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Evaluation of bowel preparation regimens for colonoscopy including a novel low volume regimen (Plenvu): CLEANSE study

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ABSTRACT

Background Poor bowel preparation is the leading cause of failed colonoscopies and increases costs significantly. Several, split preparation, 2 day regimens are available and recently, Plenvu, a low-volume preparation which can be given on 1 day has been introduced.

Aims Assess efficacy and tolerability of commonly used purgative regimens including Plenvu.

Method In this service evaluation, patients undergoing screening colonoscopy at St Mark's Hospital, London (February 2020–December 2021) were provided Plenvu (1 or 2 days), Moviprep (2 days) or Senna & Citramag (2 days). Boston Bowel Preparation Scale (BBPS) score, fluid volumes and procedure times were recorded. A patient experience questionnaire evaluated taste, volume acceptability, completion and side effects.

Results 563 patients were invited to participate and 553 included: 218 Moviprep 2 days, 108 Senna & Citramag 2 days, 152 Plenvu 2 days and 75 Plenvu 1 day.

BBPS scores were higher with Plenvu 1 and 2 days vs Senna & Citramag (p=0.003 and 0.002, respectively) and vs Moviprep (p=0.003 and 0.001, respectively). No other significant pairwise BBPS differences and no difference in preparation adequacy was seen between the groups. Patients rated taste as most pleasant with Senna & Citramag and this achieved significance versus Plenvu 1 day and 2 days (p=0.002 and p<0.001, respectively) and versus Moviprep (p=0.04).

Conclusion BBPS score was higher for 1 day and 2 days Plenvu versus both Senna & Citramag and Moviprep. Taste was not highly rated for Plenvu but it appears to offer effective cleansing even when given as a same day preparation.

INTRODUCTION

Why is bowel preparation important?

The effectiveness of bowel preparation before colonoscopy has a significant impact on procedure outcome, quality and efficiency. Where bowel preparation is successful, colonoscopy examination can be expedited without need for additional time to clean the mucosa. Clear mucosal visualisation enhances identification of colonic abnormalities and increases

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Poor bowel preparation is the leading cause of failed colonoscopies. A new 1 day low-volume regimen, Plenvu, has been introduced and requires further evaluation against standard 2 day regimens.

WHAT THIS STUDY ADDS

⇒ Plenvu 1 and 2 day regimens provided improved bowel cleansing compared with Senna & Citramag and Moviprep. However, taste was rated most pleasant with Senna & Citramag.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study shows Plenvu may be an effective alternative to standard bowel regimens with the advantage of more efficient administration when given as a 1 day regimen.

the likelihood of a complete procedure. Conversely, poor preparation has significant negative implications at the patient, endoscopist and service level and is the leading cause of failed colonoscopies.¹

Several studies have shown poor bowel preparation is associated with failure to detect adenomas in up to a third of cases. ²⁻⁵ Poor bowel preparation prolongs procedure time. ^{6 7} Where preparation is inadequate, procedures are more likely to be abandoned and need repeating causing significant inconvenience for patients. ^{8 9} In cases of suboptimal or 'fair' bowel preparation, surveillance intervals that are inconsistent or shorter may be offered. ¹⁰ Overall, poor preparation increases procedure costs by 12%–22% due to prolonged procedure times and the need for repeated procedures or earlier surveillance. ¹¹

A number of bowel preparation regimens exist with different mechanisms of action and dosing instructions (see table 1). Polyethylene glycol (PEG)-based regimens are

	Moviprep 2days	Senna & Citramag 2 days	Plenvu 2days	Plenvu 1 day
Preparation type	Polyethylene glycol (PEG)	Magnesium citrate (osmotic agent) combined with Senna (stimulant laxative)	PEG	PEG
Bowel preparation	4 sachets (both A and B) mixed with 2 L of water	2 sachets of Citramag mixed with 0.4L water and 10 Senna tablets	2 doses mixed in 1 L water	2 doses mixed in 1 L water
Administration—day before	Morning appointment: 2pm: 1.5L taken with an extra 1L of clear fluid. Afternoon appointment: 4pm: 1L taken with an extra 1L of clear fluid.	All appointments: 2pm: Take 10 Senna tablets (2 every 10 min within an hour) with clear fluid. 5pm: 1 sachet of Citramag dissolved in 0.2L hot water and taken when cooled. Drink an extra 1.5L clear fluids. 7pm: 0.5 sachet of Citramag dissolved in 0.1L water and taken. Drink an extra 1.5L clear fluids.	Morning appointment: 2pm: Mix dose 1 in 0.5L water and take with an extra 0.5L of clear fluid. 6pm: Mix dose 2 in 0.5L water and drink 0.25L and an extra 0.5L of clear fluid. Afternoon appointment: 4pm: Mix dose 1 in 0.5L water and take with an extra 0.5L of clear fluid.	
Administration — procedure day	Morning appointment: 6am: 0.5L taken on the procedure day with an extra 0.5L of clear fluid. Afternoon appointment: 7–8am: 1L taken on the procedure day with an extra 0.5L of clear fluid.	Morning appointment: 6-7am: 0.5 sachet of Citramag dissolved in 0.1 L water and taken. Afternoon appointment: 9-10am: 0.5 sachet of Citramag dissolved in 0.1 L water and taken.	Morning appointment: 6am: 0.25L of prep and an extra 0.5L of clear fluid taken. Afternoon appointment: 6–7am: Mix dose 2 in 0.5L water and drink an extra 0.5L of clear fluid.	6am: 0.5L of prep and an extra 0.5L of clear fluid taken. 8:30am: 0.5L of prep and an extra 0.5L of clear fluid taken.
Timing (bowel preparation+water)	Morning appointment: Day before 2pm: 1.5L (+1L clear fluid). Procedure day 6am: 0.5L (+0.5L clear fluid). Afternoon appointment: Day before 2pm: 1L (+1L clear fluid). Procedure day 6am: 1L (+0.5L clear fluid).	Morning appointment: Day before 2pm: Take Senna Day before 5pm: 0.2L (+1.5L clear fluid) Day before 7pm: 0.1L (+1.5L clear fluid) Procedure day 6–7am: 0.1L Afternoon appointment: Day before 2pm: Take Senna Day before 5pm: 0.2L (+1.5L clear fluid) Day before 7pm: 0.1L (+1.5L clear fluid) Procedure day 9–10am: 0.1L	Morning appointment: Day before 2pm: 0.5L (+0.5L) Day before 6pm: 0.25L (+0.5L) Procedure day 6am: 0.25L (+0.5L) Afternoon appointment: Day before 4pm: 0.5L (+0.5L) Procedure day 6–7am: 0.5L (+0.5L)	Procedure day 6am: 0.5L (+0.5L clear fluid). Procedure day 8:30am: 0.5L (+0.5L clear fluid).
Prep volume	2L	0.4 L	1L	1L
Minimum recommended extra fluid volume	1.5L	3L	1L	1L
Minimum total fluid volume	3.5L	3.4L	2L	2L
Diet	2 days before: low-residue diet Day before from 12 noon: no solid food	2 days before: low-residue diet Day before from 12 noon: no solid food	2 days before: low-residue diet Day before from 12 noon: no solid food	2 days before: low- residue diet Day before from 7pm no solid food

