

Title:

Predictors of inadequate bowel cleansing in colon capsule endoscopy: a single-center retrospective study

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Predictors of inadequate bowel cleansing in colon capsule endoscopy: a single-center retrospective study

Study population



Retrospective cross-sectional single-center study



Consecutive patients submitted to colon capsule endoscopy during a 2-year period

Methods

Low fibre diet in the 2 days before the procedure
Clear liquid diet on the day before the procedure

Bowel preparation in split-dose, using PEG solution with ascorbic acid
Two boosters of sodium phosphate solution



Outcomes

- Diabetes mellitus
- Hypothyroidism
- Active smoking
- Use of psychotropic drugs



PREDICTORS OF INADEQUATE BOWEL PREPARATION IN COLON CAPSULE ENDOSCOPY

In these patients, tailored bowel preparation protocols should be placed to improve the diagnostic yield and overall effectiveness of colon capsule endoscopy.

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Predictors of inadequate bowel cleansing in colon capsule endoscopy: a single-center retrospective study

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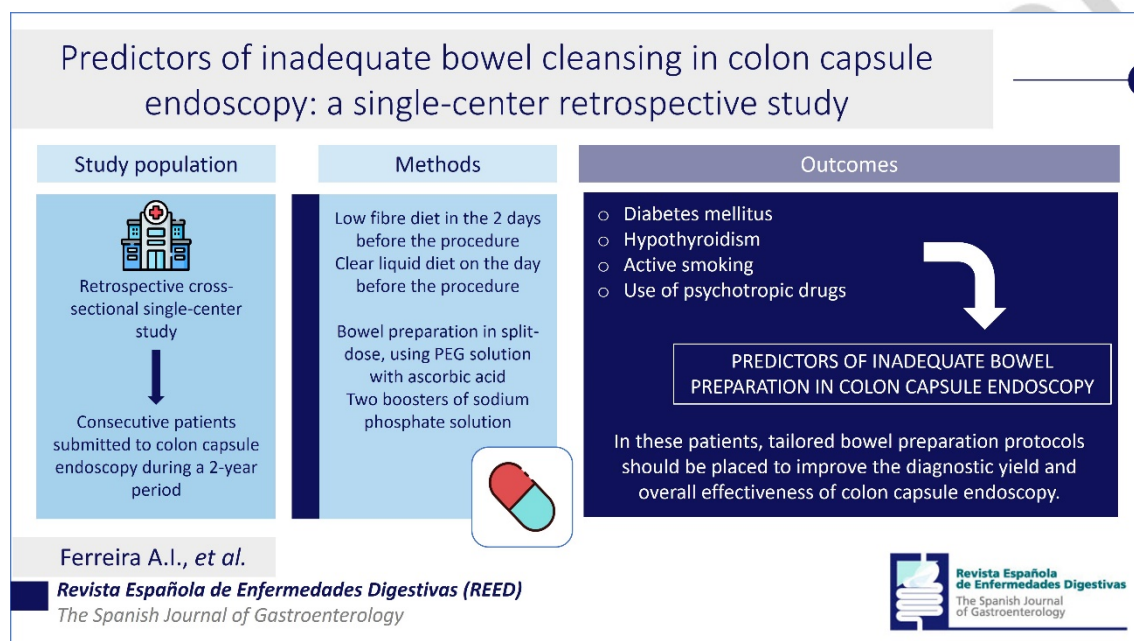
Data availability: Data supporting this study cannot be made available due to ethical and legal restrictions.

Ethics approval: The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the Institutional Ethics Review Board.

Patient consent: The patients' informed consent was waived since this is a retrospective study.

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Artificial intelligence: The authors declare that they did not use artificial intelligence (AI) or any AI-assisted technologies in the elaboration of the article.



