Screening Modified by Artificial Intelligence in Endoscopy (SMARTIE): A multicenter randomized clinical trial

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Keywords

Computer aided detection, Colonoscopy, Colorectal cancer, multicentre

Funding

Alexander Hann and **Wolfram G. Zoller** receive public funding for this work from the state government of Baden-Württemberg, Germany (**Funding cluster Forum Gesundheitsstandort Baden-Württemberg**) to research and develop artificial intelligence applications for polyp detection in screening colonoscopy. **Wolfram G. Zoller** receives additional funding to support this work by the **Eva Mayr-Stihl Foundation**, Waiblingen, Germany, the **Fischerwerke GmbH & Co. KG**, Waldachtal, Germany and the **Dieter von Holtzbrinck Stiftung GmbH**, Stuttgart, Germany.

Competing interests

The authors declare no competing interests.

Abstract

Introduction: Literature suggests that computer-aided polyp detection (CADe) systems increase adenoma detection rate (ADR) compared to traditional colonoscopy (TC). Multiple systems with comparable efficacy on benchmark datasets have been introduced, including the for research purposes freely available system EndoMind. Although intended for colorectal cancer screening, many studies have been performed in a hospital setting recruiting mostly non-screening patients. Additionally, more recent studies present conflicting data suggesting a less pronounced effect of CADe on ADR.

Aims & Methods: In this randomized clinical trial we aimed to analyze the impact of the CADe system EndoMind on ADR for screening colonoscopy in a multicenter fashion. Adult patients with an indication for colorectal cancer screening, post-polypectomy surveillance or with a positive fecal immunochemical test were eligible for participation in 5 outpatient treating centers in Germany. Exclusion criteria were inflammatory bowel disease, familial polyposis syndrome, previous radiation, or colorectal surgery. Participants were randomized prior to the intervention to the CADe or the TC group. In the first group, the EndoMind CADe system framed detected polyps with a blue box on the main examination monitor during the whole procedure. Colonoscopies were performed by examiners with over 10 years of experience. Primary outcome was ADR. Secondary outcomes included polyp detection rate and withdrawal time. ClinicalTrials.gov trial register number: NCT05006092.

Results: From November 2021 to November 2022, 928 subjects were randomized to the CADe (n = 457) and TC (n = 471) group. Baseline characteristics of patients and bowel preparation quality between both groups were similar. The rate of screening examinations was over 80% in both groups. The mean ADR was 36.8% and 33.8% for the CADe and TC group respectively (p=0.34). Polyp detection rate was 50.8% in the CADe group and 50.5% in the TC group (p=0.94). Mean withdrawal time in total and without time spent on resection was 7.5 min, 6.9 min vs 7.4 min, 6.9 min for the CADe and TC group respectively.

Conclusion: In our multicenter randomized clinical trial the usage of CADe did not improve ADR or polyp detection rate of expert endoscopists in an outpatient setting involving mainly colorectal cancer screening candidates. The evaluation of other systems in this setting is needed in order to estimate the value of CADe.