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Computer-aided Detection of Polyps Does Not Improve Colonoscopist Performance in a Pragmatic Implementation Trial

See editorial on page 332.

Artificial intelligence (AI), including computer-aided detection (CADe), could revolutionize endoscopy. The adenoma detection rate (ADR) is inversely associated with the risk of postcolonoscopy colorectal cancer.[1] The first CADe device approved in the United States (GI Genius; Medtronic, Minneapolis, MN) significantly increased the ADR and adenomas per colonoscopy (APC)[2,3] and decreased the adenoma miss rate[4] in randomized trials.

We assessed the CADe device in a 3-month trial that leveraged our Stanford Colonoscopy Quality Assurance Program[5] infrastructure to address a research priority identified by a Delphi process with international experts: studies of real-world endoscopist–AI interaction in intended clinical pathways, reporting relevant patient outcomes.[6] We performed a pragmatic implementation study in routine practice of the impact of CADe on a comprehensive set of colonoscopy quality metrics. By design, we used a minimalist deployment strategy, including standard startup training, but no additional measures that could affect endoscopist behavior. We hypothesized that lesion detection rates would be higher (particularly for endoscopists with lower baseline detection rates), procedure times would be longer, and non-neoplastic resection rates would be higher with vs without CADe.

The Supplementary Material details our methods. We conducted a retrospective pragmatic trial with historical and concurrent control subjects. CADe devices were installed in our health system's largest outpatient endoscopy unit ("CADe site") for a 3-month evaluation (February to May 2022, the implementation period). Our system's 5 other units served as control sites. After the CADe devices were returned, we first assessed CADe use; then, using a difference-in-difference approach,[7] we analyzed whether quality metrics changed as hypothesized in the CADe site, compared with control sites, during the implementation vs preimplementation periods, matching each endoscopist's number of colonoscopies. This approach accounts for a possible period effect independent of CADe use and for differences between study sites and is preferred over a simple comparison of metrics between sites with or without CADe. Endoscopists at control sites were not made aware of the CADe trial, but we made no effort to limit casual communication. Endoscopists were not aware of any hypotheses. The Stanford Institutional Review Board approved the study.

During the implementation period, CADe was used in 1008 of 1037 (97.2%) eligible colonoscopies. Of these, 619 were performed for screening/surveillance by 24 endoscopists who participate in our quality assurance program. The implementation and preimplementation period study cohorts in the CADe and control sites were comparable across demographics and colonoscopy indications (Supplementary Table 1).

During the implementation period in the CADe site, ADR was 40.1% (95% confidence interval [CI], 36.2%–44.0%) and mean APC was 0.78 (95% CI, 0.68–0.90) with CADe vs 41.8% (95% CI, 37.9%–45.8%; $P = .44$) and 0.89 (95% CI, 0.77–1.02; $P = .23$), respectively, during the preimplementation period without CADe (Figure 1, Supplementary Table 1). The detection rates for sessile serrated lesions, advanced adenomas or sessile serrated lesions, and lesion multiplicity were also comparable across periods (Supplementary Table 1, Supplementary Figure 1). In the control sites, all detection metric results without CADe use were comparable between the implementation and preimplementation periods (Supplementary Table 1, Supplementary Figure 1).

No statistically significant effect of CADe on ADR (odds ratio, 1.14; 95% CI, 0.83–1.56; $P = .41$), APC (OR, 1.08; 95% CI, 0.80–1.45; $P = .63$) or any other detection metric was detected by difference-in-difference analyses accounting for within-endoscopist correlation and adjusting for patient age and sex and procedure indication (Supplementary Table 1, Supplementary Figure 1). No effects of CADe on procedure times and non-neoplastic lesion resection rates were seen (Supplementary Table 1, Supplementary Figure 1). CADe use did not substantially mitigate differences in performance for ADR or APC (Figure 1) or for any other metric between lower vs higher tertiles of metric-specific baseline performance (Supplementary Table 1, Supplementary Figure 1).

