

Clinical Efficacy of Real-Time Artificial Intelligence-Assisted Colonoscopy in Colorectal Polyp Detection: A Prospective Multicenter Randomized Controlled Trial

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Background/Aims: Early detection and removal of colon polyps are critical for preventing colorectal cancer. Computer-aided detection (CAdE) systems have been introduced to increase the polyp detection rate (PDR) during colonoscopy, potentially enhancing its effectiveness. This study aimed to evaluate the efficacy of a CAdE system in colorectal neoplasm detection.

Methods: This prospective, randomized controlled trial was conducted at two tertiary centers (May 2023 to April 2025). Patients were randomly assigned to CAdE or conventional colonoscopy and underwent screening, surveillance, or diagnostic colonoscopy. The primary endpoint was the adenoma detection rate (ADR), while the secondary endpoints were the PDR, relative risk (RR) of polyp detection, adenomas per colonoscopy (APC), and factors influencing adenoma detection.

Results: Of 1,004 enrolled patients, 998 were randomly allocated into CAdE and conventional colonoscopy groups (497 CAdE system and 501 conventional colonoscopy). The CAdE group had greater polyp counts (2.2 per colonoscopy vs 1.4 per colonoscopy; $p < 0.001$) and APC values (1.2 vs 0.8; $p < 0.001$). The CAdE group showed significantly higher PDRs (72.2% vs 54.5%; $p < 0.001$; RR, 2.173; 95% confidence interval [CI], 1.669 to 2.828) and ADRs (52.3% vs 36.1%; $p < 0.001$; RR, 1.940; 95% CI, 1.505 to 2.499). CAdE also significantly increased the detection rate of hyperplastic polyps ($p = 0.007$; RR, 1.474; 95% CI, 1.113 to 1.952) and increased the detection rates across all sizes and locations. In multivariable analysis, CAdE use was the strongest independent predictor of adenoma detection (odds ratio, 1.914; 95% CI, 1.467 to 2.496), outweighing male sex, older age, diagnostic indication, and withdrawal time.

Conclusions: Real-time CAdE-assisted colonoscopy significantly increased PDR and ADR and proved to be a strong independent predictor of adenoma detection (cris.nih.go.kr, KCT0009664). (*Gut Liver*, 2026;20:97-106)

Key Words: Artificial intelligence; Deep learning; Colonoscopy; Colorectal neoplasms; Adenoma detection rate

INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer globally and the second leading cause of cancer-related deaths. Notably, its incidence is rising among younger populations, with recent U.S. data showing an annual rise of 1% to 2% in those under 55 years of age.¹ In South Ko-

rea, CRC ranks second in overall cancer incidence and is the most prevalent malignancy among those aged 20 to 49.² Despite its distinct molecular and clinical features and frequent late-stage diagnosis, current screening strategies remain suboptimal for effectively reducing CRC burden at the population level.³ These trends underscore the continued relevance yet limited effectiveness of current strategies,

highlighting the need for more effective approaches to early detection and prevention.

Colonoscopy plays a central role in CRC screening by enabling real-time visualization and removal of precancerous lesions, particularly colonic polyps. However, variations in lesion morphology and operator performance can limit detection.⁴ Artificial intelligence (AI)-assisted systems, especially computer-aided detection (CADE) tools, have emerged to enhance mucosal inspection by identifying polyps in real time. Adenoma detection rate (ADR) is now widely recognized as a core quality indicator in colonoscopy, given its strong inverse association with interval CRC.⁵ In this context, CADe systems not only improve lesion detection but also reduce inter-operator variability, thereby contributing to standardization of colonoscopy quality.⁶ Although previous multicenter studies have been conducted, their short study durations and high baseline ADRs limit the applicability of their findings to broader clinical settings. Furthermore, inconsistent improvements in ADR and lack of sessile serrated lesion (SSL) analyses necessitate further validation of the clinical utility of CADe systems.⁷⁻¹³ Therefore, further well-designed, multicenter prospective trials are needed to evaluate the real-world efficacy of CADe systems.

To address these limitations, we conducted a prospective, multicenter randomized controlled trial to evaluate the real-world efficacy of a real-time CADe system in enhancing adenoma detection as a key quality indicator.

MATERIALS AND METHODS

This was a prospective, single-blind, randomized, multicenter trial conducted at two tertiary hospitals in South Korea. Patients were enrolled from May 2023 to April 2025 after obtaining IRB approval at each center (Ewha University Medical Center, IRB number: 2023-07-026; Korea University Medical Center, IRB number: 2023AN0234). The

study protocol was registered with the Clinical Research Information Service (CRIS; cris.nih.go.kr, registration number: KCT0009664) prior to patient enrollment. Written informed consent was obtained from all participants before undergoing colonoscopy.

1. CADe system

A deep learning-based CADe system (ENAD-DET-01, ENdoscropy as AI-powered Device; Ainex Corporation, Seoul, Korea) was trained and validated on 245,978 high-resolution images (adenoma, $n=140,639$, 57.2%; hyperplastic polyp, $n=80,368$, 37.7%; SSL, $n=23,755$, 9.7%; cancer, $n=1,216$, 0.5%) from 18,213 histologically confirmed polyps (adenoma, $n=10,052$, 55.2%; hyperplastic polyp, $n=6,731$, 37.0%; SSL, $n=1,114$, 6.1%; cancer, $n=316$, 1.7%), including colonoscopy videos and still images. The system demonstrated per-lesion sensitivity of 100.0% and a false-positive frame rate of 0.6%. ENAD-DET-01 directly receives digital input from the endoscopy processor and outputs a bounding circle only when a polyp is recognized (Fig. 1). Detections are overlaid in real time on the monitor to assist endoscopists. To enhance temporal stability, Kalman filtering is applied as post-processing. The system operates with negligible latency, ensuring seamless real-time feedback without disrupting workflow.

