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Abstract PO-037: Biomarkers for early diagnosis of human papillomavirus-related oropharyngeal cancer FREE

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Abstract

Introduction: To counteract the rapidly increasing incidence of human papillomavirus (HPV)-related oropharyngeal cancer (OPC), development of effective biomarkers and other novel screening strategies are necessary to effectively detect early disease in well-defined high-risk populations. The most promising biomarkers are circulating tumor HPV DNA (ctHPV), antibodies (Abs) to HPV16 early (E) antigens, and persistent infection with oral oncogenic HPV. Here, we report the prevalence of ctHPV in a population of middle-aged men, a group with high OPC incidence, and evaluate concordance between the three HPV biomarkers. **Materials and Methods:** We included participants enrolled in the HPV-related Oropharyngeal and Uncommon Cancers Screening Trial of Men (HOUSTON) study between April 2017 and December 2019. The HOUSTON study was designed to evaluate biomarkers and novel screening strategies for HPV-related cancers among middle-aged men (50-64 years), the group with the highest incidence of HPV-related OPC. We tested plasma for ctHPV using a digital droplet polymerase chain reaction (ddPCR) assay (NavDx, Naveris, Waltham, MA). We previously tested the plasma from these participants for HPV16 E Abs using a novel RAPID ELISA and for prevalent oral HPV16 (oHPV16) infection in oral rinse using the cobas HPV Test (Roche Diagnostics, Indianapolis, IN). We used Fisher's exact test to determine statistical significance for the association between biomarkers ($\alpha < 0.05$). **Results:** Of 345 samples tested, 343 were adequate for ctHPV analysis. Of these, 314 were negative (92.4%) and two were positive (0.6%; both for HPV16). Twenty-four had an indeterminate (Ind) result (7.0%), meaning ctHPV levels fell outside the established parameters for a negative or positive results. All three markers were available for 340 samples with the following results: ctHPV+/Ab+/oHPV16+: 1 (0.3%); ctHPV+/Ab-/oHPV16-: 1 (0.3%); ctHPV Ind/Ab-/oHPV16+: 3 (0.9%); ctHPV Ind/Ab-/oHPV16-: 21 (6.2%); ctHPV-/Ab+/oHPV16+: 1 (0.3%); ctHPV-/Ab+/oHPV16-: 3 (0.9%); ctHPV-/Ab-/oHPV16+: 16

[Skip to Main Content](#)

(4.7%); ctHPV-/Ab-/oHPV16-: 294 (86.5%); all other combinations had no observations. ctHPV was associated with HPV16 E Abs and oHPV16 status individually and combined (individually, $p = 0.032$ for both and combined, $p = 0.025$). A ctHPV-/Ab+/oHPV16-man was diagnosed with an anal low-grade squamous intraepithelial lesion and was persistently high-risk HPV-positive at the right tonsil/base of tongue. One man was positive for all three markers and was subsequently diagnosed with stage II (T1N1) HPV16-positive/Epstein-Barr-negative nasopharyngeal cancer four months following study enrollment. Conclusions: ctHPV was rare in a general population of middle-aged men. Our results suggest that these markers in combination may be able to correctly identify early HPV-related cancers. Larger studies are needed to confirm this finding. *The authors accept sole responsibility for the statements in this abstract.*

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