

## THE REAL-WORLD EVIDENCE ON USAGE OF BOWEL PREPARATION AGENTS BEFORE COLONOSCOPY: A PAN INDIA STUDY

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### ABSTRACT

**Background:** The diagnostic accuracy of colonoscopy depends on the quality of the bowel preparation, and successful colonoscopy requires optimal visualization of the entire mucosal surface. Physicians favor preparations associated with patient compliance to achieve the best results while patients favor preparations that are low in volume, palatable, have easy to complete regimens and have better safety profile across various patient profiles.

**Methods:** A self-structured questionnaire-based survey was conducted with 120 Gastroenterologist's across India from the period May 2018 to July 2018 to understand the prescribing pattern of bowel preparation agents for colonoscopy.

**Results:** Quality bowel preparation and onset of action are the most common factors that decides choice of agent for bowel preparation opined by 75% and 45% physicians respectively. PEG (Polyethylene glycol) is the most commonly used agent for bowel preparation due to its excellent efficacy and safety profile. Most of the professionals use PEG preparation offering 118 gm/ 2 liters, even though they are aware the USFDA recommended PEG regimens offer 210 gm/2 liters. Apart from good quality of bowel preparation, Liquid PEG had shown distinct advantages of ease of administration, palatability, regimen adherence thus improving the compliance.

**Conclusion:** Liquid PEG can be considered as a better alternative for bowel cleansing before colonoscopy with additional advantages of ease of administration, palatability thus maximizing regimen adherence thereby improving the colonoscopy outcomes.

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### INTRODUCTION

Colonoscopy is one of the most commonly recommended diagnostic modality for the managing colorectal pathologies and for high quality colonoscopy, adequate colonic cleansing is utmost essential.<sup>1</sup> Despite of large published available data on methods that could optimize cleansing,<sup>2-8</sup> a substantial level of inadequate cleansing occurs in 10% to 75% of patients in randomized controlled trials.<sup>9-16</sup> Patients and endoscopists are both negatively impacted by an inadequate bowel preparation. Poor bowel preparation has been shown to result in a longer procedure time, a lower adenoma detection rate, an increased incidence of interval cancer, a higher rate of colonoscopy-related complications, and the need for repeated examination.<sup>17-19</sup> There is a tremendous financial burden associated with an inadequate preparation, with both direct and indirect costs incurred by both the patient and the endoscopists. Poor bowel preparation presents a costly and unnecessary burden not only to the patients but also to our health care system. Ultimately, the economic impact of inadequate bowel preparation is significant, with incomplete procedures resulting in 12% to 22% higher estimated costs.<sup>17, 20-23</sup>

Adequate bowel preparation is essential to ensure sufficient visualization of the colonic mucosa and to optimize lesion detection.<sup>24,25</sup> Adequate colon preparation can be affected by different bowel-cleansing agents<sup>26</sup> as well as the time between starting bowel preparation and the colonoscopy.<sup>27</sup> Colonic cleansing is commonly performed with solutions containing polyethylene glycol (PEG), the alternatives are sodium phosphate, magnesium citrate, or Bisacodyl.<sup>2-8</sup> So there is a highly need of current knowledge on adequate bowel preparation and its procedures, efficient agents, formulations and its dosage which are currently used in the practice especially in the Indian setups. In this study we explored clinicalpractice-based perspectives of Gastroenterologist for adequate bowel wash using a questionnaire-based survey.

### MATERIALS AND METHODS

A prospective survey-based study was conducted from May 2018 to July 2018. This survey was designed to know the preference of Gastroenterologists in bowel preparation based on their clinical practice. Equitable inclusion of Health Care Professionals across India to satisfy a pan India representation of the survey was adopted in the survey plan. A *Data Report Form* (DRF) comprising of 12 objective type questions on the preference for bowel preparation was designed to know their

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perspective based on their clinical practice. Each HCP evaluated at least 50 patients when responding to the survey. The key elements of the questionnaire were as follows: common indications for colonoscopy, medications before colonoscopy, commonly used agents for bowel preparations, patients' profile, factors to decide choice of agents, assessment for the efficacy of good bowel preparation, formulation of bowel preparation agents, PEG regimen, PEG dosage, USFDA recommendation on PEG dosage, percentage of patients on liquid PEG demonstrated adequate bowel preparation, scores for liquid PEG in bowel wash.

An approval from the Ethics Committee was not required as this survey involved only the Health Care Professionals' opinion regarding the preference of bowel preparation based on their clinical practice and did not involve the direct participation of any patient.

**Statistical Analysis**

Data entry was done in Microsoft Excel (Office 360) in a survey (questionnaire) specific excel spreadsheet validated for the survey questionnaire. Validation was done using built-in validation tools in MS Excel to minimize data entry errors.

