

Use of computer-assisted detection (CADe) colonoscopy in colorectal cancer screening and surveillance: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement



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SUMMARY AND RECOMMENDATION

This statement conveys the European Society of Gastrointestinal Endoscopy (ESGE) position on the use of computer-aided detection (CADe) with artificial intelligence (AI) during colonoscopy for colorectal cancer (CRC) screening or surveillance. The ESGE position is informed by the BMJ Rapid Recommendation initiative and the approach of the MAGIC Evidence Ecosystem Foundation; these include systematic reviews of currently available evidence, supplemented by microsimulation modeling and patient values and preferences, for the benefits and harms of AI CADe devices during colonoscopy.

ESGE convened a panel of European experts for this Position Statement. On December 18, 2024, panel members voted on their preferred recommendation between two choices about CADe during colonoscopy for indications of CRC screening or polyp surveillance. Out of 19 eligible votes, 13

(68.4%) voted to recommend CADe for colonoscopy, and six panel members (31.6%) voted against. Therefore, the current ESGE statement is:

Recommendation

The panel believes that most well-informed patients who have already decided to undergo colonoscopy for screening or surveillance would favor CADe assistance during colonoscopy. This is due to the potential benefits, although limited, of reduction in colorectal cancer incidence and mortality.

This recommendation is weak, because the evidence is limited with considerable uncertainty of the evidence estimates, the absolute benefits for colorectal cancer incidence and mortality are small, and there is a patient burden associated with CADe (more polyp overdiagnosis and more colonoscopy surveillance).

SCOPE AND PURPOSE

This statement conveys the European Society of Gastrointestinal Endoscopy (ESGE) position on the use of computer-aided detection (CADe) with artificial intelligence (AI) during colonoscopy for colorectal cancer (CRC) screening or surveillance.

ABBREVIATIONS

ADR	adenoma detection rate
AI	artificial intelligence
BMJ	British Medical Journal
CADe	computer-aided detection
CRC	colorectal cancer
ESGE	European Society of Gastrointestinal Endoscopy
FIT	fecal immunochemical test
PICO	population, intervention, comparator, outcome
RCT	randomized controlled trial
RR	relative risk

Colonoscopy is the gold standard examination to detect colorectal polyps and cancer. Colonoscopy is performed for diagnostic purposes in symptomatic patients, and for surveillance for detection of polyps and cancer for patients who previously had polyps removed. In many countries, colonoscopy is used for population screening to prevent colorectal cancer (CRC) by detecting and removing precancerous polyps [1]. In CRC screening programs, colonoscopy can either be applied for all individuals above a certain age (usually around 50 years), as in the United States or in Germany, or as a follow-up examination for individuals who test positive with fecal immunochemical testing, as in many countries in Europe [2], or with

other tests such as computed tomography (CT) colonography or DNA or RNA stool testing.

Detection of polyps during colonoscopy varies significantly between individual endoscopists. A low individual adenoma detection rate (ADR) is associated with increased patient risk of developing colorectal cancer after screening colonoscopy [3]. In the past 10 years, ESGE and other organizations have promoted training and certification programs to ensure high quality colonoscopy and enable endoscopists to maintain high ADRs during colonoscopy [4]. While training initiatives have increased adenoma and polyp detection for many endoscopists, there remains considerable performance variation [3,5].

In recent years, computer-aided detection (CADe) tools using artificial intelligence (AI) to assist the endoscopist in detecting colorectal polyps and cancer in real time during colonoscopy have entered the market in many countries. CADe devices have been shown to increase detection rates of small adenomas and non-neoplastic polyps [6]. However, although more than 40 randomized controlled trials (RCTs) have evaluated CADe for colon polyp detection, it is uncertain whether CADe significantly increases the detection of large adenomas (≥ 10 mm) which have the most potential for malignant transition [6].

Higher ADR with use of CADe AI tools during colonoscopy may translate to a clinically meaningful reduction of CRC risk after colonoscopy. It is however uncertain whether this potential benefit of CADe outweighs the additional burden of higher detection rates of non-neoplastic polyps and the consequential unnecessary removal of such polyps.

