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The primary aim of *Artificial Intelligence in Gastrointestinal Endoscopy* (*AIGE*, *Artif Intell Gastrointest Endosc*) is to provide scholars and readers from various fields of artificial intelligence in gastrointestinal endoscopy with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

AIGE mainly publishes articles reporting research results obtained in the field of artificial intelligence in gastrointestinal endoscopy and covering a wide range of topics, including artificial intelligence in capsule endoscopy, colonoscopy, double-balloon enteroscopy, duodenoscopy, endoscopic retrograde cholangio-pancreatography, endosonography, esophagoscopy, gastrointestinal endoscopy, gastroscopy, laparoscopy, natural orifice endoscopic surgery, proctoscopy, and sigmoidoscopy.

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Artificial intelligence: Applications in critical care gastroenterology

Deven Juneja

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Abstract

Gastrointestinal (GI) complications frequently necessitate intensive care unit (ICU) admission. Additionally, critically ill patients also develop GI complications requiring further diagnostic and therapeutic interventions. However, these patients form a vulnerable group, who are at risk for developing side effects and complications. Every effort must be made to reduce invasiveness and ensure safety of interventions in ICU patients. Artificial intelligence (AI) is a rapidly evolving technology with several potential applications in healthcare settings. ICUs produce a large amount of data, which may be employed for creation of AI algorithms, and provide a lucrative opportunity for application of AI. However, the current role of AI in these patients remains limited due to lack of large-scale trials comparing the efficacy of AI with the accepted standards of care.

Key Words: Artificial intelligence; Critical care; Gastroenterology; Hepatology; Intensive care unit; Machine learning

Core Tip: The scope and applications of artificial intelligence (AI) are rapidly increasing. It is being increasingly applied in various fields, even in healthcare settings. The data generated by critically ill patients admitted in intensive care units (ICUs) is huge, which may be helpful in developing AI algorithms aimed to aid in their management. Patients with primary gastrointestinal diseases may frequently require ICU admission for management of advanced disease or related complications. Use of AI may aid the critical care physicians in managing such patients by helping in early diagnosis, prediction of complications, assessing response to therapy and overall prognostication.

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INTRODUCTION

Artificial intelligence (AI), in simple terms, may be defined as the simulation of human intelligence in machines which are programmed to react like humans, mimicking their actions by means of multi-disciplinary approach[1]. Unlike human mind, which can assimilate only a finite amount of data, machines can accumulate and process unlimited amount of data which can be used in different applications. AI is increasingly influencing every aspect of our life, including healthcare[2].

AI is a complex and rapidly evolving technology. More subsets of AI are being introduced regularly, and each of them have their own unique properties, advantages and limitations. Certain subsets of AI are more commonly employed in healthcare settings than others. The broad subsets of AI include machine learning (ML), deep learning, and cognitive computing. ML involves learning from the prior data to predict the future data. Artificial neural network (ANN) is a subset of ML inspired by the neuronal connections of the human brain. Its further subsets include deep neural network and convolutional neural network (CNN). Other AI algorithms commonly employed in healthcare settings include decision trees, random forest, support vector machines (SVMs), and Naïve Bayes.

Modern intensive care units (ICUs) produce a vast amount of data which is conducive for formation of AI algorithms [2]. A significant proportion of ICU patients are admitted with gastrointestinal (GI) disease or develop GI complications during their ICU course, necessitating further diagnostic and therapeutic interventions. As these patients form a vulnerable group, prone to develop side effects and complications, all measures must be undertaken to reduce invasiveness and ensure safety of ICU procedures. AI can potentially aid the critical care physicians by helping in early diagnosis, predicting complications and response to therapy and providing clinical prognostication in several GI disorders in critically ill patients (Table 1).

PANCREATIC DISORDERS

Almost 25% patients with acute pancreatitis (AP) develop complications or organ failure necessitating ICU admission[3]. Severe acute pancreatitis (SAP) is associated with high morbidity and mortality, requiring intensive monitoring and organ support. Early recognition of risk factors associated with progression to severe disease and development of complications, may help in initiating therapeutic measures and improve outcomes.

Diagnosis

Diagnosis of AP is based on the clinical presentation, laboratory parameters (serum amylase and lipase levels) and imaging (ultrasonography/computed tomography scans). As per the revised Atlanta classification, two out of three diagnostic criteria should be positive to make the diagnosis[4]. However, diagnosis may sometimes be missed due to non-specific clinical presentation, difficulty in imaging and low sensitivity of the revised Atlanta criteria, which may delay the treatment[5].

Integration of AI technology may aid in early diagnosis of acute pancreatitis[6]. ANNs can accurately diagnose AP using clinical and radiological data[7]. In 10%–20% of AP cases, acute necrotizing pancreatitis (ANP) develops, thus further increasing the risk of morbidity and mortality[8,9]. AI based models may also be useful in diagnosing acute necrotizing pancreatitis, which may affect treatment and prognosis[10].

Severity prediction and assessment

Several clinical scores, based on clinical, laboratory, and radiological risk factors, have been devised to assess severity and predict outcomes in patients with SAP. However, no single score has been proven to be superior to others and the search for an ideal scoring system continues[11]. Even though these tools are commonly used in clinical practice, they have low accuracy (60%-80%)[12]. Further, these models are complex, difficult to compute and have low specificity and positive predictive value. Moreover, some of these scoring systems, like Glasgow and Ranson scores, take 48 h to complete and are not devised for serial measurements[13].

AI tools like ANN have been utilised to develop algorithms based on routine blood and serum biochemical parameters to reliably predict severity of AP[14]. When compared to different clinical scores, ANN based models have performed better than Ranson's, APACHE II, and modified Glasgow score in predicting severity in patients with AP[15-17]. Additionally, ANN based tools require lesser parameters and may be computed within 6 h of presentation, as opposed to some scores which may require up to 48 h.

Prediction of complications and organ failure

Majority of deaths due to AP, especially those occurring in the first week, are secondary to progressive organ failure[18, 19]. Moreover, progressive organ failure is the primary determinant of SAP, irrespective of any local pancreatic complication. Hence, it is imperative to determine patients at risk of developing organ failure and ensure an early

Table 1 Potential clinical applications of artificial intelligence in critical care gastroenterology

Organ involved	Clinical condition	Clinical applications
Pancreas	Acute pancreatitis	Prediction of severity; Prediction of local and systemic complications; Prediction of organ failure; Prediction of mortality
Liver	Chronic liver disease	Diagnosis; Staging of fibrosis; Prediction of complications; Predicting disease progression; Prognosis; Predicting need for liver transplantation
	Liver lesions/tumours	Diagnosis and classification; Differentiating between benign and malignant lesions
	Hepatocellular carcinoma	Diagnosis; Staging; Response to therapy
Intestine	Gastroesophageal reflux disease	Diagnosis
	Helicobacter pylori infection	Diagnosis
	Intestinal lesions	Diagnosis; Differentiating between benign and malignant lesions
	Intestinal bleeding	Predicting risk of bleeding and re-bleeding; Diagnosis; Identifying source of bleeding
Gall bladder and bile duct	Gall stones	Diagnosis; Removal of stones; Predicting need and difficulty of ERCP
	Bile duct obstruction	Diagnosis
Gastro-surgery	Appendicitis	Diagnosis
	Liver transplantation	Predict post-operative course; Predict graft failure; Predict recurrence of HCC; Predict in-hospital mortality
	Abdominal aortic aneurysm	Diagnosis; Prediction of post-operative complications; Prediction of post-operative mortality

ERCP: Endoscopic retrograde cholangiopancreatography; HCC: Hepatocellular carcinoma.

diagnosis of any organ dysfunction. ANN based model utilising commonly employed patient and laboratory parameters have been shown to accurately predict development of organ failure in AP patients[20].