Our results contrast sharply with those of randomized trials.[2–4] Despite very high enthusiasm for trialing the technology, CADe use was not associated with improved detection rates. Although a ceiling effect might apply to high performers, it would not apply to lower performers. Given that CADe clearly identifies polyps,[8] we must consider whether chance or subtle aspects of endoscopist behavior might explain our results. We caution against dismissing our study as an outlier, given a recent report of lower detection rates with vs without CADe.[9]

We were interested in the impact of a real-world, open-label implementation of CADe. We simply made CADe available, without any interventions beyond encouragement and basic startup training. We made no attempt to influence performance and had no discussions about hypotheses.

Perhaps there truly was a higher detection rate attributable to CADe *in exposed mucosa* in our study, but

Abbreviations used in this paper: ADR, adenoma detection rate; AI, artificial intelligence; APC, adenoma per colonoscopy; CADe, computer-aided detection.

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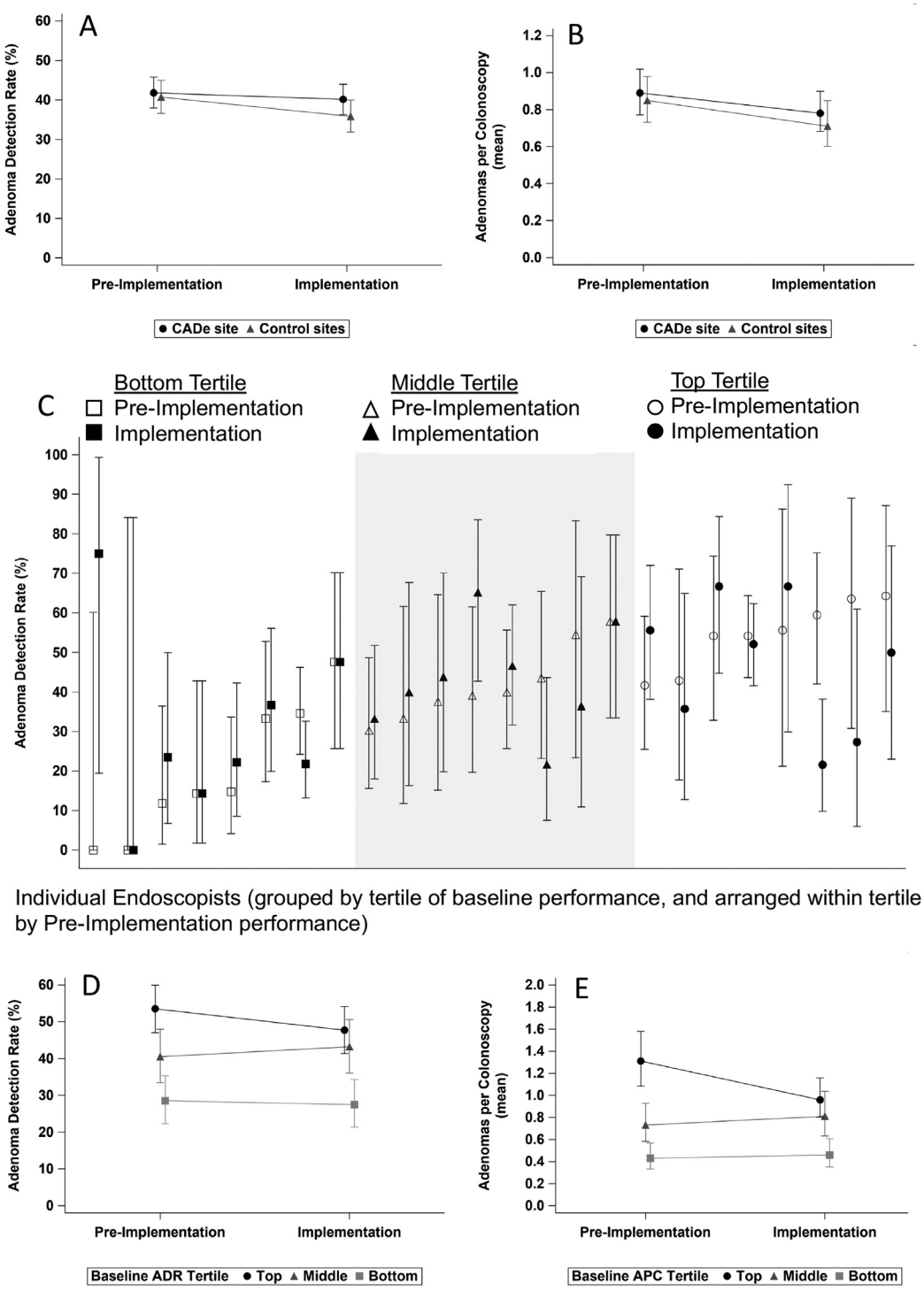