2. Study population, enrollment criteria

Eligible participants were adults aged 20 years or older undergoing colonoscopy for screening, postpolypectomy surveillance, or diagnostic colonoscopy for symptoms. Exclusion criteria included a history of colonic resection during screening, known polyposis syndrome with genetic mutations, inflammatory bowel disease or acute colitis, gastrointestinal bleeding, colonic obstruction, perforation, pregnancy, or a prior allergic reaction to sedatives. Participants with insertion failure or poor bowel preparation were excluded.

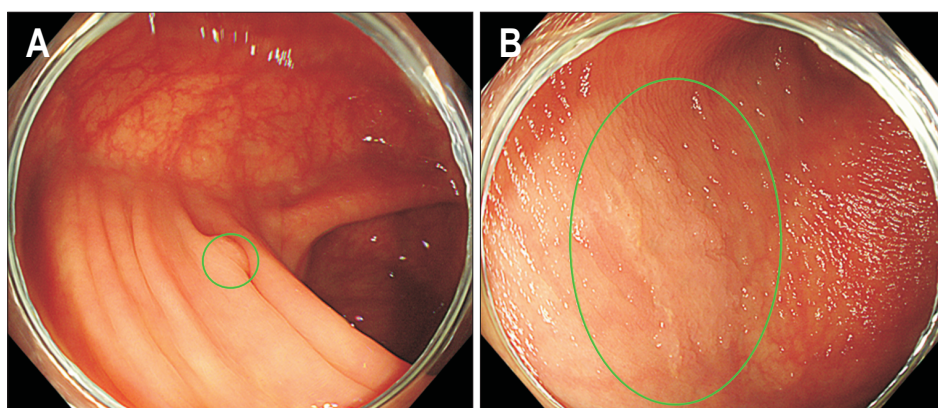


Fig. 1. Real-time highlighting of a polyp by the computer-aided detection system. (A) A small polyp less than 5-mm obscured by mucosal folds in the sigmoid colon. (B) A sessile serrated lesion with flat morphology in the transverse colon.

3. Randomization

Randomization was stratified by center to ensure balanced treatment allocation within each site. A separate computer-generated randomization list was allocated for each center using blocks of variable size (4–6). On the day of colonoscopy, eligible participants were randomized in a 1:1 ratio to either the CAdE or conventional colonoscopy group. Group assignment was concealed using a center-stratified block randomization scheme implemented through a password-protected web-based system to ensure allocation concealment. Patients were blinded to group allocation, whereas endoscopists and study investigators were unblinded.

4. Colonoscopy and procedure

Colonoscopy procedures were performed by experienced endoscopists with more than 500 prior cases.¹⁴ A total of nine endoscopists participated—six from Ewha University Medical Center and three from Korea University Medical Center. The same colonoscopy system was used across both centers (EVIS LUCERA CV-290 and HQ290, Olympus, Tokyo, Japan). All procedures began in white-light imaging mode; however, upon polyp detection, narrow-band imaging and near-focus views could be freely utilized in both groups. Colonoscopy procedure time was categorized into morning and afternoon sessions.

No procedures were performed during insertion. In the CAdE group, the AI software remained off during insertion and was activated after reaching the cecum. The software then assisted in polyp detection during withdrawal. For performance evaluation of the CAdE program, polyps were recorded as true positives only if they were clearly marked with a bounding box for more than 2 seconds and agreed upon by the endoscopist. False positives were defined as non-neoplastic findings (e.g., debris, stool, folds, bubbles, or scars) marked by the CAdE system for more than 2 seconds. Lesions deemed suspicious by the endoscopist but not identified by the CAdE from multiple angles were categorized as false negatives.

Bowel preparation methods were based on the preferences of each institution's endoscopist and included Haprep (2L PEG-Asc, Pharmbio Korea Co., Ltd., Chungju, Korea), Cleanviewal (1L PEG-Asc, Taejoon Pharm), Plenvu (1L PEG-Asc, Korea Pharma Co., Ltd., Seoul, Korea), and Orafang (oral sulfate tablets, Pharmbio Korea Co., Ltd.). For morning procedures, patients ingested half the bowel prep solution the evening before and the remainder early on the day of colonoscopy. Bowel cleanliness was assessed using the Boston Bowel Preparation Scale, with each of the three segments (left, right, transverse) scored from 0 to 3, and a total score ranging from 0 to 9. Inadequate bowel preparation was

defined as any segment scoring ≤ 1 or a total score < 6 .

5. Histopathology

All resected polyps were immediately immersed in 10% formaldehyde solution for 24 hours, after which they were processed into 2-mm slides and stained with hematoxylin and eosin. All specimens were routinely formalin-fixed and paraffin-embedded. The finalized slides were evaluated by gastrointestinal pathology specialists. All lesions were classified according to the Vienna classification.¹⁵

6. Outcomes and definition

The primary endpoint of this study was to evaluate the superiority of the CAdE system by comparing the ADR between the two groups. Secondary endpoints were (1) polyp detection rate (PDR) and the relative risk (RR) of polyp detection, (2) adenomas per colonoscopy (APC), and (3) analysis of factors influencing ADR. APC was defined as the number of conventional adenomas detected per colonoscopy. Cecal intubation time was defined as the time from anal insertion to the point when a photo of the appendix orifice was taken upon reaching the cecum. Withdrawal time was defined as the time taken from reaching the cecum to complete withdrawal of the colonoscope at the anus except procedure time. Procedure time was defined as the interval from polyp detection to its removal, and was separately recorded by an assistant. Total time was calculated from insertion to complete withdrawal, comprising the sum of insertion and withdrawal times.

