Study Protocol

Protocol ID：2025ZSLYEC-747

Title: Exploring the Clinical Value of an AI-Assisted Patient Self-Assessment App for Bowel

Preparation: A Multicenter Study

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Background and aim

Colonoscopy is a key tool for screening, diagnosing and treating colorectal cancer. Early detection and removal of polyps can substantially reduce both the clinical burden and the economic cost of advanced-stage disease. Adenoma detection rate (ADR)—the proportion of colonoscopies in which at least one adenoma is found—is the principal quality indicator; every 1 % drop in ADR increases subsequent cancer risk by 3 %. Adequate bowel preparation improves ADR, cuts the miss rate for polyps and cancers, and lowers post-colonoscopy cancer incidence, whereas poor preparation decreases polyp/ tumour detection, prolongs insertion time, increases endoscopist fatigue and may raise procedure-related complications. Yet 20–25 % of examinations are still performed under sub-optimal conditions.

The quality of cleansing depends largely on patient compliance with the purgative regimen, so intensive education is essential. Telephone calls, text messages, short videos and mini-programs have all been shown to improve compliance and preparation quality. However, early identification of individuals who are likely to prep poorly—and the opportunity to rescue them—remains an unmet need. The character of the last stool after laxative intake correlates closely with overall preparation quality; staff often ask patients to describe this stool to decide whether to proceed or delay the examination, but this is reactive rather than proactive. Allowing patients to self-assess and, if necessary, present early (out-patients) or alert staff (in-patients) for rescue could convert sub-optimal into adequate preparation.

Artificial intelligence is now widely used in gastrointestinal endoscopy. In our pilot work we developed a smartphone app that uses AI to grade stool photographs. In an internal validation set the algorithm achieved 100 % sensitivity (95 % CI 34.2–100 %) and 94.1 % specificity (90.1–96.5 %) for binary classification of adequacy. We then conducted a single-centre RCT; 461 patients (229 control, 232 app) were analysed. App users had significantly higher adequate-preparation rates (97 % vs 90 %, $P = 0.002$) and excellent-preparation rates (86.2 % vs 59.8 %, $P < 0.001$), and higher mean Boston Bowel Preparation Scale (BBPS) scores (8.2 ± 0.8 vs 7.8 ± 1.2, $P < 0.001$) as well as segment-specific BBPS sub-scores. Cecal intubation rate, polyp-detection rate (PDR) and ADR did not differ between groups. These findings suggest the app improves preparation quality, but the single-centre design limits generalisability. We now propose a multicentre study to confirm the clinical value of this AI-assisted self-assessment tool.

Methods

Study design: a multicenter, randomized controlled clinical trial.

Location: The Sixth Affiliated Hospital, Sun Yat-sen UniversitTianjin Haihe Hospital

Guangdong Second Provincial General Hospital

Dongguan Humen Hospital of Traditional Chinese Medicine

Cangzhou Central Hospital

The inclusion criteria:

(1) Age ⩾ 18 years

(2) Undergoing colonoscopy at a participating site

(3) Able to defecate in a toilet (or in a setting where stool characteristics can be observed) after taking the bowel-prep solution

(4) Proficient in using a smartphone

(5) Willing to participate voluntarily

The exclusion criteria:

① American Society of Anesthesiologists (ASA) class III or IV;

② Gastric-outlet or intestinal obstruction;

③ Active gastrointestinal bleeding;

④ Enterostomy (colostomy/ileostomy);

⑤ Status post total colectomy.

Intervention

After taking the bowel-prep solution, patients in the app group are instructed to photograph their final stool in the toilet and upload the image through our smartphone app. The AI algorithm immediately scores the prep quality. If the image is rated "poor" or "inadequate," the app displays an alert advising the patient to come to the hospital early or contact clinical staff; clinical staffs then review the photo and decide whether a rescue preparation is needed. The standard rescue was an additional packet of polyethylene glycol. If the image is rated "adequate," the patient is told the prep is acceptable and should proceed to the appointment, where clinical staffs will use the uploaded photo to confirm eligibility for colonoscopy.

The control group followed the conventional procedure: before the examination, clinical staffs asked questions and relied on the patient's verbal description of their stool to judge the adequacy

of bowel preparation. If the prep was deemed inadequate, the standard rescue was an additional packet of polyethylene glycol.

Outcome parameters

The primary outcome parameter is the comparison of the bowel preparation quality between the app group and the control group (the rate of adequate and excellent bowel preparation).

The secondary outcome parameters are: cecal intubation rate

cecal intubation time

withdrawal time (excluding polypectomy and biopsy)

polyp-detection rate (PDR)

adenoma-detection rate (ADR)

advanced-adenoma-detection rate (aADR)

use of rescue preparation

rate of rescheduled examinations due to inadequate preparation

clinical staffs' assessment time

user satisfaction score,

and post-procedural adverse events.

The results will be analyzed in full analysis set, per-protocol set and safety set.

Sample Size

Assuming that 16 % of patients have inadequate bowel preparation with the traditional regimen, and the app is expected to convert 25 % of these failures (i.e., 4 % of the total cohort) to adequate preparation, a sample size of 235 participants is required for $\alpha = 0.05$ and power = 0.80. Allowing for a 10 % dropout rate, we plan to enroll 262 subjects per arm, for a total of 524 participants.

Randomization

Stratified randomization by center. Random numbers generated in Excel by an independent statistician; sequentially numbered, sealed, opaque envelopes prepared and held by the third party. The envelopes constitute the allocation sequence; random numbers remain concealed from patients and endoscopists until the envelope is opened immediately before allocation.

Blinding

Patients cannot be blinded; operators, outcomes assessors, and pathologists will remain blinded.

Statistical analysis

All analyses were performed with SPSS version 26. Baseline characteristics were examined to assess balance across concentration groups. Normally distributed continuous variables are presented as mean ± SD and compared between groups using independent-samples t-tests; non-normally distributed continuous variables are expressed as median (interquartile range) and compared with the Wilcoxon rank-sum test. Categorical rates were compared using the χ^2 test. A two-sided $P < 0.05$ was considered statistically significant.

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