

Effectiveness of using a patient education mobile application to improve the quality of bowel preparation: a randomised controlled trial

Hang Viet Dao ,^{1,2,3} Quan Viet Dao,² Hoa Ngoc Lam ,³ Long Bao Hoang ,³ Van Thi Nguyen,³ Thuy Thi Nguyen,⁴ Dat Quoc Vu,⁵ Christopher S Pokorny,⁶ Hoa Lan Nguyen,⁷ Jeroan Allison,⁷ Robert Joel Goldberg,⁷ An Thi Minh Dao,¹ Toan Thanh Thi Do,⁸ Long Van Dao^{1,9}

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For numbered affiliations see end of article.

Correspondence to

Dr Hang Viet Dao;
daoviethang@hmu.edu.vn

ABSTRACT

Aims To determine the effectiveness of a mobile application (app) in improving the quality of bowel preparation for colonoscopy.

Method An endoscopist-blinded randomised controlled trial enrolled patients who were undergoing a colonoscopy on the same day of bowel preparation. The intervention used a Vietnamese mobile app that provides instructions on bowel preparation while patients in the comparison group received conventional instructions. Outcomes included the Boston Bowel Preparation Scale (BBPS) to assess the quality of bowel preparation and the polyp detection rate (PDR) and adenoma detection rate (ADR).

Results The study recruited 515 patients (256 in the intervention group). The median age was 42 years, 50.9% were females, 69.1% high school graduates and higher, and 45.2% from urban area. Patients in the intervention group had higher adherence to instructions (60.9% vs 52.4%, $p=0.05$) and longer length of taking laxatives (mean difference 0.17 hours, 95% CI 0.06 to 0.27). The intervention did not reduce the risk of poor bowel cleansing (total BBPS<6) in both overall (7.4% vs 7.7%; risk ratio 0.96, 95% CI 0.53 to 1.76) and subgroup analysis. PDR and ADR were similar between the two groups.

Conclusions The mobile app providing instructions on proper bowel preparation improved the practice during bowel preparation but did not improve the quality of bowel cleansing or PDR.

INTRODUCTION

Colonoscopy is a common procedure used to diagnose and manage lower gastrointestinal tract diseases, allowing physicians to detect lesions, obtain biopsy samples and perform interventions.¹ Inadequate colon cleansing preparation is associated with lower adenoma detection rates (ADRs), prolonged or incomplete procedures and missed lesions.² Upwards of one-quarter of patients

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Inadequate bowel preparation can cause lower adenoma detection rates, prolonged or incomplete endoscopy procedures, and missed lesions during colonoscopy. Several studies in other countries showed improvement in bowel cleansing quality using mobile applications (apps). Additionally, a study in Vietnam indicates that one-third of patients were willing to get assistance for bowel preparation from mobile apps.

WHAT THIS STUDY ADDS

⇒ This study determined the effectiveness of a mobile app supporting bowel preparation in improving the quality of bowel cleansing and polyp detection rate in patients having a colonoscopy on the same day of bowel preparation. It shows that the mobile app improved patients' practice of bowel preparation but did not improve the quality of bowel cleansing and clinical outcomes.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings indicated that mobile apps supporting bowel preparation could improve the practice of bowel preparation. These apps may have the potential to improve the quality of bowel cleansing and polyp detection rate in centres where conventional instructions are not adequate.

undergoing a colonoscopy have inadequate bowel preparation.³ One reason for inadequate bowel preparation is the complicated preparation process, including extensive instruction about diet and potential adverse effects, followed by comprehensive steps for taking laxative drugs to ensure the safety and quality of the colonoscopy procedures.^{1 4-6}



Some mobile applications (apps) have been developed to provide better instructions on bowel preparation and integrate features such as reminders of taking bowel preparation drugs and guidance to assess the quality of preparation. Mobile apps have been shown to achieve better bowel cleansing results compared with conventional bowel preparation practice.^{7,8} Bowel preparation protocols are different among settings and may depend on baseline conditions of the patients, and there are cultural sensitivities that need to be taken into account during the app development process. Data on the feasibility of mobile apps in bowel preparation in low-income and middle-income countries remain lacking.⁷

