

CLINICAL PRACTICE UPDATE

AGA Clinical Practice Update on the Role of Artificial Intelligence in Colon Polyp Diagnosis and Management: Commentary



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DESCRIPTION: The purpose of this American Gastroenterological Association (AGA) Institute Clinical Practice Update (CPU) is to review the available evidence and provide expert commentary on the current landscape of artificial intelligence in the evaluation and management of colorectal polyps. **METHODS:** This CPU was commissioned and approved by the AGA Institute Clinical Practice Updates Committee (CPUC) and the AGA Governing Board to provide timely guidance on a topic of high clinical importance to the AGA membership and underwent internal peer review by the CPUC and external peer review through standard procedures of *Gastroenterology*. This Expert Commentary incorporates important as well as recently published studies in this field, and it reflects the experiences of the authors who are experienced endoscopists with expertise in the field of artificial intelligence and colorectal polyps.

Keywords: Artificial Intelligence; Colon Polyps; Computer-Aided Detection; CAde; CADx; Computer-Aided Diagnosis.

Colorectal cancer (CRC) is the second most common cause of cancer deaths worldwide.¹ Screening colonoscopy reduces the risk of CRC through the removal of precancerous polyps.² Polyp detection is operator-dependent, with adenoma detection rates (ADRs) ranging widely from 7% to 53% among colonoscopists.³ Failure to detect and remove neoplastic polyps is associated with the development of post-colonoscopy interval CRC, which accounts for nearly 8% of all diagnosed CRC.⁴ Conversely, a 1% increase in a colonoscopist's ADR has been associated with a 3% decrease in future CRC risk.³ However, the majority of polyps detected during colonoscopy are diminutive and non-neoplastic.⁵ Unnecessary resection and pathologic evaluation of these non-neoplastic lesions can be associated with increased costs and risk for adverse events.

These critical issues around colon polyp detection and diagnosis have been a central focus for a range of artificial intelligence (AI) tools that have recently been introduced to the field of gastrointestinal endoscopy. As with any emerging technology, there are important questions and challenges that need to be addressed to ensure that AI tools are introduced safely and effectively into clinical endoscopic practice. This commentary incorporates important and recently published studies in the field and elaborates on the future directions of AI in colonoscopy.

Artificial Intelligence and Computer Vision

The term *artificial intelligence* refers to computer systems performing complex tasks that would normally require the use of the human brain, such as visual perception ("computer vision"), speech recognition, and decision making.⁶ Early attempts at polyp detection required explicit programming of software to recognize certain polyp features (eg, textures and shapes).⁷ These early efforts were focused on recognizing still images because computer-processing speed at that time could not support real-time, live video image analysis. Since then, major advances in deep-learning algorithms using convolutional neural networks have dramatically expanded the capabilities of computer vision for endoscopy. These contemporary algorithms are trained on large data sets and can adapt and "learn" to recognize complex objects in live video.⁸ The most important applications of AI computer vision in colonoscopy today include computer-aided detection (CAde) and computer-aided diagnosis (CADx). CAde is designed to help the endoscopist detect polyps during colonoscopy and CADx is intended to accurately predict polyp histology without the need for a tissue biopsy.

Artificial Intelligence for Detection of Colorectal Polyps (Computer-Aided Detection)

AI detection of colorectal polyps was the first target for AI technology in gastroenterology and now a myriad of studies has reported the successful application of AI for the recognition of colon polyps using CAde. These algorithms are the equivalent of a highly trained set of eyes relentlessly scanning the monitor alongside the endoscopist, while simultaneously "flagging" lesions that potentially represent precancerous polyps (Figure 1). Urban and colleagues⁹ reported one of the earliest applications of convolutional neural network-based CAde on video clips. Their algorithm

Abbreviations used in this paper: ADR, adenoma detection rate; AI, artificial intelligence; APC, adenomas detected per colonoscopy; CAde, computer-aided detection; CADx, computer-aided diagnosis; CRC, colorectal cancer; FEQ, fold evaluation quality.