Lay summary

The rate of adequate bowel preparation and complete examinations are crucial quality measures in colon capsule endoscopy (CCE). This retrospective cross-sectional, single-center study aimed to evaluate clinical and demographic factors possibly associated with inadequate bowel preparation in patients undergoing CCE. This study included consecutive patients submitted to CCE during a two-year period. The primary outcome was the adequacy of bowel preparation, using the Colon Capsule CLEansing Assessment and Report (CC-CLEAR). Secondary outcomes included the rate of complete examinations and the presence of findings throughout the colon. A total of 202 patients were included, 140 (69.3 %) with adequate bowel preparation and 62 patients (30.7 %) with inadequate bowel preparation. Patients with diabetes mellitus or hypothyroidism were more likely to have inadequate bowel preparation, as

well as smokers and patients on psychotropic drugs, namely benzodiazepines and/or antidepressants. The adequacy of bowel preparation was not associated with the detection of findings, similarly to the rate of complete examinations. On multivariable analysis, diabetes mellitus, hypothyroidism, smoking and being on psychotropic drugs were independent predictive factors for inadequate bowel preparation. In conclusion, diabetes mellitus, hypothyroidism, active smoking and the use of psychotropic drugs were identified as predictors of inadequate bowel preparation in CCE. In such patients, the bowel preparation regimen should be optimized to enhance the quality and diagnostic yield of CCE.

ABSTRACT

Introduction: the rate of adequate bowel preparation and complete examinations are crucial quality measures in colon capsule endoscopy (CCE). The aim of this study was to evaluate clinical and demographic factors possibly associated with inadequate bowel preparation in patients undergoing CCE.

Methods: retrospective cross-sectional study including consecutive patients submitted to CCE between September 2019 and August 2021. The primary outcome was the adequacy of bowel preparation, using the Colon Capsule CLEansing Assessment and Report (CC-CLEAR). Secondary outcomes included the rate of complete examinations and the presence of findings throughout the colon.

Results: a total of 202 patients were included, 140 (69.3 %) with adequate bowel preparation and 62 patients (30.7 %) with inadequate bowel preparation. Patients with diabetes mellitus or hypothyroidism were more likely to have inadequate bowel preparation (OR 2.247, 95 % CI: 1.115-4.525, $p = 0.022$, and OR 3.226, 95 % CI: 1.143-9.091, $p = 0.044$, respectively), as well as smokers and patients on psychotropic drugs, namely benzodiazepines and/or antidepressants (OR 3.115, 95 % CI: 1.381-7.042, $p = 0.005$, and OR 1.916, 95 % CI: 1.041-3.521, $p = 0.036$, respectively). The adequacy of bowel preparation was not associated with the detection of findings (right $p = 0.928$, transverse $p = 0.967$ and left colon $p = 0.632$), similarly to the rate of complete examinations ($p = 0.100$). According to multivariable analysis, diabetes mellitus (OR 2.451, 95 % CI: 1.153-5.208, $p = 0.020$), hypothyroidism (OR 3.269, 95 %

CI: 1.095-9.755, $p = 0.034$), smoking (OR 4.115, 95 % CI: 1.721-9.840, $p = 0.001$) and being on psychotropic drugs (OR 2.344, 95 % CI: 1.200-4.577, $p = 0.013$) were independent predictive factors for inadequate bowel preparation.

Conclusion: diabetes mellitus, hypothyroidism, active smoking and the use of psychotropic drugs were identified as predictors of inadequate bowel preparation in CCE. In such patients, the bowel preparation regimen should be optimized to enhance the quality and diagnostic yield of CCE.

Keywords: Colon capsule endoscopy. Bowel preparation. Colonoscopy.

INTRODUCTION

Colorectal cancer (CRC) is an important leading cause of death in Western countries, with several Gastroenterology and Oncology societies recommending its screening (1-5). The primary methods for CRC screening are colonoscopy and fecal immunochemical testing (FIT) (1,2,4). Alternative screening tests include colon capsule endoscopy (CCE), computed tomography (CT) colonography, flexible sigmoidoscopy and multitarget stool DNA test (1,6).

CCE and CT colonography are minimally invasive procedures recommended in patients with previous incomplete colonoscopy, due to technical factors or safety concerns (6,7). These methods are also recommended as alternative screening tests in patients with contraindications or unwilling to undergo colonoscopy without alarm symptoms (1,6,7).