Polyp morphology was categorized according to the Paris classification of superficial neoplastic lesions, with polypoid lesions (0-I) designated as pedunculated (Ip) or sessile (Is) and non-polypoid lesions (0-II) as flat.⁷ Polyp size was measured in millimeters using biopsy forceps and recorded by the endoscopist, then subsequently categorized using 5 mm and 10 mm thresholds. The location of each polyp was recorded and classified as follows: the cecum, ileocecal valve, and ascending colon as the right colon; hepatic flexure, transverse colon, and splenic flexure as the mid-colon; and descending colon, sigmoid colon, and rectum as the left colon.

7. Sample size calculation

The primary outcome of this study was the ADR, which served as the basis for the statistical sample size calculation. Based on prior convenience randomized controlled trials, an estimated 11% difference in ADR between the CAdE and conventional groups was assumed.⁸ The baseline ADR was set at 25.0%, in line with current guideline averages. Considering a two-sided test with an alpha value of 0.05 and a statistical power of 80%, the required sample

Table 1. Baseline Characteristics

Characteristic	Conventional colonoscopy group (n=501)	CADe group (n=497)	Total (n=998)	p-value
Age, mean±SD, yr	60.1±11.5	60.7±10.8	60.4±11.1	0.430*
Male sex, No. (%)	284 [56.7]	293 [59.0]	577 [57.8]	0.468 [†]
BMI, mean±SD, kg/m ²	24.2±3.8	24.6±3.6	24.4±3.7	0.109*
Indication, No. (%)				0.303 [†]
Screening	169 [33.7]	146 [29.4]	315 [31.6]	
Surveillance	191 [38.1]	196 [39.4]	387 [38.8]	
Diagnosis	141 [28.1]	155 [31.2]	296 [29.7]	
BBPS score, mean±SD				
Total score	7.2±1.5	7.2±1.5	7.2±1.5	0.735*
Right	2.3±0.6	2.3±0.6	2.3±0.6	0.461*
Middle	2.5±0.6	2.5±0.6	2.5±0.6	0.568*
Left	2.4±0.6	2.4±0.6	2.4±0.6	0.277*
At time, colonoscopy, No. (%)				0.825 [†]
Morning session	398 [79.4]	392 [78.9]	790 [79.2]	
Afternoon session	103 [20.6]	105 [21.1]	208 [20.8]	
Sedation, No. (%)				0.716 [†]
Sedation	484 [96.6]	478 [96.2]	962 [96.4]	
Non-sedation	17 [3.4]	19 [3.8]	36 [3.6]	
Total procedure time, mean±SD, min	16.7±9.5	19.2±11.0	18.0±10.3	<0.001*
Insertion time	4.7±3.4	4.6±2.6	4.7±3.0	0.375*
Procedure time	3.5±6.6	5.3±7.7	4.4±7.2	<0.001*
Withdrawal time	8.5±5.4	9.3±5.5	8.9±5.4	0.020*

CADe, computer-aided detection; BMI, body mass index; BBPS, Boston Bowel Preparation Score.

*Independent t-test; [†]Chi-square test.

size was calculated to be 272 colonoscopies per group (total of 544). After accounting for potential dropout, the minimum sample size was adjusted to 600 cases. Accordingly, the study aimed to enroll a total of 1,000 colonoscopy procedures across both participating centers.

8. Statistical method

RRs with 95% confidence intervals (CIs) were calculated to assess categorical differences between the two groups. To identify influencing factors on polyp and adenoma detection, univariate and multivariate logistic regression analyses were performed using a stepwise selection method. Categorical variables were analyzed using chi-square and fisher's exact test, while continuous variables were assessed using independent t-tests. A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

The baseline characteristics of the patients are presented in Table 1. A total of 1,004 patients were enrolled, with six excluded due to insertion failure or inadequate bowel preparation. The remaining 998 patients were randomized

to either the CADe system group (n=497) or the conventional colonoscopy group (n=501) (Fig. 2). The mean age of the participants was 60.4 years, and the mean body mass index was 24.4 kg/m². Most procedures were performed in the morning under sedation. The mean total procedure time was 18 minutes, with a mean insertion time of 4 minutes, procedure time of 4.4 minutes, and withdrawal time of 8.9 minutes.

The characteristics of all detected polyps and adenomas are summarized in Table 2. Among the 998 patients, polyps were identified in 632 individuals, with a total of 1,755 polyps detected. The mean number of polyps detected per colonoscopy was significantly higher in the CADe group (2.2) compared to the conventional group (1.4). There was no significant difference in polyp size between the two groups. Adenomas accounted for 55% and 56% of all polyps in the conventional and CADe groups, respectively. The majority of detected polyps were small-sized and sessile, and nearly half were located in the left colon.

The PDR was significantly higher in the CADe group at 72.2%, compared to 54.5% in the conventional group, with statistically significant differences observed across all colon segments. Similarly, the ADR was significantly higher in the CADe group (52.3% vs 36.1%). No significant differences were noted between the groups in the detection rates of SSLs or CRC. Among benign tumors, the overall detec-