AI based tools like regression tree algorithms and ANN have been used to predict complications such as acute lung injury, ARDS, portal vein thrombosis and porto-spleno-mesenteric vein thrombosis in patients with AP and AI has been proven to be more accurate than logistic regression based models in predicting these complications[21-25].

Prognostication

In spite of recent advances, mortality associated with SAP remains significant[26]. The overall mortality of ANP is approximately 15%–20%, of which there is a further twofold increase in a third of ANP cases where the necrotic tissue becomes infected[27,28]. Better understanding of risk factors associated with poorer clinical outcomes may help the physicians in instituting therapeutic measures and prognostication, as early intervention, within first 48 h, may help in improving outcomes[29].

Even though several clinical scores are commonly employed to aid in prognostication, these scores have several limitations. AI algorithms based on ANN have been shown to be better than these clinical scores in predicting clinical outcomes including length of hospital stay in patients with acute pancreatitis. Keogan *et al*[30] used ANN based on radiological and laboratory data from pancreatitis patients which performed better than both the Balthazar and Ranson scoring systems.

Data collected from acute pancreatitis patients from the Medical Information Mart for Intensive Care-III (MIMIC-III) database has shown that AI based algorithm can be effectively used to predict in-hospital mortality with an area under the curve (AUC) of 0.769. Further, AI based algorithms performed better than the commonly used scoring systems including SOFA score (AUC 0.401) and Ranson score (AUC 0.652) and logistic regression analysis (AUC 0.607) in predicting in-hospital mortality[14,31,32].

LIVER DISORDERS

Acute liver failure is a common indication for ICU admission. Patients with chronic liver disease (CLD) may also require ICU support in case of acute decompensation, development of acute on chronic liver disease or due to natural progression of CLD. Even ICU patients may develop liver dysfunction necessitating early diagnosis and intervention for improving prognosis. AI may have a potential role in early diagnosis of acute decompensation, identification of complications and prognostication in patients with liver disease.

Diagnosis of CLD

In critically ill patients, bedside ultrasonography is primarily used for diagnosis of CLD. However, it is operator dependant, qualitative in nature and have limited accuracy. Further, it may be difficult to distinguish fatty changes from early cirrhosis because of overlapping features[33]. Machine learning algorithms based on ultrasound have been applied for analysis of steatosis and the staging of liver fibrosis. Using ultrasound images, CNN based AI model has been shown to effectively assess the amount of liver steatosis with an area under the receiver operating curve (AUROC) of 0.98[34]. Deep learning-based algorithms have shown to improve accuracy for diagnosis of CLD with an AUROC of 1.0 as compared to conventional AI algorithms developed using SVM[35]. Furthermore, ML algorithms based on simple patient (age) and laboratory parameters (aspartate aminotransferase, albumin, and platelet count) have also been shown to accurately predict advanced fibrosis[36].

Liver fibrosis strongly correlates with development of hepatocellular cancer (HCC) and poor outcomes in patients with CLD. Liver biopsy remains the gold standard for detection and quantification of fibrosis. As it is an invasive procedure, it is associated with several inherent complications, especially in more vulnerable critically ill patients. Hence, non-invasive tests like bedside transient elastography measuring liver stiffness are being evaluated for such clinical conditions helping in bedside diagnosis and staging of liver fibrosis. Even though it is a comparatively newer test, it may find better applicability in ICU patients because of its high accuracy, easy repeatability, and non-invasive nature[37]. It has been shown that, AI based on transient elastography scans may further improve its accuracy and reduce subjectivity and inter-observer variations[38,39].

As AI based tools including ANN have been shown to reliably predict significant fibrosis in patients with chronic hepatitis, AI may be helpful in accurately staging liver fibrosis and may help in reducing the need for invasive procedures like liver biopsy[40,41].

Prediction of complications

CLD patients are at risk of developing local and systemic complications which may sometimes be life-threatening. Among the local complications, variceal bleed remains a common cause for increased morbidity and mortality in CLD patients. Hence, prediction and prevention of variceal bleed may improve clinical outcomes. Certain clinical scores (Child-Pugh score) and clinical parameters (hepatic-venous pressure gradient) have been successfully used as prognostic factors to stratifying the risk of variceal rebleeding[42]. However, they have limited accuracy. Diagnosis of varices requires endoscopy, which may not be feasible in many critically ill patients due to its invasive nature. ANN and ML based tools have been used to accurately predict presence of esophageal varices, obliviating the need for invasive endoscopy[43,44]. AI based algorithms also have the potential to accurately predict the risk of rebleeding in patients with liver cirrhosis which may aid the clinicians in managing such patients[45].

Prognosis

Short term prognosis of CLD depends upon development of complications and other organ dysfunction. ICU patients with CLD have high mortality rates especially if they develop other organ dysfunction requiring renal replacement therapy or invasive mechanical ventilation support[46]. On the other hand, long term prognosis depends on disease progression. Studies have shown that AI may be instrumental in identifying the cirrhotic patients at risk for disease progression and development of liver related complications including HCC, death, hepatic decompensation and even need for liver transplantation[47,48]. In CLD patients, DL-based model has been shown to be a good predictor of transplant-free survival at 1 and 3 years after diagnosis[48]. ANN algorithms based on clinical and laboratory parameters have been shown to accurately predict 1 year mortality in patients with CLD. This may aid in patient selection for liver transplantation[49].

Development of HCC may also impact clinical outcomes in such patients. ML has been employed for predicting development of HCC, diagnosis of HCC and even prediction of response to therapy[50-52].

AI may also be helpful in diagnosing focal liver lesions. AI based tools have shown to be useful in diagnosing and classifying liver nodules (cysts, hemangiomas, HCC) using ultrasound images[53,54]. DL and CNN based algorithms using MRI images, have also been shown to be effective in differentiating benign and malignant liver tumors, and classifying HCC and other tumors[55,56].

Response to therapy

In patients with liver disease it may be useful to identify patients who may respond to therapeutic interventions. This may aid in patient prognostication and triaging of limited ICU resources. ANN based models have been used to accurately predict the response to therapy with pegylated interferon alpha and ribavirin in patients with chronic hepatitis C infection, with sensitivity and specificity approaching 90%[57]. AI may also aid in predicting outcomes and risk for complications in post-liver transplantation patients[58].

INTESTINAL DISORDERS

Endoscopy is frequently employed to evaluate the gastro-intestinal tract. As it is an invasive procedure, it may be difficult to perform and associated with significant complication rates especially in critically ill ICU patients[59].

Diagnosis

Diagnosis of common GI disorders can be aided with AI based technology. ANN based model has been shown to reliably diagnose gastroesophageal reflux disease non-invasively by employing only clinical parameters[60]. CNN model based on endoscopic images has been shown to accurately diagnose *Helicobacter pylori* infection. Further, it was shown that the time required by AI to analyze the endoscopy images and make a diagnosis was significantly less as compared to experienced endoscopists (3 min and 14 s *vs* 230.1 min)[61]. Even a recently published meta-analysis reported that CNN may be as accurate as experienced physicians in making the diagnosis of *Helicobacter pylori* infection[62].

AI based algorithms have been developed to diagnose and differentiate between malignant and non-malignant esophageal diseases like Barret's esophagus and squamous cell carcinoma[63]. Moreover, AI may even be helpful in identifying early neoplastic changes to ensure timely diagnosis which may enable early intervention and aid in improving outcomes[64].

