



## Original Article

# Body mass index and quality of bowel preparation: Real life vs. clinical trials



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## ARTICLE INFO

## Article history:

Received 22 April 2015

Accepted 29 December 2015

## Keywords:

Body mass index

Colonoscopy

Bowel preparation

Obesity

Preparation quality

## ABSTRACT

**Background and study aims:** Obesity is a recognised risk factor for poor bowel preparation in retrospective studies whilst corresponding data in prospective trials are marginally reported. Aims are to evaluate the relation between body mass index (BMI) and preparation quality in retrospective and interventional prospective settings and within a single centre.

**Patients and methods:** Data from a recent colorectal cancer screening registry were retrospectively analysed for the relation between BMI and adequacy of preparation. Patients were categorised as underweight (BMI < 20 kg/m<sup>2</sup>), normal (20–25 kg/m<sup>2</sup>), overweight (25–30 kg/m<sup>2</sup>), and obese (>30 kg/m<sup>2</sup>). Data from a recent prospective colon preparation trial were similarly analysed.

**Results:** 541 registry patients were included. Multivariate analysis showed BMI to be an independent risk factor for inadequate preparation. Obesity was associated with odds ratio (OR) of 5.3 [95% confidence interval (CI) 1.4–19.8; *p* = 0.01] compared to normal BMI. A significant difference was also noted in underweight but otherwise healthy individuals (OR = 11.1, 95% CI 2–60; *p* = 0.005). In the prospective study of 195 patients, obese patients had comparable rates of inadequate preparation to normal-weight individuals (OR = 0.7, 95% CI 1.1–3.96; *p* = 0.68). Underweight patients had a significantly worse preparation compared to normal BMI individuals (OR = 8, 95% CI 1.1–58; *p* = 0.04).

**Conclusions:** In real life, bowel preparations in obese individuals have a lower quality in comparison to normal individuals. This finding is not replicated in clinical trials. This discrepancy is likely the result of focused patient education suggesting that this is primarily a dietary compliance phenomenon. Underweight individuals appear to have worse quality of preparation independent of study design or setting.

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## Introduction

Colonoscopy is the recognised gold standard for screening for colorectal cancer (CRC) with the distinct advantage of potential detection as well as removal of all visualised polyps [1]. Identifying and addressing modifiable factors that limit the diagnostic power of colonoscopy in an effort to improve its performance

characteristic is increasingly important. An inadequate bowel preparation continues to be a major hurdle towards that goal [2] with as many as 30% of patients undergoing colonoscopy having an inadequate bowel preparation [3]. This problem may even be more widespread in clinical practice than in the controlled setting of clinical trials where patients receive dedicated face-to-face detailed instructions and where investigators give due attention to accurate quality reporting.

Several explanations have been suggested for this unacceptably high rate of inadequate bowel preparations in the era of effective and increasingly tolerable preparations. Independent predictors of inadequate preparation include inpatient status, procedural indication of constipation, male gender, use of tricyclic antidepressants, history of cirrhosis, stroke, or dementia and a prior history of inadequate preparation [2]. A contributing element in clinical practice is the fact that, more often than not, a certain “preferred”

*Abbreviations:* AUBMC, American University of Beirut Medical Center; BMI, body mass index; CI, confidence interval; CRC, colo-rectal cancer; NaP, sodium phosphate; OR, odds ratio; PEG, polyethylene glycol; P/MC, sodium picosulfate and magnesium citrate.

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**Table 1**  
Modified Aronchick scale.