Figure 1. *(A)* Adenoma detection rate (ADR) and *(B)* adenomas per colonoscopy (APC) during the preimplementation and implementation periods in the computer-aided detection (CADe) and control sites. *(C)* Individual endoscopist ADR during the preimplementation and implementation periods in the CADe site, grouped by tertiles of endoscopist 12-month baseline ADR. *(D)* ADR and *(E)* APC during the preimplementation and implementation periods in the CADe site, aggregated by tertiles of endoscopist 12-month baseline metric-specific performance.

counterbalancing factors emerged. Some endoscopists may have dismissed suspected adenomas or sessile serrated lesions that were not highlighted by CADe, may have made errors in diagnosis and decisions about resection, or may have dismissed true-positive CADe prompts. Most concerning would be if, inadvertently, CADe use was accompanied by a simultaneous unconscious degradation in the *quality of mucosal exposure*, possibly due to a false sense of comfort that CADe would ensure a high-quality examination.

In contrast, the selected endoscopists in the randomized trials knew the study design and hypotheses, must have been cognizant that they could influence results on a nascent technology, and could not be blinded. It is possible that CADe in these trials encouraged better mucosal exposure or more careful lesion appraisal.

Substantial research from organizational and implementation sciences[10] suggests that how new technologies are deployed influences outcomes. Ensuring clinicians' trust in and acceptance of a technology could result in more effective application. Attention to an implementation process (eg, intentional planning for deployment, discussion about achieving the technology's potential, reflection after deployment) could improve results.

We remain optimistic about CADe, which clearly identifies polyps.[8] However, a minimalist deployment strategy may not ensure success. It may take a suite of AI features to maximize impact, including real-time assessment of mucosal exposure, CADe, lesion sizing, computer-aided diagnosis, assessment of resection adequacy, and support in generating endoscopy reports. Future challenges include ensuring that CADe detects subtle and high-risk lesions, on which current modules were not trained. Whether AI will reduce postcolonoscopy colorectal cancer and mortality is a critical question.

In summary, our results contrast sharply with those of randomized trials. In real-world practice, CADe implementation without attention to endoscopist inclination and behavior may not achieve the intended results. Better understanding of subtle factors at the interface of technology and endoscopist performance, including mucosal exposure, could inform the development of multidimensional AI suites to promote uniformly high quality in endoscopy.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org and at https://doi.org/10.1053/j.gastro.2022.12.004.

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Conflicts of interest
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Data Availability
Data and study materials cannot be made available to other researchers. Analytic methods are described in the Supplementary Material.

Supplementary Material

Methods

Our Colonoscopy Quality Assurance Program database reflects comprehensive audits based on standardized clinical documentation.[1–4] We monitor preparation quality, cecal intubation rate, procedure times, and lesion detection rates for all colonoscopy indications.

Five CADe devices were installed in the Stanford Outpatient Procedure Center (CADe site) for an evaluation period from February 16, 2022 through May 13, 2022 (the implementation period). Stanford Hospital, Stanford Cancer Center South Bay, and Stanford Health Care in Emeryville, Pleasanton, and ValleyCare were the control sites. As in our previous studies,[2,4] clinical practice proceeded without any research-specific interventions.

