 mg. **Conclusion:** The results of this study suggest that vaginal estrogen cream at doses of 0.04 mg (E2) and higher may be absorbed systemically in significant amounts. This indicates a need for further investigation, ideally with larger, prospective studies. The sampling method and accompanying assay used in this study may represent an ideal tool for further study due to the ease of sample collection and the ability of urine to capture and represent a greater proportion of the pharmacokinetic patterns exhibited by estrogen cream.
Sources of Funding: None

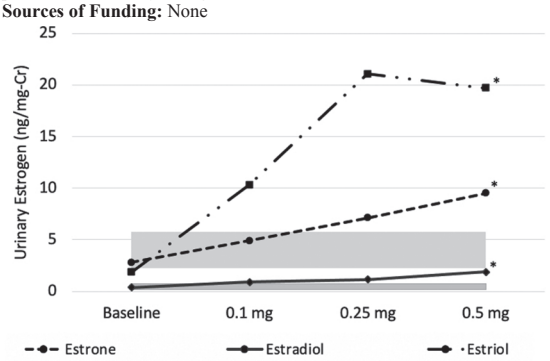


Figure 1. Median changes in the three main urinary estrogens (estrone = dashed line/circle markers, estradiol = solid line/diamond markers, estriol = dashed-dotted line/square markers) with stepwise increases in vaginal biestrogen cream doses. For reference, the grey box represents the interquartile range of estradiol postmenopausal concentrations and the blue box represents the interquartile range of follicular estradiol concentrations from the larger dataset.

P-67.
The Impact of 3,3′-Diindolylmethane on the Estrogen Profile of Postmenopausal Women Being Treated with a Transdermal Estradiol Patch

Mark Newman, MS[1], Doreen Saltiel, MD, JD[1], Bryan P. Mayfield, PharmD[1,2], Frank Z. Stanczyk, PhD, MS[3]. [1]Precision Analytical, Inc., McMinnville, OR; [2]Pharmacy Practice, Texas Tech University Health Sciences Center Jerry H Hodge School of Pharmacy, Dallas, TX; [3]Obstetrics and Gynecology and Population and Public Health Sciences, University of Southern California Keck School of Medicine, Los Angeles, CA

Objective: 3,3′-diindolylmethane (DIM) is a non-FDA-regulated supplement that is the derivative and primary in vivo product of indole-3-carbinol (I3C), a dietary phytoestrogen found in cruciferous vegetables. DIM has been studied in multiple clinical trials as a potential cancer prevention agent with mixed results. Because DIM is thought to offer protection against breast cancer, some postmenopausal women choose to use it, and, in some cases, some providers recommend it to their patients. Many of these patients may be concurrently receiving menopausal hormone therapy (MHT), and since DIM's mechanism of action involves alteration of estrogen metabolism, it is possible that a drug-drug interaction exists. The objective of this study was to examine the effect of DIM on the estrogen profiles of postmenopausal women receiving MHT treatment in the form of a transdermal estradiol (E2) patch. **Design:** This was a retrospective observational cohort study for which data were collected from a database containing 144,561 laboratory accessions from 129,883 patients processed between January 1, 2016 and December 9, 2019 (Clinical Trials ID: NCT04305093). Laboratory measurements included E2 and 9 other urinary estrogen metabolites. From this database, 1458 results were available for postmenopausal women using a transdermal E2 patch, of which 108 indicated that they were concurrently taking a DIM/I3C supplement. For comparison, results were also available for premenopausal women using DIM (n = 882), premenopausal women on no therapy, and postmenopausal women on no therapy. Wilcoxon rank sum tests, Kruskal-Wallis tests, and paired t-tests were used to assess differences between groups. **Results:** When compared to postmenopausal women using a transdermal E2 patch but not concurrently taking DIM, women using an E2 patch plus DIM had statistically significant alterations in their urinary estrogen profiles. These alterations were similar to those observed in the profiles of premenopausal women using DIM. Multivariate regression analyses to account for age, body mass index (BMI), E2 patch dose, and urinary creatinine confirmed the observed differences in estrone (p=0.004), estriol (p<0.0001), the 2-hydroxymetabolites (2-OHE1: p=0.004; 2-OHE2: p=0.004), 4-hydroxyestradiol (p=0.01), 16-hydroxyestrone (p=0.02); however, E2 (p=0.19) and 4-hydroxyestrone (p=0.1) no longer reached significance for the effect of DIM. Although E2 was no longer significant in the multivariate analysis, the point estimate (beta=0.042) was similar to the findings in premenopausal women with a 9.2% decrease in urinary E2 concentrations at each increased dose of the E2 patch. **Conclusion:** These results are a substantial addition to the literature as there are not many published studies investigating the effects of DIM on MHT, especially with large sample sizes. Postmenopausal women on transdermal E2 patch therapy (and potentially other MHT formulations) who choose to concurrently use a DIM/I3C supplement may have clinically significant changes in their urinary estrogen profiles, potentially as a result of altered estrogen metabolism. Simultaneous decreases in both E2 and 16-hydroxyestrone could combine to decrease the overall estrogenic impact of therapy on key clinical endpoints such as bone mineral density and symptom improvement. The presence and magnitude of these changes suggests that providers treating postmenopausal women with MHT should ask their patients if they are taking a DIM/I3C supplement and, if so, potentially consider MHT dose adjustment or other therapy changes.
Sources of Funding: None

P-68.
The Effects of Diet on Menstrual Pain

Serah Sannoh. Rutgers The State University of New Jersey, New Brunswick, NJ

Objective: Objective: Dysmenorrhea, or menstrual pain, is the leading cause of school absences[1] and has a prevalence rate of 90% among adolescent girls[2]. Despite the high prevalence of menstrual pain, many adolescent girls do not seek treatment for it. This pain is typically managed with the use of over-the-counter pain medication, but many times this does not remedy the pain which affects the quality of one's life. Evidence has highlighted that diets high in omega-3 fatty acids and low in processed foods, oil, and sugar reduce inflammation, which is a key contributor to menstrual pain. The Women's Health Institute promotes women's health research and brings light to areas in women's health often forgotten, such as the dysmenorrhea many adolescent girls face. Dietary solutions to menstrual pain should be researched more because one's daily diet influences their health outcomes. This project will study the effect of diet on menstrual pain and will evaluate which foods contribute to dysmenorrhea in adolescent girls and which foods can reduce the negative lifestyle effects of this condition. **Design: Design:** Research was conducted through a literature search of peer-reviewed articles and journals which were found using the search engines Rutgers Library, PubMed, and ScienceDirect. Multiple studies evaluating the relationship between period pain and specific diets were analyzed. To narrow the search results the advanced search tool was used to search for keywords such as "diet", "dysmenorrhea", "foods", "menstrual pain", "period pain", and other related terms. The advanced search tool was used to narrow my search by using "and" between keywords and by using "or" to widen my search. This study is targeted towards adolescent and college-aged girls, which is why the search terms "adolescent", "college", and "university" were also used. **Results: Results:** The results from the multiple studies were collected from nested control case studies, questionnaires, and random assignment. These studies examined the dietary patterns that result in menstrual pain. It was found that diets high in animal meats, oil, sugars, salts, and coffee contribute to an increased risk of dysmenorrhea. Studies found that foods high in omega-6 fatty acids promote inflammation and foods high in omega-3 fatty acids reduce inflammation[3]. It is very common for college aged girls in America to eat diets high in omega-6 fatty acids, since this is the bulk of the American diet. Since menstrual pain results from inflammation, it is important to have a balance of omega-6 and omega-3 fatty acids in your diet or have more omega 3- fatty acids in your diet. **Conclusion: Conclusion:** The findings from multiple studies suggest that diet does have a role in menstrual pain. To reduce this pain, it is advisable to avoid diets that trigger inflammation. The muscles in the uterus contract due to prostaglandins, which are very active in inflammatory responses. When measuring one's Dietary Inflammatory Index, it was found that those on a vegan diet, which excluded animal fat, had the lowest rates of inflammation[4]. It is advisable to adopt a diet that avoids inflammatory foods to remedy dysmenorrhea.
Sources of Funding: None

P-69.
Mental Health Profiles for Dishonorably Discharged Women

Tyler Sarich, Cell Development and Neuroscience[1], David Karcnik[2]. [1]School of Arts and Sciences, Rutgers The State University of New Jersey, New Brunswick, NJ; [2]Universidad Autonoma de Guadalajara, Zapopan, Mexico

Objective: Background: Currently, there is lots of literature on the mental health profiles of honorably discharged veterans, why they were discharged, and much more information on the individuals included in the study. Is there research done on the mental health profiles of the dishonorably discharged and if so, do these studies include women? **Objectives:** Review articles on this topic to find background information **Design: Methods:** Searching article databases like PubMed and the Rutgers Library using search terms such as "mental health", "mental health profiles", "dishonorably discharged", and "women". **Results: Results:** There were no studies found on the mental health of dishonorably discharged women from the armed forces. While we did find a couple studies about the correlation between dishonorable discharge and a few different topics like drug addiction, none of these studies included gender at all in their studies. It was also unclear in these studies why the participants were dishonorably discharged in the first place. Being dishonorably discharged has a wide range of reasons for it, most commonly drug abuse or misdemeanors in the armed forces, but it could have a correlation as to why certain women become dishonorably discharged in the first place. **Conclusion: Conclusion:** More research is needed in this field, as we did not find any data that was specifically about the mental health profiles of dishonorably discharged woman, and further studies would allow researchers to understand the mental toll that being dishonorably discharged has on women.
Sources of Funding: None

P-70.