Gastrointestinal bleed

GI bleed remains a common indication for ICU admission. Additionally, increased stress, use of steroids and presence of sepsis can predispose general ICU patients to develop GI bleed during their ICU course. Some bleeds, especially those involving the small bowel, may be difficult to identify and manage. Even though the causes for upper and lower GI bleed may be relatively easier to identify using endoscopic techniques, repeated endoscopies may be required in a significant proportion of patients at risk for recurrent bleed. This may be especially difficult in critically ill ICU patients, who may benefit most from such procedures. ML based algorithms using endoscopic images have been developed which may be useful in identifying the patients at risk of rebleed and increased mortality with up to 90% accuracy[65-68]. ML models based only on clinical parameters like age, presence of gastric ulcers or gastrointestinal disease, presence of underlying malignancy or infections and serum hemoglobin levels have also been developed which have shown to predict risk of rebleed up to 1 year with an accuracy of 84.3% which may obliviate the need for repeated bronchoscopies[69].

AI, using various algorithms, have been shown to be helpful in more accurately identifying the source of bleed in patients with small bowel bleed using images from capsule endoscopy, which may avoid further invasive tests[70-73].

Hence, AI have the potential to reduce the need for endoscopies, allow for quicker procedures (by shortening the time required for observation and analysis), and also decrease the necessity for performing endoscopic biopsies, which may be particularly beneficial for critically ill patients.

BILIARY DISORDERS

Endoscopic retrograde cholangiopancreatography (ERCP) is commonly employed to diagnose disorders of the gall bladder, bile duct and the pancreas. However, it may be difficult to perform and may be associated with significant complications. Hence, careful patient selection is of paramount importance. An ANN model has been shown to have better discriminant ability and accuracy than a multivariate logistic regression model in selecting patients for therapeutic ERCP[74]. Using data collected from endoscopic images, AI has also been used to predict difficult ERCP which may help in reducing the failure rates and performing safer procedures[75,76]. AI model based only on clinical markers has been shown be an important adjunct to more invasive procedures in evaluation of bile duct obstruction[77].

AI may also support the physicians performing the ERCP by helping to differentiate between benign and malignant lesions and aid in their classification[78,79]. AI based algorithms may also be useful in therapeutic ERCPs by increasing the probability of successful removal of biliary stones[75]. Further, data suggests that AI based interventions have the potential to reduce post-ERCP complications including acute pancreatitis[80].

Endoscopic ultrasound (EUS) has been introduced recently to aid in the diagnosis of pancreatobiliary diseases. However, the diagnostic accuracy of EUS also remains limited with most studies reporting the range to be 80%-95%[81]. AI may be instrumental in increasing the efficacy and accuracy of EUS in the diagnosis and prognostication of GI diseases [82].

GASTROINTESTINAL SURGERY

Patients frequently require ICU care in the peri-operative period of major GI surgeries for clinical stabilisation and optimisation of therapy. These patients require close monitoring for development of any post-operative complications which may affect their hospital course and increase morbidity or mortality. AI based tools may be instrumental in recognising patients at risk of developing post-operative complications who may benefit from intensive care and early intervention.

Acute appendicitis remains a common and dreaded abdominal emergency. However, its diagnosis is often missed, which may increase morbidity and mortality. ANN has shown promising results in diagnosis of acute appendicitis and has performed better than clinical scores like Alvarado clinical scoring system. This may aid in screening of patients presenting with acute abdomen and making an early diagnosis[83].

In patients undergoing liver transplantation, AI has been used to predict post-operative course, graft failure, recurrence of HCC and even survival after surgery[84-87]. ANN has also been used to predict in-hospital mortality in patients after primary liver cancer surgery[88].

Certain acute abdominal emergencies like abdominal aortic aneurysm (AAA) rupture may be associated with high mortality rates. Prompt recognition and early intervention may improve outcomes in such cases. CNN based model has been shown to have high accuracy of 99.1% with an AUROC of 0.99 for detecting AAA. Also, CNN based models may be effective in accurately detecting presence of any leak post AAA repair and predict in-hospital mortality in the post-operative period[89-91]. Further, AI using easily definable pre-operative parameters, has been shown to provide a simple and highly discriminant adjunct in accurately recognising patients at higher risk of death after AAA repair surgery[91].

Similarly, AI based algorithms have been used to predict clinical outcomes including post-operative complications and mortality in other major or emergency abdominal surgeries including bariatric and metabolic surgeries, duodenal switch surgeries, and even after inguinal hernia repair[92-95].

NON-CLINICAL APPLICATIONS

Apart from these clinical applications, AI may be helpful in several non-clinical applications in GI critical care. AI can help in assimilating and analysing huge databases, help in reducing human errors in data entry, and assist in conducting large scale multi-center trials[96]. These intelligent database systems can also improve adherence to current clinical guidelines and protocols and aid in performing clinical audits and improve performance. Further, AI may also be instrumental in providing a more individualised patient care, and hence pave the way for precision medicine in the field of gastroenterology[97].

LIMITATIONS TO AI APPLICATIONS

The literature regarding use of AI in healthcare settings is increasing. However, most of the present studies have small sample sizes and are retrospective in nature. The literature on ICU patients is even more limited, restricting the use of AI in these patients. Moreover, comparison between different studies is difficult, as they have used different types of AI tools, with new tools being added frequently. Use of patient data for developing AI algorithms may lead to privacy and medico-legal issues which need to be adequately addressed by designing and implementing appropriate regulations and guidelines. Further, issues related to liability, reliability and safety of AI applications need to be addressed before widespread implementation and acceptance of AI in the current healthcare system becomes possible.

FUTURE DIRECTIONS

AI may form an important component of healthcare management and a lucrative adjunct to intensive care physicians in the future. However, large scale trials need to be conducted, especially in ICU patients, to evaluate and validate the efficacy and safety of AI. Further, standardisation of AI tools and algorithms must be done to ensure their comparability. For AI to be integrated in the routine clinical practice, healthcare workers need to be trained regarding safe and effective use of AI to ensure its proper utilisation and interpretation. Appropriate rules and regulations must be implemented to prevent any violation of patient privacy and maintain confidentiality of patient data.

CONCLUSION

With a huge increase in digitalisation of data and increased availability of big data, AI holds immense promise to change the landscape of healthcare in the not-so-distant future. It has the potential to improve diagnostics, predict progression and complications, and predict outcomes of critically ill gastroenterology patients thereby, reducing medical errors, increasing efficiency and improving clinical outcomes. AI can potentially reduce the number of invasive procedures and hence, reduce complication rates and provide a safer environment. However, there still remains issues regarding its safety, liability, legality, and patient privacy, which need to be addressed before it is incorporated in mainstream clinical care. Even though it may not be able to replace the physician's clinical acumen, it can be a good supplement and may aid in improving patient care and safety.

FOOTNOTES

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Abstract

BACKGROUND
Artificial intelligence (AI) has potential in the optical diagnosis of colorectal polyps.

AIM
To evaluate the feasibility of the real-time use of the computer-aided diagnosis system (CADx) AI for ColoRectal Polyps (AI4CRP) for the optical diagnosis of diminutive colorectal polyps and to compare the performance with CAD EYE™

(Fujifilm, Tokyo, Japan). CADx influence on the optical diagnosis of an expert endoscopist was also investigated.