Medtronic staff provided the support that is standard for any trial period of their device. We taped small signs to endoscopist and technician monitors as reminders to consider turning on CADe, but CADe use was left to the discretion of each endoscopist for every colonoscopy. For each colonoscopy, technicians recorded whether CADe was used.

CADe use. We considered all colonoscopies performed for any indication other than inflammatory bowel disease, including colonoscopies performed by endoscopists outside our division, who are not required to use our standardized documentation.

Quality metrics. For patients undergoing only 1 colonoscopy, that colonoscopy was potentially eligible. For patients undergoing multiple colonoscopies, a colonoscopy was potentially eligible if it occurred $\geq$12 months apart from another colonoscopy; for colonoscopies that occurred within 12 months of each other, only 1 was considered, determined as the first one with extent to the cecum and adequate preparation (Boston Bowel Preparation Scale $\geq$ 2 in each segment) or the first one with polypectomy.

Potentially eligible colonoscopies were included if they occurred during the study periods, were complete to the cecum with adequate preparation, were performed by members of our division who document reliably, and were performed for a screening/surveillance indication in our ADR-Extended to all Screening/Surveillance Score.[2] The few colonoscopies performed by endoscopists outside of our division were excluded because they are not required to use standardized documentation. As reported previously,[2,4] we decided a priori to exclude 3 low-volume endoscopists who do not record pathology results reliably.

Preimplementation period. We matched the number of procedures by endoscopist because detection rates vary widely by endoscopist. We searched back in time for each endoscopist from February 15, 2022 until sufficient consecutive colonoscopies with a screening/surveillance indication were found to match the overall number performed for these aggregated indications by that endoscopist during the implementation period. Procedures performed in the CADe vs control sites were handled separately. Most colonoscopies in the preimplementation period occurred within 3 months preceding the implementation period.

Analyses. One author (U.L.) extracted data, removed personal identifiers, and assigned blinded identifiers to endoscopists.[2] We determined the fraction of all complete colonoscopies in which endoscopists chose to use CADe.

We compiled summary statistics for demographics, colonoscopy indication, and preparation scores for the preimplementation and implementation periods in the CADe and control sites. For quantifying detection rates and corresponding uncertainty, we used the Clopper-Pearson estimate of 95% CI based on the exact binomial distribution. For modeling counts, we used a modified Poisson regression to estimate means, with 95% CI estimated using robust error variances. For variables reflecting length of time, we present means and 95% CIs assuming a normal distribution.

In total cohort analyses, for each study period, and separately for the CADe and control sites, we calculated detection rates for adenoma, advanced adenoma, sessile serrated lesions, advanced sessile serrated lesions, and advanced lesions (adenoma and/or sessile serrated lesions); mean adenomas per colonoscopy, mean lesions (defined as the sum of all adenomas and sessile serrated lesions) per colonoscopy, and mean advanced lesions (defined as the sum of all advanced adenomas and advanced sessile serrated lesions) per colonoscopy; total, insertion, and withdrawal times; and resection rates for non-neoplastic lesions (total number of polyps removed minus the sum of adenomas and sessile serrated lesions shown in the main text).

In analyses stratified by tertiles of baseline performance, we first calculated baseline metrics during the 12 months preceding the CADe implementation period for each endoscopist in the CADe site. For each metric, we aggregated endoscopists into tertiles by the preceding 12-month metric-specific baseline performance and performed calculations for the CADe site by tertile. For ADR, we plotted each individual endoscopist's paired preimplementation and implementation ADR, grouped by 12-month baseline ADR into tertiles, and ranked within tertile by preimplementation ADR.