To this end, the ESGE has worked together with the BMJ Rapid Recommendation initiative and the MAGIC Evidence Ecosystem Foundation to gather all available evidence and identify knowledge gaps, commission new evidence filling the identified gaps, and develop clinical practice guidance on the benefits and harms of AI CADe devices during colonoscopy. This Position Statement outlines the ESGE considerations and pro-

vides clinical guidance recommendations for the use of CADE during colonoscopy. It replaces previous ESGE recommendations for CADE in colonoscopy [7].

The ESGE guidance presented here is based on systematic reviews of available evidence supplemented by new microsimulation modeling, considering likely patient values and preferences [8, 9, 10].

Methods

In November 2024, the ESGE Executive Committee requested ESGE members to express interest in membership of an expert panel to develop this guidance document on CADE in colonoscopy. Eligible individuals were ESGE members with expertise in colonoscopy and familiarity with CADE clinically and/or scientifically. All interested members were requested to complete a conflict of interest form. Only members without financial interests in entities associated with CADE products were eligible as voting members in the panel. ESGE members who expressed interest and were opinion leaders in the topic area but reported associations with entities could be panel members but without recommendation voting rights.

Out of 94 ESGE members who applied for the panel, 23 from 15 different countries were selected to be panel members (8 women and 15 men). A total of 20 members had voting rights and 3 did not. All panel members are authors of this Position Statement.

The panel's work was based on a living guideline [8] from the BMJ Rapid Recommendations series, a collaborative effort between the MAGIC Evidence Ecosystem Foundation and the BMJ to provide clinicians with trustworthy guidance responding to potentially practice-changing evidence. The BMJ guideline provided clinical questions, the PICO (population, intervention, comparator, outcome) searches, and the evidence provision and synthesis [8]. The BMJ–MAGIC initiative provided the ESGE panel with evidence tables containing absolute and relative risks for the outcomes of interest.

The clinical question was as follows: In adult patients (18 years or older) undergoing colonoscopy for any indication (screening, surveillance, or gastrointestinal symptoms such as blood in the stools), what are the benefits and harms of computer-aided detection (CADE)? Individuals undergoing colonoscopy for surveillance due to a history of inflammatory bowel disease were excluded.

The PICO question was as follows:

Population: People undergoing colonoscopy for screening, surveillance, or follow-up of a positive fecal immunochemical test (FIT);

Intervention: Colonoscopy with CADE;

Comparator: Colonoscopy without CADE;

Outcomes of interest: Primary outcomes were: CRC-related mortality, CRC incidence, and post-colonoscopy CRC incidence. Secondary outcomes were: adenoma detection rate, advanced adenomas per colonoscopy, serrated polyps per colonoscopy, adenomas per colonoscopy, adenoma miss rate, polypectomies of nonadenomatous polyps per colonoscopy, colonoscope

withdrawal time (inspection time), number of colonoscopies per lifetime, perforations, and bleeding events.

The BMJ guideline panel commissioned independent teams of health research methodologists, clinical experts, and biostatisticians who conducted the following work to inform the evidence for CADE in colonoscopy on the predefined outcomes of interest: (i) a systematic review of RCTs to examine the benefits and harms of CADE in colonoscopy versus colonoscopy without CADE [6]; (ii) a microsimulation modeling study to address the predefined outcomes including those which had not been evaluated by the RCTs [8]; and (iii) an evaluation of values and preferences of patients undergoing colonoscopy [10].

The microsimulation modeling study simulated 10-year follow-up for 100 000 individuals aged 60–69 years participating in CRC screening programs, using a microsimulation Markov model [9], including both patients undergoing primary screening with colonoscopy and patients undergoing colonoscopy following a positive FIT. The model incorporated data from large RCTs and registry studies, providing information on CRC risk, survival rates by cancer stage, and adenoma prevalence. For colonoscopy screening, data from a multinational RCT provided evidence of the effects of screening on cancer incidence [11, 12], and survival data were retrieved from a recent study using the NORDCAN database [13].

Data from an Italian registry study [14] were used and validated against outcomes from the Dutch national screening program to provide data for patients undergoing colonoscopy following a positive FIT test [15].