METHODS

AI4CRP was developed in-house and CAD EYE was proprietary software provided by Fujifilm. Both CADx-systems exploit convolutional neural networks. Colorectal polyps were characterized as benign or premalignant and histopathology was used as gold standard. AI4CRP provided an objective assessment of its characterization by presenting a calibrated confidence characterization value (range 0.0-1.0). A predefined cut-off value of 0.6 was set with values < 0.6 indicating benign and values ≥ 0.6 indicating premalignant colorectal polyps. Low confidence characterizations were defined as values 40% around the cut-off value of 0.6 (< 0.36 and > 0.76). Self-critical AI4CRP's diagnostic performances excluded low confidence characterizations.

RESULTS

AI4CRP use was feasible and performed on 30 patients with 51 colorectal polyps. Self-critical AI4CRP, excluding 14 low confidence characterizations [27.5% (14/51)], had a diagnostic accuracy of 89.2%, sensitivity of 89.7%, and specificity of 87.5%, which was higher compared to AI4CRP. CAD EYE had a 83.7% diagnostic accuracy, 74.2% sensitivity, and 100.0% specificity. Diagnostic performances of the *endoscopist alone* (before AI) increased non-significantly after reviewing the CADx characterizations of both AI4CRP and CAD EYE (*AI-assisted endoscopist*). Diagnostic performances of the AI-assisted endoscopist were higher compared to both CADx-systems, except for specificity for which CAD EYE performed best.

CONCLUSION

Real-time use of AI4CRP was feasible. Objective confidence values provided by a CADx is novel and self-critical AI4CRP showed higher diagnostic performances compared to AI4CRP.

Key Words: Artificial intelligence; Colorectal polyp characterization; Computer aided diagnosis; Diminutive colorectal polyps; Optical diagnosis; Self-critical artificial intelligence

Core Tip: In this study, two computer-aided diagnosis systems (CADx) [Artificial intelligence for ColoRectal polyps (AI4CRP) and CAD EYE] were compared head-to-head and showed that real-time use was feasible in clinical practice, but does not yet meet quality standards for optical diagnosis. AI4CRP provided characterizations accompanied by confidence values, enabling self-critical AI4CRP in which low confidence characterizations were excluded. Self-critical AI4CRP resulted in considerably higher diagnostic performances compared to AI4CRP. The AI-assisted endoscopists, optically diagnosing colorectal polyps after reviewing both CADx characterizations, had non-significantly higher diagnostic performances compared to the endoscopist alone (before CADx).

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INTRODUCTION

Endoscopists' task in performing colonoscopies increasingly involves optical diagnosis, the endoscopic characterization of colorectal polyps. Recently, diagnostic performance of optical diagnosis increased due to optimization of technologies such as high definition imaging, magnification, and image enhancement techniques like blue light imaging (BLI)[1,2]. Despite these optimizations, endoscopists do not consistently meet quality standards set by the American society for gastrointestinal endoscopy (ASGE) and the European society of gastrointestinal endoscopy (ESGE) for implementation of the resect-and-discard and diagnose-and-leave strategies based on optical diagnosis[3,4]. The first strategy entails diminutive (≤ 5 mm) colorectal polyps to be resected and discarded without histopathological assessment under the condition of a ≥ 90% agreement in the post-polypectomy surveillance interval between the optical and histopathological diagnosis. The second strategy states that diminutive hyperplastic polyps in the rectosigmoid can be left in situ if a negative predictive value (NPV) of ≥ 90% is reached for the optical diagnosis of adenomatous polyps. Large, multicenter studies demonstrated disappointing results on optical diagnosis, even for additionally trained (bowel cancer screening) endoscopists, hampering implementation in clinical practice[5,6]. Diagnostic performances are operator dependent, showing high interobserver variability, and rely on training and expertise[3,7,8].

Optical diagnosis with artificial intelligence (AI) has the potential to overcome this high interobserver variability by minimizing the operator dependence and providing objective optical diagnoses[9]. Accurate characterization of colorectal polyps with computer-aided diagnosis systems (CADx) may facilitate the implementation of the resect-and-discard and diagnose-and-leave strategies by meeting the set quality standards. Implementation of these strategies may lead to a reduction in unnecessary polypectomies, thereby decreasing the risk of post-polypectomy complications, reducing histopathology costs, and improving the cost-effectiveness of colonoscopy[10,11].

The primary aim of this study was to evaluate the feasibility of the real-time use of the CADx AI for ColoRectal polyps (AI4CRP) for the optical diagnosis of diminutive (≤ 5 mm) colorectal polyps. Secondary aims were a head-to-head comparison of AI4CRP with CAD EYE™ (Fujifilm, Tokyo, Japan), evaluating the diagnostic performances of self-critical AI4CRP (providing only high confidence diagnoses), the diagnostic performances of an expert endoscopist (endoscopist alone), and the influence of CADx on the optical diagnosis of an expert endoscopist (AI-assisted endoscopist).

MATERIALS AND METHODS

This prospective study was conducted at the Catharina Hospital Eindhoven, the Netherlands. The study was performed in accordance with the declaration of Helsinki and the General Data Protection Regulation. The Medical Research Ethics Committees United (W20.239, July 2021) approved the study (ClinicalTrials.gov NCT05349110).

AI4CRP

AI4CRP, developed in-house by our research group (Video Coding & Architectures, Eindhoven University of Technology, the Netherlands), is an image-based CADx exploiting convolutional neural networks. AI4CRP was previously validated and a technical explanation has been published[12,13]. AI4CRP was trained multicenter and tested using prospectively collected datasets from multiple endoscopy vendors (Fujifilm and Pentax) (Supplementary Table 1). Characterizations were made in three image modalities: high-definition white light (HDWL), BLI, and linked color imaging (LCI). AI4CRP characterized colorectal polyps as benign (hyperplastic polyp) or premalignant [adenoma and sessile serrated lesion (SSL)]. The characterization was provided by a green assist bar for benign and a red assist bar for premalignant polyps. A heatmap pointed out the area of interest (Figure 1). Distinctive from other CADx-systems, AI4CRP provided calibrated confidence characterization values (range 0.0-1.0) representing the objective confidence level of AI4CRP in its characterization. A predefined cut-off value of 0.6 was set with values < 0.6 indicating benign and values ≥ 0.6 indicating premalignant colorectal polyps. A value close(r) to 0.0 implies high confidence for a benign colorectal polyp and a value close(r) to 1.0 high confidence for a premalignant colorectal polyp. Providing these confidence values enabled a self-critical AI4CRP in which low confidence characterizations were excluded. Low confidence characterizations were defined as values 40% around the cut-off value of 0.6 (< 0.36 and > 0.76). To explore the added value of our self-critical CADx and allowing for an exploration of self-critical AI4CRP, the system was compared head-to-head with CAD EYE.

CAD EYE

CAD EYE is a commercial, video-based CAD-system developed to detect and characterize colorectal polyps. CAD EYE exploits convolutional neural networks[11]. For this study, only the characterization mode (BLI) was used. CAD EYE characterized colorectal polyps as hyperplastic (hyperplastic polyp and SSL) or neoplastic (adenoma) (note the difference in SSL characterization compared to AI4CRP). A status bar indicated the status of the characterization (complete or incomplete), a visual assist circle colored green for hyperplastic and yellow for neoplastic, a position map indicated the position of the colorectal polyp, and a characterization was displayed (Figure 1)[14].

Patients

Patients, aged ≥ 18 years, referred for screening colonoscopies, symptoms, or surveillance were eligible for participation. Consecutive patients were included if at least one diminutive colorectal polyp was encountered. Exclusion criteria were polyposis syndromes, inflammatory bowel diseases, inadequate bowel preparations (Boston bowel preparation scale < 6), and emergency colonoscopies. Patients were informed during a screening visit at the outpatient clinic before the colonoscopy. All patients provided written informed consent.

