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Original Research Article

Evaluation of Artificial Intelligence: Computer-aided Detection of Colorectal Polyps

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Abstract

Objectives: Colonoscopy is the gold standard for screening cancer and precancerous lesions in the large intestine. Recently, remarkable advances in artificial intelligence (AI) have led to the development of various computer-aided detection (CADe) systems for colonoscopy. This study aimed to evaluate the usefulness of AI for colonoscopy using CAD-EYE® (Fujifilm, Tokyo, Japan) to calculate the adenoma miss rate (AMR).

Methods: This randomized, open-label, single-center, tandem study was conducted at Fukuoka University Chikushi Hospital from February 2022 to November 2022. Patients were randomly assigned to the CADe or non-CADe group. Immediately after the completion of the first endoscopy by an endoscopist, a new endoscopist was assigned to perform the second endoscopy. As a result, different endoscopists performed the examinations in a tandem fashion. A missed lesion was defined as a newly detected colorectal polyp by the second endoscopy. Finally, the AMR was compared between the two groups.

Results: The study population comprised 48 patients in the CADe group and 46 patients in the non-CADe group. The AMR was 17.4% in the CADe group and 30.3% in the non-CADe group. Therefore, the AMR in the CADe group was statistically significantly lower than that in the non-CADe group (P=0.009).

Conclusions: The application of CAD-EYE® to colonoscopy reduced the AMR. Overall, CAD-EYE® might be useful for reducing missed colorectal adenomas.

Keywords

artificial intelligence, computer-aided detection, adenoma miss rate, adenoma detection rate

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Introduction

Colonoscopy is the gold standard for detecting cancer and precancerous lesions in the large intestine[1]. However, 22-28% of polyps[2-4] and 6-41% of adenomas[5,6] are missed by colonoscopy. Reducing the rate of missed lesions through consistent approaches has been difficult as the techniques, examination methods, etc. vary among endoscopists.

Recently, remarkable advances in artificial intelligence (AI) have led to the development of various computer-aided detection (CADe) systems for colonoscopy, which are attracting attention. Colonoscopy with AI was found to significantly increase the adenoma detection rate (ADR) and polyp detection rate (PDR) compared with colonoscopy without AI[7].

In Japan, CAD-EYE® (Fujifilm, Tokyo, Japan) was recently approved as a medical device that uses AI technology[8]. The CAD-EYE® system may allow accurate detec-

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tion of colorectal polyps and reduce the number of missed adenomas[9-12]. However, only a few reports have highlighted the ability of CAD-EYE® to detect colorectal adenomas[13,14]. Therefore, we conducted this randomized controlled trial to evaluate the usefulness of the CAD-EYE system for decreasing the adenoma miss rate (AMR).

Methods

Study design and participants

We conducted a randomized, open-label, single-center, tandem study at Fukuoka University Chikushi Hospital from February 2022 to November 2022. This clinical study was performed in accordance with the Consolidated Standards of Reporting Trial (CONSORT) statement and complied with the Declaration of Helsinki. The study was approved by the Institutional Review Board of Fukuoka University and registered with the University Hospital Medical Information Network (UMIN 000046502).

Patients aged ≥ 20 years who were scheduled for lower gastrointestinal endoscopy were enrolled in the present study. Patients were randomly assigned to the group examined with AI (CADe group) or the group examined without AI (non-CADe group). Thereafter, the first endoscopy was performed. Immediately after the completion of the first endoscopy, a new endoscopist was assigned to perform the second endoscopy. A missed lesion was defined as a newly detected colorectal polyp by the second endoscopy. The AMR were then compared between the two groups. Exclusion criteria were as follows: 1. Patients who had previously undergone colectomy; 2. Patients with inflammatory bowel disease (IBD), familial adenomatous polyposis (FAP), or other polyposis; 3. Patients experiencing difficulty with deep insertion; and 4. Patients deemed difficult to safely examine, such as those with advanced dementia. Patients who met the inclusion criterion and did not meet the exclusion criteria were enrolled in the present study. Written informed consent was obtained from all patients. As mentioned in the informed consent document, participants could freely withdraw their consent to participate in the study at any time.