Rating	Description
Poor	Re-preparation required; large amount of faecal residue precludes a complete examination
Inadequate	Inadequate but examination completed; enough faeces or turbid fluid to prevent a reliable examination; less than 90% mucosa seen
Fair–adequate	Moderate amount of stool that can be cleared with suctioning permitting adequate evaluation of entire colonic mucosa; more than 90% mucosa seen
Good	Small amount of turbid fluid without faeces not interfering with examination; more than 90% mucosa seen
Excellent	Small amount of clear liquid with clear mucosa seen; more than 95% mucosa seen

regimen is usually handed out to all patients regardless of individual characteristics. This is even more accentuated in open-access colonoscopy screening programmes. Targeting patients at increased risk for poor preparation with more aggressive cleansing regimens should decrease the overall incidence of inadequate preparations but identification of such patients requires an accurate risk stratification model that reliably differentiates individuals at high risk for having a poor preparation from the general population [4]. This in turn necessitates an extensive evaluation and examination of individual risk factors, which may not be always practiced in real life and is further confounded by our limited ability to accurately predict patient compliance and adherence.

Obesity as a risk factor represents an attractive aspect to study for many reasons. Obesity is becoming a global epidemic [5] and obese patients represent an increasingly higher proportion of the colonoscopy pool. Obesity is also a well-established risk factor for advanced neoplasia and CRC [6] dictating a high-calibre examination for obese individuals. Few studies have specifically addressed the relation between body mass index (BMI) and quality of bowel preparation. With the exception of one non-interventional trial [4], all were retrospective in nature [7–9]. Corresponding data in interventional prospective studies are casually described in the results section whilst there are no data in underweight patients.

The aim of this study was to evaluate the relation between BMI and preparation quality in “real life” clinical practice and as part of an interventional prospective study within the same practice setting and to compare the relevant published literature.

## Patients and methods

This study was divided into a non-interventional retrospective and an interventional prospective component. The non-intervention part consisted of a retrospective analysis of consecutive patients undergoing colonoscopy as part of a prospective CRC screening study performed between 2009 and 2012 at the American University of Beirut Medical Center (AUBMC). Average risk individuals, with no personal or family history of cancer, undergoing screening colonoscopy were included. All patients received routine instructions for preparation in the clinic consisting of verbal and written instructions and provided by the clinic nurse. Data including height, weight, and preparation quality were extracted from the database that also included demographic data (age, gender), clinical information (past medical history, medications), social history (smoking, alcohol, caffeine, physical activity), dietary history, and number of bowel movements per week. BMI was calculated using the formula ( $\text{weight}/\text{height}^2$ ). Patients with a BMI < 20 kg/m<sup>2</sup> were categorised as underweight; those with BMI of 20–25 kg/m<sup>2</sup> were considered normal, whereas those with a BMI of 25–30 kg/m<sup>2</sup> were considered overweight and a BMI of >30 kg/m<sup>2</sup> defined the obese category. Bowel cleansing was performed using 4L split-dose PEG (Fortrans<sup>®</sup>, IPSEN, Paris, France) with minimal dietary restriction in the form of clear liquid diet the evening before colonoscopy. Bowel preparation quality was

recorded according to the modified Aronchick scale (Table 1). Patients having excellent/good evaluation were considered to have a satisfactory preparation. This part of the study was felt to represent the real life setting where instructions and scoring were routinely performed without other influence.

The interventional prospective counterpart was also conducted at AUBMC between February and December 2013. Patients requiring elective colonoscopies were prospectively enrolled. The study coordinator provided detailed written instructions and verbal explanations to all patients, emphasising the importance of adherence to instructions to ensure a more effective procedure. Demographic data were collected as part of the study. Bowel cleansing was performed using either 4 L of menthol-enhanced PEG [10] or 2 L of ascorbic acid-supplemented PEG, both given in split-dose with minimal dietary restriction consisting of clear liquid dinner the evening before colonoscopy. An endoscopist blinded to the preparation assignment assessed quality of preparation using the modified Aronchick scale. Patients with a score of excellent or good were considered to have an adequate preparation. The study protocol had the quality of bowel preparation as primary outcome and was registered with Clinicaltrial.gov identifier: NCT01788709. This study part represented a classical clinical trial setting.