Animated Educational Videos on Cancer Screening: Resource to Educate Post-Menopausal Incarcerated Women

Evan Perkiss, Bachelors of Science in Public Health, Eliana Schach, Medical Student, Khadija Alshowaikh, MD, Juana Hutchinson-Colas, MD, James E. McGreevey, JD, MEd, MDiv, Gloria Bachmann. Women's Health Institute, Rutgers Robert Wood Johnson Medical School New Brunswick, New Brunswick, NJ

Objective: Menopause is an age-related physiological transition that usually occurs in women between the ages of 40 and 58. Addressing health issues relevant to post-menopausal incarcerated women is increasingly important as women ages 55 and older are one of the fastest-growing groups in prison and also are at high risk of developing cancer. Although data suggest that the general population and incarcerated individuals have similar prevalence rates for cancer; the incarcerated population has a higher mortality rate. The epidemiology of cancer is different in the prison population, as there is a greater prevalence of known risk factors such as smoking, HIV, alcohol, and limited screening. There also is a disparity for screening in the prison population: 77.1% of prisoners are 1.5 times more likely to be overdue for screening compared to 50.5% of the general population. Delays in screening also could explain why most prisoners receive diagnoses of some types of cancer, such as colon cancer, in later stages. Additionally, prisoners have a higher lung cancer incidence rate than the general population; probably due to a higher rate of smoking than the general population. From these data, teaching animated videos on the importance of preventive health/cancer screenings were developed by the NJ Commission on Women's Reentry (NJCWR) and the Women's Health Institute (WHI). The objective of this project is to educate incarcerated menopausal women on the importance of cancer screening to contribute to reducing mortality in this group. **Design:** The 2021 Powtoon website was used to create educational animations that were set in a correctional facility, with characters from various ethnic backgrounds to broaden representation. Voiceovers were used for individuals who prefer to listen, and speech balloons were used for those who prefer to read. **Results:** Animations on cancer screening relevant to post-menopausal incarcerated women to date include one on colorectal and one on lung cancer screening. The group is continuing to produce additional animated videos on other preventive health topics. To date, no formal data on acceptance by the women has been collected. **Conclusion:** The use of animated educational materials can be used to engage post-menopausal incarcerated women. They also are cost-effective and can represent diverse groups within the target population. Poor health literacy is shown to act as a barrier to healthcare for incarcerated individuals, limiting their ability to make informed health care decisions. Educating post-menopausal prisoners on cancer screening may improve self-advocacy and compliance with recommended testing, which could decrease health disparities. As there are growing challenges involving cancer care in prisons, it is essential to implement programs and conduct research on how these materials improve health education.

Sources of Funding: None

P-71.

Mammogram to Medical Home: Increasing Access to Care Nurse Practitioner Program

Angela Schlafley, FNP. Mammogram to Medical Home, The Rose, Houston, TX

Objective: Since 1986, The Rose has provided high quality breast care to all women, regardless of their ability to pay. Our mission is to save lives through quality health services, advocacy, and access to care for all. Texas has the highest number of uninsured individuals, and more than half of the state's uninsured residents are below 200% of the Federal Poverty Level. Without insurance, without a medical home, these women do not have the advantages of routine screening; and health issues that could be easily resolved escalate into costly chronic diseases. Approximately 1,500 uninsured women per year call The Rose seeing a mammogram but do not have a referring physician. Mammograms cannot be performed without an order. To eliminate that barrier, The Rose created a program, Mammogram to Medical Home, in which a nurse practitioner (NP) provides medical case management to uninsured women without a medical home to increase access to care. The process starts with outreach to medically underserved communities, continues through breast cancer services and ends with the patient enrolled in a medical home. Objective: To increased access to care for underserved women past child bearing age by having a NP on staff to issue an order for mammogram, offer education and health promotion, and ultimately refer a patient to a medical home convenient to the patient for primary health care creating a healthier community. **Design:** Interested patients first call The Rose and apply for sponsorship. Once qualified, the woman is scheduled for a focused assessment/breast exam with a nurse practitioner. At the initial appointment the patient answers a brief medical history and health assessment. The nurse practitioner then reviews the information, performs a focused exam, clinical breast exam and educated on the importance of having a medical home. The patient is then given the appropriate order for mammogram. After the mammogram is completed, the report is sent to the NP. If the report is benign, the patient is then navigated into a medical home to increase access to primary care. The patient is followed for 1 year with phone calls with the goal of the patient to have at least 1 visit to the recommended medical home within a year from her breast exam visit at The Rose. **Results:** The program launched in September of 2021 and the preliminary data is promising. To date, we have received 203 referrals, 87 patients have been enrolled into the program. 45 have been navigated into a medical home. Of the number seen, five cancers were diagnosed along with 2 bingn excisionals. Uninsured women who are diagnosed receive treatment through The Rose Patient Navigation Program. **Conclusion:** By offering this service, women will start with breast health care and be led into a relationship with a medical home to increase access to primary care resulting in a healthier community.

Sources of Funding: private donation

P-72.

Breast Cancer: The Effect of Endogenous and Exogenous Hormones

Tara Scott, MD. OB/GYN, Summa Health System - Akron Campus, Akron, OH

Objective: According to the American Cancer Society, the lifetime risk of developing breast cancer is 1 in 8. The median age at diagnosis is 62, so this is more often a problem in postmenopausal women. The link between both endogenous hormones and exogenous hormones has not been defined. The number one cause of death in women is heart disease, yet they fear breast cancer and often do not want to consider hormone therapy due to this fear. In a recent publication, "Workshop on normal reference ranges for estradiol in postmenopausal women, September 2019, Chicago, Illinois" in *Menopause: The Journal of The North American Menopause Society (*Vol. 27, No. 6, pp. 614-624), estradiol levels in postmenopausal women were evaluated. Part of the conclusion was "The existing data provided substantial evidence to support using estradiol to predict risk." In this didactic and informative talk, the biochemistry and physiology of female hormones in the breast will be discussed. Published literature regarding the risks of hormone therapy for breast cancer will be reviewed. Studies identifying any link between endogenous hormone patterns and breast cancer will also be reviewed. **Design:** 1. Review Hormone physiology as it pertains to cancer 2. Discuss estrogen detoxification pathways as they relate to breast cancer risk 3. Review the published literature on HRT and Breast cancer risk, and address options for hormone therapy in the high-risk patient. 4. Review the published literature on endogenous hormones and breast cancer risk, including estrogen metabolites 6. Provide strategies to shift the focus on breast cancer from early detection to prevention **Results:** The results will be presenting the literature review. **Conclusion:** 1. Endogenous hormone levels contribute to breast cancer risk and should be monitored in high-risk patients. 2. Breast cancer risks due to hormone replacement therapy varies based on the dose, duration, and preparation of the hormone given. The risks can not be extrapolated to all types of hormones. 3. Differences in estrogen metabolism can affect breast cancer risk, and levels of estrogen metabolites could help further identify high-risk patients. 4. A more comprehensive prevention for the patient at high risk for breast cancer is possible.

Sources of Funding: None

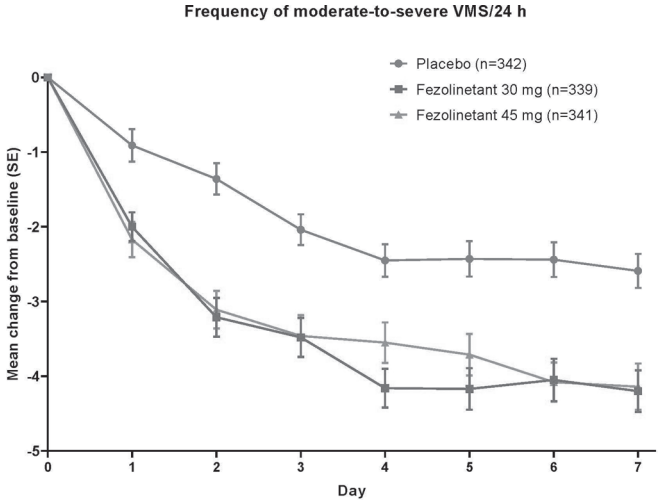
P-73.

Early response with fezolinetant treatment of moderate-to-severe vasomotor symptoms associated with menopause: pooled data from two randomized Phase 3 studies

Marla Shapiro C.M.[1], Genevieve Neal-Perry[2], Petra Stute[3], Rebecca C. Thurston, PhD[4], Wendy Wolfman[1], Marci English[5], Jun Zhao[5], Faith D. Ottery[5]. [1]University of Toronto, Toronto, ON, Canada; [2]UNC School of Medicine, Chapel Hill, NC; [3]Inselspital, Bern, Switzerland; [4]University of Pittsburgh School of Medicine, Pittsburgh, PA; [5]Astellas Pharma Global Development Inc, Northbrook, IL

Objective: Women suffering from bothersome vasomotor symptoms (VMS) need effective, rapid relief. These analyses assessed early response with fezolinetant using pooled data from SKYLIGHT 1 and 2 (NCT04003155; NCT04003142). In both studies the four co-primary efficacy endpoints were met and fezolinetant was well tolerated. **Design:** SKYLIGHT 1 and 2 were double-blind, placebo-controlled Phase 3 studies with the same design. Women ≥40–65 y with moderate-to-severe VMS (average ≥7 hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. **Results:** 1022 women were randomized and took ≥1 dose (placebo n=342, fezolinetant 30 mg n=339, fezolinetant 45 mg n=341). A trend in improvement in mean change from baseline in daily moderate and severe VMS frequency vs placebo was seen from day 1 (Figure). Significant reduction in frequency of moderate and severe VMS was evident from week 1 after start of treatment and was greater in both fezolinetant groups vs placebo. Least squares mean reduction over placebo (SE) at week 1 was –1.59 (0.28), $p<0.001$ for fezolinetant 30 mg and –1.46 (0.28), $p<0.001$ for 45 mg. At week 4, these values were –1.89 (0.32), $p<0.001$ for fezolinetant 30 mg and –2.28 (0.32), $p<0.001$ for 45 mg. Significant improvement in severity of VMS was also seen as early as week 1 after start of treatment for both fezolinetant doses and was greater with fezolinetant than placebo. Improvements in VMS frequency and severity were sustained throughout the 12-week double-blind period. **Conclusion:** Pooled data from SKYLIGHT 1 and 2 show an effect of fezolinetant on VMS frequency from day 1, reaching statistical significance at weeks 1 and 4. An effect on VMS severity was seen as early as week 1. Both effects were maintained through the 12-week double-blind period.

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Sue Cooper of Excel Scientific Solutions and funded by Astellas Pharma Inc.



P-74.

Effect of fezolinetant treatment on patient-reported sleep disturbance: pooled data from two Phase 3 studies in women with moderate-to-severe vasomotor symptoms associated with menopause

Marla Shapiro C.M.[1], Antonio Cano[2], Rossella E. Nappi[3], Nanette F. Santoro, MD[4], Marci English[5], Shayna Mancuso, DO, FACOG[5], Antonia Morga[6], Emad Siddiqui[6], Udaya Valluri[5], Faith D. Ottery[5]. [1]University of Toronto, Toronto, ON, Canada; [2]University of Valencia, Valencia, Spain; [3]University of Pavia, Fondazione Policlinico IRCCS S. Matteo, Pavia, Italy; [4]University of Colorado School of Medicine, Aurora, CO; [5]Astellas Pharma Global Development, Northbrook, IL; [6]Astellas Pharma Europe Ltd, Addlestone, United Kingdom

Objective: These analyses assess the effect of fezolinetant on patient-reported sleep disturbance using pooled data from SKYLIGHT 1 and 2 (Phase 3; NCT04003155; NCT04003142). In these studies, fezolinetant significantly improved the frequency and severity of vasomotor symptoms (VMS) vs placebo and was well tolerated. VMS associated with menopause can significantly impact sleep. **Design:** SKYLIGHT 1 and 2 were double-blind, placebo-controlled studies with the same design. Women aged ≥40–65 y with moderate-to-severe VMS (average ≥7 hot flashes/day) were randomized to once-daily placebo, or fezolinetant 30 mg or 45 mg for 12 weeks. Sleep was assessed using the Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form (PROMIS SD SF) 8b Total Score, Patient Global Impression of Change – Sleep Disturbance (PGI-C SD), and PGI of Severity – Sleep Disturbance (PGI-S SD). **Results:** The pooled group comprised 1022 women who took ≥1 study dose. Fezolinetant 45 mg demonstrated a statistically significant improvement over placebo in sleep disturbance at weeks 4 and 12 using the PROMIS SD SF 8b, PGI-C SD, and PGI-S SD (Table). Fezolinetant 30 mg demonstrated a statistically significant improvement over placebo in sleep disturbance at week 4 using the PROMIS SD SF 8b, at weeks 4 and 12 using the PGI-C SD, and at week 4 using the PGI-S SD (Table). **Conclusion:** Pooled data from SKYLIGHT 1 and 2 further demonstrate the beneficial effect of fezolinetant on three measures of patient-reported sleep disturbance as early as week 4 of treatment.

