Canadian Association of Gastroenterology | L'Association Canadienne de Gastroentérologie

Canadian Association of Gastroenterology Artificial Intelligence Special Interest Group

ARTIFICIAL INTELLIGENCE ASSISTED REAL-TIME ADENOMA DETECTION AND CLASSIFICATION DURING COLONOSCOPIES

Background	Recent advances in artificial intelligence (AI) and deep neural network (DNN) development have significantly improved colorectal polyp detection and classification through computer-assisted detection (CADe) and classification (CADx). These systems can now detect and classify colorectal polyps with >90% sensitivity, specificity, and accuracy. Combining CADx with the optical polyp diagnosis in real-time colonoscopy procedures would provide immediate histopathology prediction for 1-5 mm polyps and reduce the need for histopathology examinations, thus contributing to significant cost savings and advancing patient care. Although many research attempts to address the detection and classification of polyps using AI models, these models are limited to being used in research settings due to small sample sizes, long latency in detection, and single-center designs. A new CADe system using a Convolutional Neural Network (CNN) algorithm (GI-Genius; Medtronic) has recently become commercially available. This system could reach a sensitivity of 99.7%, false-positive rate <1%, and performed real-time analysis 82% faster than the endoscopist.[1] The use of this system resulted in a significant increase in adenoma detection rate (ADR) compared with the conventional colonoscopy (54.8% vs. 40.4%).[2] Furthermore, the GI-Genius; Medtronic CADx system is added to the module. Both CAD systems need to be tested in real-world practice with heterogeneous source of centers and endoscopists evaluating its performance. In this prospective study, we aim to evaluate the performance of the GI genius system, and create a video/image library of complete colonoscopy procedures prospectively annotated with procedural information from this large group of endoscopists to source a dataset to train and validate other novel AI-empowered CAD models.
Objective	1. to assess the detection rate of colorectal adenomas (ADR) when using the Medtronic GI genius™ AI-empowered technology in real-time endoscopy setting using the histopathology examination of the polyps as the ground truth data (reference); 2. to assess the accuracy of the GI genius™ AI-empowered technology to predict polyp histology through optical diagnosis using image-enhanced endoscopy combined with AI deep-learning analysis to differentiate the neoplastic from non-neoplastic lesions compared with the endoscopists' histology predictions and the histopathology examinations of the polyp as the reference; 3. to create a large video/image library of full-length colonoscopy procedures that are prospectively annotated by the expert endoscopists of the CAG-AI group for the exact time, location, and number of detected polyps per colonoscopy (by endoscopists and/or GI genius), histology classification of 1-10 mm polyps, important anatomical landmarks, and other colonoscopy quality indicators.
Hypotheses	We assume that the GI genius system can provide automated detection and classification of colorectal polyps in real-time colonoscopy and automatically assess the essential quality metrics, specifically ADR. Since a high ADR is correlated with a reduction in interval CRC, these automated real-time CADe can be used for quality control, feedback, and auditing as well used for future studies as a quality improvement tool and to determine adequate screening intervals based on procedural quality, ADR and CRC risk factors. Moreover, we assume that the GI genius CADx system will differentiate neoplastic from non-neoplastic lesions in real-time with high accuracy, allowing endoscopists to perform optical diagnosis. Optical diagnosis would consequently result in a high reduction in costs related to histopathology examinations and interdisciplinary communications. Creating an annotated video/image library of the complete colonoscopy procedures would also allow us to study different aspects of the data in a retrospective fashion and explore different topics, such as comparing the quality of endoscopic procedures by different endoscopists or factors influencing colonoscopy quality and ADR.

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Methodology	Eligible patients will be adults (age 45–80 years) referred to the participating centers for a diagnostic, screening, or surveillance colonoscopy. Patients would undergo the colonoscopies using the GI genius and the relevant patients' and procedure characteristics will be obtained. The primary outcome is the ADR when using the GI genius platform during live colonoscopies. The secondary outcomes include the agreement between the surveillance intervals based on the optical diagnosis of polyps with the GI genius and the pathology-based recommendation according to current guidelines.[3] We will assess the appropriateness of this system for the real-time implementation of optical diagnosis: a) we will assess the "resect and discard strategy" by calculating the diagnostic characteristics (i.e., sensitivity, specificity, negative and positive predictive value, accuracy) for distinguishing the neoplastic from non-neoplastic histology for all colorectal polyps; b) we will assess the "diagnose and leave strategy" by calculating the negative predictive value in particular for distinguishing the neoplastic from non-neoplastic histology for the rectosigmoid polyps.	
Sample size	For assessment of the ADR as the primary outcome, we assumed ≥5% increase in ADR using the GI genius-assisted colonoscopy compared with routine colonoscopy. Considering our previous study that demonstrated a 38.8% ADR at the CHUM[4], a one-group chi-squared test with a 0.05 one-sided significance level would have 80% power to detect the difference between the Null hypothesis proportion of 0.388 and the Alternative proportion of 0.438 when the sample size is 595. To compensate for a potential 5% dropout quote, we will enroll 625 patients.	
Study centers/ Investigators	**Name**	**Background**
	Dr. Alan Barkun	Professor of Medicine, Gastroenterologist, Site PI McGill University, Montreal Clinical Lead for Quebec CRC Screening Implementation Committee, Special expertise in methodology and CRC screening quality aspects
	Dr. Charles Menard	Associate Professor, Gastroenterologist, Site PI University of Sherbrooke, Quebec, Special expertise in endoscopy training (CAG colonoscopy and polypectomy training courses faculty/organizer)
	Dr. Clarence Wong	Associate Professor, Gastroenterologist, Site PI University of Alberta, provincial medical director of the Alberta Colorectal Cancer Screening program
	Dr. Fergal Donnellan	Associate Professor of Medicine, Gastroenterologist, Site PI University of British Columbia, Special expertise in endoscopy research, optical polyp diagmnosis, CRC screening
	Dr. Michael Byrne	Professor of Medicine, Gastroenterologist, Site Co-Investigator University of British Columbia, Special expertise in AI in endoscopy, AI methodology and AI R&D
	Dr. Daniel von Renteln	Associate Professor of Medicine, Gastroenterologist, Site PI University of Montreal, CHUM, Special expertise in endoscopy R&D and clinical studies related to colorectal cancer prevention and evaluation of therapeutic endoscopy procedures
	Dr. Mahsa Taghiakbari	MD, MPH, PhD cand., Biomedical Science PhD student, University of Montreal, CHUM, Special expertise in AI

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