Exclusion criteria for both study parts included age <18, pregnant or lactating women, prior intestinal resection or bariatric surgery, chronic renal disease (creatinine clearance <60 mL/min), severe congestive heart failure (New York Heart Association class III or IV), history of severe constipation (<1 bowel movement every 3 days), significant gastroparesis, chronic laxative abuse, and history of inflammatory bowel disease. Incomplete documentation was also basis for exclusion. All patients provided written informed consent and the study was approved by the Institutional Review Board.

## Statistical analysis

SPSS version 20.0 (SPSS Inc., Chicago, Illinois, United States) was used for data entry and analysis. A univariate then multivariate analysis was performed to test for the association of BMI with adequacy of the preparation. The proportions of adequate bowel preparations in each of the 4 BMI groups (underweight, normal, overweight, and obese) were calculated separately. We analysed the association of BMI with the adequacy of the prep as a categorical variable where chi-square test was used to compare these proportions using normal BMI as the reference category. Exact *p* values less than 0.05 were considered significant.

## Results

Overall 541 subjects were identified in the CRC screening database fulfilling the study inclusion criteria. These served as the study population for the retrospective part. The mean age of participants was 61 ± 8.2 years (range, 50–84) and 52.3% were males. Of those, 17 participants (3.1%) were underweight, 158 (29.2%) had a normal BMI, 259 (47.9%) were overweight, and 107 (19.8%) were

obese. There were no age differences between the BMI sub-groups but it was noted that more females were in the underweight and normal category whilst the overweight and obese categories had more males. The indication for colonoscopy was screening and bowel cleansing was performed using 4 L split-dose polyethylene glycol-based preparations. In total, 5.4% of all participants had inadequate bowel preparation.

On retrospective multivariate analysis, BMI was shown to be an independent risk factor for inadequate bowel preparation. Inadequacy rates were significantly different across BMI categories ( $p = 0.017$ ). Preparations were inadequate in 18% (3/17) of underweight individuals, and this was significantly higher than the 2% (3/158) rate recorded in normal subjects ( $p = 0.005$ ). Compared to normal BMI subjects, overweight individuals had a non-significant increase in the odds of having an inadequate preparation ( $p = 0.122$ ), where 5% (13/259) had inadequate preps. Obese individuals, on the other hand, were significantly more likely to have an inadequate bowel preparation, with 9% (10/107) having inadequate preparations compared to normal ( $p = 0.013$ ) (Fig. 1). Amongst patients with inadequate preparations, 34.5% were obese, 44.8% were overweight, 10% were normal, and 10% were underweight.

In total, 195 patients were enrolled in the prospective study. The mean age of enrolled patients was  $54.5 \pm 13.7$  years (range 21–85) and 52% were males. Of those, 6 participants (3.1%) were underweight (BMI < 20 kg/m<sup>2</sup>), 68 (34.9%) had a normal BMI (20–25 kg/m<sup>2</sup>), 73 (37.4%) were overweight (25–30 kg/m<sup>2</sup>), and 48 (24.6%) were obese (>30 kg/m<sup>2</sup>). There were no age or gender differences between the BMI sub-groups with the exception of the underweight category where there were more females. Colonoscopy was performed for colorectal cancer screening in 89 patients (45.6%), hematochezia in 26 patients (13.3%), abdominal pain in 26 patients (13.3%), change in bowel habits in 16 patients (8.2%), and for surveillance in 16 patients (8.2%); the remaining 22 patients (11.3%) had other miscellaneous indications. There was no significant clustering occurring in one preparation versus the other in BMI categories. In total, 5.1% of all participants had inadequate bowel preparation. Amongst patients with inadequate

preparations, 15.4% were obese, 38.5% were overweight, 30.8% were normal, and 15.4% were underweight.