Sources of Funding: Astellas Pharma Inc. Medical writing support was provided by Becky Ayles of Excel Scientific Solutions and funded by Astellas Pharma Inc.

Analysis visit	Statistics/response, n (%)	Placebo (N=342)	Fezolinetant 30 mg (N=339)	Fezolinetant 45 mg (N=341)
Change from Baseline in PROMIS SD SF 8b Total Score				
Baseline	Mean (SD)	26.9 (6.8)	26.9 (6.6)	26.7 (6.8)
Week 4	Mean (SD) LS mean diff vs placebo (SE) [p-value]	24.4 (7.2) – –	23.3 (7.0) –1.1 (0.5) [0.025]	22.0 (6.8) –2.3 (0.5) [>0.001]
Week 12	Mean (SD) LS mean diff vs placebo (SE) [p-value]	23.4 (7.2) – –	22.9 (7.3) –0.6 (0.5) [0.260]	21.8 (6.6) –1.5 (0.5) [0.004]
PGI-C SD				
Week 4	N Much better Moderately better A little better No change A little worse Moderately worse Much worse p-value	310 37 (11.9) 34 (11.0) 84 (27.1) 124 (40.0) 15 (4.8) 11 (3.5) 5 (1.6) –	305 54 (17.7) 45 (14.8) 89 (29.2) 100 (32.8) 10 (3.3) 4 (1.3) 3 (1.0) <0.001	318 69 (21.7) 73 (23.0) 93 (29.2) 68 (21.4) 14 (4.4) 1 (0.3) 0 <0.001
Week 12	N Much better Moderately better A little better No change A little worse Moderately worse Much worse p-value	292 45 (15.4) 53 (18.2) 76 (26.0) 85 (29.1) 19 (6.5) 10 (3.4) 4 (1.4) –	274 61 (22.3) 49 (17.9) 74 (27.0) 65 (23.7) 10 (3.6) 14 (5.1) 1 (0.4) 0.035	302 84 (27.8) 70 (23.2) 82 (27.2) 50 (16.6) 8 (2.6) 5 (1.7) 3 (1.0) <0.001
PGI-Severity SD				
Baseline	N No problems Mild problems Moderate problems Severe problems	341 22 (6.5) 75 (22.0) 164 (48.1) 80 (23.5)	337 26 (7.7) 86 (25.5) 145 (43.0) 80 (23.7)	341 22 (6.5) 72 (21.1) 175 (51.3) 72 (21.1)
Week 4	N No problems Mild problems Moderate problems Severe problems p-value	311 39 (12.5) 119 (38.3) 111 (35.7) 42 (13.5) –	305 47 (15.4) 128 (42.0) 104 (34.1) 26 (8.5) 0.028	319 51 (16.0) 148 (46.4) 105 (32.9) 15 (4.7) <0.001
Week 12	N No problems Mild problems Moderate problems Severe problems p-value	293 52 (17.7) 112 (38.2) 90 (30.7) 39 (13.3) –	275 56 (20.4) 106 (38.5) 94 (34.2) 19 (6.9) 0.115	303 62 (20.5) 130 (42.9) 99 (32.7) 12 (4.0) 0.004

LS=least squares; PGI-C SD=Patient Global Impression of Change – Sleep Disturbance; PGI-S SD=Patient Global Impression of Severity – Sleep Disturbance; PROMIS SD SF=Patient-Reported Outcomes Measurement Information System Sleep Disturbance – Short Form

P-75.

Rapid Ethnography of the Lived Experience of Menopause

Sofiya I. Shreyer, MA[1,2], Tyler Breen[2], Rebecca Lord[2], Sonja K. Billes, PhD[2], Matthew Smith, PhD[2], Pamela Peeke, MD[2]. [1]Anthropology, University of Massachusetts Amherst, Amherst, MA; [2]Embr Labs, Boston, MA

Objective: Menopause causes major life disruptions for many women. The SWAN and POAS longitudinal studies characterized the menopause transition and illustrated the diversity of the menopausal experience. However, there is a need for more ethnographic research on menopause that centers women's own perspectives and narratives. To better understand the subjective experience of menopause, we examined menopausal women's own descriptions of (1) the trajectory of the menopausal transition and (2) vasomotor symptoms (VMS, ie hot flashes and night sweats). **Design:** We conducted a rapid ethnographic assessment that included semi-structured interviews about the menopause transition and electronic surveys of the VMS experience from February 25 to March 4, 2022. To explore the menopause trajectory, postmenopausal women between 50 and 60 years of age with a last menstrual cycle in the prior 2 to 4 years were recruited via User Interviews (Brooklyn, NY). We conducted 1-hour semi-structured interviews that prompted women to discuss the timeline of menopausal symptoms and experiences, impact of menopause on daily life and activities, and attitudes, feelings, and observations about menopause. To explore the VMS experience, peri/postmenopausal women between 45 and 60 years of age who were experiencing daily hot flashes were recruited via Survey Monkey (San Mateo, CA). Survey topics included VMS frequency, emotional experience, differences in daytime and nighttime VMS, impact of VMS on activities, and a narrative of a VMS episode. Menopause experience interviews were transcribed using Otter.ai (Los Altos, CA) software. Interviews and surveys were coded for recurring themes and summarized. **Results:** Menopause experience interviews (n=8) elucidated a common menopause trajectory. Participant experience coincided with the STRAW+10 classification of early perimenopause, late perimenopause, early postmenopause, and late postmenopause. Each menopausal stage was emotionally distinct, and common pain points and experiences were described across participants. All women expressed frustration with the lack of information on menopause and cycle irregularity during early perimenopause. Late perimenopause was associated with mood changes (eg, depression, irritability, anxiety), feelings of vulnerability and stress, difficulty identifying menopausal symptoms, and adjusting to body changes. Early postmenopause was associated with the most negative experiences. Women reported the largest life disruptions due to VMS (6/8) and lack of sleep (7/8), as well as relationship challenges (4/8) due to decreases in libido and self-esteem. Late postmenopause was characterized by reports of positive experiences in most participants (5/8), including improved stability, management and/or reduction of symptoms, and self-acceptance. There were 80 responses to the VMS survey. Common physical descriptions of VMS included heat radiating from inside the body or

moving from their feet to their heads. Sweating was the most negative characteristic of VMS (36% of respondents). VMS were accompanied by negative emotional responses in 88% of respondents, most frequently dread, sadness, and helplessness. Over half (54%) reported markedly different VMS experience during the night vs day; nighttime VMS were associated with greater heat, sweat, and anxiety. **Conclusion:** In this ethnographic assessment of the menopause experience, menopausal stages were associated with distinct physiological and emotional experiences. VMS (hot flashes and night sweats) were associated with negative emotional experiences in the majority of respondents. Notably, most respondents also reported greater intensity of nighttime VMS compared with daytime VMS. Our findings may be of relevance to (1) clinicians who seek to empathize with the experiences of their patients going through menopause and (2) women preparing for the menopausal experience and seeking literature on the lived experience of menopause among other women. Results support continued qualitative research of the menopause experience in a larger, more diverse population.
Sources of Funding: Embr Labs

P-76.

Varying Impacts of Hot Flashes and Night Sweats on Depression and Stress

Sofiya I. Shreyer, MA[1], Lynnette L. Sievert[1], Daniel E. Brown[2]. [1]Anthropology, University of Massachusetts Amherst, Amherst, MA; [2]Anthropology, University of Hawai'i at Hilo, Hilo, HI

Objective: Hot flashes (HF) and night sweats (NS) are common during the menopausal transition. In literature, night sweats and hot flashes are often regarded as similar phenomena at different points in the 24-hour cycle and combined into one variable as vasomotor symptoms. HF can occur during the day or night and may or may not be associated with sweating, while night sweats are periods of intense sweating that occur during the nighttime. Our goal was to explore whether women who report NS differ in levels of stress or depression from women who report HF. **Design:** Our sample was drawn from an on-going study of brown adipose tissue and HF. Women aged 45-55 living in Western Massachusetts (n=200) were interviewed about changes in their menstrual cycle, demographic characteristics, reproductive history, and bothersomeness of HF and NS over the past two weeks (not at all, a little, somewhat, a lot). The Patient Health Questionnaire (PHQ-9) as a measure of depression and the Perceived Stress Scale (PSS-10) were self-administered by participants. Linear regression analyses were completed in SPSS separately for levels of depression and stress, adjusting for menopause status (pre, peri, post), financial comfort, and marriage. The time of day when HF were more frequent (morning, afternoon, evening, night) was also examined in relation to stress and depression scores, controlling for menopausal status (pre-, peri-, and post-menopausal), financial comfort, and marriage. **Results:** In the total sample, 70% of participants experienced HF, and 63% experienced NS during the past two weeks. Women reported the highest frequency of HF at night (54%). In linear regression models, NS were significantly associated with depression ($p<0.001$, $\beta=0.36$) and stress ($p=0.01$, $\beta=0.19$), and HF were significantly associated with only depression ($p=0.007$, $\beta=0.22$) after adjusting for menopause status, financial comfort, and marriage. Women who reported the highest frequency of HF at night had significantly higher depression scores ($p=0.004$, $\beta=0.24$) but not stress scores after adjusting for menopause status, financial comfort, and marriage. **Conclusion:** Self-reported NS and HF were both associated with depression scores, but only NS were associated with stress scores. Additionally, women who reported the highest HF frequency at night had significantly higher depression scores compared to women who had the highest HF frequency during other times of day. Our findings are congruent with previous studies that found sleep disruptions during menopause have a significant impact on quality of life and suggest that NS experience may have more severe consequences than HF. These findings warrant further exploration into the varying impacts of HF and NS on women's menopause experience.
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P-77.