Endoscopic procedure

Colonoscopies were performed by one expert endoscopist (R.M.S.). The endoscopist was additionally trained in optical diagnosis (succeeding several training sessions in optical diagnosis organized by the ESGE), performed optical diagnoses on a regular basis according to the ESGE curriculum for optical diagnosis[1], and is a teacher in optical diagnosis training sessions. The endoscopist was familiarized with both CADx-systems. He was involved in the development of AI4CRP and used CAD EYE in clinical practice for 6 months before the start of this study. A maximum of three diminutive colorectal polyps per patient were included due to time restrictions. If more than three diminutive colorectal polyps were encountered, the first three were included to minimize selection bias. The endoscopist optically diagnosed colorectal polyps real-time (*endoscopists alone*) as benign (hyperplastic polyp) or premalignant (adenoma and SSLs) using BLI and according to Japan NBI Expert Team and BLI adenoma serrated international classification (BASIC)[15,16]. The endoscopist provided a confidence level [low or high (≥ 90%)] for each optical diagnosis. Subsequently, all colorectal polyps optically diagnosed by the endoscopist were characterized by both CADx-systems in sequence. AI4CRP characterized images captured from the real-time video output in each image modality separately and calculated an overall

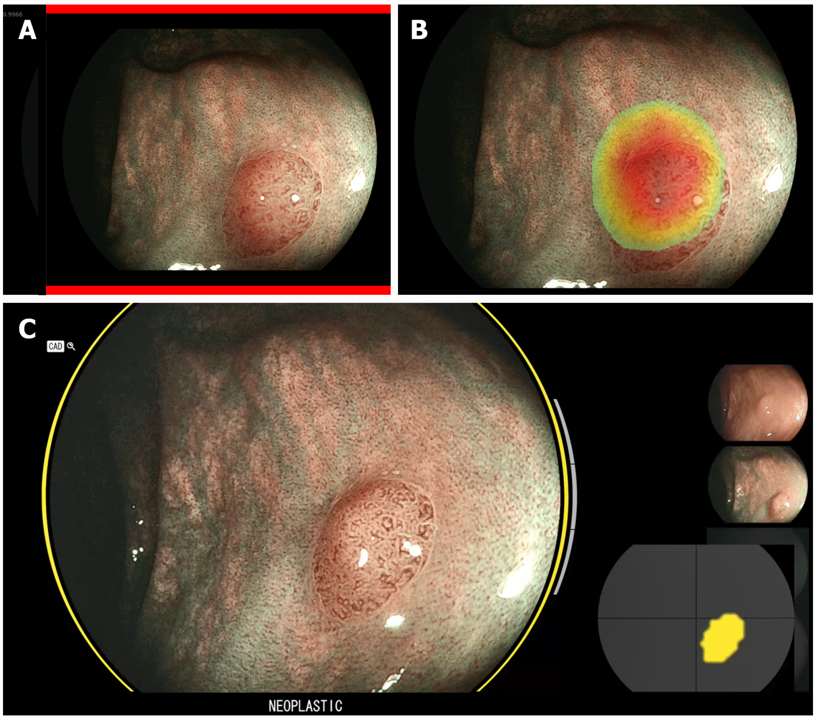

Figure 1 Endoscopic images of a tubular adenoma in blue light imaging. A: Artificial intelligence for ColoRectal Polyps (AI4CRP's) neoplastic prediction [indicated by the red assist bar and characterization value of > 0.6 (0.9966)]; B: The corresponding heatmap (pointing out the area of interest of the AI4CRP prediction); C: CAD EYE's predicted characterization [indicated by a complete (grey) status bar, a yellow visual assist circle, yellow position map, and 'neoplastic' description].

characterization using all three image modalities (multimodal imaging). Images were manually captured by a research physician. Motion-blurred images and images out-of-focus were excluded. Afterwards, CAD EYE was activated by the endoscopist to provide a characterization. Both CADx characterizations were recorded and saved. Lastly, the endoscopist optically diagnosed the colorectal polyps after reviewing both CADx characterizations (*AI-assisted endoscopist*) and again provided a confidence level.

Despite proper endoscope positioning, CAD EYE provided inconclusive characterizations, defined as unstable characterizations over time (switching diagnoses between hyperplastic and neoplastic) despite a complete status bar. The video-recorded CAD EYE characterizations were assessed by two independent expert endoscopists blinded to histopathology. Upon agreement of inconclusiveness, these characterizations were excluded from the analyses.

Outcomes

The primary outcome was the feasibility of the real-time use of AI4CRP. Feasibility was defined as seamless video output reception from the endoscopy processor without noticeable clinically relevant latency (the time from capturing the endoscopic image to outputting the analyzed results)[17] and seamless operation of the software in obtaining characterizations. Latency was not measured by AI4CRP itself or by the investigators since it is known from previous studies that small differences in latency were not noticeable for endoscopists, and therefore only clinically noticeable latency was deemed relevant[12]. Secondary outcomes were real-time diagnostic performances of (self-critical) AI4CRP and a head-to-head comparison of (self-critical) AI4CRP with CAD EYE and an expert endoscopist (endoscopist alone and AI-assisted endoscopist). Histopathology was used as gold standard and assessed according to the revised Vienna classification. Involved pathologists were specialized in gastrointestinal histopathology. Differences in characterization of SSLs by AI4CRP, CAD EYE, and the endoscopist were accounted for by histopathology in computing measures of diagnostic performance. Outcomes were reported according to the STARD (standard for reporting diagnostic accuracy studies) checklist.

Statistical analyses

Due to the feasibility design of the study, no formal sample size calculation was performed. The sample size (n = 30 patients) was based on a previous CADx feasibility study[18]. Baseline characteristics are presented as proportions (%) for categorical variables or as mean [standard deviation (SD)] for numerical variables. Feasibility was described qualitatively. Diagnostic performances were investigated in terms of diagnostic accuracy, sensitivity, specificity, and negative and positive predictive values (NPV, PPV), expressed with 95% confidence intervals. As sensitivity analysis, cluster bootstrapping was performed to account for multiple colorectal polyps per patient. Self-critical AI4CRP was analyzed post-hoc. Differences between (self-critical) AI4CRP, CAD EYE, and the endoscopist were analyzed using the McNemar test for paired proportions. Two-sided P values ≤ 0.05 were considered statistically significant. Statistical analyses were performed with IBM SPSS Statistics (IBM Corp., United States) and R (R Foundation, Austria). The statistical methods of this study were reviewed by B. Winkens from the Department of Methodology and Statistics of Maastricht University.

RESULTS

Study population

Patients who underwent a colonoscopy at Catharina Hospital Eindhoven between August and November 2021 were screened for eligibility. In total, 30 patients with 51 colorectal polyps were included (Figure 2). Patient characteristics are provided in Table 1. Mean polyp size was 2.8 mm (SD 1.0). Histopathology showed 32 tubular adenomas (62.7%), 1 tubulovillous adenoma (2.0%), 6 SSLs (11.8%), and 12 hyperplastic polyps (23.5%) (Table 2).

Feasibility

Real-time use of AI4CRP was deemed feasible in clinical practice. By means of plug-and-play AI4CRP was easily connected to the endoscopy processor. No noticeable clinically relevant latency was observed in receiving the video output from the processor and the software worked flawless without interruptions.