Several studies have compared CCE and CT colonography revealing that CCE has a higher sensitivity and specificity for the detection of polyps, mainly those with 6-10 mm, compared to CT colonography (8-12). Additionally, CCE can detect colonic inflammation and anorectal diseases, unlike CT colonography (10). In fact, CCE has been proven to be safe and effective for polyp and CRC detection in the screening setting, with results comparable to colonoscopy (8,13,14). However, the adequacy of CCE examinations can be limited by inadequate bowel preparation and incomplete examinations (10-12).

The rate of adequate bowel preparation and complete examinations are crucial quality measures in CCE (7). Some predictors of inadequate bowel preparation have been previously identified for colonoscopy. However, in CCE, since there is no possibility of distending the colon, washing or suctioning fluids and debris, preparation for CCE is different from the one for colonoscopy. Additionally, the battery life constraints of CCE limits the completion rates. Therefore, the predictors of inadequate bowel preparation in colonoscopy may differ from CCE. Populations with higher risk of inadequate bowel preparation could benefit from an optimization of the bowel preparation regimens to improve the quality of CCE studies. Therefore, the aim of this study was to evaluate demographic and clinical factors associated with inadequate bowel preparation in patients undergoing CCE, predicting the need to adjust the colon cleansing protocol. We hypothesized that specific comorbidities and lifestyle factors are independently associated with inadequate bowel cleansing in CCE. The primary endpoint was the adequacy of bowel preparation, according to Colon Capsule CLEansing Assessment and Report (CC-CLEAR). Secondary outcomes included the rate of complete examinations, the colon transit time (CTT) and the presence of findings throughout the colon.

METHODS

Study design and population

A retrospective, single-center, cross-sectional study including consecutive patients submitted to CCE was conducted at a university-affiliated hospital. The inclusion period was between September 2019 and August 2021, and all consecutive patients were included in the study, including those with incomplete examination. Patients under the age of 18 or with contraindications to the ingestion of polyethylene glycol (PEG) and sodium phosphate solutions, such as drug hypersensitivity, bowel perforation, chronic kidney disease, congestive heart failure, electrolyte imbalance or severe dehydration, were excluded. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in *a priori* approval by the Institutional Review Board.

Colon capsule endoscopy procedure

CCE was performed using the PillCam™ COLON 2 capsule (Medtronic®). Detailed written and verbal information was provided to each patient. All patients signed a written informed consent before undergoing CCE.

Patients were instructed to follow a low-fiber diet in the two days before the procedure and a clear liquid diet on the day before the procedure. Bowel preparation was performed in split-dose, using 1 l of polyethylene glycol (PEG) solution with ascorbic acid followed by 1 l of water, with the first dose being administered on the day before the procedure, between 7 and 9 pm, and the second on the day of the procedure, between 6 and 8 am. After finishing the preparation, fasting was warranted.

Patients swallowed the capsule with a glass of water with 100 mg of simethicone. One hour after ingestion, patients returned to the Gastroenterology Department and the location of the capsule was visualized using the real-time viewer. If the capsule was in the stomach, 10 mg of domperidone were administered orally. Thirty minutes after, if the capsule remained in the stomach, it was endoscopically placed in the duodenum. After confirming that the capsule had passed into the small bowel, a booster of 30 ml of sodium phosphate solution was administered, followed by ingestion of 1 l of water. Three hours later, patients ingested a second booster of 15 ml of sodium phosphate, followed by 500 ml of water. If the capsule was not excreted in the two hours after the second booster, a 10 mg bisacodyl suppository was administered.

The protocol of CCE is illustrated in figure 1.

Once the video was created using Rapid Reader Software (Medtronic®), each patient's examination was assessed by two gastroenterologists experienced in CCE. Any discrepancies were reviewed, and the final diagnosis was established per expert consensus.

Data collection

Patients' demographic and clinical data, including comorbidities, were collected from electronic medical records. Relevant comorbidities included arterial hypertension, diabetes mellitus, obesity, hypothyroidism, depression, history of stroke and dementia. Other relevant clinical data was the history of smoking, referred symptoms of

constipation, previous abdominal or pelvic surgery and being medicated with opioids or psychotropic drugs, namely benzodiazepines and/or antidepressants.