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0016-5085

<https://doi.org/10.1053/j.gastro.2023.07.010>

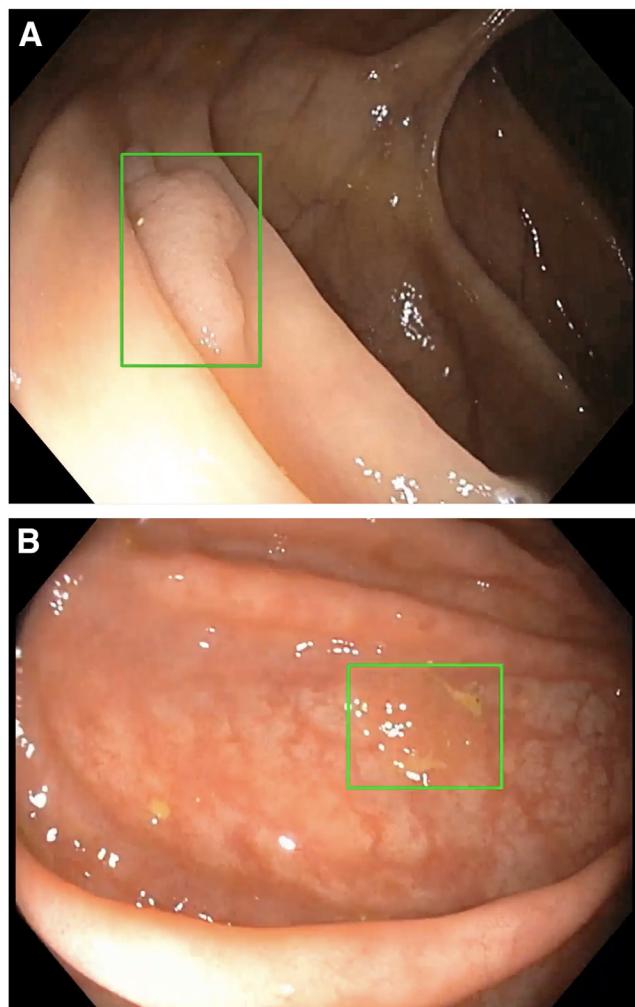


Figure 1. CAdE alert box identifying a sessile polyp (A), and flat polyp (B). Images courtesy of Tyler M. Berzin.

showed 97% sensitivity, 95% specificity, and 96% accuracy for detection of colorectal polyps, which was superior to the performance of the endoscopists. Importantly, 92% of polyps missed by the endoscopists were detected by the CAdE.⁹ In the last several years, numerous prospective, multicenter studies have found that real-time use of AI CAdE tools during colonoscopy leads to improvements in adenoma detection and other related performance metrics. A meta-analysis by Huang et al¹⁰ of 10 randomized controlled trials with 6629 patients found that both ADR (relative risk [RR], 1.43; $P < .001$) and polyp detection rate (RR, 1.44; $P < .001$) were significantly greater with AI-aided colonoscopy compared with routine colonoscopy. The adenomas detected per colonoscopy (APC) and polyps detected per colonoscopy were also significantly higher in the AI-aided group compared with the routine colonoscopy group.¹⁰

Despite these positive early results, recent studies have suggested that CAdE may not improve adenoma detection in every clinical setting. In a retrospective single-center pragmatic trial, Ladabaum et al¹¹ reported that CAdE did not

improve ADR, APC, or other detection metrics when compared with historic and concurrent controls.¹¹ In a separate, large, retrospective, observational study, Levy et al¹² reported a lower ADR in the CAdE group compared with a pre-CAdE retrospective control (30.3% vs 35.2%; $P = .001$), as well as a lower polyp detection rate and lower APC.¹² In addition to these observational studies, a recent trial from the United Kingdom with patients randomized to CAdE vs standard colonoscopy also failed to demonstrate a difference in ADR. There are several plausible explanations for the lack of benefit of CAdE across these studies. For one, the possibility of a “ceiling” effect for polyp detection among high-performing endoscopists may have accounted for the lack of incremental benefit with CAdE. In addition, there may be an unconscious behavioral change, for instance, degradation in the quality of mucosal exposure, possibly due to a false sense of security that CAdE ensures a high-quality examination. Alternatively, we should also acknowledge that in the majority of published randomized controlled trials, the endoscopists are unblinded and it is possible that this could introduce performance bias, favoring CAdE performance.