In Vietnam, colorectal cancer is the fifth most common disease and the eighth-leading cause of death, with nearly 16500 new cases, accounting for 9% of all new cancer cases in 2020.⁹ Some Vietnamese endoscopy centres perform more than 300 endoscopies on a daily basis, including nearly 100 colonoscopies, placing enormous pressure on healthcare providers to properly instruct patients on bowel preparation and ensure procedure quality.^{10,11} One study in Vietnam showed that one-third of participants struggled with conventional instructions on proper bowel preparation and most were willing to seek assistance from mobile apps.⁶ In 2020, the Institute of Gastroenterology and Hepatology developed the first mobile app in Vietnam for bowel preparation. Major features include screening for alarm symptoms which need special attentions with colonoscopy indication, diet and procedure explanation, and step-by-step instruction before and during bowel preparation. The app was expected to be a new, simple approach to improving patient's bowel preparation practices and strengthening the level of their participation. Therefore, we conducted a randomised controlled trial to compare the quality of bowel cleansing between the mobile app supported cleansing protocol and the conventional one.

METHODS

Study design

A single-blinded randomised controlled trial was conducted at Hanoi Medical University Hospital from June 2020 to June 2021.

Subjects

Eligible patients must be 18 years and older, have a colonoscopy scheduled on the same day of check-up, be able to follow study instructions and have a mobile device with access to the Internet. Exclusion criteria were: (1) a history of colorectal cancer or colon resection surgery, (2) suspected partial bowel obstruction, (3) pregnant or breastfeeding women or women who were menstruating; (4) had a neurological or psychiatric disorder or disability that may affect communication; (5) had a scheduled colonoscopy but planned to perform bowel preparation at home and (6) not willing to provide informed consent.

The intervention (mobile app)

A mobile app named 'Làm sạch đại tràng' ('Bowel Preparation' in English) was developed by the Institute of Gastroenterology and Hepatology. This app, which was designed for both the Android operating system and iOS devices, can be freely installed on participants' own mobiles.^{12,13} Two key features of this app included: (1) screening for eligibility and alarm history (such as history of abdominal surgery or allergy, current anticoagulants, bleeding symptoms) for colonoscopy indication before taking the bowel preparation medication and (2) providing detailed step-by-step instructions, including self-evaluation of the bowel preparation results.

Patients who did not pass screening (online supplemental figure S1a) underwent consultation with a physician to determine whether colonoscopy would be safe to proceed. Eligible patients then pressed a button to begin the bowel preparation process. The instructions during bowel preparation were consistent with the regimen prescribed for the patient, such as which medication to take and the amount of water to consume (online supplemental figure S1b). After reviewing the bowel preparation instructions, patients were taken to a screen that displayed detailed instructions for each step with a clock on the screen counting down how many minutes were left for the step (online supplemental figure S1c). If the procedure was successfully completed, the patient visually assessed the quality of bowel cleansing. Patients were given four pictures of different levels of cleanliness of defecation water¹⁴ and asked to choose the picture that looked similar to their last defecation (online supplemental figure S1d). Patients who have achieved the adequate quality of cleansing (level 1) were considered to be ready for undergoing a colonoscopy.

Patients could report any problems that affect their cleansing process by pressing a button during bowel preparation (online supplemental figure S1c). This showed a hotline phone number of a healthcare provider to check the problem (online supplemental figure S1e). The healthcare provider then decided whether the bowel preparation process could be resumed or should be terminated. Resuming or terminating the process was done through a web-based administration tool, which only authorised study doctors and nurses could access.

An internet connection was required for the app to function properly. Data from the app were encrypted and sent to a server, which also manages the web-based administration tool.