The primary outcome evaluated was the adequacy of bowel preparation, adequate *versus* inadequate bowel preparation, according to the CC-CLEAR (15,16). The colon was divided into three segments (right, transverse and left colon), and each segment was classified according to the estimation of the percentage of mucosa clearly visualized (0 points if less than 50 % of the mucosa was observed; 1 point if 50-75 % of the mucosa was visualized; 2 points if 75-90 % of the mucosa was observed; and 3 points if more than 90 % of the mucosa was visualized) (15,16). The overall score was the sum of each segment scores, classified as inadequate bowel preparation (0-5 points), good (6-7 points) and excellent bowel preparation (8-9 points) (15,16). If any segment had a score of 1 or less, the overall classification was also considered inadequate, independently of the overall score (15,16). In our study, the bowel preparation was considered to be adequate if 6-9 points and inadequate in 0-5 points. For patients with incomplete CCE studies, the CC-CLEAR score could not be applied, and these patients with missing values were excluded from all tests, including the CC-CLEAR scores. Bowel preparation adequacy was assessed by the reviewing physicians. Secondary outcomes included the rate of complete examinations, the CTT, the presence of findings throughout the colon, namely polyps and/or vascular lesions, as well as the presence of diverticula. A complete colon examination was considered when the capsule reached the hemorrhoidal plexus or was excreted within its battery time. CTT was defined as the time between the first cecal image and the image of the hemorrhoidal plexus or the capsule's excretion.

Statistical analysis

Categorical variables were described as frequencies and percentages, and continuous variables as mean and standard deviation (SD) if normally distributed, or as median and interquartile range (IQR) if not normally distributed. Comparison of categorical variables was performed using the Chi-squared or Fisher's exact test, which were also used to calculate the odds ratio (OR) and its 95 % confidence interval (CI). Means and medians of continuous variables were compared using independent group t tests or

Mann-Whitney U test, respectively. Multivariable analysis was performed using a binary logistic regression including significant variables on univariable analysis, to identify independent predictive factors associated with inadequate bowel preparation in CCE. A p value less than 0.05 was considered as statistically significant. Statistical analysis software IBM SPSS version 27.0 (IBM Corp., Armonk, NY, USA) was used for all tests performed.

RESULTS

Baseline characteristics of the study population

A total of 202 patients were included; most were female (71.3 %), with a mean age of 67 ± 10 years. Forty-two patients had diabetes mellitus (20.8 %) and 16 had hypothyroidism (7.9 %). More than half of the patients had previous abdominal or pelvic surgery. The baseline characteristics of the study population are detailed in table 1.

Almost all patients underwent CCE due to previous incomplete colonoscopy (97.5 %), while the remaining patients had anesthetic contraindications for colonoscopy with sedation and preferred to undergo CCE (2.5 %). Regarding the endoscopic findings, 140 patients had a complete colon examination (69.3 %) and, according to CC-CLEAR, 140 patients had adequate bowel preparation (69.3 %) and 62 patients had inadequate bowel preparation (30.7 %). The interobserver agreement for CC-CLEAR was excellent (ICC = 0.87). A total of 102 patients (50.5 %) had a conclusive CCE, with a complete examination and adequate bowel preparation. The endoscopic findings in CCE are detailed in table 2.

Factors associated with inadequate bowel preparation

There were no statistically significant differences in the adequacy of bowel preparation regarding the patients' gender and age ($p = 0.281$ and $p = 0.145$, respectively).

Patients with diabetes mellitus were two times more likely to have inadequate bowel preparation (OR 2.247, 95 % CI: 1.115-4.525, $p = 0.022$). Those with hypothyroidism, even with adequate treatment, were three times more likely to have inadequate bowel preparation (OR 3.226, 95 % CI: 1.143-9.091, $p = 0.044$). Smokers were also

three times more likely to have inadequate bowel preparation (OR 3.115, 95 % CI: 1.381-7.042, $p = 0.005$). Finally, patients on psychotropic drugs, namely benzodiazepines and/or antidepressants, were two times more likely to have inadequate bowel preparation (OR 1.916, 95 % CI: 1.041-3.521, $p = 0.036$). The association between the patients' demographics and comorbidities and the adequacy of bowel preparation is detailed in table 3.

