

## Introduction

Previous studies evaluating the role of artificial intelligence (AI) to increase the detection of polyps during colonoscopy are limited to locally deployed hardware AI systems and largely focus on expert colonoscopists in screening populations. CADDIE is a cloud-based CADe system that receives the live image stream from the endoscopy screen via the hospital's internet network, where the AI algorithm processes the images and outputs an overlay bounding box on the endoscopy screen when a suspected polyp is detected.

In this multi-centre, prospective randomized controlled trial, we aimed to assess whether the real-time cloud-based AI polyp detection system CADDIE improves adenoma detection rate (ADR) in symptomatic and surveillance patients when colonoscopy is undertaken by non-expert colonoscopists in routine clinical settings.

## Methods

We enrolled 739 patients between April 2021 and Dec 2022, scoped by 32 endoscopists with a baseline ADR below 30% from 9 UK hospitals. Exclusions included known IBD, colorectal cancer, polyposis syndromes, previous resections, and planned therapy. Each endoscopist was limited to a maximum of 60 procedures and required to perform more than 20% of this target. Patients were block randomised in a 1:1 ratio to standard of care (SOC) or intervention (CADDIE), stratified by endoscopist and indication. The study was powered to show an increase in ADR between the two arms, using a two-group z-test with 80% power, a two-sided  $\alpha$  level of 0.05 and accounting for an expected dropout rate of 10%.

## Results

124 patients were excluded from data analysis as pre-defined in the study protocol (e.g. endoscopist moving hospital before meeting minimum recruitment target), with 615 evaluable patients remaining, surpassing the recruitment goal of 594 eligible patients.

ADR was significantly higher in the CADDIE group compared to SOC (33.3% vs 25.2%) with an odds ratio (OR) of 1.46 (95% CI 1.01-2.10),  $p = 0.04$ . Proximal ADR was also higher in the CADDIE group (OR 1.67 (95% CI 1.09-2.56),  $p = 0.02$ ). Over 50% more adenomas were removed per colonoscopy (APC) in the CADDIE group compared to SOC (OR 1.49 (95% CI 1.08 - 2.06),  $p = 0.02$ ). Although results were not significant for other outcomes, the general trend was towards higher detection in the CADDIE group.

## Conclusions

We have shown a significant improvement in adenoma detection in non-expert endoscopists when using the cloud-based CADDIE AI system in a non-screening population across a wide range of UK hospitals. This increased detection was also seen in the proximal colon, where many hard to detect lesions are found. Furthermore, the total numbers of adenomas removed per colonoscopy, which is increasingly recognised as an important metric of procedure quality, was significantly increased.