Cost-effectiveness of AI-assisted colonoscopy also needs to be examined carefully, as there are several ways this technology may increase health expenditure. The adenoma detection improvements noted using CAdE are attributed mainly to the increased detection of small, nonadvanced adenomas. Indeed, one could argue that the increased detection of small benign polyps by AI could inadvertently lead to more unnecessary resections, thereby increasing cost and procedural risks. Shaukat and colleagues’ recent US multicenter, randomized, parallel study¹³ at 5 academic and community centers by 22 US board-certified gastroenterologists helped address this concern. The primary end points were APC, total number of adenomas resected divided by the total number of colonoscopies; and true histology rate, defined as the proportion of resections with clinically significant histology divided by the total number of polyp resections. There were 677 patients in the standard colonoscopy group and 682 patients in the CAdE group. APC was significantly higher in the CAdE group (standard vs CAdE, 0.83 vs 1.05) with no decrease in true histology with use of the CAdE device. Overall, the results suggest that CAdE may help improve APC without a concomitant (and potentially costly) increase in the resection of non-neoplastic lesions.

Another mechanism by which CAdE may lead to increased health expenditure is higher polyp detection leading to shorter colonoscopy surveillance intervals. One recent study by Mori and colleagues¹⁴ estimated that the use of AI during colonoscopy increased the proportion of patients requiring intensive colonoscopy surveillance by approximately 35% in the United States and 20% in Europe, with absolute increases of 2.9% and 1.3%, respectively. However, increases in ADR can increase early detection of colon cancer and save costs due to cancer management. Areia and colleagues¹⁵ conducted a study using a Markov model microsimulation to investigate the effect of implementing AI-assisted colonoscopy on colon cancer incidence,

mortality, and cost-effectiveness. Compared with no screening, the relative reduction of CRC incidence with screening colonoscopy without AI tools was 44.2% and for screening colonoscopy with AI tools was 48.9% (4.8% incremental gain). AI detection tools decreased the discounted costs per screened individual from \$3400 to \$3343 (a saving of \$57 per individual). At the US population level, the implementation of AI detection during screening colonoscopy resulted in yearly additional prevention of 7194 CRC cases and 2089 related deaths, and a yearly saving of \$290 million.¹⁵ Naturally, however, the cost-effectiveness of this technology relies on the assumptions that ADR will increase from baseline in real-world clinical practice, an outcome that still needs to be corroborated in further studies.

We are just beginning to understand more about AI-human interaction and physician attitudes toward AI in gastroenterology. A study from Nehme et al¹⁶ evaluated the real-world performance of AI-assisted colonoscopy using a commercially available CAdE platform in a fully democratized fashion, in which the entire faculty of a large US academic institution was given the opportunity to perform AI-assisted colonoscopy. The decision to activate the CAdE system was at the discretion of the endoscopist. An anonymous survey was circulated among endoscopy physicians and staff at the beginning and at the conclusion of the study period regarding their attitudes toward AI-assisted colonoscopy. CAdE was activated in 52.1% of cases. Survey results demonstrated mixed attitudes toward AI-assisted colonoscopy, with some physicians expressing concerns regarding the number of false-positive signals, the possibility of distraction (eg, due to false positives or audio alerts), and the impression that it could prolong procedure time. In our own experience, the concern for false-positive alerts remains one of the largest concerns and possible deterrents to the incorporation of AI-assisted colonoscopy. This is an area where human-AI interaction comes to the fore. Although there have been assumptions that CAdE could be a “plug and play” technology, we propose there may be a role for more formalized training to teach endoscopists how to use CAdE most effectively, including best approaches to efficiently recognize and dismiss false positives. As with many new clinical technologies, there may be a physician learning curve for CAdE. Optimizing this and other aspects of the physician-AI collaboration will be an important area of ongoing investigation. Finally, it is imperative for CAdE developers to continue to optimize CAdE system performance to balance the high sensitivity needed for avoidance of missed lesions, while limiting the noise from false-positive signals.