Multivariable analysis was performed using binary logistic regression and is presented in table 4. Diabetes mellitus (OR 2.451, 95 % CI: 1.153-5.208, $p = 0.020$), hypothyroidism (OR 3.269, 95 % CI: 1.095-9.755, $p = 0.034$), smoking (OR 4.115, 95 % CI: 1.721-9.840, $p = 0.001$) and being on psychotropic drugs (OR 2.344, 95 % CI: 1.200-4.577, $p = 0.013$) were all independent predictive factors of having inadequate bowel preparation in CCE (Hosmer-Lemeshow = 0.590, Nagelkerke $R^2 = 0.159$). A simplified risk score was developed, assigning two points to patients with diabetes mellitus, three points to those with hypothyroidism, four points to smokers and two points to individuals on psychotropic drugs. This score had a moderate accuracy in identifying patients with inadequate bowel preparation in CCE (AUC 0.710, $p < 0.001$) and having at least one of these factors was able to predict an inadequate bowel preparation in CCE with a sensibility of 86 % and a specificity of 47 %. The ROC curve is presented in figure 2.

Regarding the endoscopic findings, the adequacy of bowel preparation was not associated with the detection of polyps and/or vascular lesions in either of the three colonic segments (right colon $p = 0.928$, transverse colon $p = 0.967$ and left colon $p = 0.632$). Additionally, the presence of diverticula detected in CCE was not associated with the quality of bowel preparation ($p = 0.797$). There was also no association between the adequacy of bowel preparation and the rate of complete examinations ($p = 0.100$). However, the median CTT was significantly higher in patients with adequate bowel preparation (249 [179] vs 175 [207] minutes, $p = 0.014$).

DISCUSSION

This retrospective, single-center, cross-sectional study aimed to evaluate demographic and clinical factors associated with inadequate bowel preparation in patients

submitted to CCE. The identification of independent predictive factors of inadequate bowel preparation in CCE is essential to tailor the colon cleansing regimen and improve the quality of the examination. Previous studies have investigated factors associated with inadequate bowel preparation in colonoscopy (17,18). However, it should be noted that predictive factors of inadequate bowel preparation in CCE may be different from those of colonoscopy, because of the lack of lumen distension, ability to wash and suction fluids and debris or change the patient's position, making bowel preparation in CCE more demanding (7,10).

In our study, including a total of 202 patients submitted to CCE, the rate of complete colon examinations was 69 % and the rate of adequate bowel preparation was 69 %, which were suboptimal. A total of 102 patients (50.5 %) had a conclusive CCE with a complete examination and adequate bowel preparation. Although our protocol for bowel cleansing in CCE is standard and similar to other centers, the rate of adequate bowel preparation and complete examinations in our cohort was lower than international standards. This is probably due to inclusion bias since almost all included patients had previous incomplete colonoscopy (due to dolichocolon or angulation of the sigmoid colon). A large proportion of patients in our cohort had a history of abdominal or pelvic surgery, and half had diverticula, both factors that can be associated with incomplete examination and inadequate bowel preparation. While, in our study, neither was significantly associated with inadequate bowel preparation, previous studies have reported a link between prior abdominal and/or pelvic surgery and inadequate bowel preparation in colonoscopy (17,18).

A recent systematic review and meta-analysis, including 4,072 patients from 31 studies, demonstrated that the overall rate of adequate bowel preparation in CCE and pan-intestinal capsule endoscopy was 72.5 % and the rate of complete examinations was 83.0 % (19). In this study, the completion rate was significantly lower in elderly patients who were more than 80 years old (19).

In our cohort, diabetes mellitus, hypothyroidism, smoking and medication with psychotropic drugs, namely benzodiazepines and/or antidepressants, were independent predictive factors of having inadequate bowel preparation in CCE. In fact, the use of tricyclic antidepressants and comorbidities such as diabetes mellitus have

previously been identified as independent predictive factors for inadequate bowel preparation in colonoscopy (17,18,20). Chronic peripheral neuropathy can occur in patients with diabetes mellitus, leading to gastrointestinal motor dysfunction throughout the gut (21,22). Hypothyroidism can also be associated with intestinal dysmotility and delayed colonic transit (23). Smoking has been previously demonstrated as an independent risk factor for inadequate bowel preparation in colonoscopy (24). Smoking increases the CTT, which can lead to inappropriate bowel preparation due to a greater amount of residues in the colon (24). Antidepressants have been associated with the inhibition of bowel motility and therefore inadequate bowel preparation (18).

