

## Efficacy Of Prucalopride, In Colonoscopy Given Along Polyethylene Glycol-Based Bowel Preparation Prior To Colonoscopy: A Prospective Randomized Trial In Southern India

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### ABSTRACT

**Background/Aims:** Adequate preparation is essential for optimal Colonoscopy outcomes. Polyethylene Glycol (PEG)based regimens are commonly used; however, inadequate Bowel cleansing remains frequent, often due to delayed colonic transit. Prucalopride, a selective 5-HT<sub>4</sub> receptor agonist, enhances colonic motility and may improve Bowel preparation when used as an adjunct. This study aimed to compare the efficacy of PEG combined with Prucalopride versus PEG alone.

**Methods:** This randomized prospective study was conducted at a tertiary care centre in southern India between January 2025 and January 2026. A total of 134 patients scheduled for Colonoscopy were randomized into two groups: Group A received PEG alone and Group B received PEG +Prucalopride. Bowel preparation quality was assessed using the Boston Bowel Preparation Scale (BBPS). The primary outcome was adequate Bowel preparation (BBPS ≥6). Secondary outcomes included Colonoscopy procedure time, Loop formation during Colonoscopy, and patient adherence.

**Results:** Baseline characteristics were comparable between the groups. Intervention Group demonstrated significantly higher mean BBPS scores ( $7.16 \pm 1.53$  vs.  $5.42 \pm 1.24$ ) and a higher rate of adequate Bowel preparation (88.1% vs. 68.7%;  $p = 0.011$ ). Mean Colonoscopy procedure time was significantly shorter in Group B ( $29.46 \pm 6.31$  minutes vs.  $51.76 \pm 5.91$  minutes;  $p < 0.001$ ). Loop formation was observed in 32 patients (23.7%), with a higher incidence in the control group (72%) compared to the intervention group (28%). Patient adherence did not differ significantly between groups.

**Conclusions:** Adding Prucalopride to PEG significantly improves Bowel cleansing quality, reduces procedure time, and decreases Loop formation during Colonoscopy without compromising patient adherence.

**Keywords:** Colonoscopy; Polyethylene Glycol (PEG); Prucalopride; Boston Bowel Preparation Score

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### INTRODUCTION

Colonoscopy is the gold standard investigation for the diagnosis, surveillance, and therapeutic management of colorectal diseases, including colorectal cancer, inflammatory Bowel disease, colorectal polyps, and diverticular disease.<sup>1</sup> The diagnostic accuracy and therapeutic success of Colonoscopy are highly dependent on the quality of Bowel preparation.<sup>2</sup> Inadequate Bowel cleansing compromises mucosal visualization, increases adenoma miss rates, prolongs procedure duration, and often necessitates repeat Colonoscopy examinations, thereby increasing healthcare costs and patient burden.<sup>2-5</sup>

Polyethylene Glycol (PEG)-based Bowel preparation regimens are widely used owing to their iso-osmotic properties, minimal electrolyte shifts, and favourable safety profile across diverse patient populations.<sup>6</sup> Despite these advantages, reported rates of inadequate Bowel preparation with PEG-based regimens range from 20% to 30% in routine clinical practice.<sup>2,3</sup> Several patient-related factors such as advanced age, chronic constipation, diabetes mellitus, hypothyroidism, chronic kidney disease, and reduced mobility have been associated with poor Bowel preparation outcomes.<sup>7</sup> One of the principal mechanisms contributing to inadequate Bowel preparation is delayed colonic transit. Osmotic laxatives alone may be insufficient in such

patients, as they primarily increase intraluminal water content without directly addressing impaired colonic motility. This has led to growing interest in the use of prokinetic agents as adjuncts to standard Bowel preparation regimens.

Prucalopride is a highly selective serotonin (5-HT<sub>4</sub>) receptor agonist that enhances colonic peristalsis by stimulating high-amplitude propagating contractions.<sup>8</sup> Unlike earlier 5-HT<sub>4</sub> agonists, Prucalopride demonstrates minimal cardiovascular adverse effects due to its receptor selectivity. Its efficacy and safety in the treatment of chronic constipation have been well established.<sup>8</sup> These pharmacodynamic properties make Prucalopride an attractive adjunct to PEG for Bowel preparation.

Several studies have explored the role of Prucalopride in Bowel preparation, reporting improved cleansing quality, enhanced patient satisfaction, and reduced procedure times.<sup>9-11</sup> However, existing literature is limited by small sample sizes, heterogeneous study designs, and variable Bowel preparation protocols. Furthermore, data from the Indian subcontinent remain sparse. The present study was therefore undertaken to evaluate the efficacy of PEG combined with Prucalopride compared with PEG alone for Bowel preparation prior to Colonoscopy in a tertiary care centre.

