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Overall acceptability and efficacy of commonly used bowel preparations for colonoscopy in Italian clinical practice. A multicentre prospective study

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ABSTRACT

Background & aims: The recent enormous increase in colonoscopy demand prompted this multicentre observational study assessing overall acceptability and efficacy of commonly used bowel preparations in Italian clinical practice.
Methods: Consecutive outpatients undergoing colonoscopy were recruited from 9 major gastroenterological centres in Italy. Each patient evaluated overall acceptability of the bowel cleansing preparation through a 0–100 mm Visual Analogue Scale. The Visual Analogue Scale score was dichotomized by a median split: 80–100 (high acceptability) vs. 0–79 (low acceptability). Bowel cleansing was assessed through a validated scale. The influence of potential individual determinants on patients' acceptability and cleansing efficacy of the bowel preparations was determined by multivariate analyses.
Results: 599 evaluable patients were enrolled; 57.3% received 4L-PEG preparations, 29.5% 2L-PEG preparations and 13.2% 2-glasses-solutions (Na-phosphate/Mg-citrate/Na-picosulphate-containing preparations). Overall acceptability was significantly higher for 2L-PEG and 2-glasses solutions than 4L-PEG (adjusted odds ratio, 4.72; and adjusted odds ratio 2.07, respectively). Successful bowel cleansing achieved with 4L-PEG (85.9%) was similar to 2L-PEG (85.3%; adjusted odds ratio 0.82) and significantly higher than 2-glasses solutions (69.6%; adjusted odds ratio 0.34 vs. 4L-PEG). Split regimen, lower total preparation volume and colonoscopy reason (periodical control vs. 1st procedure) were significantly associated with high acceptability. Age ≥60 years, dissatisfaction with the preparation taken, and ≤4/week bowel movements were major determinants of a poor bowel cleansing.
Conclusions: 2L-PEG and 4L-PEG preparations provide the most effective bowel cleansing for colonoscopy in clinical practice, with a significantly higher acceptability for 2L-PEG preparations.

1. Introduction

Colonoscopy plays a pivotal role in the diagnosis and treatment of most colorectal pathologies, particularly in the colorectal cancer (CRC) screening setting. Large studies have shown that colonoscopy, when used as part of an integrated faecal occult blood screening programme or as a unique screening modality

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(screening colonoscopy), is able to decrease CRC incidence and mortality by detecting cancers at an early stage and by removing their precursor lesions (adenomas) [1–6].

The introduction of an organized CRC screening programme in Italy in 2005, which is run at a regional level, has resulted in an enormous increase in demand for colonoscopy over the last few years [7]. Today, more than 1.5 million colonoscopies are performed yearly in Italy and approximately 40% of them are ordered for CRC screening and surveillance [7].

However, we should bear in mind that colonoscopy is an invasive and embarrassing exam, not devoid of risks and discomfort that causes fear and anxiety in the majority of patients. An ideal colonoscopy requires proper technical experience, adequate colon cleansing and patient cooperation in order to be considered successful, highly effective and accurate [8]. In particular, inadequate bowel preparation is considered the most important barrier to successful colonoscopy, being associated with prolonged intubation time, increase discomfort for the patient, high adenoma miss rates as well as earlier repeat colonoscopy recommendations regardless of the presence of polyps [9,10]. Furthermore, it has been shown that many gastroenterologists, as a result of inadequate bowel preparation, often recommend follow-up colonoscopy earlier than the time recommended by national guidelines [11]. Therefore an effective bowel preparation, which is deemed acceptable both by patients and endoscopists is vital in achieving high-quality colonoscopic evaluations.

In current clinical practice in Italy, various bowel preparation regimens are prescribed by different specialists according to those they have found to be most effective based on their own experience and past training. These regimens include large volume polyethylene glycol (PEG) solutions (4L-PEG), reduced volume PEG solutions (2L-PEG), hyperosmotic low volume solutions, and oral sennosides or bisacodyl. However, data concerning suboptimal or inadequate bowel preparation for colonoscopy as well as the acceptability of various regimens in current clinical practice are limited, especially following recent cautionary advice regarding the use of oral sodium phosphate bowel preparations [12,13]. This lack of data prompted us to perform a multicentre prospective observational study to assess overall acceptability and efficacy of most commonly used bowel preparations in clinical practice in Italy.