There was no significant association between BMI and the quality of bowel preparation ( $p = 0.14$ ). Preparations were inadequate in 33% (2/6) of underweight individuals, significantly higher than the 6% (4/68) rate recorded in normal individuals ( $p = 0.039$ ). Overweight individuals were slightly more likely to have an inadequate preparation, where 7% (5/73) had inadequate preparation ( $p = 0.82$ ). Obese individuals on the other hand had a non-significant decrease in inadequate preparation rate to 4% (2/48) compared to normal ( $p = 0.68$ ) (Fig. 2). The odds ratio for inadequate bowel preparation vs. different BMI categories in the retrospective study (real life) and prospective clinical trial setting are shown in Fig. 3.

## Discussion

The association between BMI and quality of bowel preparation has been the subject of investigation of a small number of trials with a positive association noted between obesity and inadequate preparation. With the exception of one non-interventional prospective trial [4], all these studies were retrospective in nature [7–9]. Although the association was positive in the non-interventional trial, data extracted from interventional trials provide a different conclusion. A literature search of the past 15 years for randomised controlled trials involving more than 80 subjects identified 15 prospective trials that reported on the association of BMI and quality of preparation in the results section [11–25] (only two [15,24] stated this information in the study abstract). None of the 15 studies found a significant association. Confounding factors such as difference in study designs, type of preparation, study populations, and preparation scoring scales may have contributed to these seemingly paradoxical results between retrospective and prospective studies. To reconcile these findings, we attempted to address this relationship by performing a retrospective review of a CRC screening database as well as analysing a recently completed prospective randomised trial. The advantage

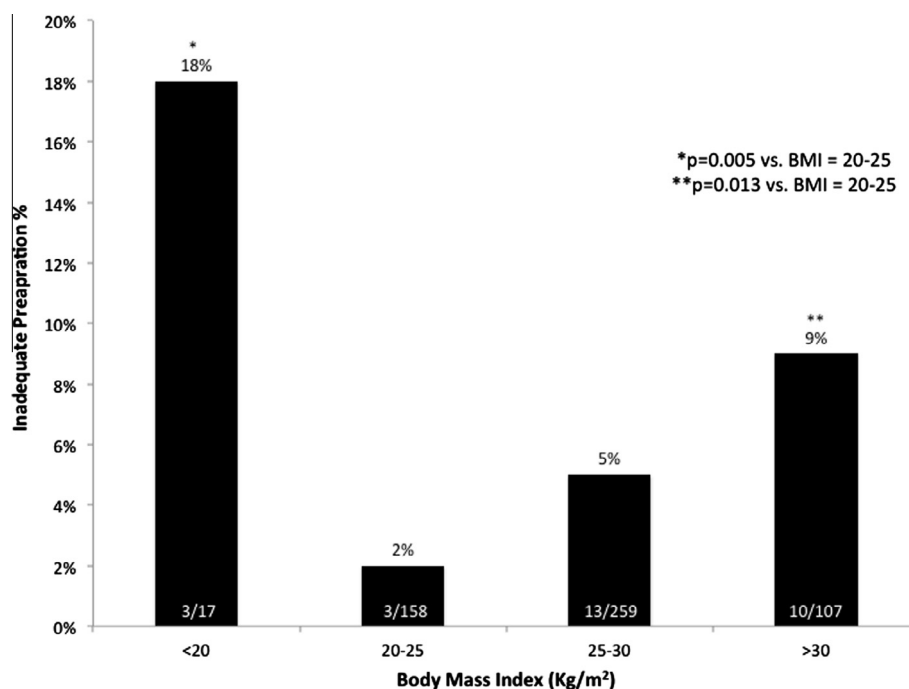


Fig. 1. Distribution of inadequate bowel preparation over BMI categories (real life).