Self-reported and biometrically measured hot flashes in relation to ambient temperature and humidity

Lynnette L. Sievert, PhD[1], Sofiya I. Shreyer, MA[1], Daniel E. Brown[2]. [1]Anthropology, University of Massachusetts Amherst, Amherst, MA; [2]Anthropology, University of Hawaii at Hilo, Hilo, HI

Objective: Warm ambient temperatures provoke hot flashes in the laboratory, but outside the laboratory the temperature to hot flash relationship is less consistent. A study in Bangladesh and London found that temperature and humidity at 12:00 and 18:00 were not associated with self-reported or biometrically measured hot flashes. However, in Spain and three South American countries, higher temperatures and humidities were associated with more frequent and problematic hot flashes. The study reported here differs from previous work in that we asked women to carry an ambulatory temperature and humidity monitor while wearing an ambulatory hot flash monitor. The purpose of this study was to examine the relationship between concurrent temperature, humidity, and hot flash experience. We hypothesized more frequent hot flashes with higher ambient temperatures. **Design:** Women aged 45 to 55 years were drawn from western Massachusetts for an ongoing cross-sectional study (n=195) from October through April (2019-2023). Exclusion criteria included use of medications that dampen hot flashes. Hot flashes were queried with a semi-structured questionnaire: During the past two weeks, have you been bothered by hot flashes (not at all, a little, somewhat, a lot)? Currently, how often do they occur (from less than 1/month to 5+ times/day, scored 0-8)? Hot flashes were also assessed by sternal skin conductance using a Biolog ambulatory hot flash monitor (3991x/1-SCL, UFI, Morro Bay, CA). Subjective hot flashes during the 24-hour study period were recorded with buttons on the hot flash monitor. Ambient temperature and humidity were continuously recorded with the GSP-6 Temperature and Humidity Data Logger Recorder (Elitech Technology, San Jose, CA). Menopausal status was categorized as pre-, peri- (change in cycle length >6 days) and post- (absence of menses for 12 months). Univariate relationships between temperature (maximum, minimum, mean), humidity (maximum, minimum, mean), and hot flashes (yes/no) were examined by t-tests. Temperature, humidity, and hot flash bothersomeness were examined by ANOVA. Pearson correlations were used to evaluate temperature, humidity, and hot flash frequencies (from the questionnaire and Biolog monitor). Logistic regression was also applied to examine temperature and humidity measures in relation to hot flashes while adjusting for menopausal status. **Results:** Mean ambient temperatures ranged from 16.3 to 30.1°C (mean 24.5°C, s.d. 2.8); mean humidities ranged from 18.9 to 68.6% (mean 40.8%, s.d. 9.2). Minimum temperature was positively associated with minimum ($r=0.508$, $p<0.001$) and mean ($r=0.316$, $p<0.001$) measures of humidity. Hot flash bothersomeness was described as not at all (31%), a little (23%), somewhat (23%), and a lot (24%). In univariate analyses, maximum, minimum, and mean temperatures and humidity levels were not associated with hot flashes (yes/no) or with the bothersomeness of hot flashes. Temperature measures were not correlated with current frequency of hot flashes or with the frequency of objective or subjective hot flashes during the study period. However, the current frequency of hot flashes was negatively correlated with minimum ($r=-0.205$, $p<0.01$) and mean ($r=-0.196$, $p<0.01$) levels of humidity, so that as humidity levels increased, the likelihood of hot flashes decreased. Although participants were keen to wear the monitor for 24-hours, the Biolog monitor quit during 38% of the studies. In the majority of cases, participants restarted the monitor. Compared to monitors that continued to function, monitors that quit were more likely to be worn when minimum temperatures were lower (mean 6.8°C vs. 8.9 °C, $p=0.03$), minimum humidity levels were lower (mean 17.2% vs. 22.6%, $p<0.001$), and mean humidity levels were lower (mean 37.2% vs. 43.0%, $p<0.001$). **Conclusion:** The hypothesized positive relationship between temperature and hot flashes was not supported. Instead, as humidity levels increased, the likelihood of hot flashes decreased. This preliminary study will be followed by syncing of the temperature, humidity, and hot flash data in order to study how changes in temperature and/or humidity may provoke hot flashes.
Sources of Funding: NSF Grant #BCS-1848330

P-78.

Endometrial Safety, Efficacy and Tolerability of Ospemifene Compared to Current Therapies for the Treatment of Vulvovaginal Atrophy: A Systematic Literature Review and Network Meta-Analysis

James A. Simon[1], Alex Ferenczy[2], Black Denise[3], Catherine Royer[4], Alex Castonguay[4], Rafik Marouf[5], Catherine Beauchemin, Ph.D.[6,4]. [1]The George Washington University School of Medicine, and IntimMedicine Specialists, Washington DC, DC; [2]McGill University Department of Pathology, Montreal, QC, Canada; [3]University of Manitoba, Winnipeg, MB, Canada; [4]Peripharm Inc., Montreal, QC, Canada; [5]Duchesnay Inc, Blainville, QC, Canada; [6]Universite de Montreal, Montreal, QC, Canada

Objective: Vulvovaginal atrophy (VVA) is a chronic condition that is caused by reduced estrogen levels during menopause. Ospemifene is a novel selective estrogen receptor modulator developed for the treatment of moderate to severe VVA symptoms in postmenopausal women. The objective is to perform a systematic literature review (SLR) and network meta-analysis (NMA) to assess the efficacy and safety of ospemifene compared to current therapies for the treatment of VVA. **Design:** The SLR was conducted in MEDLINE, Embase and PubMed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) requirements. The review question was established using the PICO framework (Population, Intervention, Comparators, Outcomes). Study population consisted of postmenopausal women with moderate to severe dyspareunia and/or vaginal dryness. Studies involving a comparison with ospemifene (intervention) and at least one of the comparators were considered: local estrogen therapies (ET) such as conjugated estrogens (CE) cream, estradiol (E2) ring and inserts, prasterone ovules and lubricants. Efficacy outcomes were change from baseline in the percentages of superficial and parabasal cells, vaginal pH or most bothersome symptom (MBS) of vaginal dryness or dyspareunia. Safety endpoints included the occurrence of treatment emergent adverse events (TEAE), serious TEAE, urinary tract infection, headaches, hot flashes and discontinuation due to adverse events. Endometrial outcomes were endometrial thickness and histologic classifications (proliferative, atrophic, inactive endometrium, endometrial polyp, hyperplasia and carcinoma). For efficacy and safety outcomes, a Bayesian NMA was performed. Treatments of interest at their commercialized dosages in Canada, United States and Europe were considered for the efficacy analyses, while all dosages were used for safety analyses. Endometrial outcomes were compared in descriptive analyses. **Results:** The SLR identified a total of 636 articles, of which 44 (N= 12,637) met the eligibility criteria. Efficacy data were analyzed at 12 to 14 weeks, while the last timepoint was used for safety analyses (up to 52 weeks). NMA results showed that ospemifene was statistically not different compared to other active therapies in most efficacy and safety results. For endometrial outcomes, there were between 25% and 32% of unsatisfactory biopsies in ospemifene studies, and between 8% to 47% for other treatments. As expected, the percentages of patients with atrophic endometrium, ranging from 51% to 99% at baseline, decreased by 8% to 100% post-treatment. In general, endometrial proliferation increased post-treatment, ranging from 0% to 13% at baseline and from 0% to 92% post-treatment. In patients treated with ospemifene, proliferation varied from 0% to 2% at baseline, and increased by 3% to 18% post-treatment. For all treatments, the endometrial thickness post-treatment was under the recognized clinical cut-off value of 5 millimeters (mm) for postmenopausal women. Specifically for patients treated with ospemifene, the endometrial thickness in mm varied from 2.1 to 2.3 at baseline and from 2.5 to 3.2 post-treatment (i.e., a maximal mean change of 1.1 mm). Endometrial carcinoma or hyperplasia post-treatment were reported in 3 studies in patients on local ETs, while no cases were observed in ospemifene

trials. Endometrial polyps were reported in 2 local ETs studies (including one participant with atrophic polyp in placebo group) and only one endometrial polyp was reported in all patients treated with ospemifene. No polyps with atypical hyperplasia were reported. **Conclusion:** This study confirms the efficacy, safety and tolerability of ospemifene therapy for postmenopausal women with moderate to severe symptoms of VVA. The findings are largely similar to current therapies on the market.
Sources of Funding: This study was funded by Duchesnay Inc.

P-79.

Crila® Herbal Supplement is Associated with a Clinically Meaningful Effect on Symptoms Evaluated Using the Menopause-Specific Quality of Life Survey

Bernard Somers, PhD[1], Betsy Singh[2], Pablo Gonzalez[3], Laura Camacho[4], Alejandro Avendano[3], Nadina Jose[5]. [1]Medicinal Chemistry, Rutgers The State University of New Jersey, New Brunswick, NJ; [2]BRCG Medical Research Group, Midlothian, VA; [3]PanAmerican Clinical Research, Queretero, Mexico; [4]PanAmerican Clinical Research, Guadalajara, Mexico; [5]Rutgers University Newark, Newark, NJ

Objective: To assess the severity of menopausal symptoms with Crila® capsules taken twice daily, stratified by weight. As a novel, non-estrogenic, plant-based alternative, Crila is a proprietary extract from the patented cultivar Crinum Latifolium L var. crilae Tram & Khanh. **Design:** In 2019, A Prospective Open-Label Dietary Supplement clinical study was approved by two Ethics Committees in Mexico to study oral Crila® herbal supplements (Crinum latifolium L var. crilae Tram & Khanh) in menopausal women. In 2020-2021, women in Guadalajara and Queretaro took the estrogen-free botanical supplement twice daily over a 90-day period and evaluated their symptoms every 30 days according to MENQOL - a Menopause-Specific Quality of Life validated survey. Sixty-one women with menopausal symptoms received 4 to 10 capsules of Crila® for 3 months. This study was conducted utilizing a decentralized design at two centers in Mexico. Primary inclusion criteria: female subjects at least 45 years of age, BMI 26–30, and experiencing at least 35 vasomotor symptoms per week (average of 5/day) for the previous 3 months. Subject's total study duration was 90 days from screening (Day 1) through conclusion of the Final Visit (Visit 4) (Day 90). **Results:** Sixty-one women finished the study. Impact of oral Crila® capsules on the severity of menopausal symptoms was assessed using the MENQOL. When compared to Visit 1, all 3 following visits have a significantly lower total score (P, 0.001 <0.05) (Figure 1, Table 2). Total score of Visit 2, is significantly different than total scores of the other 3 visits (P<0.05) (Figure 1, Table 2). Visit 2 has a significantly higher total score than Visit 3 (P, 0.02<0.05) and Visit 4 (P, 0.001<0.05) (Figure 1, Table 2). There is no significant difference between total score of Visit 3 and Visit 4 (P, 0.22>0.05) (Figure 1, Table 2). When comparing Visit 1 to all 3 subsequent visits, a significant decrease was observed in vasomotor, psychological, physiological, and sex-based components of MENQOL (Figure 1, Table 1). Safety and tolerability of oral Crila® capsules was assessed by the frequency and severity of AEs, relationship of AEs to IP, vital signs, physical abnormalities. Crila® was well tolerated and none of the participants experienced any adverse reactions. **Conclusion:** Sixty-one women completed the study at the height of the COVID-19 pandemic. Data analysis confirmed 93% experienced symptom improvement. A decentralized design was key to study completion. The observed positive outcome supports the potential for larger sample size and longer duration studies.
Sources of Funding: Crila Health Pte. Ltd. (Singapore)

