

A descriptive investigation of the adequacy of bowel preparation prior to colonoscopy: protocol of a retrospective study

Indagine descrittiva sull'adeguatezza della preparazione intestinale prima della colonscopia: protocollo di uno studio retrospettivo

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Key words: bowel preparation, colonoscopy, cleansing, scale, procedure outcome.

ABSTRACT

Background: colonoscopy is the most widely used technique for examining the colorectal mucosa. The diagnostic accuracy and therapeutic reliability of the examination depend on many factors including the quality of colon cleansing and bowel preparation. The aim of the study is to determine the standard of bowel preparation in patients undergoing colonoscopy.

Methods: an observational, retrospective, single-center study. Inpatients and outpatients undergoing colonoscopy at the Alessandria Hospital's SS Digestive Endoscopy between 1 January 2021 and 31 December 2021 will be eligible. The study will use the Boston Bowel Preparation Scale to assess bowel preparation. Study data will be collected by reviewing medical records and entered into the online computerized platform "Electronic Data Capture".

Conclusions: assessing the quality of bowel preparations is crucial to monitoring and detecting any problems that will be later reflected in the outcome of the procedure and enables the practitioners involved to seek possible solutions.

Background: la colonscopia rappresenta la tecnica più utilizzata per lo studio della mucosa coloretale. L'accuratezza diagnostica e la certezza terapeutica dell'esame dipendono da molti fattori tra cui la qualità della pulizia intestinale. Scopo dello studio è quello di rilevare il livello di preparazione intestinale nei pazienti sottoposti a colonscopia.

Metodi: studio osservazionale, retrospettivo, monocentrico. Saranno considerati i pazienti ambulatoriali e ricoverati sottoposti a colonscopia presso la SS Endoscopia Digestiva dell'ospedale di Alessandria nel periodo compreso tra 1 Gennaio 2021 e 31 Dicembre 2021. Lo studio prevede l'utilizzo della Boston Bowel Preparation Scale per valutare la preparazione intestinale. I dati dello studio verranno raccolti attraverso l'analisi delle cartelle cliniche e successivamente inseriti sulla piattaforma informatizzata online "Electronic Data Capture".

Conclusioni: la valutazione della qualità delle preparazioni intestinali è fondamentale per poter monitorare e rilevare eventuali problematiche che si riflettono poi sull'esito della procedura e consente agli operatori coinvolti di cercare delle possibili soluzioni.

BACKGROUND

The gold standard for direct visualization of the colon is the endoscopic colonoscopy which is currently the most widely used method of screening for colorectal cancer,¹ diagnosis and treatment of inflammatory and infectious diseases of the colon and terminal ileum.² The endoscopic examination is considered safe and has a low rate of adverse events, although the burden of bowel preparation and investigation is a challenge for patients.³

The diagnostic accuracy and therapeutic certainty of the examination depend on many factors including the quality of bowel cleansing.⁴

The most common method of bowel preparation consists of a change in diet the day before the examination and the oral intake of a cathartic agent with laxative properties in a single or fractionated dose.⁵ When fractionated, the first dose of bowel preparation should be taken the day before the procedure and the last dose within 5 hours of the colonoscopy with completion at least 2 hours before the procedure begins.⁵

Bowel preparation agents can be classified in different ways, including volume administered (low volume/high volume), osmolality (isotonic/hypoosmotic/hyperosmotic) or main functional ingredient (PEG, sodium pico sulphate, sodium phosphate [NaP]).⁶ Furthermore, it is important that the patient, especially if

elderly or already debilitated, maintains adequate hydration during the preparation to minimize possible adverse effects due to the intake of laxative preparations (dehydration and hydro electrolyte imbalances).⁷

Adequate bowel hygiene is defined according to two important assessment rates: cecal intubation rate and adenoma detection rate, respectively the intubation rate and the adenoma removal rate.⁸ The former makes it possible to evaluate as a percentage the colonoscopies in which, thanks to good cleanliness, it proved possible to reach the cecum endoscopically and examine the entire colon; the latter, and more important in terms of evaluating the quality of the procedure, indicates the percentage of colonoscopies in which at least one adenoma was identified and removed.⁸ Adequate bowel preparation ensures high procedure accuracy, optimal imaging of the colon mucosa and an increased rate of adenoma detection.⁹ Poor bowel preparation is associated with greater technical difficulties, increased perforation risks, procedure interruption, diagnostic delays, reduced adenoma and carcinoma detection rates, and increased healthcare costs.¹⁰

Several scales have been developed to assess bowel preparation. Nevertheless, the Boston Bowel Preparation Scale (BBPS) has proven to be the most validated scale and has been recommended for use in clinical settings.¹¹

It has been reported in the body of literature that rates of incomplete colonoscopies, defined as the inability to achieve effective cecal intubation and visualization of the mucosa, vary between 20% and 30 % due to inadequate bowel preparation.¹²

The quality of bowel preparation is influenced both by factors related to the patient's medical history as well as factors related specifically to the patient themselves.

Potential causes related to the patient's medical history may include: chronic constipation, chronic use of laxatives, use of particular medications such as tricyclics, antidepressants, opioids, calcium antagonists, being hospitalized, obesity or being significantly overweight, having had previous bowel preparations for a colonoscopy that were later found to be inadequate, diseases such as stroke, dementia, diabetes and cirrhosis.⁶

The risk factors of inadequate preparation that concern the patient are: male gender, older age, a low level of education and low/medium socio-economic status, little concern and participation in maintaining one's own health, language, the time lapse between booking and performing the examination and, very frequently, non-adherence to the instructions provided either due to a lack of understanding of the information or a lack of motivation and self-awareness of the patient.¹³

Knowledge of the number of interrupted or not performed procedures due to inadequate bowel preparation and the relationship with predictive factors could guide professionals in the implementation of targeted interventions.