AI4CRP

AI4CRP was able to characterize all 51 colorectal polyps. Eight images were excluded because the images were out of focus and four because of motion blur. For these colorectal polyps, a second image was taken by the endoscopist. AI4CRP showed a sensitivity of 82.1% (95%CI 0.66-0.92) and a diagnostic accuracy of 80.4% (95%CI 0.66-0.90) in BLI, which was significantly higher compared to HDWL (sensitivity 59.0%, P = 0.022 and diagnostic accuracy 66.7%, P = 0.007) (Table 3, Supplementary Figure 1). NPV was also highest in BLI (56.3%, 95%CI 0.31-0.79), but not significantly different from other image modalities. Self-critical AI4CRP excluded 14 low confidence characterizations [27.5% (14/51), tubular adenomas n = 7, SSLs n = 3, hyperplastic polyps n = 4]. Self-critical AI4CRP showed higher diagnostic performances on all metrics compared to AI4CRP (sensitivity 89.7% and diagnostic accuracy 89.2%) (Table 4).

CAD EYE

CAD EYE was able to provide a characterization for all but two colorectal polyps (n = 49, 96.1%), which were diagnosed inconclusively. CAD EYE had a sensitivity of 74.2% (95%CI 0.55-0.87), a specificity of 100.0% (95%CI 0.78-1.00), a NPV of 69.2% (95%CI 0.48-0.85), and a diagnostic accuracy of 83.7% (95%CI 0.70-0.92) (Table 4).

Expert endoscopist

The endoscopist (endoscopist alone) optically diagnosed 47 (92.2%, 47/51) colorectal polyps with high confidence. Before AI (endoscopist alone), sensitivity was 97.4% (95%CI 0.85-1.00), specificity 77.8% (95%CI 0.40-0.96), NPV 87.5% (95%CI 0.47-0.99), and diagnostic accuracy 93.6% (95%CI 0.81-0.98) (Table 4). Although this study was not powered to detect a difference between the endoscopist alone and the AI-assisted endoscopist, after reviewing characterizations of both CADx-systems specificity, PPV, NPV, and diagnostic accuracy increased non-significantly for the AI-assisted endoscopist (Table 4, Supplementary Figure 2). The number of optical diagnoses made with high confidence also increased [endoscopist alone 92.2% (47/51) *vs* AI-assisted endoscopists 96.1% (49/51), P = 0.500] (Supplementary Table 2).

Diagnostic performances of the AI-assisted endoscopist were higher compared to both CADx-systems, except for specificity for which CAD EYE performed best. Comparing diagnostic performances of AI4CRP with the endoscopist alone showed a significantly higher sensitivity (P = 0.031) and a non-significantly higher specificity and diagnostic accuracy for the endoscopist (P = 1.000 and P = 0.180, respectively) (Supplementary Figure 2). The AI-assisted endoscopist also had a significantly higher sensitivity (P = 0.031) and a non-significantly higher specificity and diagnostic accuracy (P = 0.500 and P = 0.289, respectively) than AI4CRP. Self-critical AI4CRP did not show any significant difference with the endoscopist alone and the AI-assisted endoscopist. Compared with CAD EYE, the endoscopist alone had a significantly higher diagnostic accuracy (P = 0.004) and sensitivity (P = 0.016), while specificity was non-significantly lower (P = 0.500) (Supplementary Figure 2). The same accounted for the comparison between CAD EYE and the AI-assisted endoscopist. Performing cluster bootstrapping to correct for multiple colorectal polyps per patient did not change the conclusions (Supplementary Table 3). Analysis according to colorectal polyp location are presented in Supplementary Table 4.

DISCUSSION

AI4CRP use for the optical diagnosis of diminutive colorectal polyps was feasible and showed promising results. The novelty of our AI4CRP lies in providing objective confidence values. Self-critical AI4CRP achieved considerably higher diagnostic performances compared to AI4CRP. Reviewing characterizations by AI4CRP and CAD EYE did non-significantly increase the performance of the AI-assisted endoscopist.

Real-time use of AI4CRP was feasible and did not obstruct clinical workflow. No clinically relevant time delays in obtaining CADx characterizations were observed. This study compared two CADx-systems head-to-head, namely AI4CRP and CAD EYE. By comparing a commercially available CADx with an in-house developed CADx, comparison between the systems and a self-critical system was possible. Diagnostic performances of both CADx-systems were non-significantly inferior compared to the performance of the expert endoscopist, with the exception of specificity, were CAD

Table 1 Baseline characteristics of patients, *n* (%)

	Patients, *n* = 30
Gender, female	13 (43.3)
Age in years, mean (SD) [range]	65.8 (8.4) [50-78]
Indication colonoscopy	
Bowel cancer screening program	15 (50.0)
Surveillance	10 (33.3)
Symptoms	5 (16.7)
Family history positive for CRC	5 (16.7)
BBPS, mean (SD)	6.6 (1.4)
Number of colorectal polyps per patient[1]	
1 colorectal polyp	15 (50.0)
2 colorectal polyps	9 (30.0)
3 colorectal polyps	6 (20.0)

[1]A maximum of three colorectal polyps were included per patient.
BBPS: Boston bowel preparation scale; CRC: colorectal cancer.

Table 2 Baseline characteristics for colorectal polyps, *n* (%)

	Colorectal polyps, *n* = 51
Location	
Cecum	7 (13.7)
Ascending colon	8 (15.7)
Transverse colon	15 (29.4)
Descending colon	5 (9.8)
Sigmoid	10 (19.6)
Rectum	6 (11.8)
Size, mean (SD) [range]	2.8 (1.0) [2-5]
Morphology	
Sessile (Paris Is)	45 (88.2)
Flat-elevated (Paris IIa)	6 (11.8)
Histopathology	
Tubular adenoma, LGD	32 (62.7)
Tubulovillous adenoma, LGD	1 (2.0)
Sessile serrated lesion, no dysplasia	6 (11.8)
Hyperplastic polyp, no dysplasia	12 (23.5)
Resection technique – cold snare	51 (100.0)

LGD: Low grade dysplasia.

EYE demonstrated the best performance. This difference in specificity between (self-critical) AI4CRP and CAD EYE, can be explained by the differences in characterizing SSLs. Performances of both CADx-systems should be improved for utility in clinical practice.

Objective assessment of the confidence level as performed by self-critical AI4CRP is a novelty. Diagnostic performances were considerably higher for self-critical AI4CRP compared to AI4CRP. CAD EYE does not provide a confidence value while inconclusive diagnoses occurred (3.9%). However, these inconclusive diagnoses were marked by expert consensus

Table 3 Diagnostic performances of artificial intelligence for ColoRectal polyps in different image enhancement modes

	AI4CRP (*n* = 51)			
	BLI, % (95%CI)	HDWL, % (95%CI)	LCI, % (95%CI)	Multimodal imaging, % (95%CI)
Sensitivity	82.1 (0.66-0.92)	59.0 (0.42-0.74)	76.9 (0.60-0.88)	71.8 (0.55-0.84)
Specificity	75.0 (0.43-0.93)	91.7 (0.60-1.00)	83.3 (0.51-0.97)	91.7 (0.60-1.00)
PPV	91.4 (0.76-0.98)	95.8 (0.77-1.00)	93.8 (0.78-0.99)	96.6 (0.80-1.00)
NPV	56.3 (0.31-0.79)	40.7 (0.23-0.61)	52.6 (0.29-0.75)	50.0 (0.29-0.71)
Diagnostic accuracy	80.4 (0.66-0.90)	66.7 (0.52-0.79)	78.4 (0.64-0.88)	76.5 (0.62-0.87)

AI4CRP: Artificial intelligence for ColoRectal polyps; BLI: Blue light imaging; CI: Confidence interval; HDWL: High definition white light; LCI: Linked color imaging; NPV: Negative predictive value; PPV: Positive predictive value.