The model considered patients between 60 and 69 years of age at colonoscopy with or without CADE, a 10-year timeframe for follow-up, and assumed 100% participation for screening and surveillance. To account for variability in ADR, the model used ADR thresholds from large observational studies, applying different categories to simulate the performance of endoscopists with varying skill levels [16]. The model applied estimates from a recent observational cohort to model the association between ADR and CRC incidence and mortality over 10 years [3]. Sensitivity analyses were conducted to test the robustness of the assumptions that incorporated data on surveillance guidelines, polyp removal practices, and adverse event rates from screening trials, and pooled data from various screening programs [9].

The BMJ panel did not find relevant studies on values and preferences for CADE in colonoscopy. Thus, the BMJ panel made the best inferences about what most patients would want, and the ESGE panel followed the same approach.

Results

Systematic review of randomized trials

The systematic review of randomized trials comparing colonoscopy with and without CADE included 44 RCTs with more than 30 000 patients [6]. The mean polyp detection rate was 54.0% with CADE colonoscopy compared to 46.5% with colonoscopy without CADE (relative risk [RR] 1.21, 95%CI 1.14–1.27); the ADR was 44.7% with CADE versus 36.7% without CADE; (RR 1.21, 95%CI 1.15–1.28), and the advanced colorectal neoplasia

detection rate (at least one advanced adenoma and/or advanced sessile serrated lesion) was 12.7% with CADE and 11.5% without CADE (RR 1.16, 95%CI 1.02–1.32).

With respect to patient burden and harm, the detection rate for non-neoplastic polyps was 34.0% with CADE versus 28.8% without CADE (RR 1.11, 95%CI 1.04–1.19) and the mean withdrawal time was 10.33 minutes with CADE versus 9.68 minutes without CADE (mean difference 0.53 minutes, 95%CI 0.30–0.77 minutes).

Microsimulation modeling

The microsimulation modeling study estimated a 10-year CRC incidence of 71 per 10000 patients who undergo colonoscopy with CADE versus 82 per 10000 patients without CADE (11 fewer colorectal cancers per 10000 [0.11%]), and a 10-year CRC mortality of 15 per 10000 patients with CADE versus 13 per 10000 patients without CADE (2 fewer deaths per 10,000 [0.02%]) (► **Table 1**) [9].

According to the model, CADE resulted in 8 more patients with adenomas per 100 colonoscopies, and in a mean difference of 0.01 more patients with advanced adenomas per colonoscopy (► **Table 2**). Consequently, with CADE, 635 more patients per 10000 would require colonoscopy surveillance over 10 years as compared to colonoscopy without CADE [9] (► **Table 3**). There were no differences in perforation or bleeding.

Certainty of evidence and Strength of recommendation

Based on the available evidence, the BMJ panel considered the evidence for the primary outcomes of CRC incidence and mortality to be of low certainty, and thus recommendations as weak. The ESGE panel agrees with this judgment.

While the systematic review of RCTs [6] found none that have investigated the primary outcomes of CRC incidence and mortality, it provided low-certainty evidence that CADE may enhance polyp detection. The microsimulation modeling study indicates that CADE may have a small impact on CRC incidence, and a negligible impact on mortality. Because this is based on modeling, it is considered of low certainty. Also, low-certainty evidence suggests that CADE increases the number of colonoscopies performed per patient over a 10-year period.

Recommendation

All ESGE panel members reviewed the evidence provided by the BMJ panel and discussed it during an online meeting on December 17, 2024.

Following the approach of the BMJ initiative, the ESGE panel provided all its members with two mutually exclusive choices for recommendation, but with one difference: the ESGE panel decided that each of the two choices for recommendation should apply only to patients who undergo colonoscopy for detection of polyps (primary screening or colonoscopy after positive FIT testing) or polyp surveillance, based on the BMJ PICO search terms, and not to patients who are undergoing colonoscopy for clinical symptoms. Given the uncertainty of the evidence, the panel members agreed that any recommendation should be weak.

Thus, panel members were asked to vote on whether to suggest against or for the routine use of CADE for adults undergoing colonoscopy for screening or surveillance, using the following statements to encapsulate the rationale and values and preferences informing the recommendation. The two voting choices were as follows:

► **Table 1** Comparison of computer-aided detection (CADE) colonoscopy versus colonoscopy without CADE, by microsimulation modeling: primary colorectal cancer (CRC) outcomes [8].