Study procedures

All patients scheduled for colonoscopy at Hanoi Medical University Hospital between June 2020 and June 2021 were screened and invited to participate in the study. Patients who were eligible and provided informed consent were randomly allocated in a 1:1 ratio to the intervention group using the mobile app or the control group (conventional practice). We used block randomisation (block size of 6) using computer-generated random

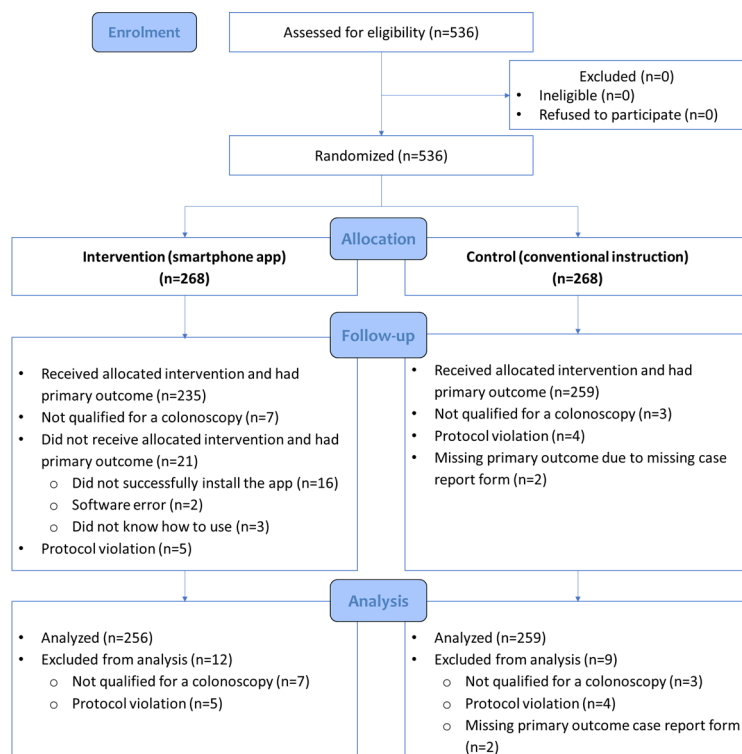


Figure 1 Flow diagram of the study.

sequences. Due to the nature of this study, patients could not be blinded. To ensure the accuracy of our primary outcome assessment, which was quality of bowel cleansing, evaluators were blinded to patient's group assignment.

After randomisation, both groups received conventional bowel preparation instructions, which were written and verbally explained by medical staff. The intervention group was instructed to download and instal the app on their mobile. The control group then proceeded to bowel preparation per routine practice. After patients completed bowel preparation, they were given a questionnaire about their adherence to the bowel preparation. All qualified participants underwent colonoscopy on the afternoon of the day they were recruited. The study flow is summarised in the Consolidated Standards of Reporting Trials (CONSORT) flow diagram in [figure 1](#).

Bowel preparation

The laxative regimen used for this study consisted of three sachets of high-volume polyethylene glycol and electrolytes—Macrogol 4000 (Fortrans), divided into three doses. Each sachet was dissolved with a litre of water and patients would finish the dose within 45–60 min. They were advised to drink the solution slowly to avoid intolerance, abdominal fullness and potential vomiting (online supplemental figure S2).

During bowel preparation, patients were encouraged to walk frequently and massage the abdomen clockwise along the colonic tract. They were anticipated to have at least eight to ten defecation episodes during this period. They were instructed to contact the clinical provider if

they experienced any significant symptoms or discomfort (online supplemental figure S2).

Study outcomes

The primary outcome of this trial was quality of bowel cleansing using the Boston Bowel Preparation Scale (BBPS).¹⁵ The colon was divided into three segments: the cecum and ascending colon (right colon), transverse colon and descending colon (left colon). Each segment received a 'segment score' from 0 to 3. These segment scores were added for a total BBPS score, ranging from 0 to 9. The BBPS score was assessed during endoscopy by one of our five endoscopists with >5 years of experience. These endoscopists were trained on BBPS before implementation and blinded to patient allocation. A colon with a total BBPS score from 6 to 9 points was considered good preparation; below those scores, it was considered poor preparation.¹⁶ We analysed the outcome in terms of both its numerical value (from 0 to 9) and the binary classification (good/poor preparation).