Data for responses to multiple questions were expressed as numbers with percentage (%) for each response. Percentage values were calculated based on the total number of responders for each question independently.

**RESULTS**

The survey questionnaire was sent to 120 participating Gastroenterologists across India and received the response from all of them. In the present study, findings indicated that abnormal bowel habits and rectal bleeding are emerged as first two common indications for colonoscopy in India as highlighted by 44(36.68%) and 29(24.17%) of Health Care Professionals (HCPs) respectively (Figure 1), in which around 90% of HCPs use bowel wash before colonoscopy. In addition, 36% HCPs also prefer to add a laxative along with bowel preparation agent.

Generally, PEG (Polyethylene glycol) is the most commonly used agent for bowel preparation as highlighted by ~99% HCPs. Other agents used by HCPs are sodium phosphate (62%) and sodium sulphate (51%) (Figure 2). But specifically, in elderly patients, around 94% of HCPs opined that PEG solution is the most preferred agent in bowel preparation. Similarly, in children also around 88% of HCPs preferred PEG solution only.

Majority of the HCPs considered that quality bowel preparation (75%) and onset of action (45%) are the most common factors that decides choice of agent for bowel preparation. More than 40% of study participants preferred to use Chicago scale to assess the efficacy of good bowel preparation, followed by ~32% preferred to use Boston scale, followed by ~23% preferred to use Aronchick scale for the assessment of efficacy of good bowel preparation. More than three-fourth of the study participants opined that ready-mix liquid formulation of bowel preparation agents is generally preferred, followed by 25 (20.83%) opined that any other, followed by 21 (17.50%) said that Powder formulation and only 3 (2.50%) said that tablet (Figure 3).

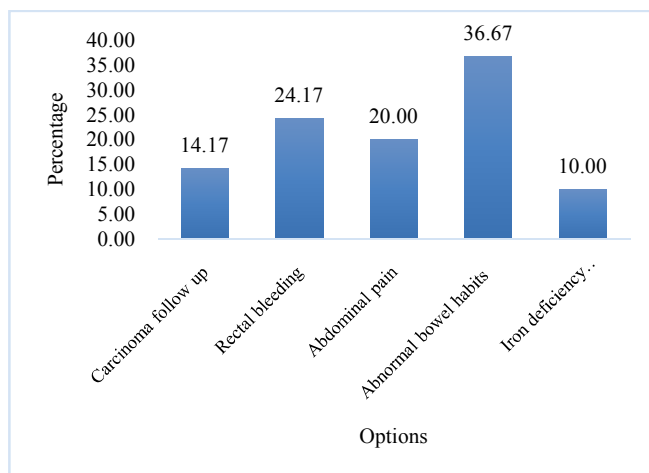
Around three-fourth of the study participants use PEG preparations offering 118 gm/ 2 liters dilution and 38% of

HCPs use 210 gm/ 2 liters is the PEG for the bowel preparation (Figure 4). More than 50% study participants preferred Day 1: Bisacodyl + Day 2: PEG 2 L PEG regimen generally used for the bowel wash in their clinical practice (Table 1).

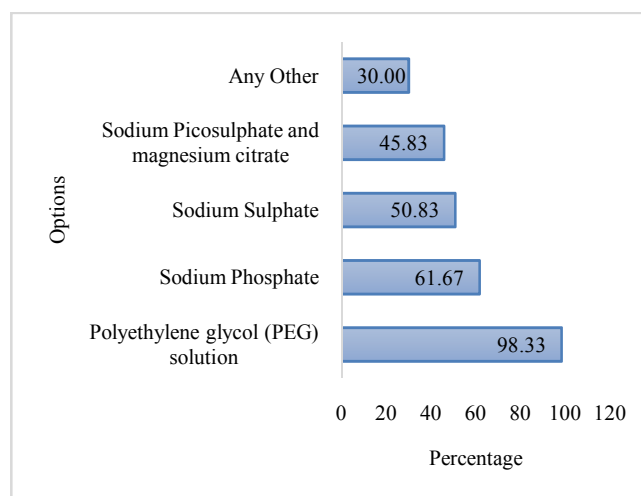
Around 85% of HCPs are aware that 210 grams per 2L is the USFDA recommended dosage of PEG (Figure 5). Similarly, more than 3/4<sup>th</sup> of study participants replied that >80% of their patients on liquid PEG that have demonstrated adequate bowel preparation in their clinical practice, (Figure 6). Maximum score of Liquid PEG in bowel wash on Quality of Bowel Preparation, followed by Ease of Administration, followed by Regimen Adherence and taste.