A score created with these variables had a moderate accuracy in identifying patients with inadequate bowel preparation in CCE and having at least one of these factors was associated with inadequate bowel preparation in CCE. Therefore, in clinical practice, patients with one of these factors should have a tailored bowel preparation for CCE. Although the ideal regimen for colon cleansing in CCE has not yet been standardized, several studies have proposed regimens to improve the quality of bowel preparation (25-29). In these patients, the rate of complete examinations could be improved by the use of gastrografin in addition to the standard sodium phosphate booster protocol, which has been suggested to improve the rate of adequate bowel preparation (25). The extension of the low-fiber diet or clear liquids for two or more days before the procedure, as well as four senna tablets on the day before the procedure, were also safe and effective strategies to improve the rate of adequate bowel preparation in CCE (26). Adding simethicone (100-200 mg) to the colon cleansing protocol in colonoscopy has been consistently shown to significantly improve the mucosal visibility and the quality of bowel preparation (27,28). Nevertheless, its use in CCE has not been evaluated and there is no protocol regarding the dose or timing of administration (19). The addition of the prokinetic prucalopride to the standard colon cleansing protocol was associated with an increase of complete examinations, adequate bowel preparation and polyp detection rates in CCE (29). However, it was also associated with higher prevalence of adverse events, such as nausea, headache and fatigue (29).

A recent systematic review and meta-analysis, including patients submitted to CCE and pan-intestinal capsule endoscopy, supports: a) a low-fiber diet on the day before the procedure; b) PEG as the purgative solution in a split-dose method; c) the routine use of sennoside laxative administered prior to the purgative solution; and d) the routine use of prokinetics before capsule ingestion (19). Another systematic review and meta-analysis, which focused on CCE, revealed that using PEG as purgative and sodium phosphate as booster was the most common practice among the 46 included studies (30). However, they were not able to show superiority of a specific colon cleansing regimen regarding completeness or cleanliness rate (30).

In our cohort, neither the use of opioids, nor a history of stroke or dementia could be associated with inadequate bowel preparation, probably due to the low prevalence of these patients in our sample. However, studies in colonoscopy have demonstrated the association between these and inadequate bowel preparation (18,20,31).

Other factors have been associated with inadequate bowel preparation, namely chronic constipation, hospitalization status and previous history of inadequate bowel preparation (17,18,20). To the best of our knowledge, only two studies have previously identified predictors of inadequate bowel preparation in CCE (32,33). In a study from De Sousa Magalhães et al., previous inadequate colon cleansing, impaired patient mobility and chronic use of antidepressants and laxatives were independent factors correlating with inadequate bowel cleansing in CCE (32). Gimeno-García et al. identified constipation as a unique independent predictive factor of inadequate bowel preparation (33). In this study, age was associated with inadequate bowel preparation, although it was not an independent predictive factor in multivariate analysis (33). In our cohort, there were no statistically significant differences in the adequacy of bowel preparation regarding the patients' age.

We acknowledge some limitations of our study, most notably its retrospective design and single-center setting, which may restrict the generalizability of our findings. This study included a moderate sample size, with no external validation, and there are some potential unmeasured confounders, such as other comorbidities or medications that could influence bowel cleansing. Nevertheless, the study possesses several strengths. This is one of the few investigations specifically designed to evaluate