2. Methods

This was a multicentre, observational, prospective study, in outpatients undergoing colonoscopy, conducted in 9 centres from northern, central and southern Italy. The study protocol was approved by the Ethical Committees of all the participating centres and the study was registered at the Italian Register of observational studies and at ClinicalTrials.gov (identifier: NCT01626196).

2.1. Population

Consecutive patients undergoing bowel cleansing procedures according to each centre's usual clinical practice, entered the study just before colonoscopy, using a competitive enrolment. Patients were of both sexes, aged ≥18 years and were admitted for a routine colonoscopy for various reasons.

Patients were excluded in cases of pregnancy or breastfeeding and in accordance with the listed contra-indications to the relevant product used for the bowel cleansing procedure. Undergoing a previous colonoscopy during the previous five years or having taken enemas the day preceding the colonoscopy were additional exclusion criteria.

2.1.1. Study plan

Written informed consent was obtained from all patients who agreed to participate in the study. After obtaining informed consent, the patients' demographic, anthropometric and socio-economic data, and medical/pharmacological history were collected. Additionally, the investigator assisted the patients in filling in a questionnaire exploring acceptability, satisfaction, tolerance and adherence to the bowel cleansing preparation taken. The investigator instructed the enrolled patient not to inform the endoscopist performing the colonoscopy about the bowel preparation taken.

Following completion of the Patient Questionnaire, patients underwent colonoscopy. The endoscopists, unaware of the type of bowel cleansing preparation used by the patient, performed the scheduled endoscopic examination according to usual clinical practice, recording data on bowel cleansing and on other selected variables.

2.1.2. Objective

The primary objective of the study was to evaluate, in outpatients receiving bowel cleansing preparations prior to colonoscopy, the influence of selected risk factors on the following three primary outcomes: (1) patient's acceptability of the bowel cleansing preparation; (2) successful bowel cleansing; and (3) successful caecal intubation.

2.2. Primary outcomes

The acceptability of the bowel cleansing preparation (which represents a general scale providing the attitudes, in terms of acceptability, satisfaction and tolerance, towards the bowel cleansing preparation used) was evaluated by each patient through a 0–100 mm Visual Analogue Scale (VAS), ranging from 0 (totally unacceptable) to 100 (fully acceptable), recorded in the Patient Questionnaire. The VAS score was dichotomized by a median split, in 80–100 (high acceptability) vs. 0–79 (low acceptability).

A successful bowel cleansing was assessed using a validated cleansing scale (the Harefield Cleansing Scale©; HCS [14]). The endoscopist, trained through the use of instructive guidelines including informative pictorial images, rated the grade of bowel cleansing for each of the predefined areas of the bowel (rectum, sigmoid colon, descending colon, transverse colon and ascending colon) using the following 0–4 score: 0 = irremovable, heavy, hard stools. Colonoscopy incomplete; 1 = semi-solid, only partially removable stools. Incomplete mucosa visualization; 2 = brown liquid or small amounts of semi-solid residual stools, fully removable by suction or displaceable, thus allowing complete mucosa visualization; 3 = clear liquid; 4 = empty and clean. The grade of the overall colon cleansing was rated as follows: A all 5 segments scored 3 or 4; B = 1 or more segments scored 2; C = 1 or more segments scored 1; D = 1 or more segments scored 0. Grades A and B were considered as success, and grades C and D as failure.

Finally, the blinded endoscopist recorded any reasons for an incomplete colonoscopy, i.e. not being able to examine the cecum. Successful caecal intubation was verified by visualization of the lips of ileocaecal valve and the appendiceal orifice.

2.2.1. Risk factors

Secondary outcomes included other measures of cleansing procedure acceptability and satisfaction, tolerance and adherence to the cleansing procedure, collected through the Patient Questionnaire.

The potential risk factors, whose influence on the three primary outcomes was investigated in the present study, included centre characteristics, patient's socio-demographic characteristics (e.g., age, sex, education, cohabitation), anthropometric measures (including self-reported weight and height, used to derive body mass index, BMI), lifestyle habits (e.g., tobacco smoking and alcohol drinking), medical and pharmacological history, clinical factors