**Table 1** Which PEG regimen generally used for the bowel wash in your clinical practice?

Options	No. of Participants	Percent
Day 1: Bisacodyl + Day 2: PEG 2 L	62	51.67
Day 1: Bisacodyl and PEG 1 L + Day 2: PEG 1 L	14	11.67
Day 1: PEG 2 L + Day 2: PEG 2 L	21	17.50
Day 1: PEG 1 Ls + Day 2: PEG 1 L	10	8.33
Day 1: - + Day 2: 2L PEG	21	17.50
Any other (Please specify)	5	4.17



**Figure 1** Common indications for colonoscopy in clinical practice



**Figure 2** Commonly used agents for bowel preparation

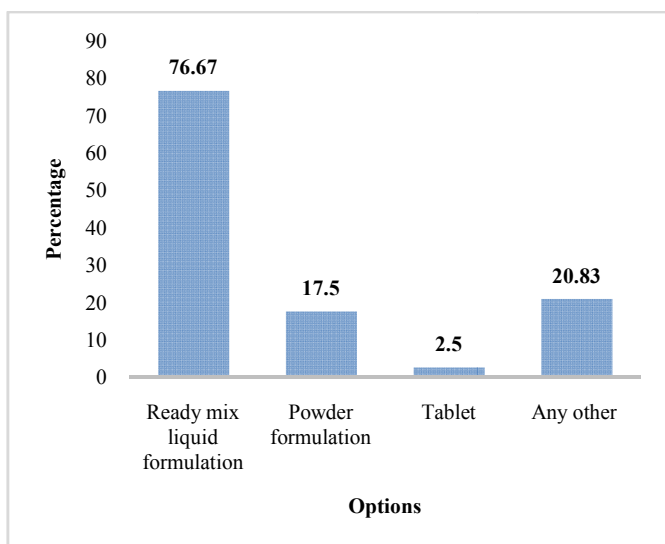


Figure 3 Generally preferred formulation for bowel preparation agents

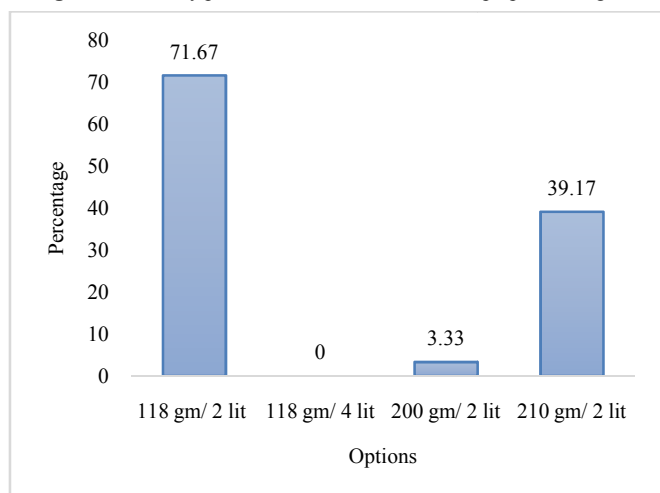


Figure 4 Generally used PEG dosage (in grams) for the bowel preparation

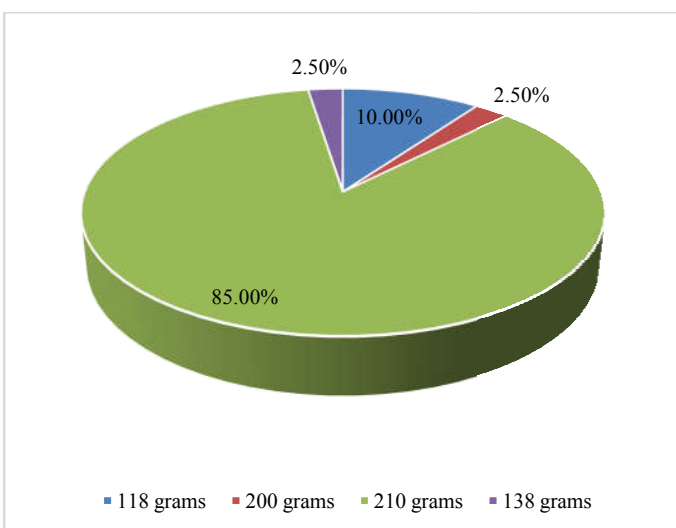


Figure 5 Awareness regarding USFDA recommended dosage of PEG (in grams) per 2 L dilution