We used generalized estimating equations to estimate associations between CADe implementation and study outcomes. Our models accounted for correlation of observations within endoscopists using the robust sandwich estimator and for other potential predictors. We applied generalized estimating equation techniques by regressing each outcome on a set of variables: an indicator for colonoscopy in the CADe site or control site, an indicator for colonoscopy in the preimplementation or implementation period, an interaction between these 2 indicators (corresponding to the parameter of interest ["does change in ADR differ with vs without CADe?"]), and patient age and sex and colonoscopy indication. Correlation of outcomes across colonoscopies within endoscopist was accounted for through robust sandwich estimation.

The association between CADe implementation and outcomes was estimated through the coefficient of the interaction term (difference-in-difference estimator),

interpreted as the mean difference in changes of the outcome from the preimplementation period to the implementation period comparing the CADe site vs the control sites. For binary outcomes (eg, adenoma detected/not), we assumed a binomial distribution and logit as the link function. Odds ratios, 95% CIs, and *P* values are reported. For counts (eg, APC), we assumed a Poisson distribution with the log link. If over-dispersion was detected (φ estimated using Pearson's χ^2 statistic and degrees of freedom; over-dispersion if $\varphi > 1$), we used a negative-binomial distribution instead. Risk ratios, 95% CIs and *P* values are reported. For continuous outcomes (eg, withdrawal time), we assumed a normal distribution or a log-normal distribution if the assumption of normality and equal variance of the residuals from the model was invalid. For absolute or percent relative changes within the CADe site, 95% CIs and *P* values are reported. For our primary outcome (ADR), family-wise Type I error was controlled at level = 0.05. Analyses were performed using SAS v9.4 (SAS Institute Inc, Cary, NC).

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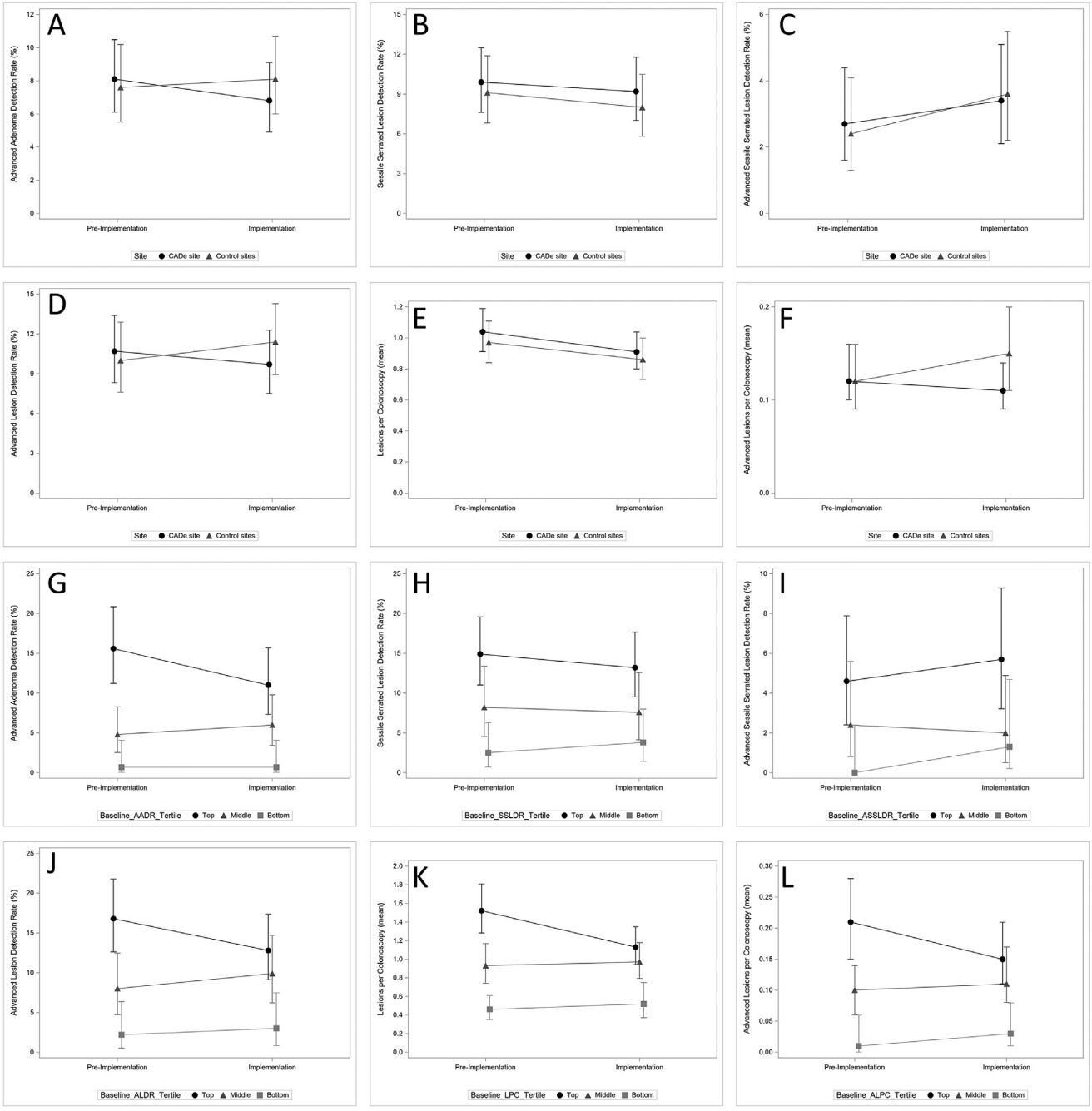