Artificial Intelligence for Characterization of Colorectal Polyps (Computer-Aided Diagnosis)

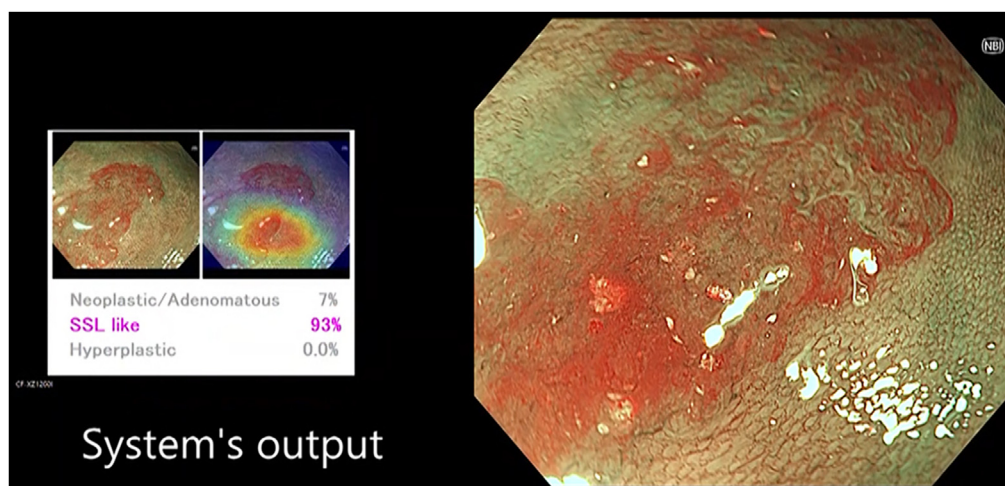
For many years, expectations have grown that optical diagnosis of colorectal polyps would enable “resect-and-discard” or “diagnose-and-leave” strategies, reducing the need for polypectomy and/or histopathology processing for diminutive polyps. The American Society for Gastrointestinal Endoscopy created an initiative in 2011 entitled

“Preservation and Incorporation of Valuable Endoscopic Innovations” that identified optical characterization of colorectal polyps <5 mm in size as a key area for new endoscopic technologies. In order to safely adopt a diagnose-and-leave strategy for suspected hyperplastic polyps <5 mm in the rectosigmoid, endoscopists, supported by endoscopic technologies, should provide a $\geq 90\%$ negative predictive value for adenomatous histology. In order to adopt a resect-and-discard strategy for colorectal polyps <5 mm, the endoscopic technology used to determine histology of these polyps should provide $>90\%$ agreement in assignment of post-polypectomy surveillance intervals compared with decisions based on pathology assessment of all identified polyps.¹⁷ Overall, adenomas in the colon <5 mm and hyperplastic polyps in the rectosigmoid <5 mm account for $>80\%$ of all polyps detected during screening and surveillance colonoscopy.¹⁸ If resect-and-discard or diagnoses-and-leave strategies were more broadly adopted in clinical practice, the potential economic savings could be substantial, with yearly savings estimated between \$33 million and \$150 million per year.^{19,20}

CADx tools may play an important role in supporting physicians' ability to perform optical diagnosis during colonoscopy by providing real-time reliable histopathological predictions for colon polyps (Figure 2).²¹ Although current methods of optical polyp diagnosis typically rely on virtual chromoendoscopy, such as narrow band imaging, there is promise that CADx tools may be able to perform this task with white light alone. Combining CAdE polyp detection with white-light CADx holds particular promise for supporting more efficient approaches toward diagnosing and managing polyps during colonoscopy.