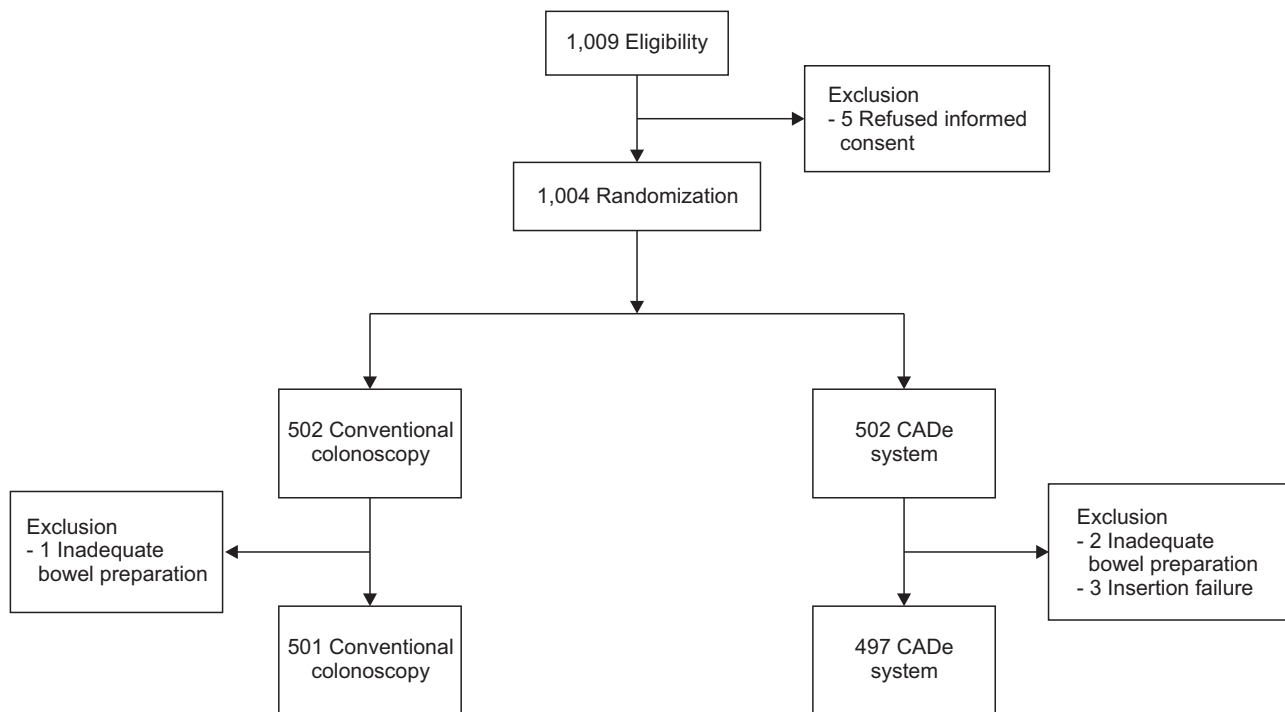


Fig. 2. Flowchart of patient enrollment. CAdE, computer-aided detection.

tion rate of hyperplastic polyps was higher in the CAdE group, particularly in the mid-colon (4.0% vs 9.9%) (Table 3).

Table 4 presents a per-polyp analysis based on histology, polyp size, morphology, and location. Overall, the CAdE group demonstrated a significantly higher detection rate for all polyps (RR 2.173, 95% CI, 1.669 to 2.828). Detection rates for adenomas and hyperplastic polyps were also significantly increased in the CAdE group, with RRs of 1.940 and 1.474, respectively. Across all size categories, the CAdE group identified significantly more polyps. In terms of morphology, detection rates were higher in the CAdE group for all types except flat lesions. Additionally, CAdE significantly improved detection across all colonic segments.

In the multivariable logistic regression analysis, male sex, older age, the use of CAdE, diagnostic colonoscopy, and longer withdrawal time were significantly associated with increased odds of adenoma detection. Among all evaluated factors, the use of the CAdE system showed the highest odds ratio for adenoma detection (OR, 1.914), indicating a strong association (95% CI, 1.467 to 2.496) (Table 5).

DISCUSSION

This study was a multicenter, single-blind, randomized

clinical trial designed to evaluate the clinical efficacy of a CAdE system over conventional colonoscopy in polyp and adenoma detection. The primary endpoint of the study was to evaluate whether the use of AI-based CAdE system leads to a superior ADR compared to conventional colonoscopy. The CAdE system significantly improved overall polyp detection. It increased the detection of diminutive polyps (1–5 mm) by 1.39-fold and enhanced detection of pedunculated and sessile polyps by 71.3% and 88.0%, respectively. Detection rates improved consistently across all colonic segments (66.1% to 74.8%). Furthermore, use of CAdE system increased APC and improved ADR (difference, 16.2%; RR, 1.940; OR, 1.914). Our findings provide robust and generalizable evidence that CAdE not only significantly increases overall PDR and ADR but also alters the detection pattern across polyp histology, morphology, and location. This study contributes insights into optimizing polyp detection strategies and offers clinical justification for broader implementation of CAdE systems in routine colonoscopic practice.

The ADR during colonoscopy is widely used as a key quality indicator and is known to be inversely associated with the incidence of interval CRC. However, because most endoscopy reporting systems do not routinely incorporate histopathological assessment, calculating ADR can be cumbersome. As a result, the PDR has been adopted as a surrogate marker for ADR.¹⁶ PDR can be calculated immediately without the need for pathology results, mak-