In all examinations, a biopsy was performed on all detected colorectal polyps. However, whitish polyps and small polyps of the sigmoid colon of the rectum that were determined to be endoscopically hyperplastic polyps were excluded. In the second endoscopy, the lesions that had been biopsied were recognized as the lesions detected by the first endoscopy; additional biopsy was not performed on these lesions. The examining endoscopists recorded the location of the colorectal polyps, macroscopic type, tumor size, and level of bowel preparation on the case report form (CRF) following completion of the examination. The examination time was later determined from the video recordings and defined as the time excluding the polyp observation time and the time of biopsy performance from the entire duration of the examination. Upon confirmation of the histopathological diagnosis of biopsy specimens, the CRF was filled and stored. An expert was defined as an endoscopist with ≥ 10 years of experience in performing endoscopy, and a non-expert was defined as an endoscopist with < 10 years of experience in performing endoscopy. In addition, all lesions requiring resection were endoscopically resected at a later date.

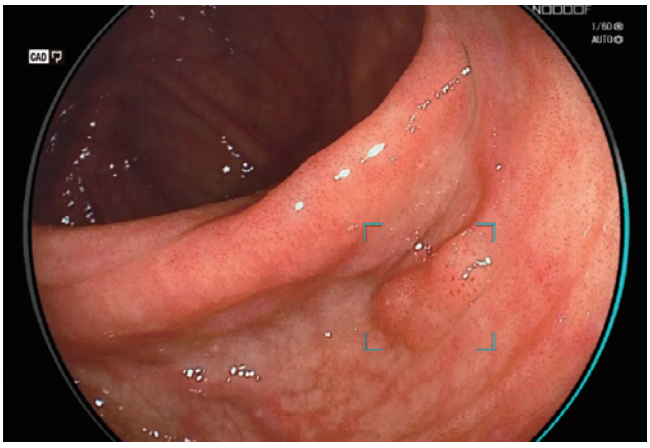

Figure 1. Function of CAD-EYE®. For CADe, a polyp is surrounded by the annotation box when CAD EYE® detects a polyp with WLI. Upon recognition, an alarm is then activated to draw attention to the polyp in approximately 0.2–0.3 s.

Intervention (endoscopy system)

A Fujifilm-manufactured endoscope system (ELUXEO 7000, FUJIFILM Co., Tokyo, Japan) was employed in this study. The endoscope was EC-760ZP (FUJIFILM Co., Tokyo, Japan). The above-mentioned system with a function expansion unit, "EX-1," in which the "EW10-EC02" software was installed, served as the system equipped with CADe function (CAD-EYE®, FUJIFILM Co., Tokyo, Japan). CAD-EYE® is a system that assists with endoscopic diagnostic imaging and differntial diagnosis by detecting areas that appear to be colorectal polyps in real time (shown in Figure 1). For the lesion detection assist function, this system analyzes the endoscopic images received from the processor, detects areas of potential lesions, and displays endoscopic images superimposed with the results on the monitor. The lesion detection algorithm uses the deep learning architecture. When endoscopic images are input, lesion location is output. In the development process of this program, AI modules with the "lesion detection assist function" were created by providing endoscopic images and correct data (on lesion location and type) as training data for this architecture for training. These modules do not change by post-marketing learning. The performance evaluation test of the

lesion detection assist function according to observation mode yielded the following results for detection sensitivity: 94.5% (95% confidence interval [CI]: 92.0-96.9%) for white light imaging (WLI) and 96.0% (95% CI: 93.9-98.1%) for linked color imaging[10]. Notably, this system extracts and displays areas of potential lesions on colonoscopic images acquired by operators for lesion detection, alerting operators and drawing their attention to the location of potential lesions to aid lesion detection.

Outcome measurements

The primary endpoint was a comparison of the AMR between the CADe and non-CADe groups. The AMR was calculated by dividing the number of adenomas detected by the second endoscopy by the number of colorectal adenomas detected by the first and second endoscopies. The polyp miss rate (PMR) was calculated similarly.