In addition to the primary outcome, we also examined the polyp detection rate (PDR) and ADR. The PDR was the proportion of patients with at least one polyp detected during the colonoscopy, and the ADR was the proportion of patients with at least one adenoma confirmed by histopathology. At our centre, only polyps ≥ 5 mm in diameter or polyps less than 5 mm but having neoplastic characteristics will be sent to the pathology department; therefore, we considered patients with no polyps sent to the pathology department to be 'not having adenoma'.



Data collection and measurements

All data were collected using paper case report forms by study nurses, endoscopists or participants (self-report questionnaires). Data were then entered into a database on KoboToolbox.¹⁷

In addition to the primary BBPS outcome, we also compared the quality of bowel cleansing by participant's self-assessment of defecation water. The cleansing level images were demonstrated in the app and patients were instructed to conduct this self-assessment after they had defecated at least eight to ten times. The evaluation was done using a visual scale with four levels,¹⁴ rating the status of the defecation water from 1 (clear water) to 4 (yellow colour of stool). Only level 1 was considered to be good quality of cleansing (online supplemental figure S1e).

We collected demographic data and clinical data (gastrointestinal complaints, history of prior colonoscopy), the process of bowel preparation (start time, end time and symptoms that developed during preparation), and patient's adherence to the instructions for bowel preparation (the amount of laxatives and water taken and frequency of activities—walking and massaging abdomen—while taking laxatives). We also asked if they had inadequate intake of laxatives (failed to take three doses of laxatives and the amount of water intake was <80%) or did not have sufficient mobilisation (spent <50% of the preparation time on walking and massaging abdomen). These questions were used to assess compliance, in which adequate intake of laxatives plays the most important role.

Sample size calculation

The sample size was calculated based on the proportion of adequate bowel preparation at Hanoi Medical University reported in a previous study, which was 82%–86%.¹¹ Assuming that an increase of 10% (from 85% to 95%)

by using the mobile app, a significance level of 0.05 (two sided) and a power of 80%, the minimal sample size was 138 participants in each group. Adding an additional 8% to account for missing the primary outcome for various reasons, we decided to recruit 150 participants in each group (300 in total).

Statistical analysis

Analysis was done on an intention-to-treat basis; patient's group was determined by their initial random assignment. Patients with missing primary outcome were excluded. The process of bowel preparation and outcomes were compared between the intervention and control groups using the χ^2 test (for categorical variables) and t-test or Mann-Whitney U test (for continuous variables), where appropriate. The primary outcome was further analysed in several a priori defined subgroups. These subgroups included age (≥ 50 vs < 50 years), sex, level of education (below high school vs high school or above), residency (urban vs rural) and history of colonoscopy. Data were analysed by using Stata V.16.1/BE (StataCorp).

RESULTS

Baseline characteristics

A total of 515 patients were recruited and had primary outcome in this study, of which 256 patients used the bowel preparation app. The median age of study participants was 42 years, 50.9% of the participants were females, 69.1% had an education of high school or higher and 45.2% from urban area. Approximately 90% of the participants had gastrointestinal symptoms and 40% had a history of having undergone colonoscopy. About three-fourths of participants consumed solid food or fibre food within 1 day prior to colonoscopy, and only

Table 1 Baseline characteristics of study patients

	Control (n=259)	Intervention (n=256)	Total (n=515)
Female sex (n, %)	140 (54.1)	122 (47.7)	262 (50.9)
Age, median (IQR)	43.0 (34–51)	40.0 (34–49)	42.0 (34–50)
BMI (n, %)			
Underweight (<18.5)	18 (6.9)	27 (10.5)	45 (8.7)
Normal (18.5 to <23)	169 (65.3)	152 (59.4)	321 (62.3)
Overweight/obesity (≥ 23)	72 (27.8)	77 (30.1)	149 (28.9)
Having gastrointestinal symptoms before examination (n, %)	229 (88.4)	221 (86.3)	450 (87.4)
History of prior colonoscopy (n, %)	111 (42.9)	85 (33.2)	196 (38.1)
Last meal (n, %)			
Solid food	183 (70.7)	204 (79.7)	397 (75.1)
Fibre food	195 (75.3)	199 (77.7)	394 (76.5)
Fruits with seeds	36 (15.3)	34 (15.2)	70 (15.3)
Coloured/carbonated drink	52 (22.4)	68 (30.0)	120 (26.1)

Bold values are statistically significant.
BMI, body mass index.

