Introduction:

Reducing polyp miss rate (PMR) is imperative in reducing post-colonoscopy colorectal cancer incidence. Artificial Intelligence-based Computer-Aided Detection (CADe) systems are intended to support colonoscopists to reduce PMR. The GI Genius™ intelligent endoscopy module (Medtronic ltd.) is a CADe system, compatible with endoscopy systems from most manufacturers.

Methods:

COLO-DETECT assessed clinical effectiveness of the GI Genius™ intelligent endoscopy module in routine colonoscopy practice by comparing GI Genius™-assisted colonoscopy (GGC) with standard colonoscopy (SC). COLO-DETECT was a multi-site parallel-arm randomised controlled trial, undertaken in ten English NHS Trusts, amongst adults attending for colonoscopy for colorectal cancer screening (screening subpopulation), or gastrointestinal symptoms / surveillance (symptomatic subpopulation). Randomisation was 1:1, stratified by age category (<60y, 60-73y, ≥74y), sex, colonoscopy indication (screening / symptomatic, and NHS Trust. The trial statistician and co-chief investigators were blinded.

Primary outcome was mean adenomas per procedure (MAP); key secondary outcome was adenoma detection rate (ADR). Primary analysis was intention-to-treat.

A patient and public involvement representative contributed to all stages of the trial. COLO-DETECT was prospectively registered (ISRCTN: 10451355). The protocol was prospectively published.

COLO-DETECT was funded by Medtronic ltd. who had no role in trial design, delivery, or reporting.

Results:

2032 participants were recruited 29/03/21-06/04/23: 28% were <60y, 61·5% were 60-73y, and 10·5% were ≥74y; 55·7% were male; 60·6% were undergoing bowel cancer screening. Randomisation allocation was equal (1015 to GGC, 1017 to SC).

MAP for GGC was 1·56 (SD 2·82) vs 1·12 (SD 1·91) for SC (IRR 1·30; 95% CI 1·15-1·47; p<0·001). ADR was 56·6% (GGC) vs 48·4% (SC), (OR 1·47; 95% CI 1·21-1·78; p<0·001).

GGC demonstrated smaller mean polyp size (5·18mm vs 5·78mm; 95% CI -1·08 – -0·11; p=0·016), more 0-IIa polyps (34% GGC vs 27% SC; p=0·002), and higher sessile serrated lesion (SSL) detection rate (11·6% vs 8·3%; OR 1·49; 95% CI 1·09-2·03; p=0·012).

Within the screening subpopulation MAP was 2·08 (SD 3·36) in the GGC group vs 1·61 (SD 2·16) in the SC group (IRR 1·29; 95% CI 1·12-1·48; p<0·001), and ADR was 68% in the GGC group vs 61% in the SC group (OR 1·37; 95% CI 1·07-1·74; p=0·011).

Within the symptomatic subpopulation MAP was 0·76 (SD 1·33) in the GGC group vs 0·57 (SD 1·18) in the SC group (IRR 1·33; 95% CI 1·03-1·71; p=0·027) and ADR was 39% in the GGC group vs 28·5% in the SC group (OR 1·65; 95% CI 1·2-2·26; p=0·002).

Advanced adenoma detection rate and cancer detection rate did not differ between GGC and SC overall, or within the screening or symptomatic subpopulations.

Colonoscopic adverse events were equally distributed between the trial arms with none related to the trial intervention.

Conclusions:

GI Genius™ increases MAP and ADR in routine colonoscopy practice, in all patients as well as symptomatic and screening subpopulations. Increased detection is of smaller, flat polyps and included increased detection of SSLs, which are over-represented among lesions causing post-colonoscopy colorectal cancer. These increases occurred despite high baseline MAP and ADR in the control arm. COLO-DETECT supports the adoption of GI Genius™ into colonoscopy practice to increase detection of premalignant polyps.