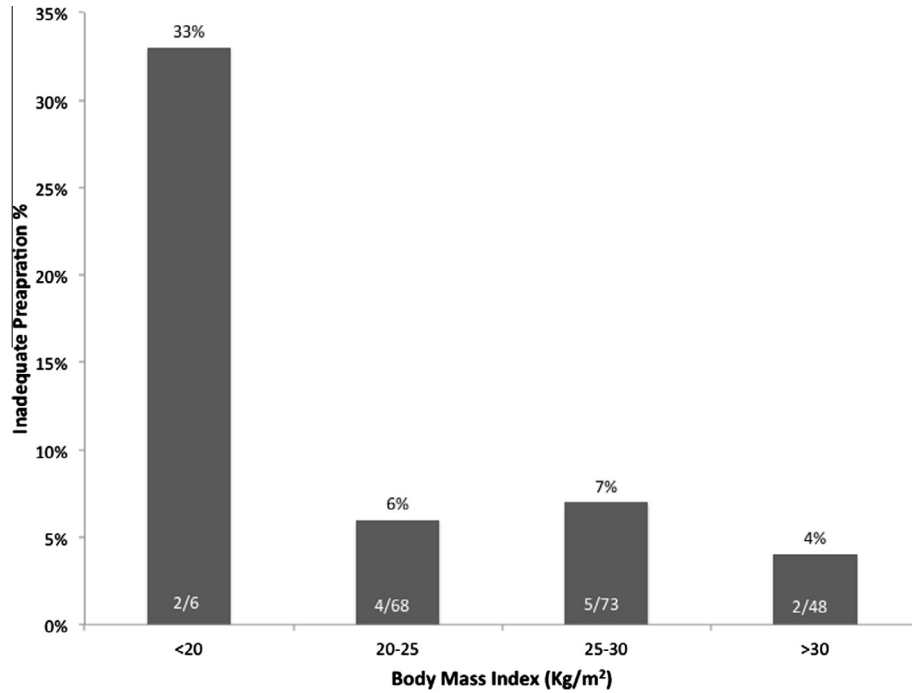


Fig. 2. Distribution of inadequate bowel preparation over BMI categories (clinical trial).