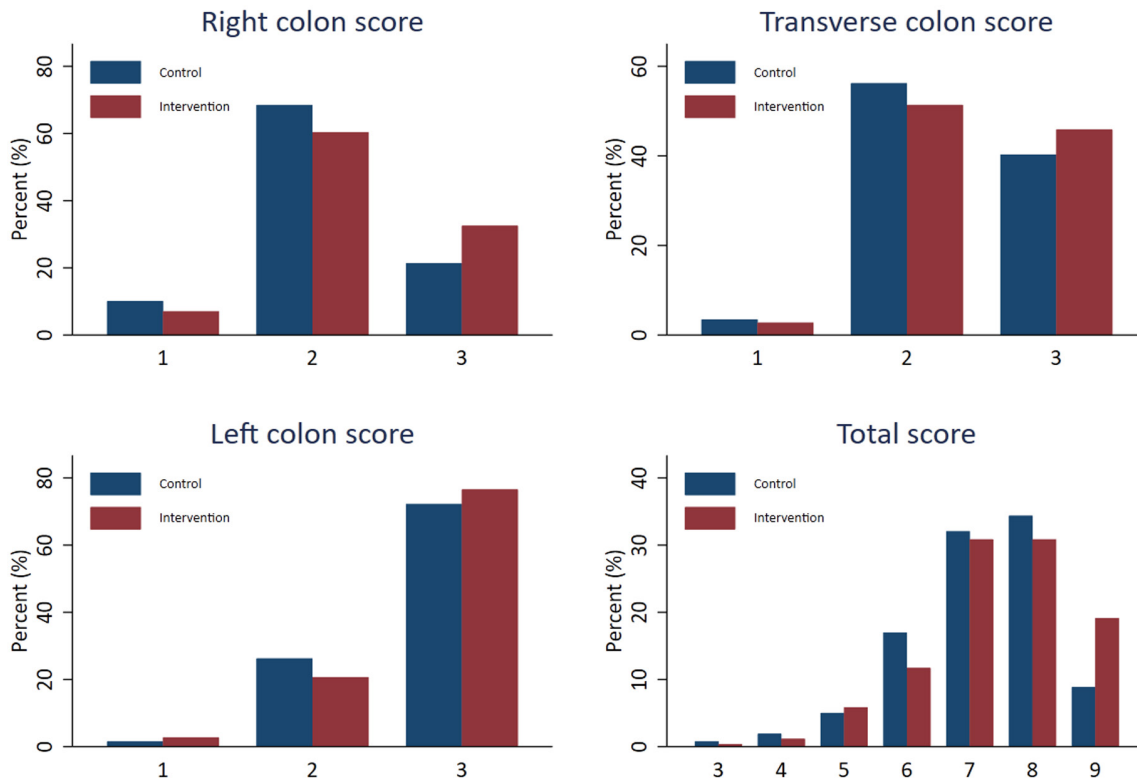


Figure 2 Component and total BBPS scores between the control and intervention group. The bar charts show the percentage of rating scores for the colon segments and the total BBPS. The percentage of the highest score (3 for segment scores and 9 for total score) was higher in the intervention group, suggesting an improvement in the quality of cleansing compared with the control group. However, this improvement was not clinically significant. BBSP, Boston Bowel Preparation Scale.

15% consumed fruits with seeds or coloured/carbonated drink (table 1).

Primary and secondary outcomes

The distribution of both the component scores and total BBPS score was similar between the two trial groups (figure 2). Although the median total BBPS score was higher in the intervention group (median (IQR) 7.5 (7–8) vs 7.0 (7–8), p=0.02), this difference was not clinically significant. Using the criterion of total BBPS<6 as poor quality of cleansing, the proportion of poor cleansing was non-significantly lower in the intervention (7.4% vs 7.7%;

risk ratio 0.96, 95% CI 0.53 to 1.76). The PDR and ADR were similar between the two groups (table 2).