Table 2. Polyp and Adenoma Characteristics

Characteristic	Conventional colonoscopy (n=501)	CADe system (n=497)	Total (n=998)	p-value
No. of total polyps during colonoscopy	683	1,072	1,755	NA
No. of polyps per colonoscopy, mean±SD	1.4±2.0	2.2±2.6	1.8±2.3	<0.001 [†]
Size of polyp per polyp, mean±SD, mm	5.8±4.6	5.8±4.8	5.8±4.7	0.748 [‡]
Polyps pathology, No. (%)				0.699 [‡]
Adenoma*	380 [55.6]	602 [56.2]	982 [56.0]	
Hyperplastic	182 [26.6]	306 [28.5]	488 [27.8]	
SSL	21 [3.1]	31 [2.9]	52 [3.0]	
Cancer	7 [1.0]	10 [0.9]	17 [1.0]	
Inflammatory polyp or normal mucosa	93 [13.6]	123 [11.5]	216 [12.3]	
Polyp size category, No. (%)				0.582 [‡]
Diminutive (1–5 mm)	428 [62.7]	696 [64.9]	1,124 [64.0]	
Small (6–9 mm)	168 [24.6]	242 [22.6]	410 [23.4]	
Large (≥10 mm)	87 [12.7]	134 [12.5]	221 [12.6]	
Polyp morphology, No. (%)				0.218 [‡]
Pedunculated	54 [7.9]	89 [8.3]	143 [8.1]	
Sessile	581 [85.1]	929 [86.7]	1,510 [86.0]	
Flat	48 [7.0]	54 [5.0]	102 [5.8]	
Polyp location, No. (%)				0.265 [‡]
Right	204 [29.9]	286 [26.7]	490 [27.9]	
Middle	167 [24.5]	258 [24.1]	425 [24.2]	
Left	312 [45.7]	528 [49.3]	840 [47.9]	
No. of total adenoma during colonoscopy	380	602	982	NA
No. of APC, mean±SD	0.8±1.5	1.2±1.8	1.0±1.7	<0.001 [†]
Size of adenomas per adenoma, mean±SD, mm	5.8±4.4	6.0±4.6	5.9±4.5	0.613 [‡]
Adenoma size category, No. (%)				0.800 [‡]
Diminutive (1–5 mm)	226 [59.5]	362 [60.1]	588 [59.9]	
Small (6–9 mm)	108 [28.4]	161 [26.7]	269 [27.4]	
Large (≥10 mm)	46 [12.1]	79 [13.1]	125 [12.7]	
Adenoma morphology, No. (%)				0.767 [‡]
Pedunculated	44 [11.6]	63 [10.5]	107 [10.9]	
Sessile	322 [84.7]	520 [86.4]	842 [85.7]	
Flat	14 [3.7]	19 [3.2]	33 [3.4]	
Adenoma location, No. (%)				0.020 [‡]
Right	127 [33.4]	175 [29.1]	302 [30.8]	
Middle	110 [28.9]	146 [24.3]	256 [26.1]	
Left	143 [37.6]	281 [46.7]	424 [43.2]	

CADe, computer-aided detection; NA, not available; SSL, sessile serrated lesion; APC, adenomas per colonoscopy; HGD, high grade dysplasia.

*Advanced adenomas (n=4; HGD or villous): conventional 1 (0.2%), CADe 3 (0.6%); histology: 1 villous adenoma, 3 HGD adenomas; [†]Independent t-test; [‡]Chi-square test.

ing it a more practical indicator in clinical settings. In this study, the PDR was significantly higher in the CADe group compared to the control group (72.2% vs 54.5%), demonstrating the superiority of CADe-assisted colonoscopy in enhancing polyp detection. Among these outcomes, ADR increased by 16.2% with CADe use (52.3%) compared to the non-CADe group (36.1%). This significantly exceeds the standard recommendation of 40% for male patients.¹⁷ However, the use of the CADe system did not significantly improve SSL detection rate (SSLDR) or cancer detection in current study. This may be attributed to the relatively low prevalence of SSLs and cancers compared to adenomas, the subtle and flat morphology of SSLs that challenges current CADe algorithms, and the possibility that the system was

primarily trained on conventional adenomas rather than SSLs or advanced neoplasia.

In a study evaluating the polyp detection effect of a Chinese CADe system, routine colonoscopy demonstrated a PDR of 29.1%, whereas CADe-assisted colonoscopy achieved a higher detection rate (45.0% vs 29.1%), with ADR improved from 20.3% to 29.1% (95% CI, 1.213 to 2.135), confirming its efficacy.⁷ Another study reported an ADR of 54.8% with the CADe system, compared to 40.4% with conventional colonoscopy. This 14.4% difference was interpreted as reflecting the miss rate of conventional colonoscopy.¹⁸ Another study reported that the use of a CADe program resulted in an ADR as high as 71.4%, compared to 65.0% in the control group.¹¹ A key point to note in ran-

domized controlled trials utilizing CAdE programs is the remarkable increase in ADR. These findings suggest that the CAdE system contributes to the detection of subtle lesions that might otherwise be overlooked by endoscopists.

Table 3. Detection Rate Stratified by Polyp Pathology and Location

Variable	Conventional colonoscopy (n=501)	CAdE system (n=497)	p-value
PDR, No. (%)	273 (54.5)	359 (72.2)	<0.001*
Right	126 (25.1)	178 (35.8)	<0.001*
Middle	107 (21.4)	160 (32.2)	<0.001*
Left	180 (35.9)	244 (49.1)	<0.001*
ADR, No. (%)	181 (36.1)	260 (52.3)	<0.001*
Right	81 (16.2)	117 (23.5)	0.003*
Middle	77 (15.4)	101 (20.3)	0.041*
Left	98 (19.6)	163 (32.8)	<0.001*
SSLDR, No. (%)	15 (3.0)	25 (5.0)	0.101*
Right	8 (1.6)	12 (2.4)	0.357*
Middle	4 (0.8)	9 (1.8)	0.158*
Left	4 (0.8)	7 (1.4)	0.356*
CDR, No. (%)	6 (1.2)	10 (2.0)	0.306*
Right	0	2 (0.4)	0.155*
Middle	0	4 (0.8)	0.064 [†]
Left	6 (1.2)	4 (0.8)	0.753 [†]
HPDR, No. (%)	117 (23.4)	154 (31.0)	0.007*
Right	32 (6.4)	47 (9.5)	0.073*
Middle	20 (4.0)	49 (9.9)	<0.001*
Left	83 (16.6)	101 (20.3)	0.126*

CAdE, computer-aided detection; PDR, polyp detection rate; ADR, adenoma detection rate; SSLDR, sessile serrated lesion detection rate; CDR, cancer detection rate; HPDR, hyperplastic polyp detection rate.