Figure 1

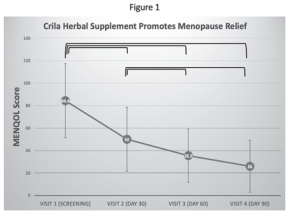

Table 1

Menopause: MEN-QOL		Mean	N	Std. Deviation	Std. Error Mean	Mean Difference	Significance One-Sided p	Significance Two-Sided p
Part 1	Vasomotor (Baseline)	11.66	61	3.099	0.401	<.001	<.001	
	Vasomotor (Visit)	6.02	61	3.914	0.45			
Part 2	Vasomotor (Baseline)	11.66	61	3.099	0.401	<.001	<.001	
	Vasomotor (Second)	3.92	61	3.494	0.447			
Part 3	Vasomotor (Baseline)	11.66	61	3.099	0.401	<.001	<.001	
	Vasomotor (Visit)	3.33	61	3.097	0.397			
Part 4	Psych (Baseline)	20.87	61	8.949	1.146	<.001	<.001	
	Psych (First)	13.02	61	5.659	1.105			
Part 5	Psych (Baseline)	20.87	61	8.949	1.146	<.001	<.001	
	Psych (Second)	10.11	61	7.986	1.023			
Part 6	Psych (Baseline)	20.87	61	8.949	1.146	<.001	<.001	
	Psych (Final)	8.72	61	6.106	0.782			
Part 7	Physic (Baseline)	43.08	61	19.057	2.44	<.001	<.001	
	Physic (First)	24.93	61	16.602	2.126			
Part 8	Physic (Baseline)	43.08	61	19.057	2.44	<.001	<.001	
	Physic (Second)	17.92	61	14.366	1.84			
Part 9	Physic (Baseline)	43.08	61	19.057	2.44	<.001	<.001	
	Physic (Final)	13.15	61	13.794	1.766			
Part 10	Sex (Baseline)	8.75	61	5.224	0.669	<.001	<.001	
	Sex (First)	3.97	61	5.103	0.653			
Part 11	Sex (Baseline)	8.75	61	5.224	0.669	<.001	<.001	
	Sex (Second)	3.51	61	4.407	0.564			
Part 12	Sex (Baseline)	8.75	61	5.224	0.669	<.001	<.001	
	Sex (Final)	2.69	61	4.9	0.578			
Part 13	Total (Baseline)	84.41	61	32.897	4.211	<.001	<.001	
	Total (First)	49.95	61	29.446	3.842			
Part 14	Total (Baseline)	84.41	61	32.897	4.211	<.001	<.001	
	Total (Second)	36.46	61	29.722	3.037			
Part 15	Total (Baseline)	84.41	61	32.897	4.211	<.001	<.001	
	Total (Final)	29.95	61	29.078	2.959			

Table 2

(I) Visit	(J) Visit	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
1	2	34.459*	4.947	0.000	21.66	47.26
	3	48.951*	4.947	0.000	36.15	61.75
	4	58.459*	4.947	0.000	45.66	71.26
2	1	-34.459*	4.947	0.000	-47.26	-21.66
	3	14.492*	4.947	0.019	1.69	27.29
	4	24.000*	4.947	0.000	11.2	36.8
3	1	-48.951*	4.947	0.000	-61.75	-36.15
	2	-14.492*	4.947	0.019	-27.29	-1.69
	4	9.508	4.947	0.222	-3.29	22.31
4	1	-58.459*	4.947	0.000	-71.26	-45.66
	2	-24.000*	4.947	0.000	-36.8	-11.2
	3	-9.508	4.947	0.222	-22.31	3.29

*. Mean difference is significant at the 0.05 level.

P-80.

The Use of Cannabis for Relief of Menopause Symptoms

Lauren Streicher, MD. Obstetrics and Gynecology, Northwestern University Feinberg School of Medicine, Chicago, IL

Objective: It is estimated that at least 1 of 4 post-menopause women use cannabis. Despite the frequency of consumption, there is a paucity of information regarding the use of cannabis for the relief of vasomotor symptoms, insomnia, low libido, and orgasmic function in the menopause population. Studying the efficacy of cannabis for the relief of specific symptoms is challenging since the pharmacology is complex and dictated by variables such as route of consumption, genetics, sex, age, medical co-morbidities, medications, and concomitant use of estrogen. In addition, one cannot count on the same level of consistency with individual products as with a commercial pharmaceutical. The objective of this study was to determine current practices of cannabis use for the relief of specific symptoms. **Design:** 310 women self-described as peri- or post-menopause, who currently or had recently used cannabis for relief of menopause symptoms, were recruited via social media and invited to complete an online survey. For each symptom, respondents were asked about the strain(s) of cannabis, the route(s) of consumption, and the perception of efficacy. Women were also asked about the role and awareness of their health care clinician in their use of cannabis. This is the pilot of an ongoing study to include a minimum of 1000 post-menopause women from across the nation. **Results: Vasomotor symptoms:** *Type(s) of Cannabis consumed:* Sativa-16.19% Indica- 24.76% Hybrid- 22.86% Unknown-8.57% THC- 18.10% CBD-9.52%. *Route(s) of consumption:* Edible-38.4% Sublingual 11.54% Smoke or Vape 49.04% Topical 0.96%. *Perceived Efficacy: Yes-67.31% A little 28.85% Not at all 3.85%* **Sleep:** *Type(s) of Cannabis consumed:* Sativa- 5.75% Indica-38.51% Hybrid-16.67% Unknown -8.62% THC- 16.09%CBD-14.37%79.31%, *Route of consumption:* Edible- 45.93% Sublingual-12.21% Smoke or Vape- 40.70% Topical- 1.16%, *Perceived Efficacy: Yes 79.31- A little-18.97% Not at all- 1.72%* **Libido:** *Type(s) of Cannabis consumed: Sativa*-18.29% Indica-6.10% Hybrid-32.93% Unknown -7.32% THC-26.83% CBD-8.54%, *Route of consumption:* Edible- 40.24% Sublingual- 3.66% Smoke or Vape-47.56% Topical-8.54%, *Perceived Efficacy: Yes-60.98% A little-32.93% Not at all-6.10%* **Vaginal dryness and painful sex:** *Type(s) of Cannabis consumed:* Sativa-18.92% Indica-2.7% Hybrid- 29.73% Unknown -8.11% THC- 18.92%CBD-21.62%, *Route of consumption:* Edible- 24.32% Sublingual- 0% Smoke or Vape- 40.54% Topical- 35.14%, *Perceived Efficacy: Yes*-57.89% *A little-28.95% Not at all-13.16%* **Orgasm:** *Type(s) of Cannabis consumed:* Sativa-22.81% Indica-5.26% Hybrid- 36.84% Unknown - 10.53%- CBD-3.51% THC 21.05%, *Route of consumption:* Edible- 33.33% Sublingual- 0% Smoke or Vape- 59.65% Topical- 7.02%, *Perceived Efficacy: Yes-70.69% A little 22.41% Not at all-6.9%* **Does your health care professional know you use cannabis?** Yes, I told him or her: 48.73% No, I wasn't asked: 43.65% No, I was asked but did not tell the truth: 7.61% **Who advised you what to buy?** No one, I figured it out on my own: 54.82% A person who worked at the dispensary: 15.23% Friend or relative: 13% Misc. sources (social media, cannabis websites) 10.66% A physician, nurse, or other health care profession: 5.58% **Conclusion:** The routes of consumption and phytocannabinoid strains used to alleviate symptoms are highly variable yet do not seem to impact perceived efficacy. The *perception* of relief of symptoms is consistently high, however, the impact of a placebo effect cannot be determined, and the efficacy of individual practices cannot be determined. Most women who are asked about cannabis use by their health care professional will respond honestly, but over 40% of women are not asked. A health care professional is the least likely source of information in terms of what to buy, the safest route of consumption, or dosage. This study confirms the wide variability in cannabis use in the menopause population and will be useful in not only understanding current practices but will also inform the design of future studies.
Sources of Funding: None

P-81.

Designing and delivering a feminist research-informed return of results to midlife women: A method to understand and 'foreground' marginalized voices

Lisa J. Taylor-Swanson, PhD, MAcOM[1], Julie Fritz[2], Belinda Anderson[3], Anna Camille Moreno, DO[5], Paula Gardiner, MD[4]. [1]College of Nursing, University of Utah, Salt Lake City, UT; [2]College of Health, University of Utah Health, Salt Lake City, UT; [3]Pace University, New York, NY; [4]University of Massachusetts System, Boston, MA; [5]University of Utah Health, Salt Lake City, UT

Objective: Midlife women's experiences have not been adequately represented historically as most research is framed within and is interpreted by dominant conceptual categories largely developed by privileged individuals. Midlife women are thus a marginalized group with experiences that are shaped by a multiplicity of social locations, including race, sexuality, dis/ability, age, social class, and gender. Rather than starting with empiricist a priori categories of experience, this study initiated an inquiry informed by feminist standpoint theory. This is a method to understand and 'foreground' marginalized voices. We asked about the experiences of midlife women and subsequently returned the results to participants to confirm or clarify the research team's interpretations. The purpose of this study was to design and deliver a feminist research-informed return of results (RoR) to midlife women as a part of a larger project to design an integrative medical group (IMGV) visit for peri- and post-menopausal individuals. **Design:** We conducted an engagement session with 9 midlife women and then employed qualitative analysis of the transcribed session. The research team then tabled themes, codes, and exemplar quotes. The data tables were presented during a RoR. Six of 9 engagement session participants attended the RoR. IRB ethics review was obtained. **Results:** The research team reviewed the data tables with midlife women and asked for corrections, confirmations, and clarifications. Participants provided corrections (e.g., we incorrectly listed Somalian and it was corrected to Somali). Participants also confirmed codes and themes in the data tables. Participants clarified comments made and provided additional input. For example, after the engagement session, women's thinking changed after hearing other women's perspectives thus changing their perspectives. Several women mentioned that they had initiated care from a healthcare provider; one participant found a menopause group on Facebook and found the discussion there helpful. Participants emphasized the need for community- and language-specific tailoring to the IMGV; that the biggest identified need is education about this topic; and that gathering in a community to discuss these topics was deeply meaningful and life-changing. Dissemination of findings has included both traditional and non-traditional venues. **Conclusion:** Midlife women participating in a RoR corrected, confirmed, and clarified the research team's qualitative analysis of an engagement session transcript, thus 'foregrounding' participants' lived experiences. Results indicate that participants were deeply engaged in the research and dissemination process and that there is a great need for more education about peri- and post-menopausal transitions, symptoms, and interventions.