Supplementary Figure 1. *(A)* Advanced adenoma detection rate, *(B)* sessile serrated lesion detection rate, *(C)* advanced sessile serrated lesion detection rate, *(D)* advanced lesion detection rate, *(E)* lesions per colonoscopy, and *(F)* advanced lesions per colonoscopy during the pre-implementation and implementation periods in the CADe (computer-aided detection) site and control sites. *(G)* Advanced adenoma detection rate (AADR), *(H)* sessile serrated lesion detection rate (SSLDR), *(I)* advanced sessile serrated lesion detection rate (ASSLDR), *(J)* advanced lesion detection rate (ALDR), *(K)* lesions per colonoscopy (LPC), and *(L)* advanced lesions per colonoscopy (ALPC) during the preimplementation and implementation periods in the CADe site, aggregated by tertiles of endoscopist 12-month baseline metric-specific performance.

Supplementary Table 1. Patient Demographics, Colonoscopy Indications, Bowel Preparation Quality, Lesion Detection Rates, Procedure Times, and Non-Neoplastic Lesion Resection Rates in the Preimplementation and Implementation Periods in the CADe and Control Sites and Lesion Detection Rates by Tertiles of Metric-specific 12-Month Baseline Endoscopist Performance in the Preimplementation and Implementation Periods in the CADe Site