In subgroup analysis, the risk of poor cleansing in the intervention group was lower in female patients, urban patients and patients who had no previous history of colonoscopy but was higher in male patients, rural patients and patients who had a history of colonoscopy (online supplemental figure S3). All these differences were not statistically significant.

Table 2 Primary and secondary outcomes between two trial groups

Outcomes	Control (n=259)	Intervention (n=256)	P value
Quality of bowel cleansing			
Total BBPS score, median (IQR)	7 (7–8)	7.5 (7–8)	0.02*
Poor cleansing (total BBPS<6), n (%)	20 (7.7)	19 (7.4)	0.90†
Polyp detection rate, %	23.2	23.4	0.94†
Adenoma detection rate, %	8.9	9.0	0.97†
Bold values are statistically significant. *t-test. †Pearson’s χ^2 test. BBPS, Boston Bowel Preparation Scale.			

**Table 3** Characteristics and outcomes of the bowel preparation process

	Control (n=259)	Intervention (n=256)	P value
Adequate bowel preparation			
Adequate laxative, n (%)	252 (97.3)	242 (94.5)	0.11*
Adequate walking, n (%)	221 (85.3)	227 (89.0)	0.21*
Adequate massaging the abdomen, n (%)	133 (52.4)	154 (60.9)	0.05*
Length of laxative intake (hour), median (IQR)	2.3 (2.0–2.6)	2.4 (2.2–2.8)	<0.001†
Total length of bowel preparation (hour), median (IQR)	3.8 (3.2–4.4)	3.9 (3.4–4.5)	0.12†
No of bowel movement, median (IQR)	10.0 (8.0–12.0)	10.0 (9.0–12.0)	0.41†
Qualified for colonoscopy, n (%)	259 (100)	256 (100)	

*Pearson's χ^2 .
†Mann-Whitney U test.

The bowel preparation process

Both the intervention and control group had a high proportion of adequate laxative (95.9% overall). The proportion of abdominal massage among patients in the intervention group was significantly higher than in the control group (table 3). Patients in the intervention groups also spent a significantly longer time taking laxatives (mean length 2.49 vs 2.33 hours; difference 0.17 hours, 95% CI 0.06 to 0.27). The total length of bowel preparation, number of bowel movement and the proportion of patients who qualified for colonoscopy were similar between the two groups.

Agreement with patient's self-assessment

In the 512 patients who had both self-assessment and BBPS assessment, 494 (96.8%) reported successful bowel preparation based on observing their defecation water. Among these, 36 (7.3%) had a BBPS of ≥ 6 (clean bowel preparation). Among 18 patients who reported poor quality of cleansing based on self-assessment, 17 (94.4%) had clean bowel preparation based on the BBPS score. Considering 'poor quality of cleansing' a positive test, compared with the BBPS score assessed by the expert, patient's self-assessment had a sensitivity of 5.6% (95% CI 0.1% to 27.3%) and a specificity of 92.7% (95% CI 90.1% to 94.8%). The results were similar between the control and intervention groups (online supplemental table S2).

DISCUSSION

This is the first study evaluating the effectiveness of a mobile app for bowel preparation in Vietnam. In short, the app improved the practice during bowel preparation but did not improve the quality of bowel cleansing assessed by the BBPS.

In our study, the proportion of patients taking the full prescribed doses of laxatives was high in both groups. More patients in the intervention group adhered to bowel preparation instructions. This suggests that the reminder feature in the app may help patients follow the instructions and thus better control the preparation process and duration. The quality of bowel preparation

is a determinant of the quality of colonoscopy.^{18–21} However, bowel preparation has been perceived to be the most burdensome part of colonoscopy, and inadequate knowledge was identified as obstacles to the uptake of screening colonoscopy.²² The 2019 European Society of Gastrointestinal Endoscopy²³ suggested the use of enhanced instructions for bowel preparation (eg, using a mobile app) to improve bowel cleanliness.