Real-time CADx clinical trials are starting to emerge, and results are encouraging. Hassan and colleagues²² recently conducted a study using simultaneous CAdE and CADx algorithms during screening colonoscopy. The CADx module worked with high-definition white-light unmagnified endoscopy and implemented a convolutional neural network classifier that ran in real time on several images of the same lesion to build up a prediction of adenoma or nonadenoma. For each polyp, CADx output and subsequent endoscopist diagnosis with advanced imaging were matched against the histology gold standard. Overall, 544 polyps were removed in 162 patients, of which 295 (54.2%) were rectosigmoid histologically verified lesions <5 mm. CADx diagnosis was feasible in 98.6% of polyps, and the negative predictive value for rectosigmoid lesions <5 mm was 97.6%. There were 242 of 295 lesions (82%) that were amenable for a “leave in situ” strategy. Based on CADx output, 212 of 544 (39%) would be amenable to a resect-and-discard strategy, resulting in a 95.9% agreement between CADx and histology-based surveillance intervals according to US guidelines. This study provided important evidence that a real-time CADx system was able to exceed the 90% negative predictive value for adenomatous histology required for the leave in situ strategy in standard white-light endoscopy. In the study population, a CADx-assisted diagnose-and-leave strategy would result in a 44.4%

Figure 2. CADx demonstrating diagnostic prediction for a suspected sessile serrated lesion. Images courtesy of Yuichi Mori and Masahi Misawa.



reduction of all of the polypectomies and related costs. Moreover, with the addition of a CADx-assisted resect-and-discard strategy for certain small polyps requiring resection, this would have further reduced the need for pathology to only 17% of the lesions detected in the study, with a >95% agreement with histology-based post-polypectomy surveillance.

An important promise of AI CADx algorithms is the possibility of supporting endoscopists to perform optical diagnosis with a higher baseline level of reliability and confidence. A recent study by Barua et al²³ demonstrated that a CADx-based tool (in this case, requiring a 520× magnifying colonoscope) did not increase diagnostic sensitivity, but importantly, improved the confidence level of endoscopists in rendering a diagnosis (high confidence diagnosis for 74.2% during standard visual inspection vs 92.6% when supported by CADx). Increasing endoscopist confidence in optical diagnosis may be an important step toward broader implementation of leave in situ and resect-and-discard strategies, but successful implementation will also require CADx tools that seamlessly integrate the endoscopic workflow, without the need for image enhancement or magnification. In addition, broad CADx adoption will likely depend on innovations in reimbursement models (currently, pathology fees are an important revenue stream for many gastroenterology practices) and clarification around the medical-legal concerns raised by leaving polyp in situ or discarding resected polyps after CADx-supported diagnosis.

Artificial Intelligence Improving the Quality of Colonoscopy Technique (Computer-Aided Quality Assessment)

Missed adenomas during colonoscopy can result from “cognitive errors” when the endoscopist fails to recognize adenomas that are visualized on the screen, or “exposure errors” due to blind spots and incomplete mucosal exposure

that can be related to the withdrawal speed during colonoscopy, endoscopist skill, degree of bowel cleansing, and other factors. Current CADE systems do not address exposure errors during colonoscopy. Studies indicate that higher-quality colonoscopy withdrawal technique is associated with a lower miss rate for adenomas and 4 complementary skills contribute to higher inspection quality to overcome exposure errors: fold examination, mucosal cleaning, luminal distension, and adequacy of time spent viewing.²⁴ Developments in computer-aided techniques are starting to focus on measures to overcome exposure errors. These tools can be defined as computer-aided quality-assessment systems and represent a third group of computer-aided techniques in colonoscopy along with CADE and CADx.

Meticulous colonic-fold examination is a particularly critical determinant of whether or not polyps appear in the field of view.²⁵ Although physical devices like distal attachment caps may play a critical role in improving fold examination, AI systems to support quality control of fold examination are also now being investigated. Liu and colleagues²⁶ developed and studied an AI-based system for measuring fold evaluation quality (FEQ). One hundred and three consecutive colonoscopies performed by 11 colonoscopists were collected for evaluation. Three experts graded the FEQ of each colonoscopy, after which the recorded colonoscopies were evaluated by the AI system. The system was assessed by correlating its FEQ evaluation against expert scoring, historical ADR, and withdrawal time of each colonoscopist. The AI system’s evaluations of the FEQ of each endoscopist were significantly correlated with expert scores, historical ADR, and withdrawal time. For colonoscopies performed by colonoscopists with previously low ADRs (<25%), AI assistance significantly improved the FEQ, evaluated by both the AI system and experts. Other promising computer-aided quality assessment technologies include withdrawal “speedometers,” technology to “paint” the colon surface on a graphical representation of the colon, and systems that score the