Table 4 Diagnostic performance of artificial intelligence for ColoRectal polyps, self-critical artificial intelligence for ColoRectal polyps, CAD EYE, and the endoscopist

	AI4CRP[1], % (95%CI), *n* = 51	Self-critical AI4CRP[1], % (95%CI), *n* = 37	CAD EYE, % (95%CI), *n* = 49	Endoscopist alone[2], % (95%CI), *n* = 47	AI-assisted endoscopist[2,3], % (95%CI), *n* = 49
Sensitivity	82.1 (0.66-0.92)	89.7 (0.72-0.97)	74.2 (0.55-0.87)	97.4 (0.85-1.00)	97.4 (0.85-1.00)
Specificity	75.0 (0.43-0.93)	87.5 (0.47-0.99)	100.0 (0.78-1.00)	77.8 (0.40-0.96)	90.9 (0.57-1.00)
PPV	91.4 (0.76-0.98)	96.3 (0.79-1.00)	100.0 (0.82-1.00)	94.9 (0.81-0.99)	97.4 (0.85-1.00)
NPV	56.3 (0.31-0.79)	70.0 (0.35-0.92)	69.2 (0.48-0.85)	87.5 (0.47-0.99)	90.9 (0.57-1.00)
Diagnostic accuracy	80.4 (0.66-0.90)	89.2 (0.74-0.96)	83.7 (0.70-0.92)	93.6 (0.81-0.98)	95.9 (0.85-0.99)

[1]AI4CRP and self-critical AI4CRP both in BLI mode.
[2]Optical diagnosis by the endoscopist only taking into account diagnoses made with high confidence.
[3]Optical diagnosis by the endoscopist after reviewing predictions of both AI4CRP and CAD EYE.
AI4CRP: Artificial intelligence for ColoRectal polyps; AI: Artificial intelligence; BLI: Blue light imaging; CI: Confidence interval; NPV: Negative predictive value; PPV: Positive predictive value.

and are not objective as for self-critical AI4CRP. Rondonotti *et al*[19] reported higher numbers of CAD EYE characterizations being unstable over time (7.9%) or not possible (1.3%). Self-critical AI4CRP made low confidence characterizations in 27.5%. Providing an objective confidence level can be seen as a form of explainable AI which may increase endoscopists' trust in CADx and therefore has potential applicability in real-time endoscopy practice. At the same time, one can argue that CADx should be of added value particularly in colorectal polyps deemed difficult by endoscopists. Interestingly, the low confidence diagnoses made by the endoscopist were high confidence diagnoses by AI4CRP in 75.0% of cases. Furthermore, self-critical AI4CRP was performed post-hoc. In real-time colonoscopy, endoscopists could do another attempt in gaining a high confidence characterization by repositioning the colonoscope and thereby optimize the endoscopic imaging possibly lowering the number of low confidence characterizations. Future studies should investigate if defining low confidence characterizations as diagnosis with a confidence value of 40% around the cut-off value is sufficient.

CADx utility in clinical practice will not be in a stand-alone fashion, but in aiding endoscopists. A strength of this study is the AI-assisted performances of the endoscopist, in contrast to previous studies in which endoscopist alone or AI-assisted non-expert endoscopist *vs* CADx were investigated[11,20]. The non-significant increase between the diagnostic performances of the endoscopist alone and the AI-assisted endoscopist is comparable with results of Hassan *et al*[21]. Furthermore, Jin *et al*[22] only showed an increase for non-experts and not for experts. Here, the number of optical diagnoses made with high confidence did increase for AI-assisted optical diagnosis.

Most CADx-systems have been trained to operate in a single image enhancement modality, i.e. narrow band imaging (NBI) or BLI. Zachariah *et al*[23] and Biffi *et al*[24] trained their systems using both HDWL and NBI or BLI, respectively. They compared the diagnostic performances of their CADx in HDWL with the performances in the image enhancement modality and found no significant differences. This favors the use of HDWL since the interpretation of image enhancement modalities requires training[25], limits generalizability, and hampers the utility of AI-assisted CADx by undertrained endoscopists. A strength of our study is that AI4CRP was trained with multiple image enhancement modalities, namely HDWL, BLI, LCI, and i-scan 1, 2, and 3. In contrast to Zachariah *et al*[23] and Biffi *et al*[24], AI4CRP's diagnostic performances were significantly higher in BLI compared to HDWL. Future research should, therefore, investigate the effect of different image enhancement modalities (especially BLI) on the output of CADx compared to

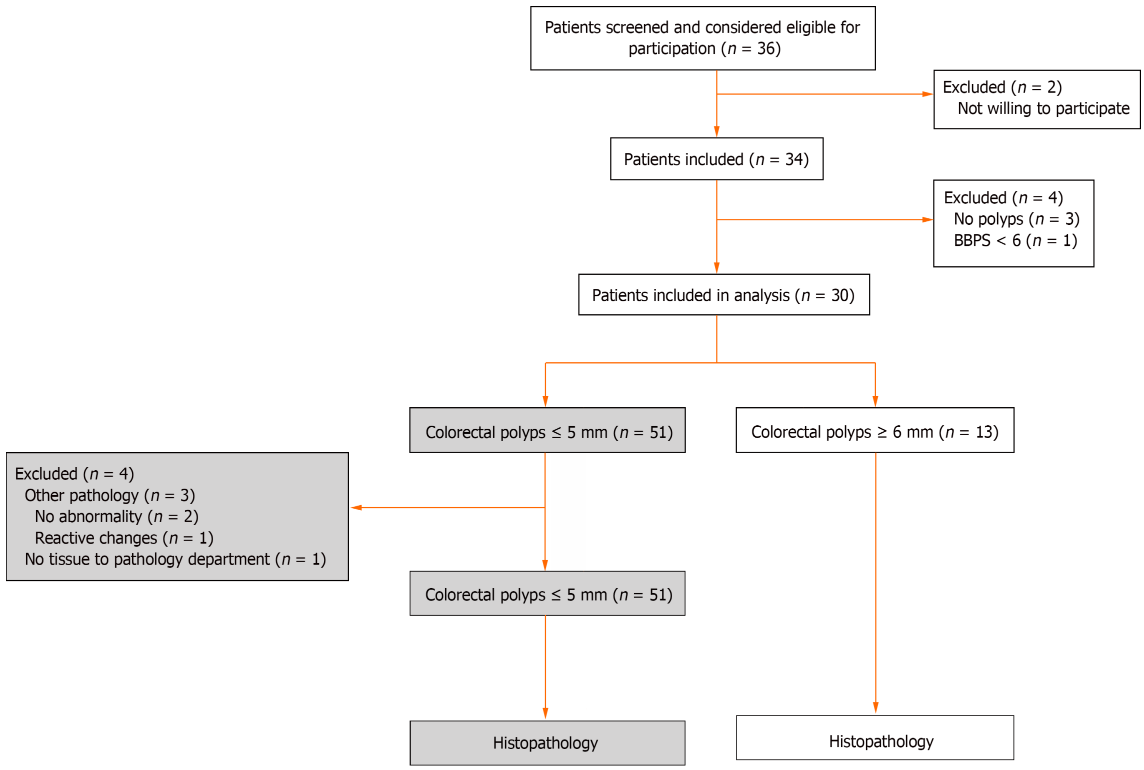

Figure 2 Study flow chart of patient enrolment and colorectal polyp inclusion. BBPS: Boston bowel preparation scale.

HDWL.

