Arab Journal of Gastroenterology 17 (2016) 11–16

Contents lists available at ScienceDirect

Arab Journal of Gastroenterology

journal homepage: www.elsevier.com/locate/ajg

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^2), normal (20–25 kg/m^2), overweight (25–30 kg/m^2), and obese (>30 kg/m^2). 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.

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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http://dx.doi.org/10.1016/j.ajg.2015.12.001
1687-1979/

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 (weight/height^2). Patients with a BMI < 20 kg/m^2 were categorised as underweight; those with BMI of 20–25 kg/m^2 were considered normal, whereas those with a BMI of 25–30 kg/m^2 were considered overweight and a BMI of >30 kg/m^2 defined the obese category. Bowel cleansing was performed using 4L split-dose PEG (Fortrans®, 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