level of adequate mucosal exposure during colonoscopy.²⁷ In the future, these types of AI-based systems may support trainees and lower-performing endoscopists to reduce exposure errors and, more broadly, may empower physician practices and hospital systems with more nuanced and actionable data on an array of factors that contribute to colonoscopy quality.

Challenges and Future Directions

Several CAdE systems have become commercially available in the United States and across the world in the last several years, but despite the robust early data supporting a role for CAdE in adenoma detection, clinical adoption has been slower than expected. Rex and colleagues²⁸ have proposed several contributing potential factors. First, there is a long history of adjunctive polyp detection devices that have received approval from the US Food and Drug Administration, but then failed to reach widespread use. Examples include ultrawide angle endoscopy systems, and distal attachments or hoods that can flatten folds on withdrawal. The limited adoption of this entire category suggests that colonoscopists attach a relatively low price point to the value of increasing detection gains produced by “add-on” devices. Thus far, there is no separate reimbursement for CAdE or other polyp-detection devices, and physicians are not sold on the concept that reimbursement from a higher number of polypectomies and future increased procedure volume (owing to shorter surveillance intervals) might offset the cost of these devices. A second factor that may contribute to slow CAdE adoption is that the technology is not yet integrated directly into endoscopes or video processors. This is a substantial change from previous electronic enhancements, like high-definition video, digital chromoendoscopy, and magnification, all of which have been integrated as part of newer endoscope packages as these technologies have become available. The current iteration of CAdE as a separate, add-on digital device introduces an additional layer of complexity and cost that may seem daunting for some endoscopy units. A third factor in the CAdE adoption curve, as discussed earlier, is the distraction and aggravation that some endoscopists have reported with CAdE false positives. This performance issue is already being mitigated by newer iterations of CAdE algorithms, but nonetheless early frustration may discourage physicians from considering AI adoption in the future.

Overall, CAdE and CAdx diagnosis are just the first of a wave of AI tools that will support gastrointestinal endoscopic practice. The functionality of AI for colonoscopy will rapidly expand toward computer-aided quality assessment and AI automated completion of procedures notes. These and other innovative AI tools are moving along various stages of the developmental and regulatory pathway. Eventually, we predict an AI suite of tools for colonoscopy will seem indispensable, as a powerful adjunct to support safe and efficient clinical practice. AI tools that improve colonoscopy quality may become more accepted, and perhaps demanded, by payors, administrators, and possibly

even by well-informed patients who want to ensure the highest-quality examination of their colon. Beyond the immediate applications of AI for colonoscopy, AI has also revealed itself as a powerful lens through which to explore insights into how humans perform endoscopy, with all our inherent strengths and limitations. As technological innovation progresses, we can expect that the future for AI in endoscopy will be a hybrid model, where the unique capabilities of physicians and our AI tools will be seamlessly intertwined to optimize patient care.

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Received January 23, 2023. Accepted July 17, 2023.

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Author Contributions

All authors participated in the design and concept of the manuscript. Jason Samarasena contributed to the initial draft of the manuscript. All authors contributed to the editing and critical revision of the manuscript for important intellectual content.

Conflicts of interest

The authors disclose the following: Jason Samarasena is a consultant for Medtronic, Olympus, Neptune Medical, Applied Medical, Conmed, and Steris; receives educational grant support from Cook Medical and Conmed; and is a shareholder in SatisAI Health. Dennis Yang is a consultant for Medtronic, Olympus, Fujifilm, Apollo Endosurgery, and Microtech and receives research grant support from Microtech and 3D-Matrix. Tyler M. Berzin is a consultant for Medtronic, Vision AI, Microtech, Magentiq Eye, Boston Scientific, and RSIP Vision.