Medtronic News

First U.S. trial using GI Genius™ intelligent endoscopy module shows 50% reduction in missed colorectal polyps with artificial intelligence (AI) technology versus standard colonoscopy

Findings published in *Gastroenterology* show that AI technology assisted coloscopy improves the accuracy of polyp detection, which plays an important role in the prevention of colorectal cancer

DUBLIN, March 16, 2022 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, today announced final findings from a randomized, international, multi-center study that confirmed the effectiveness of the GI Genius™ intelligent endoscopy module, which uses AI as an aid in detecting colorectal polyps during colonoscopy, potentially helping to prevent colorectal cancer (CRC). The study, published on March 15 in *Gastroenterology,* the official medical journal of the American Gastroenterological Association, found that the use of GI Genius in conjunction with colonoscopy significantly decreases the miss rate (2x) of colorectal polyps and adenomas compared to standard colonoscopy.

In colonoscopies performed as part of the study, adenoma miss rate (AMR) was significantly lower when GI Genius was used as compared to a non-AI-assisted colonoscopy (15.5% vs 32.4%; p-value <0.001). These findings demonstrate that the use of GI Genius during colonoscopy significantly decreases the miss rate of both adenomas and polyps, further confirming the benefit GI Genius adds to colonoscopy procedures.[1] The study further found that false negative rates, when a GI Genius-assisted colonoscopy detected adenoma(s) after an initial standard colonoscopy did not, were much lower than that of non-AI-assisted colonoscopies (6.8% vs. 29.6%). In this study, a false negative indicates patients with an initial standard colonoscopy where no adenoma was detected were subsequently found to have at least one adenoma during a second AI-assisted colonoscopy.

"We know that colonoscopy is the gold standard for colon cancer screening and this study unequivocally demonstrates that AI-technology can help physicians better detect polyps during the procedure," said Dr. Austin Chiang, M.D., M.P.H., chief medical officer of the Gastrointestinal business, which is part of the Medical Surgical Portfolio at Medtronic. "As a gastroenterologist, I worry about missed polyps because around half of all cases of post-colonoscopy colorectal cancer may be attributed to not catching them during the index colonoscopy.[2,3] The impact of missed polyps could ultimately be the difference between life and death when we consider that 90% of patients with colon cancer can beat it when it's caught early."[4]

"These findings emphasize the value of artificial intelligence in increasing precancerous polyp detection in colonoscopy,"said *Douglas K. Rex, M.D., MASGE, president,* American Society for Gastrointestinal Endoscopy. "The purpose of most colonoscopies is to prevent patients from getting colon cancer. So, the more help I get in finding polyps the better. I have a very high adenoma detection rate but, in my experience, there are times GI Genius has identified polyps that I might have otherwise missed."

The findings confirm topline results of the DETECT study from November 2021 that both AMR and polyp miss rate (PMR) significantly improve when GI Genius is used during colonoscopy. The study was funded by Cosmo Pharmaceuticals, the developer and manufacturer of Medtronic's GI Genius system.

"This study underscores that the GI Genius system better supports physicians working to detect polyps and lesions," said Michael Wallace, M.D., M.P.H., John C. Andersen Professor of Medicine at Mayo Clinic, who led the study. "I could not be prouder of the work we have done in partnership with Medtronic to bring to market a disruptive technology that is improving colorectal cancer screenings and potentially saving lives."

The study (clinicialtrials.gov identification number: NCT03954548) was conducted in eight centers across the U.S.,Italy, and the United Kingdom in university hospitals and community clinics. Study subjects included male and female patients aged 45 or

older undergoing a screening or surveillance colonoscopy for colorectal cancer. Overall, 249 subjects were randomized (1:1) in the study, of whom 230 subjects completed the study and were included in the analysis, undergoing two consecutive colonoscopies that were randomly assigned in order of which they were conducted: one with GI Genius and a colonoscopy with white light endoscopy.

Medtronic is the exclusive worldwide distributor of the GI Genius module which was granted De Novo authorization from the U.S. FDA on April 9, 2021. In addition to the United States, the GI Genius module is available in Europe and select markets in Asia, Australia, and the Middle East.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Dublin, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 90,000+ passionate people across 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic (NYSE: MDT), visit www.Medtronic.com and follow @Medtronic on Twitter and LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

[1] https://www.cosmopharma.com/news-and-media/news-releases/2021/19-11-2021

[2] Zhao S, Wang S, Pan P, et al. Magnitude, Risk Factors, and Factors Associated With Adenoma Miss Rate of Tandem Colonoscopy: A Systematic Review and Meta-analysis. Gastroenterology 2019;156:1661-1674.e11

[3] Robertson, D.J.; Lieberman, D.A.; Winawer, S.J.; Ahnen, D.J.; Baron, J.A.; Schatzkin, A.; Cross, A.J.; Zauber, A.G.; Church, T.R.; Lance, P.; et al. Colorectal Cancers Soon after Colonoscopy: A Pooled Multicohort Analysis. Gut 2014, 63, 949–956.

[4] National Cancer Institute. Cancer stat facts: colon and rectum cancer. National Cancer Institute Website. http://seer.cancer.gov/statfacts/html/colorect.html. Accessed Feb. 7, 2017.

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https://news.medtronic.com/2022-03-16-First-U-S-trial-using-GI-Genius-TM-intelligent-endoscopy-module-shows-50-reduction-in-missed-colorectal-polyps-with-artificial-intelligence-AI-technology-versus-standard-colonoscopy