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P-82.

Midlife Women's Symptom Experience and Access to Medical and Integrative Health Care: Informing the Adaptation of an Integrative Medical Group Visit for Peri- and Post-Menopause

Lisa J. Taylor-Swanson, PhD, MAcOM[1], Julie Fritz[2], Kari D. Stoddard[1], Belinda Anderson[3], Melissa Cortez, DO[2], Lisa Conboy[4], Xiaoming Sheng, PhD[1], Naomi Flake[2], Ana Sanchez-Birkhead, PhD[1], Louisa Stark, PhD[2], Marisol Jones, MBA[2], Anna Camille Moreno, DO[2], Sara Farah[2], Luul Farah[2], Doriena Lee[2], Heather Merkley, DHSc, RHIA[5], Lori Pacheco[2], Wendy Sanders[2], Fahina Tavake-Pasi[2], Jeanette Villalta[2], Cinnamon Geppelt, BSN, RN[1], Paula Gardiner, MD[6]. [1]College of Nursing, University of Utah, Salt Lake City, UT; [2]University of Utah Health, Salt Lake City, UT; [3]Pace University, New York, NY; [4]Harvard Medical School, Boston, MA; [5]College of Health Professions, Weber State University, Ogden, UT; [6]University of Massachusetts System, Boston, MA

Objective: Individuals in peri- and post-menopause often seek healthcare to better manage symptoms. However, many individuals who seek healthcare do not receive treatments for their symptoms. And, some lack access to providers of both medical care and evidence-based integrative health interventions such as acupuncture. Integrative medical group visits (IMGV) are a potential solution to this problem, which is the provision of medical care for multiple patients being seen by one provider. The present study gathered the opinions of midlife women about interest in and desired design elements of IMGV for peri- and post-menopause related symptoms and concerns. **Design:** An Engagement Session with midlife women and two Community Advisory Board (CAB) sessions with community members and healthcare providers were conducted. In the Engagement Session, we sought to learn about midlife women's experiences in peri- and post-menopause, specifically their symptom experience, barriers, and facilitators to accessing medical and integrative health providers, and their interest in and suggestions for the design of an IMGV. In the CAB sessions, we sought to inform the adaptation of an IMGV for peri- and post-menopause. Qualitative research methods were used to summarize session results. **Results:** Nine women participated in the Engagement Session. Eight community members and four healthcare providers participated in the two CAB sessions. Community members were diverse in terms of race/ethnicity, religious affiliation, and were highly educated. Themes included: an interest in participating in this conversation; that medical terms were mostly unfamiliar, and that terminology was less important than having a conversation; many symptoms were experienced; social factors affected participants, stressing the need for communication on this topic; receiving both unhelpful and helpful healthcare, a desire for whole person care; a need for information about what conditions Integrative Health interventions can treat, barriers to accessing both conventional and integrative care providers, and facilitators that included knowledge about insurance coverage. The group expressed great interest in the proposed IMGV model but expressed concerns about barriers such as a lack of time available, childcare, lack of insurance coverage, and language. Ideas for adaptation of the IMGV included: training community health workers, attention to midlife women's pain and opioid prescriptions, choice of online, mobile, and in-person formats, and educational content for partners and family. **Conclusion:** These findings highlight the importance of engagement with stakeholders before and during the adaptation of IMGV, and the great need among midlife women, particularly racially/ethnically diverse women, for education about peri- and post-menopause, evidence-based interventions, and self-care strategies.

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P-83.

Low Drug-Drug Interaction Risk of Estetrol (E4), a Promising New Estrogen for the Treatment of Menopausal Symptoms

Jean-Michel Foidart[2,5], Wulf Utian[1], Céline Gerard[2], Guillaume Chatel[2], Ulysse Gaspard[3], Mélanie Taziaux[2], Rogiero A. Lobo[4]. [1]Case Western Reserve University School of Medicine, Cleveland, OH; [2]Estetra SRL, an affiliate company of Mithra Pharmaceuticals, Liege, Belgium; [3]Universite de Liege, Liege, Belgium; [4]Columbia University Irving Medical Center, New York, NY; [5]Universite de Liege, Liege, Belgium

Objective: Polypharmacy is common among postmenopausal women and exposes them to the risks of inappropriate drug use and drug-drug interactions (DDI). Most estrogens are influenced metabolically by drugs which affect key metabolic enzymes. To investigate the DDI potential of E4, several *in vitro* studies with metabolizing enzymes were performed. A clinical study was also conducted to evaluate the consequence of inhibiting the main enzyme responsible for E4 metabolism. **Design:** *In vitro* studies on human hepatocytes or human liver microsomes and recombinant enzymes were conducted to evaluate the role of drug metabolizing enzymes on E4 metabolism [cytochrome P450 enzymes (CYP), UDP-glucuronosyltransferases (UGT) and sulfotransferases (SULT)]. We also assessed the potential of E4 to inhibit or induce these enzymes. Finally, we performed a clinical study to determine the effect of UGT inhibition on the pharmacokinetics (PK) of E4. In this open-label two period, two-way cross-over study, 24 healthy female volunteers received two single doses of a product containing E4 15 mg once alone and once in combination with valproic acid 500 mg twice daily, a strong UGT inhibitor. The consequence of UGT inhibition was quantified by serial plasma measurements of E4 up to 168h after drug administration. **Results:** Effects of other drugs on E4 (E4 as a substrate) CYP enzymes, a superfamily of enzymes that functions as monooxygenases did not play a significant role in the metabolism of E4. Consequently, E4 does not interact with drugs that inhibit or induce CYP enzymes. *In vitro* and *in vivo* studies showed that UGT2B7 was the main enzyme involved in E4 glucuronidation and that SULT1 was the dominant enzyme for sulfation of E4. The clinical phase 1 study confirmed the role of UGT in the metabolism of E4. UGT inhibition by valproic acid increased total E4 exposure and maximum concentration only by 1.13 and 1.36-fold, respectively. Because the effect of UGT inhibition on E4 pharmacokinetics is minimal, no clinically relevant effects are expected during coadministration of drugs that inhibit UGT activity. Effect of E4 on other drugs (interference by E4) Studies on the effect of E4 on other drugs showed that E4 neither induces nor inhibits CYP or UGT enzymes, except for a very minimal inhibition of CYP3A4, UGT1A9 and UGT2B7 isoforms. The half maximal inhibitory concentration (IC50) of these *in vitro* effects were several hundred times above the anticipated clinical maximum concentrations, indicating a low potential for clinically relevant DDIs. Also, there was no evidence of time-dependent inhibition of CYP enzymes. **Conclusion:** Based on these *in vitro* and *in vivo* drug interaction studies on metabolising enzymes, E4 is not expected to have a potential risk for DDI. Unlike other estrogens, CYP enzymes do not play a major role in the metabolism of E4 and can therefore be combined with drugs that inhibit or induce CYP or UGT enzymes without compromising its safety or efficacy.

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P-84.

Safety, Tolerability and Usability of Oral Estradiol (E2) and Progesterone (P4) versus Two Formulations of Daré HRT1, an Intravaginal Ring containing Bioidentical E2 and P4, in a First-In-Woman Phase I Study

Christine Mauck, MD MPH[1], Louise Hull, MBChB[2], Bronwyn Stuckey, MBBS FRACP[3], Kimberly A. Hartman, MD[1], Sabrina M. Johnson, MIM, MSc[1], Nadene Zack, MS[1], Jennifer Kiang, MS[1], Andrea R. Thurman, MD[1], David Friend, PhD[1]. [1]Dare Bioscience, San Diego, CA; [2]PARC Clinical Research, University of Adelaide, Adelaide, SA, Australia; [3]Keogh Institute For Medical Research Inc, Nedlands, WA, Australia

Objective: DARE-HRT1 is an ethylene vinyl acetate (EVA) co-polymer monthly intravaginal ring (IVR) of bioidentical 17β estradiol (E2) and progesterone (P4), being developed for treatment of moderate-to-severe vasomotor symptoms (VMS) with or without symptomatic vulvo-vaginal atrophy (VVA). **Design:** Daré HRT1-001 was a first-in-woman study of 28d treatment: 80 μg/d E2 + 4 mg/d P4 (IVR1) vs. 160 μg/d E2 + 8 mg/d P4 (IVR2) vs. oral E2 1 mg/d + oral P4 100 mg/d (ORAL). Participants completed a daily diary to record treatment emergent adverse events (TEAEs). At the end of treatment, IVR users completed an acceptability questionnaire. **Results:** Enrolled participants (n=34) were randomized to use IVR1 (n=10), IVR2 (n=12) or ORAL (n=12). Three participants were withdrawn from the study: two IVR2 users for unrelated TEAEs and one ORAL user for exclusionary pre-treatment laboratory criteria, thus 31 participants (IVR1=10, IVR2=10, ORAL=11) completed the study. Table 1 demonstrates that the TEAE profile of the IVRs were generally similar to the referent ORAL regimen. TEAEs were determined to be related to study product use more commonly with IVR2. However, one of the 12 IVR2 participants accounted for 26 of 47 reported TEAEs in that group. Endometrial biopsies were not performed routinely unless an endometrial stripe was >4 mm or for clinically significant postmenopausal bleeding (PMB). One IVR1 participant had an endometrial stripe increase from 4 mm at screening to 8 mm at end of treatment. Her endometrial histology was benign. Two other endometrial biopsies were also performed during the study for PMB and were benign. There were no clinically meaningful laboratory or vital sign abnormalities or trends identified in observed values or changes from baseline. Pelvic speculum examination identified no clinically significant abnormalities in any participant at any visit. Usability data are reported in Table 2, demonstrating both IVRs were highly acceptable. **Conclusion:** Both DARE-HRT1 IVRs, E2 80 μg/d + P4 4 mg/d (IVR1) and E2 160 μg/d + P4 8 mg/d (IVR2) were safe and well-tolerated in healthy postmenopausal women. TEAE profiles were comparable to the referent marketed ORAL regimen.