	CADe Site, Preimplementation Period	CADe Site, Implementation Period	Control Sites, Preimplementation Period	Control Sites, Implementation Period	Difference-in-Difference, Odds Ratio or Risk Ratio	*P* value[a]
Demographics						
No. of colonoscopies	619	619	538	553		
No. of endoscopists	24	24	27	28		
Female patients, n (%)	315 (50.9)	330 (53.3)	259 (48.1)	274 (49.5)		
Mean patient age, y (SD)	56.6 (10.1)	57.3 (10.3)	59.9 (10.4)	60.2 (10.8)		
Median patient age, y (interquartile range)	55 (49-64)	56 (49-65)	60 (51-68)	60 (51-69)		
Colonoscopy indication, n (%)						
Screening first	213 (34.4)	227 (36.7)	170 (31.6)	186 (33.6)		
Screening not first	160 (25.8)	163 (26.3)	158 (29.4)	166 (30.0)		
Surveillance	182 (29.4)	188 (30.4)	177 (32.9)	177 (32.0)		
Family history	64 (10.3)	41 (6.6)	33 (6.1)	24 (4.3)		
Mean Boston Bowel Preparation Scale score (95% CI)	8.4 (8.3-8.4)	8.4 (8.3-8.5)	8.3 (8.2-8.4)	8.2 (8.1-8.3)		
Lesion detection rates						
Adenoma detection rate (ADR) (95% CI)	41.8 (37.9-45.8)	40.1 (36.2-44.0)	40.7 (36.5-45.0)	35.8 (31.8-40.0)	1.14 (0.83-1.56)	.41
Advanced adenoma detection rate (95% CI)	8.1 (6.1-10.5)	6.8 (4.9-9.1)	7.6 (5.5-10.2)	8.1 (6.0-10.7)	0.77 (0.51-1.17)	.22
Sessile serrated lesion detection rate (95% CI)	9.9 (7.6-12.5)	9.2 (7.0-11.8)	9.1 (6.8-11.9)	8.0 (5.8-10.5)	1.05 (0.64-1.73)	.83
Advanced sessile serrated lesion detection rate (95% CI)	2.7 (1.6-4.4)	3.4 (2.1-5.1)	2.4 (1.3-4.1)	3.6 (2.2-5.5)	0.81 (0.39-1.68)	.58
Advanced lesion detection rate (95% CI)	10.7 (8.3-13.4)	9.7 (7.5-12.3)	10.0 (7.6-12.9)	11.4 (8.9-14.3)	0.79 (0.52-1.19)	.26
Mean APC (95% CI)	0.89 (0.77-1.02)	0.78 (0.68-0.90)	0.85 (0.73-0.98)	0.71 (0.60-0.85)	1.08 (0.80-1.45)	.63
Mean lesions per colonoscopy (95% CI)	1.04 (0.91-1.19)	0.91 (0.80-1.04)	0.97 (0.84-1.11)	0.86 (0.73 – 1.00)	0.99 (0.74-1.32)	.95
Mean advanced lesions per colonoscopy (95% CI)	0.12 (0.10-0.16)	0.11 (0.09-0.14)	0.12 (0.09-0.16)	0.15 (0.11-0.20)	0.75 (0.46-1.23)	.25
Procedure times and non-neoplastic lesion resection rates						
Mean total time, min (95% CI)	26.1 (25.3-26.9)	26.7 (25.8-27.6)	19.8 (19.2-20.5)	20.0 (19.1-20.9)	1.01 (0.91-1.11)	.91
Mean insertion time, min (95% CI)	8.5 (8.1-8.9)	8.6 (8.2-9.0)	6.8 (6.4-7.3)	7.1 (6.6-7.6)	0.97 (0.84-1.11)	.63
Mean withdrawal time, min (95% CI)	17.5 (16.7-18.2)	18.0 (17.2-18.8)	13.2 (12.5-13.9)	12.8 (12.1-13.5)	1.07 (0.95-1.20)	0.29
Mean total time when no polyp removed, min (95% CI)	22.7 (21.7-23.8)	25.3 (23.7-27.0)	18.5 (17.5-19.6)	17.9 (16.8-19.1)	1.10 (0.91-1.32)	.33
Mean total time when polyp removed, min (95% CI)[b]	28.2 (27.0-29.3)	27.5 (26.4-28.6)	20.7 (19.8-21.7)	21.9 (20.5-23.2)	0.95 (0.86-1.05)	.30
Mean insertion time when no polyp removed, min (95% CI)	9.2 (8.5-10.0)	8.9 (8.1-9.7)	7.8 (7.0-8.6)	7.7 (6.7-8.6)	0.97 (0.76-1.23)	.78