*Chi-square test; [†]Fisher exact test.

Furthermore, this supports the clinical utility of CAdE in improving ADRs, which is crucial for the prevention of CRC. However, the variability in results across studies warrants careful consideration. First, it is necessary to analyze whether the differences are attributable to variations among CAdE systems. Second, differences in adenoma prevalence across study populations may contribute to the observed discrepancies. Third, variability in endoscopist skill levels is also likely to influence ADR outcomes. These factors may collectively account for the differences in ADR reported across studies. Therefore, to accurately assess the effectiveness of CAdE systems, well-designed studies that include head-to-head comparisons of different systems and control for lesion characteristics and operator-related variables are essential. Additionally, future research should incorporate subgroup analyses based on patient demographics and adenoma distribution to ensure a more comprehensive evaluation.

When comparing detection rates by anatomical location, the CAdE system tends to improve detection more evenly in the right colon than in the left. This may reflect the higher baseline polyp prevalence typically seen in the left colon. Hyperplastic polyps are more frequently encountered in the left colon and generally have low malignant potential.¹⁹ In contrast, SSLs are more commonly found in the right colon and are associated with a higher risk of progression to CRC, particularly through the serrated neoplasia pathway.²⁰ Given these anatomical and pathological distinctions, the ability of CAdE systems to

Table 4. Polyp Detection Rates and Relative Risks According to Polyp Characteristics in CAdE and Conventional Colonoscopy Group

Polyp characteristic	Conventional colonoscopy (n=501)	CAdE system (n=497)	Total (n=998)	RR	95% CI
Histology, No. (%)					
All polyps	273 (54.5)	359 (72.2)	631 (63.2)	2.173	1.669–2.828
Adenoma	181 (36.1)	260 (52.3)	441 (44.2)	1.940	1.505–2.499
Hyperplastic polyp	117 (23.4)	154 (31.0)	271 (27.2)	1.474	1.113–1.952
SSL	15 (3.0)	25 (5.0)	40 (4.0)	1.716	0.894–3.296
Cancer	6 (1.2)	10 (2.0)	16 (1.6)	1.694	0.611–4.697
Inflammatory polyp or normal mucosa	62 (12.4)	79 (15.9)	141 (14.1)	1.338	0.935–1.915
Size category, No. (%)					
1–5 mm	142 (28.3)	176 (35.4)	318 (31.9)	1.386	1.061–1.811
6–9 mm	66 (13.2)	90 (18.1)	156 (15.6)	1.457	1.032–2.058
≥10 mm	65 (13.0)	93 (18.7)	158 (15.8)	1.544	1.094–2.179
Morphology, No. (%)					
Pedunculated	32 (6.4)	52 (10.5)	84 (8.4)	1.713	1.082–2.710
Sessile	250 (49.9)	324 (65.2)	574 (57.5)	1.880	1.458–2.425
Flat	27 (5.4)	37 (7.4)	64 (6.4)	1.412	0.846–2.357
Location, No. (%)					
Right colon	126 (25.1)	178 (35.8)	304 (30.5)	1.661	1.264–2.181
Middle colon	107 (21.4)	160 (32.2)	267 (26.8)	1.748	1.315–2.324
Left colon	180 (35.9)	244 (49.1)	424 (42.5)	1.720	1.335–2.216

CAdE, computer-aided detection; RR, relative risk; CI, confidence interval; SSL, sessile serrated lesion.

Table 5. Univariate and Multivariate Logistic Regression Analysis for Factors Associated with Adenoma Detection Rate

Variable	Univariate logistic regression analysis			Multivariate logistic regression analysis		
	p-value	OR	95% CI	p-value	OR	95% CI
Age	<0.001	1.636	1.265–2.117	<0.001	1.672	1.273–2.196
Sex (ref. female)	<0.001	1.047	1.034–1.061	<0.001	1.050	1.036–1.064
BMI	0.139	1.026	0.992–1.061			
CADe system use (ref. non-use)	<0.001	1.932	1.499–2.490	<0.001	1.914	1.467–2.496
Indication (ref. diagnostic)						
Screening	0.264	0.781	0.507–1.205	0.012	0.642	0.455–0.906
Surveillance	0.171	0.771	0.531–1.119	0.004	0.620	0.447–0.861
BBPS	0.941	0.995	0.881–1.124			
Session time (ref. afternoon)	0.540	1.102	0.808–1.504			
Withdrawal time	0.001	1.045	1.018–1.073	0.021	1.030	1.004–1.057

OR, odds ratio; CI, confidence interval; BMI, body mass index; CADe, computer-aided detection; BBPS, Boston Bowel Preparation Score.

enhance detection in the right colon is particularly relevant for SSL identification. In the present study, the SSLDR was 5% in the AI group and 3% in the non-AI group, showing no statistical significance but a trend toward higher detection with the CADe system across all segments. A recent Korean study reported a similar SSLDR of 5.7% with AI, and a significantly higher detection rate with CADe compared to non-AI colonoscopy (5.7% vs 2.5%).²¹ These differences in SSLDR across studies may be explained by several factors. Variation in endoscopist expertise and attentiveness to subtle serrated lesions may have contributed to the observed differences. Additionally, interobserver variability in pathological interpretation of SSLs across centers may have affected the reported detection rates.