The secondary endpoints were as follows: 1. comparison of the PMR between the two groups; 2. comparison of the ADR and PDR in the first endoscopy between the two groups; 3. comparison of the mean number of adenomas per procedure and the mean number of polyps per procedure in the first endoscopy between the two groups; 4. comparison according to the number of years of experience of the examining endoscopists (non-experts and experts); and 5. characteristics of lesions missed in the first endoscopy.

Sample size

The sample size in the present study was calculated according to the results of a previous study[15]. The results of this previous study showed that the AMR was 13.89% in the CADe group and 40.00% in the non-CADe group according to lesion analysis of images obtained using different colonoscopic procedures. The sample size was calculated to assure 80% of power for the χ^2 test of the two groups with a two-sided α level of 0.05. Thus, 90 patients were required. To account for dropouts and withdrawals, this study had a necessary sample size of 100 patients.

Randomization and masking

Patients enrolled in the present study were randomly assigned to the CADe or non-CADe group with three stratification factors: history of colorectal polyps (present/absent), age (< 70 years / ≥ 70 years), and sex (male/female). For the random allocation sequence, a minimization method using UMIN-ICDR (Individual Case Data Repository) was employed to randomly assign patients. Group assignment was performed immediately before examination by a physician who did not perform the examination. The first and second endoscopies were performed by similarly skilled endoscopists. The examining endoscopists recorded each finding in the CRFs. The CRFs were handed to the study secretariat for CRF storage at the data center. Data were collected at the completion of the present study.

Colonoscopy procedure

The examination was performed by endoscopists at Fukuoka University Chikushi Hospital. The expert endoscopist who performed the first endoscopy differed from that who performed the second endoscopy. Similarly, the non-expert who performed the first endoscopy differed from that who performed the second endoscopy.

To prepare the bowel for total colonoscopy, patients were instructed to eat a low residue diet on the day before examination, take sodium picosulfate (Laxoberon®, Teijin Pharma, Tokyo, Japan) before bedtime, and drink 2 L of polyethyleneglycol (Moviprep®, EA Pharma, Tokyo, Japan) on the morning of the examination. The bowel preparation level for total colonoscopy was evaluated by the endoscopists performing the first endoscopy using the Boston bowel preparation score (BBPS).

Statistical analysis

All statistical analyses were performed using SPSS software (version 22.0 for Windows; IBM Japan, Ltd., Tokyo, Japan). Fisher's exact test was performed for comparison between the two groups, and Student's t-test was performed to analyze continuous variables, such as tumor size. A P value less than 0.05 was considered to indicate significance.

Results

Study population

A total of 100 patients who were scheduled for total colonoscopy between February 2022 and November 2022 were enrolled in this study. After random assignment, 50 patients were equally assigned to the CADe and non-CADe groups. Figure 2 shows the flow diagram. The following patients were excluded from the first endoscopy: three patients who experiencing difficulty with deep insertion, two patients with poor bowel preparation, and one patient with a history of colorectal surgery. Consequently, 48 and 46 patients in the CADe and non-CADe groups, respectively, were analyzed. Patient characteristics are shown in Table 1. The objectives of the examination were screening, detailed examination of abdominal symptoms, and surveillance. The insertion time, observation time, or BBPS in either endoscopy procedure did not significantly differ between the two groups. Table 2 shows the clinicopathological findings of all detected polyps. No significant differences were observed in the location, size, shape, or pathological findings of polyps between the two groups.