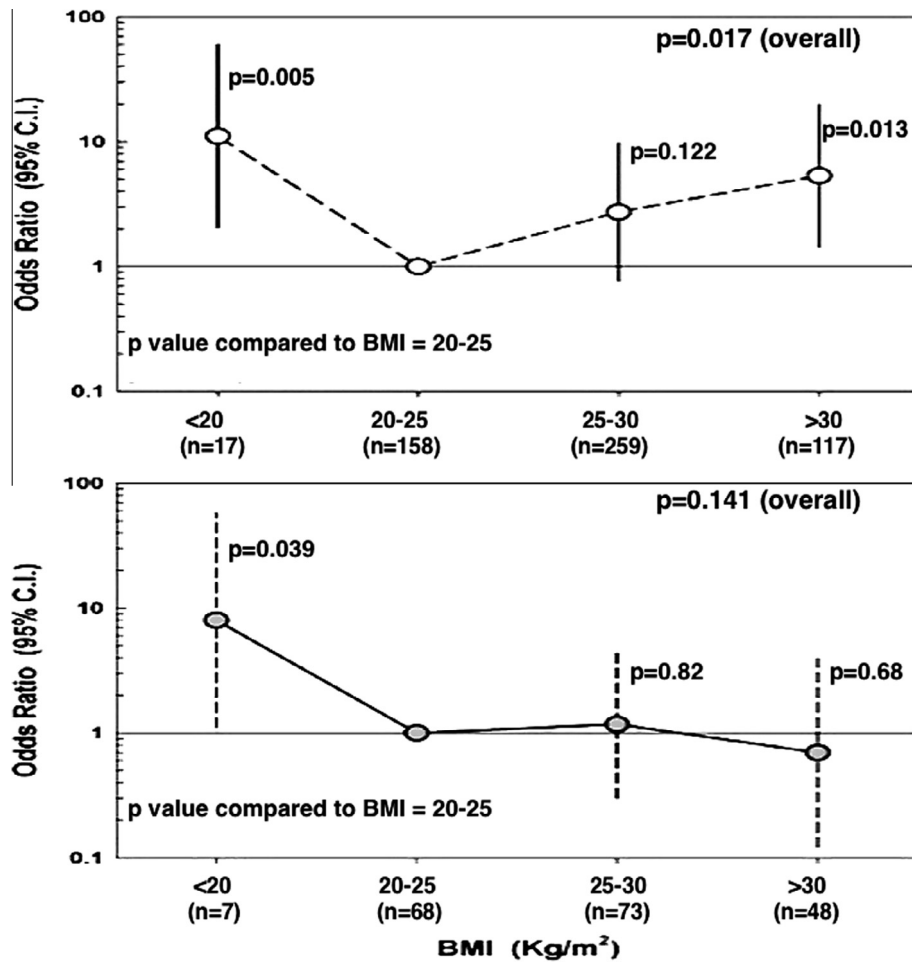


Fig. 3. Odds ratios for inadequate bowel preparation vs. different BMI categories in real life (upper) and clinical trial setting (lower). Normal BMI = reference.

**Table 2**

Published trials reporting an association between body mass index (BMI) and bowel preparation quality (PEG = polyethylene glycol; NaP = sodium phosphate; P/MC = sodium picosulfate and magnesium citrate).

Study	Patients	Nature	Bowel preparation used	Association between obesity and quality
Ell et al. (2003) [14]	175	Prospective	PEG (split) vs. sulphate-free PEG vs. NaP	No association
Hwang et al. (2005) [16]	80	Prospective	PEG vs. NaP (split)	No association
Ell et al. (2008) [13]	308	Prospective	PEG vs. PEG + ascorbic acid (split)	No association
Szajda et al. (2008) [24]	102	Prospective	PEG vs. sulphate-free PEG	No association
Di Palma et al. (2009) [12]	787	Prospective	Sodium sulphate vs. PEG + ascorbic acid (split)	No association
Cohen et al. (2010) [11]	107	Prospective	PEG + ascorbic acid vs. PEG + bisacodyl (±split)	No association
Rex et al. (2010) [21]	136	Prospective	PEG vs. magnesium citrate low-volume PEG (split)	No association
Park et al. (2010) [20]	232	Prospective	P/MC (split)	No association
Fok et al. (2012) [15]	99	Prospective	P/MC	No association
Hassan et al. (2012) [4]	2811	Prospective <i>non-interventional</i>	Multiple (PEG/PEG + ascorbic acid/NaP/PEG + bisacodyl/sennosides/split/others)	Negative association
Katz et al. (2013) [17]	603	Prospective	P/MC vs. PEG + bisacodyl	No association
Rex et al. (2013) [22]	601	Prospective	P/MC vs. PEG + bisacodyl (split)	No association
Seo et al. (2013) [23]	197	Prospective	PEG (split)	No association
Manes et al. (2013) [19]	285	Prospective	P/MC vs. PEG + ascorbic acid (±split)	No association
Valiante et al. (2013) [25]	264	Prospective	PEG vs. split PEG + simethicone + bisacodyl	No association
Liu et al. (2014) [18]	605	Prospective	PEG or NaP	No association
Borg et al. (2009) [7]	1588	Retrospective	N/A	Negative association
Fayad et al. (2012) [8]	2163	Retrospective	PEG (split)	Negative association
Czornog et al. (2013) [9]	773	Retrospective	N/A	Negative association
Current study	541	Retrospective	Split PEG	Negative association
Current study	195	Prospective	PEG + menthol vs. PEG + ascorbic acid (split)	No association

of this double-headed approach lies in the fact that the studies were both performed using split-bowel preparations within the same practice thereby limiting confounders (e.g. gender in the large Veterans Affairs study [8]) and allowing meaningful and direct comparison.