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of evidence (Quality of evidence)
		Routine practice colonoscopy	CADE colonoscopy	
CRC incidence 10 years	Modeling evidence	82 per 10000	71 per 10000	Very low
		Difference: 11 fewer per 10000 (95%CI 35 fewer–17 more)		
CRC-related deaths 10 years	Modeling evidence	15 per 10000	13 per 10000	Low
		Difference: 2 fewer per 10000 (95%CI 10 fewer–18 more)		
Post-colonoscopy CRC incidence 10 years	Modeling evidence	34 per 10000	23 per 10000	Very low
		Difference: 11 fewer per 10000 95%CI 22 fewer–12 more		

CI, confidence interval.

► **Table 2** Comparison of CADe colonoscopy versus colonoscopy without CADe. Secondary outcomes: Adenoma detection and miss rates [8].

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of evidence (Quality of evidence)
		Routine practice colonoscopy	CADe colonoscopy	
Adenoma detection rate	Relative risk: 1.22 (95%CI 1.16–1.29) Based on data from 30 674 participants in 40 studies	37 per 100	45 per 100	Low Due to serious risk of bias Due to serious publication bias
		Difference: 8 more per 100 (95%CI 6 more–11 more)		
Adenoma miss rate	Relative risk: 0.47 (95%CI 0.36–0.6) Based on data from 2018 participants in 6 studies	35 per 100	16 per 100	Moderate Due to serious risk of bias
		Difference: 19 fewer per 100 (95%CI 22 fewer–14 fewer)		
Adenomas per colonoscopy	Based on data from participants in 39 studies	0.65 per 1 colonoscopy Mean	0.87 per 1 colonoscopy Mean	Low Due to serious risk of bias Due to serious publication bias
		Difference: MD 0.22 more (95%CI 0.16 more–0.28 more)		
Advanced adenomas per colonoscopy	Based on data from participants in 26 studies	0.12 per 1 colonoscopy Mean	0.13 per 1 colonoscopy Mean	Moderate Due to serious risk of bias
		Difference: MD 0.01 more (95%CI 0.01 fewer–0.02 more)		

MD, difference of the mean.

► **Table 3** Comparison of CADe colonoscopy versus colonoscopy without CADe, by microsimulation modeling. Secondary outcomes: Burden and harms.

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of evidence (Quality of evidence)
		Routine practice colonoscopy	CADe colonoscopy	
Individuals needing follow-up post index colonoscopy 10 years	Modeling evidence	2645 per 10 000	3280 per 10 000	Low
		Difference: 635 more per 10 000 (95%CI 582 more–688 more)		
Perforation 10 years	Modeling evidence	1 per 10 000	1 per 10 000	Low
		Difference: 0 fewer per 10 000 (95%CI 0 fewer–0 fewer)		
Bleeding 10 years	Modeling evidence	19 per 10 000	20 per 10 000	Low
		Difference: 1 more per 10 000 95%CI 9 fewer–11 more		

- Recommendation against CADe
The benefits on the critical outcomes of CRC incidence and post-colonoscopy cancer incidence remain very uncertain. For CRC-related mortality, the evidence is of low certainty suggesting a trivial or no benefit. The potential burdens – including more frequent surveillance colonoscopies, increased health-related anxiety and overdiagnosis – are

likely to exist for many patients. The uncertainty of any benefits, and the high likelihood that many patients would experience the burdens led the panel to conclude that most well-informed patients would not favor CADe assistance. In concluding with a weak recommendation against the routine use of CADe, the panel placed higher value on avoiding the burdens than on the uncertain benefits.

■ Recommendation for CADe

Given the uncertain benefits on critical outcomes, the panel believes that most well-informed patients who have already decided to undergo colonoscopy would favor CADe assistance. This is due to the potential benefits, although limited, of reduction in colorectal cancer incidence and mortality. The weak recommendation for colonoscopy with CADe places greater value on the potential of avoiding colorectal cancer and death, rather than avoiding the potential burden of more frequent surveillance colonoscopies, increased health-related anxiety, and overdiagnosis.

Voting results and final recommendation

On December 18, 2024, all panel members were asked to vote on their preferred recommendation amongst the two choices above, using an online voting tool that secured anonymous votes for each panel member. Out of the 23 panel members, three did not have voting rights, and one panel member did not vote. Thus, there were 19 eligible votes. Six panel members (31.6%) voted against recommending CADe for colonoscopy, while 13 (68.4%) voted for recommending CADe for colonoscopy for the indications of screening or polyp surveillance.