Sources of Funding: USA

Table 1: Proportion of participants reporting various TEAEs in each product group

VARIABLE N/GROUP TOTAL (%)	IVR1 (N=10)	IVR2 (N=12)	ORAL (N=11)	Fisher
PROPORTION OF PARTICIPANTS PER GROUP REPORTING:				
At least one TEAE	8 (80%)	9 (75%)	8 (73%)	> 0.99
Mild TEAE	7 (70%)	9 (75%)	8 (73%)	> 0.99
Moderate TEAE	1 (10%)	2 (17%)	0 (0%)	0.63
Reproductive System TEAE	6 (60%)	7 (58%)	5 (45%)	0.82
Gastrointestinal System TEAE	2 (20%)	3 (25%)	1 (9%)	0.74
Neurologic System TEAE	2 (20%)	1 (8%)	3 (27%)	0.55
Vaginal Spotting or Postmenopausal Bleeding	2 (20%)	3 (25%)	1 (9%)	0.74
TOTAL TEAEs REPORTED	30	47	17	NA
TEAE Related to Study Product (% total TEAEs)	18 (60%)	37 (79%)	8 (47%)	0.04

Table 2: Usability Data

Proportion of IVR Group Reporting:	IVR1 (N=10)	IVR2 (N=11)*	Fisher's Exact p
PROPORTION REPORTING IVR WAS VERY EASY OR SOMEWHAT EASY:			
To insert	9 (90%)	11 (100%)	0.48
To remove	8 (80%)	9 (82%)	> 0.99
PROPORTION OF PARTICIPANTS WHO STRONGLY AGREE OR AGREE:			
IVR was comfortable to use	9 (90%)	10 (91%)	> 0.99
IVR was convenient to use	10 (100%)	10 (91%)	> 0.99
IVR works with my lifestyle	9 (90%)	10 (91%)	> 0.99
OTHER QUESTIONS			
Overall IVR comfort was very comfortable or comfortable	8 (80%)	10 (91%)	0.59
Very or somewhat likely to use the IVR for a condition or disease that is related to women's health (e.g., hormone replacement, overactive bladder, uterine fibroids)	8 (80%)	10 (91%)	0.59
Very or somewhat likely to use the IVR for a condition or disease not related to women's health (e.g., high blood pressure, diabetes)	7 (70%)	10 (91%)	0.31

*** One IVR2 participant did not provide usability data**

P-85.

Evidence of Hippocampal Dysfunction in the Postmenopause: A Study of Hippocampal Amplitude during Task-Based fMRI

Jacob van Doorn[1], Rachel A. Schroeder, BS[1], Matthew Glasser, PhD[2], Michael Harms, PhD[2], Thomas Nichols, PhD[3], Beau Ances[2], Melissa Terpstra[4], Essa Yacoub[5], David Salat[6], Susan Bookheimer[7], Pauline Maki, PhD[1]. [1]Psychiatry, University of Illinois Chicago, Chicago, IL; [2]Neurology, Washington University in St Louis, St Louis, MO; [3]University of Oxford, Oxford, United Kingdom; [4]University of Missouri, Columbia, MO; [5]University of Minnesota Medical School Twin Cities, Minneapolis, MN; [6]Massachusetts General Hospital, Boston, MA; [7]University of California Los Angeles, Los Angeles, CA

Objective: Reliable changes in memory performance are observed in the menopause transition, suggesting that the menopause transition may be an inflection point for accelerated brain aging in women. Initial functional magnetic resonance imaging (fMRI) studies suggest that those changes may be due in part to changes in the function of the hippocampus, a brain area rich in estrogen receptors. Typically, hippocampal function is measured in fMRI studies by a single cognitive probe, like a word memory task or at rest. An alternative and potentially more sensitive measure of hippocampal function is hippocampal amplitude, which is the standard deviation of the concatenated hippocampus time series across cognitive tasks that differ in reliance on memory processes. Here we examined whether age differences in hippocampal amplitude differed by menopause stage. We hypothesized that compared to a premenopausal group of women, peri- and postmenopausal groups would show larger age-related differences in hippocampal amplitude, indicative of accelerated hippocampal aging in the menopause transition and into the postmenopause. **Design:** Participants included 187 women aged 40-60 (mean 50.1 ± 5.8) years from the Perimenopause Substudy of the Human Connectome Project in Aging (HCP-A). Women were excluded if they were on hormonal medications or had a hysterectomy and/or oophorectomy. All participants completed two fMRI tasks, a Face-Name task that relies on the hippocampus and a Go/No-go task that does not rely on the hippocampus. We examined hippocampal blood-oxygen level dependent (BOLD) amplitude across the two tests. All participants also completed the Rey Auditory Verbal Learning Test (RAVLT), a measure of verbal learning and memory. Menopause status was determined using the STRAW+10 questionnaire. We performed regression analyses, with left and right hippocampal amplitudes as the outcome measure and age, menopause stage, and age-by-stage interactions, controlling for education, race, and APOE status. **Results:** The sample included premenopausal ($N = 74$), perimenopausal ($N = 51$), and postmenopausal ($N = 62$) groups of women, which differed in key factors that influence brain function, including age, education, race and APOE status ($p < .05$). Although we controlled statistically for these confounding effects, to test our hypotheses we focused on age-differences by stage as measured by stage x age interactions. The postmenopause group, but not the perimenopause group, showed a more positive association between age and amplitude than the premenopause group in both the left ($\beta = 0.825$, $p = 0.006$) and right ($\beta = 0.692$, $p = 0.022$) hippocampus. Both left and right hippocampal BOLD amplitudes were negatively associated with RAVLT (Left $\beta = -0.149$, Right $\beta = -0.148$, $p < 0.01$), and positively associated with age (Left $\beta = 0.218$, Right $\beta = 0.189$, $p < 0.05$). Finally, on the RAVLT, postmenopausal women performed worse than both premenopause and perimenopause ($F(2,177) = 6.42$, $p < 0.01$). **Conclusion:** In women aged 40-60, we found evidence of hippocampal dysfunction in the postmenopause but not perimenopause. Specifically, postmenopausal women showed a more positive association of left and right hippocampal amplitude with age, and positive amplitude was associated with worse memory on the RAVLT. The postmenopause stage may be an inflection point for adverse changes in the ability of the hippocampus to function differentially in response to task demands.

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P-86.

Physical and Psychological Effects of Negative Cultural Perceptions of Menopause

Eesha Vijayakumar[1], Etphane D. Barthelus, Master of Public Health[2], Gloria Bachmann, MD[2]. [1]Rutgers The State University of New Jersey, New Brunswick, NJ; [2]Robert Wood Johnson Women's Health Institute, New Brunswick, NJ

Objective: Currently, there are over 50 million postmenopausal women in the United States. However, general public discussion and knowledge of menopause usually centers on the negative physical symptoms. Although many women have adverse symptoms and physical changes related to estrogen loss, it may be important to also stress positive perceptions of menopause; that is, as a period of multifaceted transformation encompassing a variety of positive and negative physical, mental, emotional, and spiritual experiences. This review will explore the available U.S. data on the physical and psychological effects of presenting a negative cultural perception of menopause. **Design:** A literature review was conducted using Rutgers Libraries QuickSearch Database. Keywords included "United States," "menopause experience," "attitude, "culture," "physiological," and "psychological." Groups being compared in the literature were classified as optimistic (viewing menopause with lesser negative expectations) and pessimistic (viewing menopause in a distressed manner) for simpler pattern-based comparison. **Results:** Data suggest that groups viewing menopause pessimistically consistently had more severe negative symptoms. Out of the analyzed literature, physical experiences were an arithmetic average of 3.379 times more common in pessimistic groups (hot flashes: 5.091 times more common; severe vaginal dryness: 1.334 times more common; sweats: 1.947 times more common; general negative physiological symptoms: 5.286 times more common). Negative psychological symptoms, including aggressiveness, stress, and irritability, were an average of 3.000 times more common amongst the pessimistic groups. Since attitude has a substantial impact on the physical and psychological menopausal experience, a cultural shift towards an empowering perception of menopause and female aging should be considered. **Conclusion:** The adverse menopausal issues that many women face at this time must be addressed. However, it may be beneficial to emphasize the positive aspects of menopause as well. There should be a focus on menopause as an opportunity for multidimensional transformation, supported by society and the health care team. However, to further assess the potential of menopause as an opportunity for growth and the extent to which culture affects individual attitudes, research should be done to confirm that a cultural shift in menopause can truly increase the rate of women who have positive menopausal experiences. Additionally, the mechanisms by which attitude can determine the physical experience of menopause, possibly via the placebo effect, must be researched for greater acceptance and understanding.

Sources of Funding: None

P-87.

"Self-diagnosis by Google": A qualitative study of sources of menopause information

Amber Watts, PhD, Zara Hassan, Juliamaria Coromac-Medrano, Pilar Thangwaritorn, Genna Losinski. Psychology, University of Kansas College of Liberal Arts and Sciences, Lawrence, KS

Objective: Research suggests that middle-aged women feel undereducated about what to expect during the menopausal transition. A recent study recommended "anticipatory guidance" to prepare women for symptoms they may experience in their 40s, but do not expect until age 50. In the interest of developing effective menopause education strategies, our study evaluated sources from which women received menopause information, expectations about menopause, and experiences with menopause related healthcare information. **Design:** We conducted semi-structured interviews with 27 women (ages 39-57) of diverse races and sexual identities from across the U.S. 25% reported no menstrual cycle changes (premenopausal), 40% reported signs consistent with perimenopause, 25% reported no periods for 12+ months (post-menopausal), and 10% were unable to determine menstrual status (i.e., no bleeding due to birth control or uterine ablation). We recruited participants using purposive and snowball sampling. We asked participants to reflect on 1) where they sought and received menopause information, 2) their expectations about menopause, and 3) their experiences with menopause healthcare information. We used interpretative phenomenological analysis to analyze responses. Data processing occurred in condensation and categorization stages. **Results:** Women reported seeking and receiving menopause information from friends, family, the internet, and more rarely, healthcare providers. We summarized women's expectations of menopause in three general themes: 1) lack of information, 2) stereotypes, and 3) mother's experience. Most women described a general lack of discussion about menopause with friends and family. For example, "[we're] too embarrassed to talk about it on social media," "when it comes to women's situation, no one ever actually goes into anything," and "there's things you just don't talk about as a lady." A surprisingly high number of participants indicated that friends and family members from previous generations could not provide information about natural menopause because they underwent surgical menopause. Many were surprised that their healthcare providers did not discuss the menopausal transition with them ("anticipatory guidance") and expressed dissatisfaction with responses when asking their providers direct questions. One summarized by saying that when it comes to information about menopause, "we're on our own." Another quipped that women have to "self-diagnose by Google." Women discussed stereotypes about menopause they perceived in society and media depictions. These included description of menopausal women as "crazy" or "bitchy." Some descriptions overlapped with women's interpretations of behaviors they observed in their own mother during her transition (e.g., "selfish," "angry," "a jerk"). Women reported overwhelmingly negative experiences seeking menopause-related healthcare information including feeling dismissed or subject to ageist and sexist attitudes. Most women, several of whom worked in healthcare, felt that healthcare providers in general are poorly educated about menopause and offered unsatisfying menopause information. Though most women reported they did not directly discuss menopause during their mothers' transitions, many women relied on limited knowledge of their mothers' experiences to guide them. Some reported not wanting to repeat their mothers' unpleasant moods and symptoms, while others recalled their mothers' experiences saying, "She never had a single hot flash" or "my mom can barely remember it." Others reported having already left home before their mothers' transitions, thus they had little information about it. **Conclusion:** Our findings suggest a clear need to provide women broad access to high quality menopause education. Women reported relying on friends, family, and the internet more than healthcare providers, while reluctance to discuss menopause publicly was often a barrier. Successful menopause

education strategies might benefit from building on existing close relationships with women who have already experienced menopause. The current generation of women are sophisticated users of technology and would likely benefit from increased access to high quality menopause information and discussion forums online.
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P-88.