predictive factors for inadequate bowel preparation in CCE, a diagnostic modality increasingly employed as an alternative to colonoscopy in selected populations. Unlike colonoscopy, CCE does not allow colonic distension, washing, suctioning of fluids and debris or changing the patient's position. Additionally, the limited battery life of the capsule imposes time constraints that can impact completion rates. As a result, bowel preparation for CCE differs significantly from that of colonoscopy, and predictors of inadequate preparation may not be directly comparable between the two procedures. Importantly, in our study, a multivariable analysis was performed, enhancing both the robustness and statistical power of our analyses. Furthermore, our findings emphasize the critical importance of optimizing bowel preparation regimens in CCE and confirm that previously identified predictive factors of inadequate bowel preparation in colonoscopy also apply to CCE. By identifying specific comorbidities (such as diabetes mellitus, hypothyroidism, smoking and the use of psychotropic drugs) as independent risk factors for inadequate bowel cleansing, our study provides valuable evidence to inform tailored bowel preparation protocols aimed at improving diagnostic yield and overall effectiveness of CCE. In these patients we suggest the use of gastrografin in addition to the standard sodium phosphate booster protocol, the extension of the low-fiber diet or clear liquids for two or more days before the procedure, and the administration of four senna tablets on the day before the procedure. Future studies should validate these findings prospectively, in multicenter cohorts, as well as identify ideal strategies for optimizing bowel preparation.

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Table 1. Baseline characteristics of the study population

Variable	Study population (n = 202)
<i>Gender - n (%)</i>	
Female	144 (71.3)
Male	58 (28.7)
Age, in years - mean $\pm$ SD	67 $\pm$ 10
Arterial hypertension - n (%)	117 (57.9)
Diabetes mellitus - n (%)	42 (20.8)
Obesity - n (%)	18 (8.9)
Hypothyroidism - n (%)	16 (7.9)
Depression - n (%)	42 (20.8)
History of stroke - n (%)	4 (2.0)
Dementia - n (%)	1 (0.5)
Smoking - n (%)	28 (13.9)
Constipation - n (%)	31 (15.3)
Previous abdominal or pelvic surgery - n (%)	104 (51.5)
Opioid use - n (%)	2 (1.0)
Benzodiazepines and/or antidepressants use - n (%)	74 (36.6)

SD: standard deviation.

Table 2. Endoscopic findings in colon capsule endoscopy

Variable	Study population (n = 202)
Complete colon examination - n (%)	140 (69.3)
CTT, in minutes - median (IQR)	209 (216)
<i>Bowel preparation, according to CC-CLEAR - n (%)</i>	
Excellent	69 (34.2)
Good	71 (35.1)
Inadequate	62 (30.7)
<i>Detection of polyps - n (%)</i>	
Right colon	50 (24.8)
Transverse colon	36 (17.8)
Left colon	47 (23.3)
<i>Detection of vascular lesions - n (%)</i>	
Right colon	9 (4.5)
Transverse colon	5 (2.5)
Left colon	1 (0.5)
Presence of diverticula - n (%)	95 (47.0)

CTT: colon transit time; IQR: interquartile range; CC-CLEAR: Colon Capsule CLEansing Assessment and Report.

Table 3. Factors associated with inadequate bowel preparation in colon capsule endoscopy

Variable	Adequate bowel preparation (<i>n</i> = 140)	Inadequate bowel preparation (<i>n</i> = 62)	<i>p</i> value
Gender - <i>n</i> (%)			
Female	103 (73.6)	41 (66.1)	0.281
Male	37 (26.4)	21 (33.9)	
Age, in years - mean ± SD	66 ± 11	69 ± 9	0.145
Arterial hypertension - <i>n</i> (%)	80 (57.1)	37 (59.7)	0.736
Diabetes mellitus - <i>n</i> (%)	23 (16.4)	19 (30.6)	0.022
Obesity - <i>n</i> (%)	11 (7.9)	7 (11.3)	0.430
Hypothyroidism - <i>n</i> (%)	7 (5.0)	9 (14.5)	0.044
Depression - <i>n</i> (%)	30 (21.4)	12 (19.4)	0.738
Smoking - <i>n</i> (%)	13 (9.3)	15 (24.2)	0.005
Symptoms of constipation - <i>n</i> (%)	19 (13.6)	12 (19.4)	0.293
Previous abdominal or pelvic surgery - <i>n</i> (%)	70 (50.0)	34 (54.8)	0.526
Psychotropic medications (benzodiazepines and/or antidepressants) - <i>n</i> (%)	46 (32.9)	30 (48.4)	0.036

SD: standard deviation. Statistically significant *p* values are highlighted in bold.