Primary endpoint

The AMR, the primary endpoint of this trial, was 17.4%

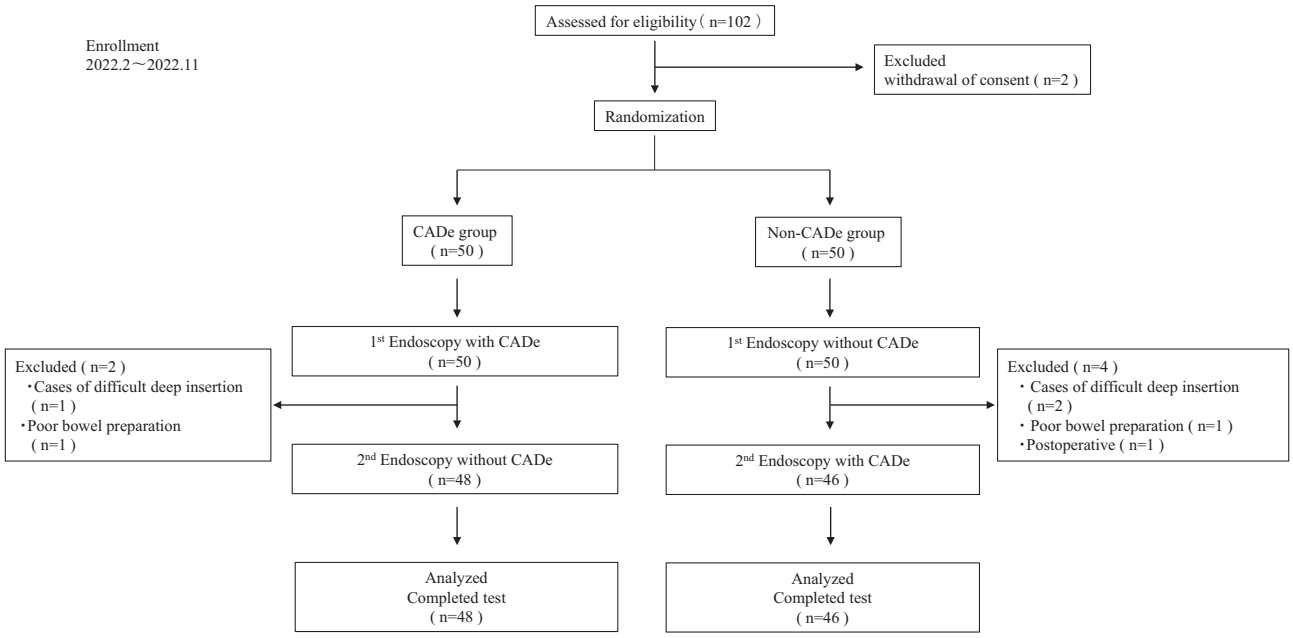

Figure 2. Flow diagram depicting this study. After random assignment, 50 patients were equally assigned to the CADe and non-CADe groups. 2 and 4 patients, were excluded in the CADe and non-CADe groups, respectively. Consequently, 48 and 46 patients in the CADe and non-CADe groups, respectively, were analyzed.

Table 1. Baseline Characteristics of Patients.

	CADe group (n=48)	Non-CADe group (n=46)
Indication, n (%)		
Screening	29 (60.4%)	27 (58.7%)
Symptomatic	4 (8.4%)	8 (17.4%)
Surveillance	15 (31.2%)	11 (23.9%)
Age, mean±SD	67.4±3.6	70.7±2.6
Sex, n, male/female	31/17	29/17
BMI, mean±SD	22.7±1.4	22.5±0.9
History of CRC	18 (37.5%)	19 (41.3%)
Boston prep score	8.52±0.62	8.4±0.8
Endoscopist, n		
Expert/Non-expert	19/29	20/26
First examination		
Insertion time, mm:ss, median	6:21 (4:50-8:09)	7:23 (5:13-12:02)
Observation time, mm:ss, median	14:41 (11:52-20:03)	14:17 (11:59-16:41)
Second examination		
Insertion time, mm:ss, median	5:15 (3:14-7:37)	6:20 (4:01-9:01)
Observation time, mm:ss, median	9:27 (7:12-12:03)	11:05 (8:54-16:45)

CADe, computer-aided detection mm:ss, minutes:seconds

in the CADe group and 30.3% in the non-CADe group (P= 0.009) (Table 3).

Secondary endpoints

1. The PMR was 17.0% in the CADe group and 31.9% in the non-CADe group (P<0.001) (Table 3). 2. The ADR was 75% in the CADe group and 71.7% in the non-CADe group, and the PDR was 79.2% and 82.6%, respectively. No statistically significant differences in ADR and PDR were found between the two groups (Table 4). 3. The mean number of adenomas per procedure was 2.8 in the CADe group and 2.0 in the non-CADe group (P<0.001). The mean number of polyps per procedure was 3.6 in the CADe group and 2.5 in the non-CADe group (P=0.148) (Table 4). 4. The AMR was compared according to the number of years of experience of the examining endoscopists (non-experts and

Table 2. Detected Polyps in the CADe and Non-CADe Groups.