Self-critical AI4CRP and CAD EYE reached a NPV of ≥ 90% for rectosigmoid polyps according to the quality standard for the diagnose-and-leave strategy by the ASGE[3]. Both CADx-systems also met the quality standard of the ESGE for the diagnose-and-leave strategy and self-critical AI4CRP also the ESGE quality standard for the resect-and-discard strategy[4]. Previously, CAD EYE and GI-Genius (Medtronic, United States) also met the PIVI quality standards[26,27]. Although the risk of cancer in diminutive colorectal polyps is very low, misdiagnosis does pose risks when leaving adenomatous polyps in situ[28,29]. In an international survey, two-thirds of endoscopists considered implementation of resect-and-discard not feasible because of the fear of making incorrect optical diagnoses[30]. Studies should investigate if this fear of incorrect optical diagnosis may be leveraged with CADx.

No consensus exists on the characterization of SSLs between different CADx-systems. Where CAD EYE, a CADx by Sánchez-Montes *et al*[31], and Zachariah *et al*[24] characterizes SSLs as hyperplastic, other systems excluded SSLs[9,11,32-34]. Rondonotti *et al*[19] marginalized the clinical relevance of SSLs because of their low prevalence among diminutive rectosigmoid polyps. Albeit this low prevalence, given that SSLs bear a malignant potential[35,36], differentiating them from hyperplastic polyps is advocated and promotes clinical utility of CADx. AI4CRP, characterizing SSLs as premalignant, pursued to do just that because of the high need of improving SSL diagnosis[31]. Expanding CADx characterizations to multiple-class characterizations, allowing for the separate diagnosis of SSLs, more in line with clinical practice, would facilitate CADx implementation into clinical practice even further.

The main strength of this study is the head-to-head comparison of two CADx-systems characterizing the same colorectal polyps in sequence. Certain limitations of our study should also be acknowledged. Due to the feasibility design, no formal sample size calculation was performed and the number of included colorectal polyps was limited. Both CADx-systems were compared with only one expert endoscopist and testing was performed single center, limiting generalizability. AI4CRP is an image-based CADx, whereas CAD EYE is video-based. Both systems characterized the same colorectal polyps in a sequential approach rather than a parallel approach. The sequential approach led to both CADx-systems analyzing slightly different colorectal polyp frames potentially introducing bias. Bias could also have occurred since AI4CRP was trained with data from the same hospital in which it was tested in this study, possibly favoring AI4CRP performances, while this is not true for CAD EYE. An important limitation was the semi-automated use of AI4CRP. Images had to be manually captured by a research physician, limiting functional use of AI4CRP in clinical practice. A fully automated approach is currently under development. Furthermore, images out of focus or motion blurred imaged were excluded and a new image had to be taken. Although inconvenient, this only hampered the work flow minimally, but could have introduced bias. An image quality indicator alongside the CADx characterization, could be helpful in quantifying and reducing this bias.

CONCLUSION

In conclusion, real-time use of AI4CRP was feasible and achieved promising results. Self-critical AI4CRP, excluding low confidence characterizations, showed increased diagnostic performances compared to AI4CRP. The objective assessment of the confidence level is a novelty with great potential applicability in real-time endoscopy practice. Diagnostic performances of the AI-assisted endoscopist, after reviewing both CADx characterizations, were higher compared to both CADx-systems. Diagnostic performances of the AI-assisted endoscopist were non-significantly superior to the endoscopists alone. In the future, larger sized studies should expand on our findings.

ARTICLE HIGHLIGHTS

Research background

The importance of optical diagnosis, the endoscopic characterization of colorectal polyps, increases. However, correct endoscopic characterization and differentiation between benign and premalignant polyps remains difficult even for experienced endoscopists.

Research motivation

The ability of modern-day computer-aided diagnosis systems (CADx) to automatically recognize informative patterns in datasets can potentially improve accurate characterization of colorectal polyps and facilitate the implementation of treatment strategies based on optical diagnosis by meeting set quality standards.

Research objectives

Aim of this study was to evaluate the feasibility of the real-time use of the in-house developed CADx-system artificial intelligence for ColoRectal polyps (AI4CRP) for the optical diagnosis of diminutive (≤ 5 mm) colorectal polyps. Secondary aims were a head-to-head comparison of AI4CRP with CAD EYE™ (Fujifilm, Tokyo, Japan), evaluating the diagnostic performances of self-critical AI4CRP (providing only high confidence diagnoses), the diagnostic performances of an expert endoscopist (endoscopist alone), and the influence of CADx on the optical diagnosis of an expert endoscopist [artificial intelligence (AI)-assisted endoscopist].

Research methods

The two CADx-systems (AI4CRP and CAD EYE) were compared head-to-head. Colorectal polyps were characterized as benign or premalignant and histopathology was used as gold standard. AI4CRP provided characterizations accompanied by confidence values, enabling self-critical AI4CRP in which low confidence characterizations were excluded. The AI-assisted endoscopists, optically diagnosed colorectal polyps after reviewing both CADx characterizations.

Research results

Real-time use of AI4CRP was deemed feasible in clinical practice. AI4CRP showed a sensitivity of 82.1%, a specificity of 75.0%, a negative predictive value of 56.3%, and a diagnostic accuracy of 80.4%. Self-critical AI4CRP excluded 14 low confidence characterizations, resulted in considerably higher diagnostic performances compared to AI4CRP. CAD EYE had a sensitivity of 74.2%, a specificity of 100.0%, a negative predictive value of 69.2%, and a diagnostic accuracy of 83.7%. Diagnostic performances of the endoscopist alone (before AI) increased non-significantly after reviewing the CADx characterizations of both AI4CRP and CAD EYE (AI-assisted endoscopist). Diagnostic performances of the AI-assisted endoscopist were higher compared to both CADx-systems, except for specificity for which CAD EYE performed best.

Research conclusions

Real-time use of AI4CRP was feasible. Objective confidence values provided by a CADx is novel and self-critical AI4CRP showed higher diagnostic performances compared to AI4CRP. Reviewing characterizations by AI4CRP and CAD EYE did not increase the performance of the AI-assisted endoscopist.

Research perspectives

Future studies should expand on our findings and further investigate the added value of self-critical CADx-systems.

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FOOTNOTES

Author contributions: van der Zander QEW, Schreuder RM, Masclee AAM, and Schoon EJ substantially contributed to the study design; van der Zander QEW developed the study protocol under supervision of Masclee AAM and Schoon EJ, Kusters CHJ, Dehghani N, Scheeve T, de With PHN, and van der Sommen F developed the in-house CADx-system AI4CRP; van der Zander QEW, Schreuder RM, Thijssen A, and van der Ende - van Loon MCM did the data acquisition and processed the data; van der Zander QEW did the data analyses; Winkens B oversaw the data analyses and provided critical review of the data analyses; van der Zander QEW did the data interpretation and drafted the manuscript; Schreuder RM, Thijssen A, Kusters CHJ, Dehghani N, Scheeve T, Winkens B, van der Ende - van Loon MCM, de With PHN, van der Sommen F, Masclee AAM, and Schoon EJ provided a constructive review of the manuscript for important intellectual content. All authors approved the final version of the manuscript before submission. All authors had full access to all the data in the study and accept responsibility for all aspects of the work regarding accuracy, integrity, and publication.

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Data sharing statement: The data supporting the findings of this study are available from the corresponding author upon reasonable request. This data includes deidentified participant data. Additional documents that will be made available are the study protocol, the statistical analysis plan, and the informed consent forms. Data will be available following publication with no end date. Requests should be methodologically sound proposals with the purpose to achieve aims in the approved proposal. Data requestors will need to sign a data access agreement after approval of a proposal.

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