Table 4. Multivariate analysis of independent predictive factors of inadequate bowel preparation in colon capsule endoscopy

Variable	Regression coefficient	Odds ratio	Odds ratio CI 95 %	<i>p</i> value
Diabetes <i>mellitus</i>	0.896	2.451	1.153-5.208	0.020
Hypothyroidism	1.184	3.269	1.095-9.755	0.034
Smoking	1.415	4.115	1.721-9.840	0.001
Psychotropic medications (benzodiazepines and/or antidepressants)	0.852	2.344	1.200-4.577	0.013

CI: confidence interval. Statistically significant *p* values are highlighted in bold.

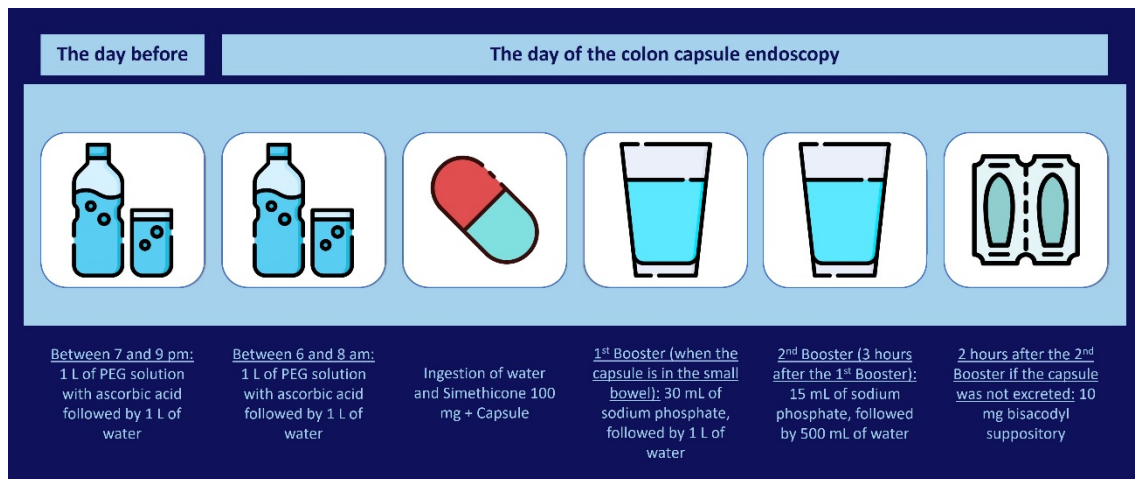


Fig. 1. Graphical illustration of the protocol for colon capsule endoscopy. PEG: polyethylene glycol.

Simplified risk score for inadequate bowel preparation in CCE

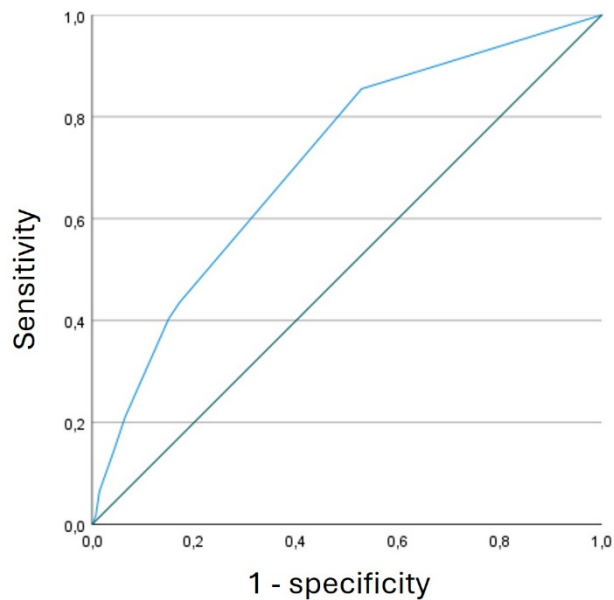


Fig. 2. ROC curve of the simplified score to predict inadequate bowel preparation in colon capsule endoscopy. CCE: colon capsule endoscopy.