	CADe group (n=171)	Non-CADe goup (n=113)	p value
Location, n (%)			
Cecum	7 (4.1)	6 (5.3)	0.631*
Ascending colon	63 (36.8)	31 (27.4)	0.099*
Transverse colon	42 (24.6)	38 (33.6)	0.096*
Descending colon	25 (14.6)	10 (8.8)	0.147*
Sigmoid colon	28 (16.4)	25 (22.1)	0.223*
Rectum	6 (3.5%)	3 (2.7%)	0.687*
Tumor size, n (%)			
5 mm≤	119 (69.6)	79 (69.9)	0.954**
6-9 mm	42 (24.6)	29 (25.7)	0.834**
≥10 mm	10 (5.8)	5 (4.4)	0.600**
Morphology, n (%)			
Ip	4 (2.3)	1 (0.9)	0.362*
Is	132 (77.2)	83 (73.4)	0.472*
Isp	11 (6.4)	9 (8.0)	0.621*
IIa	24 (14.1)	20 (17.7)	0.404*
Histological type, n (%)			
Adenoma	133 (77.8)	92 (81.4)	0.459*
Adenocarcinoma	1 (0.6)	1 (0.9)	0.767*
Sessile serrated lesion	27 (15.8)	15 (13.2)	0.559*
Others	10 (5.8)	5 (4.4)	0.600*

*Fisher's exact test, **Student-t test CADe, computer-aided detection

Table 3. Miss Rate of Adenoma and Polyp.

	CADe group (n=161)	Non-CADe group (n=132)	p value*
Adenoma miss rate, %	17.4	30.3	0.009

	CADe group (n=206)	Non-CADe group (n=166)	
Polyp miss rate, %	17.0	31.9	<0.001

*Fisher's exact test CADe, computer-aided detection

experts). Among the non-experts, the AMR was 18.4% in the CADe group and 31.6% in the non-CADe group (P= 0.032). Among the experts, the AMR was 15.9% in the CADe group and 26.5% in the non-CADe group (P=0.210) (Table 5). The PMR in the CADe group was significantly lower than that in the non-CADe group among non-experts and experts (P=0.011 and P=0.032, respectively) (Table 6). 5. The first endoscopy missed 35 lesions in the CADe group and 53 lesions in the non-CADe group. Comparisons of the location, tumor size, shape, and histopathological diagnosis revealed no significant differences between the two groups (Table 7).

Discussion

According to the findings of the present study, the use of CAD-EYE® significantly reduced the AMR and PMR. Therefore, AI might be useful for reducing the number of lesions missed by colonoscopy. A high rate of missing lesions may be associated with a high risk of developing interval cancer, which is defined as a cancer detected during the period after screening or surveillance examination and before subsequent examination performed using a recommended interval[15]. Although missing lesions and the development of interval cancer are attributable to various factors, such as poor bowel preparation, polyp shape, and polyp location, human factors, such as the level of experience of the endoscopists, and whether they are fatigued or dis-

Table 4. Adenoma and Polyp Detection.

Experts and non-experts	CADe group (n=48)	Non-CADe group (n=46)	p value*
Adenoma detection rate, %	75	71.7	0.721
Polyp detection rate, %	79.2	82.6	0.672
Mean number of adenomas per procedure	2.8	2.0	<0.001
Mean number of polyps per procedure	3.6	2.5	0.148

Experts	CADe group (n=19)	Non-CADe group (n=20)	
Adenoma detection rate, %	79	65	0.588
Polyp detection rate, %	79	80	1.000
Mean number of adenomas per procedure	2.84	1.25	0.491
Mean number of polyps per procedure	1.2	1.65	0.064

Non-experts	CADe group (n=29)	Non-CADe group (n=26)	
Adenoma detection rate, %	72.4	76.9	0.637
Polyp detection rate, %	79.3	84.6	0.641
Mean number of adenomas per procedure	2.79	2.58	0.315
Mean number of polyps per procedure	3.45	3.08	0.588

*Fisher's exact test CADe, computer-aided detection

Table 5. Comparison of the AMR among Non-experts and Experts.

