MEDTRONIC REVIEW
CLINICAL PAPER

Medtronic provides the following synopsis of the following clinical publication:

TITLE Efficacy of Real-Time Computer-Aided Detection of Colorectal Neoplasia in a Randomized Trial

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RATIONALE

Missed colorectal polyps during a screening colonoscopy can contribute to false negative diagnosis and may develop into interval colorectal cancer (CRC) over time. Thus, it is important to reduce the miss rate of polyps to reduce the risk of interval CRC. This study tested the safety and efficacy of an endoscopic real-time Computer-Aided Polyp Detection (CADe) technology. This is an important trial, as previous assessments of deep learning technologies for polyp detection have largely been retrospective.

AIMS

The primary outcome measure for this analysis was adenoma detection rate (ADR). This was powered as a non-inferiority, intention-to-treat analysis. The secondary outcomes were proximal ADR, total number of polyps detected, sessile serrated adenoma detection rate, mean number of adenomas per colonoscopy (APC), withdrawal time, and cecal intubation rate.

STUDY DESIGN

This was a parallel, randomised, multicenter trial performed in 3 sites in Italy that participated in the organised population CRC screening programme.

METHODS

Patients were recruited sequentially under real world conditions in three Italian centres, and then randomised to either CADe (GI-Genius, Medtronic) or standard High Definition (HD) colonoscopy. Patients aged 40 to 80 years-old undergoing colonoscopy for primary CRC screening or post-polypectomy surveillance, as well as for work-up following FIT positivity (cutoff=20 µg Hb/g faeces) or for symptoms/signs were included. Patients with a history of colorectal cancer, IBD, a previous colonic resection, antithrombotic therapy precluding polyp resection, and those unable to consent were excluded. Importantly, all colonoscopies were performed by experienced screening colonoscopists who had performed over 2000 procedures. Only 6 gastroenterologists performed the interventions with two in each centre.

RESULTS

- The study found a 14% absolute increase in ADR, and a 30% relative increase in the ADR when the CADe system was used compared to patients with HD colonoscopy alone.
- The improved performance of the device was maintained in the detection of both flat (42% increase) and polypoid lesions (36% increase).
- The performance of the CADe technology was not influenced by polyp location; CADe was 28% more likely to detect polyps in the proximal colon and 53% more likely detect polyps in the distal colon.
- Much of the improved performance was in the detection of smaller polyps (<10 mm). CADe was 78% more like to detect polyps 6-9 mm and 26% more likely to detect polyps <5 mm.
- CADe patients were also 50% more likely to have multiple polyps detected.
- There was no difference in SSA detection rates between the groups.
- APC relative risk increased by 46% when using CADe.
- CADe did not increase the withdrawal time and there were no differences in non- neoplastic resection rates between the groups suggesting it is equivalent to current best practice.

DISCUSSION, STRENGTHS AND LIMITATIONS

This study was well designed, randomized and included a large sample size. This study demonstrates that CADe allows endoscopists to identify a significantly larger proportion of patients with adenomas, as well as a higher number of adenomas per patient. One limitation is that the operator was not blinded to the randomization which could result in operator-related bias; however, the ADR results were consistent among all 3 centres.

CONCLUSIONS

In conclusion, this work suggests that failure in polyp recognition is a clinically relevant cause of miss rate. CADe is safe and effective.

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