## METHODS

### Study Design and Population

This prospective, single-centre study was conducted in the Department of General Surgery at Karpaga Vinayaga Institute of Medical Sciences and Research Centre, Chengalpattu District, Tamil Nadu. The study period extended from January 2025 to December 2025 for a period of 1 year. Institutional ethics committee approval was obtained prior to study initiation. Participant information sheet and written informed consent was obtained from all participants.

Adult patients aged 18 years and above scheduled for elective diagnostic or therapeutic Colonoscopy were included. Patients with known Bowel obstruction, severe inflammatory Bowel disease flare, previous colorectal surgery, pregnancy, hypersensitivity to study drugs, or inability to comply with Bowel preparation instructions were excluded.

### Randomization and Bowel Preparation Protocol

After confirming eligibility and obtaining written informed consent, participants were allocated in a 1:1 ratio to the control or intervention group using an odd-even allocation method. Each consecutively enrolled participant was assigned a serial enrolment number in chronological order. Allocation was then performed as follows:

- Even-numbered participants were assigned to Group A (Control: PEG alone)
- Odd-numbered participants were assigned to Group B (Intervention: PEG + Prucalopride)

This allocation process was applied uniformly throughout recruitment until the target sample size was achieved (n=134; 67 per group).

Bowel preparation was carried out over two days. On Day 1, participants were kept on a clear liquid diet. On day 2, participants were kept Nil Per Oral (NPO) and started on appropriate intravenous fluids.

- **Standard Regimen:** Participants received 2 litres of PEG solution per day at 10:00 AM and 4:00 PM for 2 days along with dietary restrictions, consuming the PEG solution within one hour of preparation.

- **Adjunct Regimen:** The intervention group followed the standard PEG protocol but additionally received Prucalopride 2 mg at 2:00 pm along with dietary restrictions

### Outcome Measures

Bowel preparation quality was assessed during Colonoscopy using the Boston Bowel Preparation Scale (BBPS).<sup>4</sup> The BBPS evaluates cleanliness of the right, transverse, and left colon on a scale of 0 to 3, yielding a total score ranging from 0 to 9. A total BBPS score of 6 or higher was considered adequate Bowel preparation.

Secondary outcomes included mean BBPS score, Colonoscopy procedure time, Loop formation and patient adherence. Adherence was defined as the degree to which participants followed the regimen:

- Full Adherence: Consumed 90% or more of the solution and strictly followed dietary restrictions.
- Partial Adherence: Consumed 50–89% of the solution or deviated from dietary instructions.
- Non-Adherence: Consumed less than 50% of the solution or failed dietary restrictions.

### Statistical Analysis

Data were analyzed using appropriate statistical software. Continuous variables were expressed as mean  $\pm$  standard deviation (SD), and categorical variables as frequencies and percentages. Intergroup comparisons were performed using the Chi-square test or t-test as appropriate. A p-value  $< 0.05$  was considered statistically significant.

## RESULTS

A total of 134 patients were included, with 67 patients in each group. Baseline demographic characteristics and comorbidities were comparable between the two groups (Table 1).

### Bowel Preparation Efficacy

The mean BBPS score was significantly higher in the PEG plus Prucalopride group ( $7.16 \pm 1.53$ ) compared with the PEG alone group ( $5.42 \pm 1.24$ ;  $p < 0.001$ ). Adequate Bowel preparation (BBPS score  $\geq 6$ ) was achieved in 88.1% of patients in Group B versus 68.7% in Group A ( $p = 0.011$ ) (Table 2).

### Secondary Outcomes

Mean Colonoscopy procedure time was significantly shorter in the intervention group ( $29.46 \pm 6.31$  minutes) compared with the control group ( $51.76 \pm 5.91$  minutes;  $p < 0.001$ ). Adherence rates were similar between groups, with no statistically significant difference

observed in full, partial, or non-adherence rates (Table 3).

During Colonoscopy a total of 32 incidence of Loop formation was documented (n=32) (23.70%). Out of 32 documented Loop formations during the study 23 belonged to the Control group and 9 belonged to Intervention group (Table 4). Similarly, poor preparation in the left colon—indicative of Alpha Loops (Image1) or N-Loops (Image 2) impeding distal clearance—was observed in 20.9% of control patients but only 8.8% of the intervention group. In our control group, the transverse colon was the most poorly prepared segment, with **23.9%** of patients showing poor visualization. This is consistent with the presence of Gamma Loops (Image 3), which was caused due to pooling of fluid and faecal debris. In the intervention group, the rate of poor preparation in this Transverse segment was significantly lesser that compared to Control group. The Control group had a higher rate (20.9%) of poor preparation in the Left Colon suggesting a high incidence of Alpha and N Loops impeding transit thus prolonging procedure time significantly.