	CADe group (n=98)	Non-CADe group (n=98)	p value*
Non-experts, %	18.4	31.6	0.032

	CADe group (n=63)	Non-CADe group (n=34)	
Experts, %	15.9	26.5	0.210

*Fisher's exact test CADe, computer-aided detection

Table 6. Comparison of the PMR among Non-experts and Experts.

	CADe group (n=122)	Non-CADe group (n=118)	p value*
Non-experts, %	18.0	32.2	0.011

	CADe group (n=84)	Non-CADe group (n=48)	
Experts, %	15.5	31.3	0.032

*Fisher's exact test CADe, computer-aided detection

tracted, are also important[16]. As this study shows, the use of AI during colonoscopy can reduce risk, especially in human factors.

In a study using CAD-EYE®, the AI-assisted system used in the present study, Nakashima et al. highlighted its usefulness by revealing an ADR of 59.4% in the CADe group; this rate was significantly higher than the 47.6% found in the control group (P=0.018). These investigators also found an AMR of 11.9% in the CADe group; this rate was lower than the 26.0% found in the control group (P=0.037)[13]. Nakashima et al. reported results derived from colonoscopy performed by three expert endoscopists; however, in the present study, both experts and non-experts performed the examination. In addition, Nakashima et al. only examined the AMR in the location limited to the sigmoid colon and rectum. In contrast, we analyzed the entire large intestine. Accordingly, the advantage of our current study is our examinations were performed in settings closer to those in actual clinical practice. In another study using CAD-EYE®, Yamaguchi et al. revealed that the AMR of 25.6% in the CADe group was significantly lower than that of 38.6% in the control group (P=0.033), despite no significant difference between the ADR of 58.4% in the CADe group and that of 61.0% in the control group (P=0.690)[14]. Nevertheless, the back-to-back method, in which trainees and experts share the responsibility of examining each location, was employed by these investigators. In the present study, a different method was employed. In particular, the examining endoscopists observed the entire large intestine in the first endoscopy, as performed in actual clinical practice, and then another endoscopist with a similar level of experience observed the entire large intestine in the second endoscopy. Al-

Table 7. Comparison of Missed Lesions.

	CADe group (n=35)	Non-CADe goup (n=53)	p value
Location, n (%)			
Cecum	11.4	3.8	0.210*
Ascending colon	40	35.8	0.820*
Transverse colon	11.4	22.6	0.261*
Descending colon	14.3	11.3	0.748*
Sigmoid colon	14.3	17.0	1.000*
Rectum	8.6	9.4	1.000*
Tumor size, n (%)			
5 mm≤	94.3	86.8	0.398**
6-9 mm	2.9	13.2	0.138**
≥10 mm	2.9	0	0.398**
Morphology, n (%)			
Ip	0	0	1.000*
Is	68.6	83.0	0.127*
Isp	17.1	3.8	0.052*
IIa	14.2	13.2	1.000*
Histological type, n (%)			
Adenoma	82.9	75.5	0.443*
Adenocarcinoma	0	0	1.000*
Sessile serrated lesion	14.3	22.6	0.414*
Others	2.9	1.9	1.000*

*Fisher's exact test **Student-t test CADe, computer-aided detection

though the previous studies using CAD-EYE® employed different examination methods from that used in the present study, both showed decreases in the AMR, thereby aligning with the results of the present study. However, the method used in the present study further aligned with actual clinical practice as no bias occurred in the selection of examining endoscopists from experts and non-experts, and observations from the entire large intestine were used. It should be noted, however, that the tandem study is easily influenced by the examiner's intentions. In addition, I think the second endoscopists must be experts for both groups to find missed polyps more accurately than non-experts. Although the PMR was not evaluated in the two previous studies, the present study revealed a significant decrease in this rate in the CADe group, further indicating the usefulness of CAD-EYE®. Notably, a study found an ADR of 71.4% in the CADe group and 65.0% in the control group (P=0.09), which indicated no significant difference despite the use of AI[17]. Such finding implies that the usefulness of AI cannot necessarily be evaluated using ADR alone. Therefore, the usefulness of AI with factors, such as the AMR and PDR, must be comprehensively evaluated.