The aim of this study is to measure the level of bowel preparation in patients undergoing a colonoscopy through a retrospective investigation.

Objectives

The aim of this study is to detect the rate of inadequate bowel preparation in patients who were referred to the SS High Complexity Digestive Endoscopy of Alessandria for colonoscopy from 1 January 2021 to 31 December 2021. Furthermore, it is expected to: i) assess the relationship between inadequate bowel preparation according to the Boston Bowel Preparation Scale and

the type of preparation employed; ii) describe the sociodemographic factors of patients with inadequate bowel cleansing.

MATERIALS AND METHODS

This is an observational, retrospective study.

Both, out-patients and in-patients undergoing an endoscopic colonoscopy at the SS High Complexity Digestive Endoscopy of the SS. Antonio e Biagio e Cesare Arrigo National Hospital of Alessandria in the period between 1 January 2021 and 31 December 2021 will be considered.

Given the retrospective nature of the study, patients will be contacted by telephone and the study will be explained to them. Only after the patient's acceptance and informed consent has been signed will it be possible to proceed with data collection from medical/nursing records and reports, during the period between 1 January 2021 and 31 December 2021. The data collected will include the following variables: age, gender, nationality, type of preparation employed, and patient's hospital admission (in-patient or out-patient).

Tools

For this study, the Boston Bowel Preparation Scale (BBPS)¹⁴ was applied. This is a 9-point scale designed to assess bowel preparation after all cleansing procedures. Each segment of the colon, right colon, transverse colon and left colon is assigned points from 0 to 3 in terms of colon cleansing. The total score can, therefore, vary from a minimum of 0 to a maximum of 9. Where a score of 0 indicates an unprepared colon, a non-visualized mucosa due to the presence of solid feces that cannot be suctioned. Score 1 indicates a partial vision of the colic mucosa, incomplete due to the presence of residual feces and obscured fluid. Score 2 indicates a good vision of colic segments while small fragments of feces or small amounts of obscured fluid persist. 3 indicates no stool fragments or clear liquids. Higher scores indicate better preparation (2-3), lower scores (0-1) indicate inadequate preparation.¹⁵

In addition, medical/nursing records will be considered for demographic data collection and the type of preparation practiced by the patient.

Data collection

Study data will be collected through the analysis of medical records and then entered into the computerised online platform "Electronic Data Capture" (REDCap). The electronic tool is compliant with current clinical trial and privacy regulations (GCP E6(R2)-IHC, European Regulation 2016/679 - GDPR), is validated (GCP E6(R2)-IHC). All changes to data are recorded and tracked electronically, access is password protected, located within the company server and automatically backed up.

All data in the database, set up specifically for the study, can never be traced back to the individual patient: through coding procedures, the research center investigator assigns an identification code to each subject.

Statistical analysis

The data will be processed in aggregate form, and a descriptive and correlation analysis will be conducted. The categorical variables will be presented as frequencies and percentages and continuous data as mean and standard deviation, according to their distri-

bution. Categorical data will be analysed using Chi-Square tests. The level of significance is considered to be $p < 0.05$ and analyses will be conducted with the help of SPSS version 25 software.

DISCUSSION

The main aim of our study is to investigate the level of bowel preparation in patients undergoing colonoscopy.

Studies have reported that bowel preparation is inadequate in 15-30% of all colonoscopies, with varying rates according to medical facilities and patient populations.^{5,12} The quality of a colonoscopy depends on adequate imaging, which is based on the quality of bowel cleansing. It has been demonstrated that up to 26% of adenomas are not detected by standard colonoscopy. This rate could be reduced by adequate bowel preparation;¹⁵ therefore, an appropriate method must be carefully tailored to the patient's physical condition before the exam.²

A number of product- and patient-related factors may influence the quality of bowel preparation,¹⁶⁻¹⁸ including comorbid conditions and the use of certain pharmacological substances. A retrospective single-centre study¹⁹ (n=404) of patients undergoing a screening or diagnostic colonoscopy, reported that those who had diabetes were significantly at higher risk of poor-quality bowel preparation than those without the disease.

Non-compliance with preparation instructions has been demonstrated to be a strong predictor of poor bowel preparation.²⁰ An analysis of average-risk patients undergoing routine screening colonoscopy showed that 86.7% of patients with poor bowel preparation had not completed the preparation or had not followed the written instructions on preparation times or dietary restrictions.²¹ Effective patient education is associated with greater adherence to dosage instructions and higher-quality bowel preparation.¹⁷ Tolerability is strongly influenced by the properties of the bowel preparation product and the administration regimen.²² Low-volume and fractionated dose regimens are associated with better tolerability,²³ but cause adverse effects including dehydration, hyponatremia and hydro electrolyte imbalances more frequently than high-volume regimens.²⁴ The selection of an agent for bowel preparation is based on multiple product-related factors, including efficacy, safety, tolerability, volume and easy administration, together with the patient's medical history and preferences.

CONCLUSIONS

Adequate bowel preparation prior to a colonoscopy is a precondition for performing a high-quality, safe and effective procedure.

Evaluation of the quality of bowel preparations is essential in assessing and detecting possible problems that are then reflected in the outcome of the procedure and enables the professional providers involved to pursue possible solutions.

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