Although the improvement in the quality of bowel cleansing was demonstrated by both the median total BBPS and the proportion of good cleansing, these differences were not clinically significant, which may explain the non-superiority findings in the rates of detecting polyps and adenomas. In this study, the quality of cleansing using the conventional method was already high (>90%), even higher than the quality reported in a previous study conducted at the same centre (between 82% and 86%).¹¹ This may be explained by the excellent practice of the nurses at Hanoi Medical University Hospital in providing bowel cleansing instructions. Contrary to our study's results, most previous interventional studies demonstrated better outcomes in bowel cleansing among patients using a mobile app.^{8,24} In these studies, the control group often had a lower proportion of adequate cleansing (between 70% and 80%). This suggests that the mobile app may be more effective in the settings where conventional instructions are not adequate to provide good quality of cleansing.

We also found that patient's self-assessment of quality of bowel cleansing using pictures on the mobile app agreed with the assessment done by endoscopists using the BBPS during endoscopy. Patient's self-assessment had excellent specificity in detecting inadequate cleansing but had very poor sensitivity. In a previous study, almost all patients judged their preparation to be adequate but only 74.9% of the cases were considered adequate by endoscopists.²⁵ This suggests that the visual self-assessment tool in the mobile app can be trusted if patient rates that their cleansing is not adequate, but self-rating of adequate cleansing may require further examination of endoscopy nurses and doctors.

This is a randomised controlled trial with low proportion of missing outcome data, allowing a valid inference of the effectiveness of the mobile app. However, the study was conducted in a big central hospital where quality of bowel cleansing is already high; therefore, the results might not be generalised to hospitals at lower levels. Because we only studied patients with colonoscopy performed on the same day of bowel preparation, the effectiveness on split-dose afternoon colonoscopy is not known. Although we had examined the ADR, since not all polyps were collected for histopathological evaluation, patients with adenomas may have been misclassified as 'no adenomas'. This non-differential misclassification of outcome would bias the ADR towards the null, but given the very small magnitude of the difference between the two groups, we think this bias is negligible.

CONCLUSION

In short, the mobile app improved the practice during bowel preparation but did not improve the quality of bowel cleansing assessed by the BBPS.

Author affiliations

¹Department of Internal Medicine, Hanoi Medical University, Hanoi, Viet Nam

²Endoscopy Center, Hanoi Medical University Hospital, Hanoi, Viet Nam

³Research and Training Department, Institute of Gastroenterology and Hepatology, Hanoi, Viet Nam

⁴Department of Artificial intelligence, RMIT International University School of Science Engineering and Technology, Ho Chi Minh City, Viet Nam

⁵Department of Infectious Disease, Hanoi Medical University, Hanoi, Viet Nam

⁶Department of Medicine, Sydney Hospital, Sydney, New South Wales, Australia

⁷Department of Population and Quantitative Health Sciences, University of Massachusetts Chan Medical School, Worcester, Massachusetts, USA

⁸Department of Biostatistics and Medical Informatics, Hanoi Medical University, Hanoi, Viet Nam

⁹Institute of Gastroenterology and Hepatology, Hanoi, Viet Nam

Twitter Long Bao Hoang @drgothmania

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and the study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice. Ethical approval was given by the Hanoi Medical University Institutional Review Board (IRB-VN01.001/IRB00003121/FWA 00004148) with No.278/GCN-HDDCYSH-DHYHN. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request. This study is governed by the hospital where the study was conducted. The hospital requires that requests to access to all datasets, even properly anonymised, must be approved. To access the dataset, please contact the principal investigator of

this study. We will consider the purpose of data sharing and seek administrative approval from the hospital accordingly.

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ORCID iDs

Hang Viet Dao <http://orcid.org/0000-0002-3685-9496>

Hoa Ngoc Lam <http://orcid.org/0000-0002-2256-5016>

Long Bao Hoang <http://orcid.org/0000-0002-2829-3875>

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