In the present study, the ADR was high in both groups, with no significant difference found. One reason for this may be that the endoscopists were aware of the purpose of the study (i.e., to compare endoscopic outcomes with and without the CADe system) and therefore performed more careful endoscopic observations than usual. In addition, the fact that the study included many patients at high risk for colorectal polyps may have contributed to the higher ADR and PDR in both groups. Although the ADR and PDR were high, the AMR was approximately 30% in the non-CADe group. Notably, many adenomas were missed. In the CADe group, approximately 20% of colorectal adenomas were also missed. When the lesions missed in the present study were compared between the CADe and non-CADe groups in terms of location, tumor size, shape, and histopathological diagnosis, no significant differences were observed in any of these features. To fully exploit the function of CADe, endoscopists should secure a good visual field and ensure observations are performed without blind spots. In addition, more cases are needed to elucidate the characteristics of missed lesions and enable advances in AI.

According to the recommendations stated in the guidelines for colonoscopy, an examination time of at least 6 min is necessary. Yoshida et al. showed that the PDRs of CAD-EYE® with normal- and high-speed observation were 85.0% and 67.0% for WLI, respectively (p=0.002), even with the use of CAD-EYE®. According to these investigators, despite the use of CAD-EYE®, the PDR decreased upon prompt removal of the endoscope[18]. In both groups in this study, the examination time was more than 6 minutes, so it is unlikely that the missed lesions in this study were due to high-speed observation.

According to a previous report, the overall ADR was higher in the CADe group than that in the control group (53.3% vs 44.5%; relative risk [RR]: 1.22; 95% CI: 1.04-1.40; P<0.01 for non-inferiority and P=0.02 for superiority) among less experienced endoscopists, and the usefulness of CADe was reported. Based on their results, the use of CADe contributed to a significantly higher ADR[19]. Notably, non-experts and experts were separately examined in the present study. The AMR for non-experts was significantly reduced using CADe, whereas no significant difference was observed for experts. For both non-experts and experts, the PMR was significantly reduced using CADe. Based on these results, CADe is considered useful, especially for reducing the number of adenomas missed by non-experts.

The present study had some limitations. First, this study was performed at a single center, and a small sample size was employed. Therefore, multicenter studies with larger sample sizes are warranted.

Second, a pathological diagnosis was made based on the biopsy of detected lesions, which might be slightly inferior in diagnostic accuracy to the pathological diagnosis based on endoscopically resected specimens. However, as biopsy specimens were used for pathological diagnosis in both the CADe and non-CADe groups, the effect of their use on the comparison of the AMR between the two groups, which was the primary outcome, was very small. Third, the ADR and PDR in both the CADe and non-CADe groups were higher than those reported previously. As the endoscopists were aware of the study objective (i.e., to compare the performance of endoscopy with and without the CADe system), they may have performed a more careful endoscopic observation than usual. In addition, the inclusion of many patients with a high risk of colorectal polyps may have been one of the factors contributing to the high ADR and PDR in both groups.

In conclusion, the present study suggests that the application of CAD-EYE® to total colonoscopy reduces the AMR. Moreover, CAD-EYE® is highlighted to be useful for reducing the number of missed colorectal adenomas.

Conflicts of Interest

There are no conflicts of interest.

Author Contributions

Study concept and design: Hiratsuka Y, Hisabe T; acquisition of data: Hiratsuka Y; histopathological diagnosis and immunohistochemical examination: Nimura S; study supervision: Hisabe T, Ohtsu K, Yasaka T, Takeda K, Miyaoka M, Ono Y, Kanemitsu T, Imamura K, Takeda T, Hasegawa R, Nimura S, Yao K.

Approval by Institutional Review Board (IRB)

This study complied with the principles of the Declaration of Helsinki and was approved by the Institutional Review Board of the participating institution (UMIN 000046502).

Consent to Participate

Written informed consent was obtained from all study participants. As indicated in the informed consent document, participants could freely withdraw their consent to participate in the study at any time.

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