We evaluated the effect of CADe exposure on the probability of polyp detection using RR. Specifically, the ADR increased from 36.1% in the non-CADe group to 52.3% in the CADe group, reflecting a 16.2% improvement. The RR for all neoplastic polyps was 2.17, suggesting that CADe substantially contributed to the detection of neoplastic lesions, including adenomas. Notably, CADe significantly improved hyperplastic polyp detection, consistent with prior study.⁷ In addition to enhancing ADR, it may help reduce interval CRC by improving subtle lesion detection and standardizing colonoscopy quality. CADe use notably improved the detection of small polyps (1–5 mm) (RR, 1.39), which are often missed during visual inspection. This may support its potential role in early lesion identification and, from a long-term perspective, in CRC prevention. Detection was also significantly improved in the right and middle colon (RR, 1.661 and 1.748, respectively), regions typically associated with a higher risk of interval cancers, indicating the strategic value of CADe in these anatomically challenging areas. However, statistical significance was not reached for certain lesions such as serrated polyps, cancers, and flat lesions, likely due to small sample

sizes. Further investigation is warranted to determine whether this reflects a limitation of current deep learning algorithms.

In the analysis of factors influencing polyp detection, after adjusting for other variables, the use of the CADe system was associated with an approximately 1.914-fold increase in the likelihood of adenoma detection. This implies that the use of AI can improve ADR and, in turn, reduce the risk of cancer development or progression of advanced lesions.²² Underlining its clinical relevance, AI-assisted colonoscopy may contribute to lowering the risk of metachronous advanced neoplasia following polypectomy. An interesting finding is that the odds of adenoma detection were approximately 36% and 38% lower in screening and surveillance colonoscopies, respectively, compared to diagnostic colonoscopy (screening: OR, 0.642; $p=0.012$; surveillance: OR, 0.620; $p=0.004$). This may be attributed to the higher lesion prevalence in symptomatic patients undergoing diagnostic colonoscopy, whereas screening and surveillance target asymptomatic individuals with lower baseline lesion rates.²³ In surveillance, prior lesion removal may further reduce target lesions, potentially limiting the benefit of CADe.²⁴ Additionally, male sex and older age—both established risk factors—may be linked to unhealthy lifestyle choices such as smoking and alcohol consumption.²⁵

Compared with the false-positive rates reported in other studies (5.4% to 12.3%),²⁶ the false-positive rate in our study indicated 8.7%, meaning that 1 in 12 negative colonoscopies triggered at least one false alarm. In practice, most false alerts resolved within seconds, the effect on withdrawal time was minimal, and ADR gains were preserved, indicating an acceptable clinical balance. However, when visualization is suboptimal, workload may increase, and this can be addressed by threshold tuning and related measures.

Currently, CAdE remains in early clinical implementation and its cost is not yet defined. With wider adoption and technical refinement, costs should fall and routine use will be more feasible. Beyond improving ADR, CAdE may reduce operator burden and fatigue, improve efficiency, and lower long-term healthcare costs through earlier prevention, supporting its economic and clinical value in real-world practice. Our study has several limitations. First, the miss rate of adenomas and polyps was not assessed. The number of lesions, particularly adenomas and polyps, that were truly present but not identified during the procedure was not assessed or quantified. While ADR and PDR represent the proportion of detected lesions, they do not provide information on how many lesions were missed. In a U.S. multicenter randomized controlled trial, the CAdE system reduced the adenoma miss rate (20.12% vs 31.25%; OR, 1.80; 95% CI, 1.08 to 3.02; $p=0.0247$) and increased the number of APC (1.19 ± 2.03 vs 0.90 ± 1.55 , $p=0.0323$) compared to conventional colonoscopy.⁹ ADR alone does not capture missed lesions.⁹ A second-look endoscopy would be required to accurately determine the miss rate, but this was not feasible due to design limitations and practical constraints. This limitation may have led to an overestimation of the diagnostic performance of the CAdE system. Second, endoscopist capability is known to play an important role in ADR.²⁷ Factors such as withdrawal technique and endoscopic style, in addition to endoscopist fatigue as suggested in previous studies, may influence ADR. Therefore, the results may not fully account for the influence of operator skill level or procedural setting. Future studies should aim to control for or incorporate these variables in the analysis to provide a more comprehensive evaluation. Last, withdrawal time differed significantly (8.5 minutes vs 9.3 minutes) and was associated with ADR. Withdrawal time differed modestly between groups and was independently associated with ADR. However, the magnitude of this difference is too small to plausibly account for the large ADR improvement observed with CAdE. Notably, CAdE use remained associated with higher ADR after adjustment for withdrawal time and other covariates, indicating an effect beyond additional inspection time.

In conclusion, this multicenter randomized trial demonstrated that CAdE significantly improves real-time detection of colorectal polyps and adenomas. Incorporating CAdE into routine colonoscopy practice may serve as a key strategy to standardize quality and further reduce the burden of CRC.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

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AUTHOR CONTRIBUTIONS

Study concept and design: H.J.J., B.K., E.S.J., S.K. Data acquisition: H.J.J., B.L., S.H.K., H.S.C., E.S.K., E.S.J., S.K., C.M.M. Data analysis and interpretation: H.J.J., E.S.J. Drafting of the manuscript: H.J.J. Critical revision of the manuscript for important intellectual content: B.K., E.S.J., S.E.K., C.M.M., B.L., S.K., H.S.C., J.M.L., E.S.K., Y.T.J. Statistical analysis: H.J.J. Obtained funding: B.K. Administrative, technical, or material support: B.K., J.M.L., E.S.K. Study supervision: B.K., H.J.C. Approval of final manuscript: all authors.

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DATA AVAILABILITY STATEMENT

Data analyzed in this study are available from the corresponding author upon reasonable request.