An interesting observation is the consistent finding of obesity as a risk factor for poor preparation in every study conducted in a “real-life” non-interventional setting, in sharp contrast to data from prospective clinical trials (Table 2). Our results match these observations. In real life, it appears that obesity negatively impacts preparation quality. Interestingly, the J-shaped curve linking BMI to preparation quality (Fig. 3) is not dissimilar from other curves seen almost universally with BMI studies. This seemingly strong association is not confirmed in the setting of clinical trials. At first glance a Hawthorne effect seems like a plausible explanation but some factor other than direct observation may be at play in this particular situation.

The method and intensity of instructions are obviously very different between the two settings, with higher emphasis placed on adherence to instructions and compliance with dietary restrictions in trial settings. This effect is assumed to be responsible for the difference observed. Although obese patients may have worse bowel preparation in real life, this low performance characteristic appears to be instruction-dependent. The preparation quality in obese individuals in our clinical trial matches that of individuals with normal BMI and is likely the result of focused face-to-face patient education emphasising adherence. This suggests that this may be primarily a dietary compliance phenomenon. In general, patients who are obese tend to have a different pattern of dietary behaviour with more frequent and larger meals including evening snacking compared to non-obese patients. Modifying this behaviour for a single day in compliance with proposed dietary restrictions may be particularly challenging to this subgroup of patients. Obese patients will need higher levels of incentive to comply with dietary restrictions and focused education and extensive counselling become essential in such individuals. The use of 4 L split-dose PEG preparation with minimal dietary restrictions in our clinical practice may have even downsized this dietary compliance phenomenon. The decrement in quality of bowel preparation could arguably be further accentuated with the use of low volume prepa-

rations requiring more rigorous and restrictive (hence hunger-promoting) diets.

In a US national survey involving 288 gastroenterologists, those reporting  $\geq 10\%$  suboptimal bowel preparations identified compliance with diet as one of the most important patient barriers [26]. Proper patient education before colonoscopy is critical to ensure adherence and consequently satisfactory bowel preparation. There is limited evidence however to support a causal relationship and it is estimated that  $<20\%$  of inadequate preparations are the result of patients' reported failure to adequately follow instructions [27–31]. However, proper patient education is clearly important and appears to be enhanced with targeted face-to-face explanation of procedure details along with clear explanation of incentive benefit. In support are studies showing better bowel preparation with visual educational instructions vs. traditional verbal and written instructions [32,33] and with 10 min of physician-delivered patient education [34]. Comprehension of instructions and compliance are clearly tied as evidenced by lower compliance with instructions of a written colonoscopy preparation leaflet in patients with lower health literacy [35].

Independent of study design or setting, underweight individuals had a worse quality of preparation. This sub-population is generally underrepresented in preparation studies including this study and in many instances not analysed independently. This limits the power of this observation or the ability to speculate on the potential causes behind this differentially worse performance.

In conclusion, the results of this study suggest that obesity is not a direct risk factor for inadequate bowel preparation but is rather a marker of such a negative outcome. Given the consistent lack of association in prospective clinical trials, it stands to reason that obesity is, in real life, a marker of a negative behavioural factor, namely diet non-compliance. Obese patients should receive intensive education and coaching regarding full compliance with dietary modifications and bowel preparation instructions.

Lastly, our study suggests that underweight individuals have a worse quality of preparation independent of study design or setting. This is thought to be an instruction-independent phenomenon, but with the small number of patients the power of this observation or the ability to speculate on the potential causes behind this differentially worse performance is limited.

## Contributorship

*Sharara AI:* Study idea, concept, design and supervision; interpretation of data; review of the literature; drafting of the manuscript. Guarantor of the study.

*Harb AH:* Data collection and statistical analysis, tabulation and interpretation of data, results and figures, review of literature, regulatory administration, drafting of the manuscript.

*Sarkis FS:* Patient recruitment, data collection and statistical analysis, tabulation and interpretation of data, review of literature, regulatory administration.

*Chalhoub JM:* Tabulation and interpretation of data, review of literature, drafting of results.

*Habib RH:* data analysis and interpretation, statistical oversight.

## Conflict of interest

The authors declared that there was no conflict of interest.

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