## DISCUSSION

This prospective study demonstrates that the addition of Prucalopride to a PEG-based Bowel preparation regimen significantly improves Bowel cleansing quality and procedural efficiency without adversely affecting patient adherence. Patients receiving PEG plus Prucalopride achieved significantly higher BBPS scores and a greater proportion of adequate Bowel preparation compared with those receiving PEG alone.

Delayed colonic transit is a well-recognized contributor to inadequate Bowel preparation, particularly in patients with chronic constipation and metabolic comorbidities.<sup>7</sup> Prucalopride enhances colonic motility through selective 5-HT<sub>4</sub> receptor stimulation, thereby facilitating colonic emptying and complementing the osmotic action of Polyethylene Glycol (PEG).<sup>8</sup> The synergistic effect observed in the present study supports this mechanistic rationale. Our findings are consistent with previous studies by Sun et al.<sup>9</sup> and Kerdsin et al.<sup>10</sup>, who reported superior Bowel cleansing outcomes with PEG-Prucalopride combinations. Similarly, Corleto et al.<sup>11</sup> demonstrated improved right-sided colonic cleansing with Prucalopride, a region commonly associated with inadequate preparation.

A notable secondary outcome of this study was the significant reduction in Colonoscopy procedure time in the intervention group. Inadequate Bowel preparation necessitates repeated washing and suctioning with undue Loop formation especially in sigmoid colon, predominantly formation of alpha Loop and secondarily formation of gamma Loop in transverse colon. Finally few enlargements of distal colon resulting in n Loop formation, which prolongs procedure duration and increases operator fatigue.<sup>2,3</sup> Improved Bowel cleanliness likely facilitated uninterrupted mucosal inspection, allowing for more efficient examinations and improved endoscopy unit workflow.

Importantly, patient adherence did not differ significantly between groups, indicating that the addition of a single low-dose Prucalopride does not increase the perceived burden of Bowel preparation. This finding is clinically relevant, as poor tolerance and non-compliance remain major barriers to effective Bowel preparation. Although some studies have reported reduced compliance with adjunctive agents, such discrepancies may be attributable to differences in dosing regimens and patient populations.<sup>12</sup>

The strengths of this study include its prospective design, standardized Bowel preparation protocol, and use of a validated scoring system.

Limitations include its single-centre design and modest sample size. Future multicentric randomized controlled trials with larger populations are warranted to further validate these findings and assess cost-effectiveness and patient-reported outcomes.

In conclusion, Polyethylene Glycol combined with Prucalopride is superior to Polyethylene Glycol alone for Bowel preparation prior to Colonoscopy. This regimen significantly improves Bowel cleansing quality, reduces procedure time and Loop formations without compromising patient adherence.

## DECLARATIONS

Conflicts of Interest-The authors have no conflicts of interest to declare.

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**TABLES**

**Table 1. Baseline Demographic Characteristics**

Characteristic	Group A (Control) (N=67)	Group B (Intervention) (N=67)
Age (Years), Mean ± SD	50.40 ± 14.80	49.5 ± 15.74
Male Gender, n (%)	34 (50.7%)	33 (48.5%)
<b>Comorbidities, n (%)</b>		
Diabetes Mellitus (DM)	23 (34.3%)	22 (32.8%)
Hypertension (HTN)	19 (28.4%)	18 (26.9%)
Hypothyroidism	5 (7.5%)	8 (11.8%)
Coronary Artery Disease (CAD)	7 (10.4%)	12 (17.8%)
Cerebrovascular Accident (CVA)	4 (6.0%)	3 (4.5%)
Chronic Kidney Disease	3 (4.5%)	7 (10.3%)

SD, standard deviation.

**Table 2. Bowel Preparation Efficacy (Primary Outcome)**

Variable	Group A (Control)	Group B (Intervention)	P-value
Total BBPS Score, Mean ± SD	5.42 ± 1.24	7.16 ± 1.53	< 0.001*
Adequate Prep (Score ≥ 6), n (%)	46 (68.7%)	59 (88.1%)	0.011*

\*BBPS, Boston Bowel Preparation Scale; SD, standard deviation. *Statistically significant.*

**Table 3. Secondary Outcomes**

Variable	Group A (Control)	Group B (Intervention)
Procedure Time (min), Mean ± SD	51.76 ± 5.91	29.46 ± 6.31
Full Adherence, n (%)	38 (56.7%)	35 (52.2%)
Partial Adherence, n (%)	23 (34.3%)	27 (40.3%)
Non-Adherence (Nil), n (%)	6 (9.0%)	5 (7.5%)

SD, standard deviation.

**Table 4. Incidence of Loop formation**

	Count (n)	Percentage (%)
Total Population (N=135)	32	23.70%
Control Group (PEG alone)	23	34.30%

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Intervention (PEG + Prucalopride)	9	13.20%
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PEG, Polyethylene Glycol