REFERENCES

1. Siegel RL, Wagle NS, Cercek A, Smith RA, Jemal A. Colorec-

- tal cancer statistics, 2023. *CA Cancer J Clin* 2023;73:233-254.
2. Jung KW, Kang MJ, Park EH, et al. Prediction of cancer incidence and mortality in Korea, 2024. *Cancer Res Treat* 2024; 56:372-379.
3. Akimoto N, Ugai T, Zhong R, et al. Rising incidence of early-onset colorectal cancer: a call to action. *Nat Rev Clin Oncol* 2021;18:230-243.
4. Lee J, Cho WS, Kim BS, et al. Impact of user's background knowledge and polyp characteristics in colonoscopy with computer-aided detection. *Gut Liver* 2024;18:857-866.
5. Rex DK, Anderson JC, Butterly LF, et al. Quality indicators for colonoscopy. *Gastrointest Endosc* 2024;100:352-381.
6. Makar J, Abdelmalak J, Con D, Hafeez B, Garg M. Use of artificial intelligence improves colonoscopy performance in adenoma detection: a systematic review and meta-analysis. *Gastrointest Endosc* 2025;101:68-81.e8.
7. Wang P, Berzin TM, Glissen Brown JR, et al. Real-time automatic detection system increases colonoscopic polyp and adenoma detection rates: a prospective randomised controlled study. *Gut* 2019;68:1813-1819.
8. Hassan C, Spadaccini M, Iannone A, et al. Performance of artificial intelligence in colonoscopy for adenoma and polyp detection: a systematic review and meta-analysis. *Gastrointest Endosc* 2021;93:77-85.e6.
9. Glissen Brown JR, Mansour NM, Wang P, et al. Deep learning computer-aided polyp detection reduces adenoma miss rate: a United States multi-center randomized tandem colonoscopy study (CADET-CS Trial). *Clin Gastroenterol Hepatol* 2022;20:1499-1507.e4.
10. Quan SY, Wei MT, Lee J, et al. Clinical evaluation of a real-time artificial intelligence-based polyp detection system: a US multi-center pilot study. *Sci Rep* 2022;12:6598.
11. Ahmad A, Wilson A, Haycock A, et al. Evaluation of a real-time computer-aided polyp detection system during screening colonoscopy: AI-DETECT study. *Endoscopy* 2023;55: 313-319.
12. Seager A, Sharp L, Neilson LJ, et al. Polyp detection with colonoscopy assisted by the GI Genius artificial intelligence endoscopy module compared with standard colonoscopy in routine colonoscopy practice (COLO-DETECT): a multi-centre, open-label, parallel-arm, pragmatic randomised controlled trial. *Lancet Gastroenterol Hepatol* 2024;9:911-923.
13. Park DK, Kim EJ, Im JP, et al. A prospective multicenter randomized controlled trial on artificial intelligence assisted colonoscopy for enhanced polyp detection. *Sci Rep* 2024;14:25453.
14. Spier BJ, Benson M, Pfau PR, Nelligan G, Lucey MR, Gaumnitz EA. Colonoscopy training in gastroenterology fellowships: determining competence. *Gastrointest Endosc* 2010;71:319-324.
15. Schlemper RJ, Riddell RH, Kato Y, et al. The Vienna classification of gastrointestinal epithelial neoplasia. *Gut* 2000;47:251-255.
16. Murphy B, Myers E, O'Shea T, Feeley K, Waldron B. Correlation between adenoma detection rate and polyp detection rate at endoscopy in a non-screening population. *Sci Rep* 2020;10:2295.
17. Rex DK, Anderson JC, Butterly LF, et al. Quality indicators for colonoscopy. *Am J Gastroenterol* 2024;119:1754-1780.
18. Repici A, Badalamenti M, Maselli R, et al. Efficacy of real-time computer-aided detection of colorectal neoplasia in a randomized trial. *Gastroenterology* 2020;159:512-520.e7.
19. Turner JS, Henry D, Chase A, Kpodzo D, Flood MC, Clark CE. Adenoma detection rate in colonoscopy: does the participation of a resident matter? *Am Surg* 2018;84:1064-1068.
20. Kim SY, Kwak MS, Yoon SM, et al. Korean Guidelines for Postpolypectomy Colonoscopic Surveillance: 2022 revised edition. *Intest Res* 2023;21:20-42.
21. Park JB, Bae JH. Effectiveness of a novel artificial intelligence-assisted colonoscopy system for adenoma detection: a prospective, propensity score-matched, non-randomized controlled study in Korea. *Clin Endosc* 2025;58:112-120.
22. Gupta S, Earles A, Bustamante R, et al. Adenoma detection rate and clinical characteristics influence advanced neoplasia risk after colorectal polypectomy. *Clin Gastroenterol Hepatol* 2023;21:1924-1936.e9.
23. Corley DA, Jensen CD, Marks AR, et al. Adenoma detection rate and risk of colorectal cancer and death. *N Engl J Med* 2014;370:1298-1306.
24. Hassan C, Spadaccini M, Mori Y, et al. Real-time computer-aided detection of colorectal neoplasia during colonoscopy: a systematic review and meta-analysis. *Ann Intern Med* 2023;176:1209-1220.
25. Shrubsole MJ, Wu H, Ness RM, Shyr Y, Smalley WE, Zheng W. Alcohol drinking, cigarette smoking, and risk of colorectal adenomatous and hyperplastic polyps. *Am J Epidemiol* 2008;167:1050-1058.
26. Lee JY, Jeong J, Song EM, et al. Real-time detection of colon polyps during colonoscopy using deep learning: systematic validation with four independent datasets. *Sci Rep* 2020;10:8379.
27. Atkins L, Hunkeler EM, Jensen CD, et al. Factors influencing variation in physician adenoma detection rates: a theory-based approach for performance improvement. *Gastrointest Endosc* 2016;83:617-626.e2.