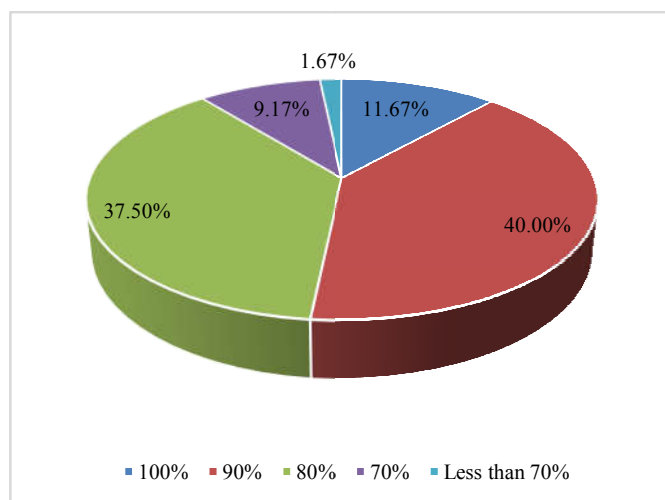


Figure 6 Percentage of patients on liquid PEG that have demonstrated adequate bowel preparation

## DISCUSSION

Colonoscopy is the standard method of choice to evaluate colonic mucosa and the distal ileum and plays an important role in diagnosis and treatment. Its successful implementation depends on many factors, but colon cleansing is considered as one of the important key factor.<sup>28</sup> Unlike other screening tests, colonoscopy is also dependent on pre-procedure bowel preparation. If the bowel preparation is poor, significant pathology may be missed. Present study revealed many facts in Health Care Professionals perspective on preferred options in bowel wash before proceeding to colonoscopy procedures.

In the present study, it was indicated that abnormal bowel habits and rectal bleeding are the two most common indications for colonoscopy in India. Similar kind of findings was reported in the study conducted by Berkowitz I *et al.* in which they found rectal bleeding and abnormal bowel habit are the most common indication of colonoscopy along with other indications like cancer follow-up, polyp follow-up, abdominal pain and iron deficiency anemia.<sup>29</sup> In another study conducted by Stapley *et al.* reported that rectal bleeding and a change in bowel habit are both strongly predictive of colorectal cancer and inflammatory bowel disease and the common indication for the colonoscopy. These findings can be correlated with present study findings.<sup>30</sup>

Bechtold ML *et al.* reported that successful colonoscopy is directly dependent on the quality of bowel wash.<sup>31</sup> Our findings also similar to that of reported study as almost all the respondents prefer bowel wash before colonoscopy. Many studies reported that adequate bowel preparation is essential to ensure sufficient visualization of the colonic mucosa and to optimize lesion detection for successful colonoscopy and the deciding factors for the choice of agents for bowel preparation.<sup>32,33</sup> Similar findings were observed in the present study also. Gerard DP *et al.* found that Chicago Scale demonstrated the excellent validity and reliability when compared to other bowel preparation scales.<sup>34</sup> This was in correlation with our study.

Our study showed that most of the HCPs are using the preparations offering 118 gms/2 liters of PEG, while they are aware that USFDA recommends various PEG regimes offering 210 gms/ 2 liters. This could be because of unavailability of

the PEG preparation offering the recommended dosage, which is very critical for adequate bowel preparation.

In the present study, we found that ready mix liquid formulation of bowel preparation agents was generally preferred. In contrast to our study, few studies showed that powder formulation of PEG exhibited an effective laxative among pediatric<sup>35-37</sup> and adult populations.<sup>38-40</sup>

In many studies, the most important predictors of poor colon preparation include the inability of patients to follow instructions for bowel preparations and the inability to complete large-volume bowel preparations such as large-volume PEG.<sup>41,42</sup> Thus, it follows that patient compliance can be improved by simplifying the instructions and reducing the volume of bowel preparation agents. Lichtenstein *et al.* conducted a questionnaire-based study to evaluate the balanced PEG solution combined with 20 mg of bisacodyl with regard to acceptability and found similar kind of results to the one in the present study.<sup>43</sup> A systemic review and meta-analysis conducted by Enestvedt *et al* reported that PEG preparation would produce an excellent bowel preparation compared with other methods.<sup>44</sup> In many other studies also 2L PEG preparations have been found to achieve equivalent levels of bowel cleansing with enhanced patient experience.<sup>45-50</sup> All these findings are in consistent with the present study and provide a strong correlation with the existing literature.

## CONCLUSION

The importance of an adequate quality of cleansing for colonoscopy is well known. The efficacy, tolerance, and safety have to be considered when choosing the agent for each patient. The schedule of administration, including timing and the diet chosen, has implications for the quality of cleansing. PEG is the gold standard drug for bowel preparations basis its efficacy and safety profile. It is important to use PEG in right dose as recommended. Liquid PEG can be considered as a better alternative for bowel cleansing before colonoscopy with additional advantages of ease of administration, palatability thus maximizing regimen adherence thereby improving the colonoscopy outcomes.

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