Supplementary Table 1. Continued

	CADe Site, Preimplementation Period	CADe Site, Implementation Period	Control Sites, Preimplementation Period	Control Sites, Implementation Period	Difference-in-Difference, Odds Ratio or Risk Ratio	*P* value[a]
Mean insertion time when polyp removed, min (95% CI)	8.1 (7.6-8.6)	8.4 (7.9-8.9)	6.2 (5.7-6.6)	6.6 (6.0-7.2)	0.99 (0.83-1.17)	.87
Mean withdrawal time when no polyp removed, min (95% CI)	13.4 (12.6-14.2)	16.3 (14.8-17.8)	10.7 (10.1-11.3)	10.1 (9.5-10.7)	1.26 (1.00-1.59)	.052
Mean withdrawal time when polyp removed, min (95% CI)[b]	20.0 (18.9-21.0)	19.0 (18.1-19.9)	14.9 (13.8-15.9)	15.2 (14.1-16.3)	0.96 (0.84-1.10)	.55
Mean non-neoplastic polypectomy per colonoscopy (95% CI)	0.7 (0.6-0.8)	0.8 (0.7-0.9)	0.5 (0.4-0.6)	0.4 (0.4-0.5)	1.35 (0.94-1.96)	.11

Lesion detection rates by tertiles of metric-specific 12-month baseline endoscopist performance in the preimplementation and implementation periods in the CADe site

	CADe Site, Preimplementation Period Detection Rate (95% CI)	CADe Site, Implementation Period Detection Rate (95% CI)
ADR		
Top	53.5 (47.0-60.0)	47.7 (41.3-54.2)
Middle	40.5 (33.4-48.0)	43.2 (36.0-50.7)
Bottom	28.5 (22.2-35.4)	27.5 (21.3-34.3)
Advanced adenoma detection rate		
Top	15.6 (11.2-20.9)	11.0 (7.3-15.7)
Middle	4.8 (2.5-8.3)	6.0 (3.4-9.8)
Bottom	0.7 (0.0-4.1)	0.7 (0.0-4.1)
Sessile serrated lesion detection rate		
Top	14.9 (11.0-19.6)	13.2 (9.5-17.7)
Middle	8.2 (4.5-13.4)	7.6 (4.1-12.6)
Bottom	2.5 (0.7-6.3)	3.8 (1.4-8.0)
Advanced sessile serrated lesion detection rate		
Top	4.6 (2.4-7.9)	5.7 (3.2-9.3)
Middle	2.4 (0.8-5.6)	2.0 (0.5-4.9)
Bottom	0.0 (0.0-2.4)	1.3 (0.2-4.7)
Advanced lesion detection rate		
Top	16.8 (12.6-21.8)	12.8 (9.1-17.4)
Middle	8.0 (4.7-12.5)	9.9 (6.2-14.7)
Bottom	2.2 (0.5-6.4)	3.0 (0.8-7.5)

	CADe Site, Preimplementation Period Mean (95% CI)	CADe Site, Implementation Period Mean (95% CI)
APC		
Top	1.31 (1.08-1.58)	0.96 (0.80-1.16)
Middle	0.73 (0.58-0.93)	0.81 (0.63-1.04)
Bottom	0.43 (0.33-0.57)	0.46 (0.35-0.61)
Lesions per colonoscopy		
Top	1.52 (1.28-1.81)	1.13 (0.94-1.35)
Middle	0.93 (0.74-1.17)	0.97 (0.79-1.18)
Bottom	0.46 (0.35-0.61)	0.52 (0.37-0.75)

Supplementary Table 1. Continued

	CADe Site, Preimplementation Period Mean (95% CI)	CADe Site, Implementation Period Mean (95% CI)
Advanced lesions per colonoscopy		
Top	0.21 (0.15-0.28)	0.15 (0.11-0.21)
Middle	0.10 (0.06-0.14)	0.11 (0.08-0.17)
Bottom	0.01 (0.00-0.06)	0.03 (0.01-0.08)

Values are n (%) unless otherwise defined.
[a]ADR was prespecified as the outcome for the primary analysis. Other analyses are secondary. These *P* values are not adjusted for multiplicity of tests.
[b]Includes the time needed to perform polypectomy.