The effect of acute exercise on hot flash experience in healthy perimenopausal individuals

Sarah Witkowski, PhD[1], Lorna Murphy[1], Sara Buszkiewicz[1], Lynnette L. Sievert, PhD[2]. [1]Exercise & Sport Studies, Smith College, Northampton, MA; [2]University of Massachusetts Amherst, Amherst, MA

Objective: Hot flashes (HFs) are a thermoregulatory, heat dissipation event experienced by about 80% of women. The HF experience includes both the subjective perception and objective measurement of physiological HFs. Exercise is activity requiring physical effort that is planned and performed to maintain or improve health. Regular exercise has influences on thermoregulation, leading to a more efficient heat dissipation response. The relationship between HFs and acute exercise remains unclear with some finding increases in either objectively measured or subjectively reported HFs and others reporting decreases following exercise. As the HF experience has been associated with CVD risk, particularly in perimenopausal individuals, we seek to better understand the relation between physical activity and HF experience in this population. The objective of this analysis was to evaluate the effect of a single bout of moderate intensity exercise on the subjective and objective HF experience in perimenopausal women. **Design:** Healthy perimenopausal (defined by the STRAW+10 criteria) individuals aged 43-54 who were not taking hormone therapy or other medications that may influence HF experience were enrolled. Habitual physical activity was evaluated through the International Physical Activity Questionnaire (IPAQ). Participants were tested under 2 conditions; one in which women did not undergo acute exercise, and in the second, women were given a dose of 30-minutes of moderate-intensity treadmill exercise, in addition to a 5-min warm-up and 5-min cool-down. Moderate exercise was defined as 64-76% of age-predicted max heart rate [206.9-(0.67*age)] and qualified with a rating of perceived exertion (Borg RPE) every 2 minutes during exercise. Participants were instructed to not exercise in the 12hr prior to each study visit and during the 24-hr following the visit. After each session, participants were monitored for 24-hr for HFs. Objective HF experience was recorded via sternal skin conductance with an ambulatory monitor (Biolog, UFI, Morrow Bay, CA) and defined by a ≥2umho increase in skin conductance over 30s and/or a distinctive HF pattern (rapid rise followed by a slow descent). For subjective HF experience, participants were asked to press a button on the monitor when they felt a HF or enter the data in the HF diary. Average temperature and humidity during monitor wear periods were recorded. Frequency of HF of each type per hour of wear was calculated. Data were included if at least 10hr of HF monitor data was collected. Data were evaluated for assumptions of statistical testing. When data failed these assumptions, nonparametric tests were used to analyze the data. In this case, the Related Samples Wilcoxon Signed Rank Test was used to evaluate paired data, and Kendall's Tau was used to evaluate correlations. **Results:** Participants were 49.7±3 yr old and had a mean habitual physical activity of 4254±2485 MET-min/week. At this time, valid data for 2 testing visits was collected on 17 participants for objective data and 18 participants for subjective data. Data from 3 participants was excluded due to Biolog monitor malfunction such that <10hr of data was collected. There was a statistically significant reduction in objectively measured HFs between the non-exercise and exercise conditions ($z=-2.040$, $p=0.041$). The median frequency of objective HFs in the non-exercise condition was 0.132HF/hr vs. 0.0937HF/hr in the acute exercise condition. There was no difference between subjective HFs between conditions (non-exercise median = 0.05HF/hr, exercise median = 0.041HF/hr, $z=-0.408$, $p=0.683$). Average temperature and humidity did not correlate with HF experience for either testing visit (all $p>0.1$). **Conclusion:** Our data support a reduction in objective HF experience in the 24-hr following an acute bout of moderate exercise with no effect on the subjective HF experience in healthy perimenopausal women. Understanding the role of physical activity and exercise on HF experience can advance efforts to provide accurate information to women undergoing menopause and optimize therapies for this population.
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An Argentinian Population Study on Menopause

Daniela Faranna[3], Debora Yankelevich, retired[1], Aura Gonzalez Yamil[2], Marta Tutzer[2]. [1]gynecology, Hospital de Clinicas Jose de San Martin, Buenos Aires, Argentina; [2]gynecology, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina; [3]gynecology, Hospital General de Agudos Donacion Santojanni, Buenos Aires, Argentina

Objective: As life expectancy has increased, the menopause most women spend more than one-third of their lives after menopause A significant number, experience most bothersome menopausal symptoms. There s few data on women attitudes about seeking information on menopause and the adherence to precription. On the other hand, little is known about the response of HPs regarding menopausal symptoms. The objective of this study is to describe various characteristics among this female population aged 40-80 years. **Design:** A population based, cross-sectional study has been conducted from September 2020 to May 2022. A total of 1359 postmenopausal women, in Argentina, completed an online structured self questionnaire RENAME (Registro Nacional de Menopausia) regarding: age of menopause, educational level, smoking status, climacteric symptoms, access to healthcare providers and use of MHT or non hormonal therapies. **Results:** The population mean age was 61.1 years (SD 7.3) Average age of menopause was 49.4 years (SD 4.77) Women were divided in groups according to educational levels: 53.1% university, 22.1% tertiary education, 19.4% completed high school. No association between hot flashes and educational status was observed. Regarding climacteric symptoms 52.9% (n:719) reported hot flashes, 47.1% (n: 640) night sweats and 32.3% (n:439) sleep disorders. More than a half 52.1% (n:708) complained of vaginal dryness, recurrent cystitis 10.2% (n:138), and 24.7% (n:335) painful intercourse. The great majority (72.7%) sought health counseling regarding symptoms from their physicians; 79% received medical advice, but only 47.9% received a prescription. 22.7% of these women used MHT, but only 12.7% continued it for more than 6 months. Non hormonal therapy was employed by 11.6% women and 4.3% used both therapies (hormonal and non hormonal). **Conclusion:** Based on the results of the present study, climacteric symptoms were highly prevalent. According to the literature, hot flushes, night sweats and vaginal dryness were the major complaints. Paradoxically, although they were fully informed about this period of life, few received either hormonal or nonhormonal treatment. HPs have a great role in improving patients' acceptance and adherence to hormonal treatment. Continuing medical education in this field, is essential for postmenopausal women care and treatment.
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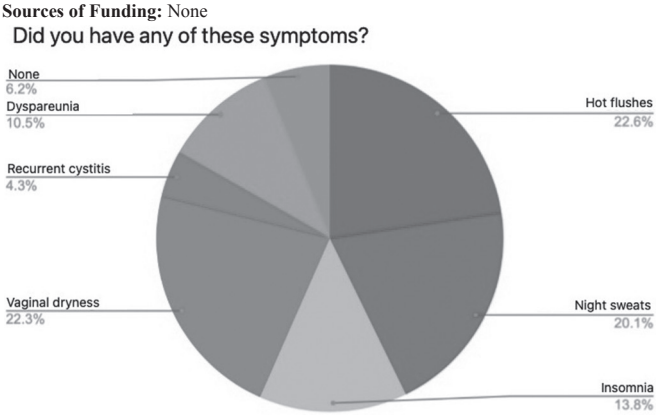

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Racial and Ethnic Differences in Menopausal Symptoms: A Cross-sectional Study of 44,678 Women

Eduardo Hariton, MD, MBA[1,2], Jerrine Morris, MD MPH[1,2], Alicia Jackson[2], Emily Hu, MD[2], Leah Millheiser[2,3]. [1]University of California San Francisco, San Francisco, CA; [2]Evernow Inc, San Francisco, CA; [3]Obstetrics and Gynecology, Stanford University, Stanford, CA

Objective: The objective of this study is to understand the differences in self-reported menopausal symptoms by race and ethnicity. **Design:** All women who completed an online intake questionnaire at Evernow, a menopause-focused telemedicine platform, from May 2020 to March 2022 were included. The questionnaire consisted of demographic information, a medical history, and the validated Menopause Rating Scale (MRS). Respondents reporting the presence of symptoms with a severity rating of "3" or "4" were classified as having moderate to severe symptoms. Descriptive characteristics and chi squared tests were performed with those self-reporting White race/ethnicity serving as the reference group. Adjusted odds ratios were calculated to assess the relationship between race/ethnicity and symptom severity after accounting for body mass index (BMI). All analyses were performed with Statistical Analysis Software (SAS®) version 9.4. **Results:** Of the 44,678 women who completed the intake survey and reported ethnicity, the majority (75.2%) self-reported White race/ethnicity, followed by Hispanic (10.9%), and Black (8.6%). Less than 2% of respondents declined to report their race/ethnicity and were not included in this analysis. After adjustment for BMI, Black women were more likely to report greater severity in 10 of the 16 MRS symptoms with the greatest difference in severity of hot flashes (aOR 1.6; 95% CI 1.5-1.8); they reported less severity only in weight changes (aOR 0.6; 95% CI 0.5-0.7). Similarly, Hispanic women reported greater severity in 7 of the 16 menopausal symptoms as compared to White women with the greatest difference in severity of skin and hair changes (aOR 1.4; 95% CI 1.2-1.5). East Asian women reported similar symptom severity as White women except lower severity in night sweats (aOR 0.5; 95% CI 0.3-0.8), sleep disruption (aOR 0.6; 95% CI 0.3-0.9), and heart discomfort (aOR 0.4; 95% CI 0.2-0.8). **Conclusion:** This is the largest study to date to compare the symptoms of menopausal women by race and ethnicity. When compared to White women, Black and Hispanic women were more likely to report moderate to severe menopausal symptoms, while East Asian women were less likely to do so. More research is needed to understand these differences in symptomatology and explore how to best use these findings to improve our counseling and treatment approaches.
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