Thus, the final ESGE recommendation is as follows:

RECOMMENDATION

The panel believes that most well-informed patients who have already decided to undergo colonoscopy for screening or surveillance would favor CADe assistance during colonoscopy. This is due to the potential benefits, although limited, of reduction in colorectal cancer incidence and mortality.

This recommendation is weak, because the evidence is limited with considerable uncertainty of the evidence estimates, the absolute benefits for colorectal cancer incidence and mortality are small, and there is patient burden associated with CADe (more polyp overdiagnosis and more colonoscopy surveillance).

Discussion

The ESGE and BMJ panels considered that the detection of adenomas (especially diminutive [≤ 5 mm] or small [6–9 mm] adenomas) may both be beneficial to patients but also contribute to more polyp overdiagnosis. With increasing polyp detection rates, the likelihood of both effectiveness and overdiagnosis also increases (namely, detection of polyps that could have developed to cancer versus detection of polyps that would not have progressed to cancer during the patient's remaining lifetime) [17].

A higher proportion of patients referred for surveillance colonoscopy due to higher ADRs increases the negative consequences of overdiagnosis. Thus, tools intended to increase polyp detection rates can increase colonoscopy effectiveness in reducing CRC incidence and mortality and at the same time increase harms and burdens for patients, by overdiagnosis of clinically insignificant polyps, more surveillance, and by adverse events of polyp removal (such as bleeding and perforation). Reassuringly, the BMJ model does not predict more bleeding or perforations with CADe [9].

The BMJ panel used the GRADE methodology [8]. A weak recommendation using GRADE is most appropriate for circumstances in which there is a close balance between benefits and harm and/or uncertainty in the evidence. A weak recommendation indicates a panel's belief that clinicians and patients may choose CADe or not during colonoscopy, depending on their values and preferences for benefits, harms, and burden. Values and preferences vary across different settings and contexts, and for different patients. Both the uncertainty regarding the provided estimates, and the likelihood of variability in values and preferences for individuals support a weak recommendation. The typical implication of a weak recommendation is shared decision-making between patients and their health care providers.

The majority of the ESGE panel considered the potential benefits of CADe in net benefits for CRC incidence and mortality to outweigh the potential harms and burdens of CADe, while a minority of panel members believed that the absolute net benefits (9 fewer cancers and 2 fewer cancer deaths per 10 000 patients) were too small to justify the harms of overdiagnosis of non-neoplastic polyps and increased surveillance. This shows that there is considerable uncertainty of the evidence and its interpretation, and variation of values and preferences amongst the ESGE panel members.

Our approach of voting and transparent reporting aims at providing a transparent decision-making process at ESGE and encourages endoscopists and the public to make their own, informed choices using the available evidence provided here.

The ESGE panel decided to restrict each of the two choices for recommendation to be applied only to patients who undergo colonoscopy for screening (primary screening or colonoscopy after positive FIT testing) or polyp surveillance indications. Thus, at this time, ESGE does not provide any recommendation regarding CADe for patients who undergo colonoscopy for indications other than screening or polyp surveillance. ESGE will provide recommendations for clinical indications when more evidence becomes available.

Disclaimer

The legal disclaimer for ESGE Guidelines [18] applies to this Position Statement.

Conflict of Interest

G. Antonelli has received consultancy fees from Medtronic, Olympus, Cosmo IMD, and Odin Vision. R. Bisschops has received speaker's and consultancy fees and research grants from Fujifilm, Pentax, Medtronic, and Norgine; consultancy fees from GI supply, CDX diagnostics, Boston Scientific, and Cook; and speaker's fees from Ipsen and Medivators; he is involved in the set-up of a spinoff from his university regarding AI in endoscopy. M. Bretthauer has received European Union Grants no. 101057099 and 101156165. I. Gralnek declares collaboration with Olympus, Pentax, Medtronic, Motus GI, ERGO GI, and ERBE. M. Pellise has received speaker fees from Olympus and Mayoli, consulted Olympus through her hospital and received material from Fujifilm. The remaining authors declare no relevant conflicts of interest.

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