commonly used due to their performance and safety profile but have traditionally required a high volume preparation of up to 4L. ¹² More recently, PEG regimens have been combined with ascorbic acid to reduce the volume required to 2L (e.g. Moviprep). Giving an increased ascorbic acid content, a new IL PEG regimen called Plenvu has been developed. Magnesium citrate is an alternative bowel preparation regimen, which works as an osmotic agent increasing intraluminal volume. ¹³ When combined with the stimulant laxative senna, bowel cleansing is significantly improved so a Senna plus Citramag regimen has emerged. ¹⁴ Although the Senna & Citramag regimen can be ingested with low fluid volumes it is still recommended that 2–3 L of fluid are taken with

it to avoid risk of dehydration and that it should not be used in patients with significant renal impairment.

In view of the importance of bowel preparation, societal guidelines exist to help optimise bowel preparation administration and efficacy. ¹² ¹⁵ It is recommended at least 90% of colonoscopies have adequate bowel preparation. There are also a number of quality scales including the Boston Bowel Preparation Scale score (BBPS) and Harefield Cleansing Scale which can be used to score bowel preparation outcomes. ^{16–18}

How can bowel preparation be optimised?

Several factors influence bowel preparation quality. Patients with increasing age, comorbidity and those that are hospitalised have poorer bowel preparation cleansing

quality although these are not modifiable factors. ¹⁹ Modifiable patient factors may include medications such as iron supplements or opiate-based medications, which may adversely affect bowel preparation if these are not withheld before the procedure. Dietary modification with low residue diet also infuences outcomes. Patient compliance with bowel preparation and dietary instructions may be influenced by patient motivation, education (e.g. language barrier), communication techniques for explanation (e.g. use of video). Product-related factors also affect ease of bowel preparation administration such as taste, preparation volume and dosing regimen as well as timing of administration (e.g. timing of last dose closer to the procedure has been shown to improve cleansing ²⁰).

Of these, choice of bowel preparation regimen is relatively easy to modify. For example, split-dosing has been shown to increase bowel preparation efficacy.²¹ As bowel preparation is frequently cited the 'worst' part of the procedure, ²² ²³ any intervention that improves compliance is therefore welcome.

Aim of this study

A novel low-volume bowel preparation regimen, Plenvu (Norgine), that can be administered as a 1 day or 2 day regimen has recently emerged. This could offer the potential for enhanced compliance and potentially improved bowel preparation outcomes. Although previous studies have evaluated Plenvu against higher volume PEG-based regimens, there is limited evaluation of Plenvu against other established preparation regimens including Senna & Citramag. ^{24–28} Therefore, the aim of this study is to evaluate the efficacy of Plenvu regimens versus commonly used bowel preparation regimens in terms of bowel cleansing effectiveness and patient acceptance.

METHODS

Study design

In this service evaluation, patients undergoing bowel cancer screening colonoscopy at St Mark's Hospital, London (Feb 2020–Dec 2021) were provided with either Plenvu (1 or 2 day regimen), Moviprep (2 day regimen) or Senna & Citramag (2 day regimen). All patients attended a preassessment clinic where a specialist screening practitioner allocated the bowel preparation and provided an information leaflet explaining the procedure and bowel preparation process (see table 1). Bowel preparation allocation took into consideration previous bowel preparation (if a previous regimen offered good cleansing the same preparation was used), comorbidities and patient preference (fluid and tablet tolerance). Plenvu and Senna & Citramag were not given to patients with significant cardiac, liver or renal disease who were instead given Moviprep. The 1 day Plenvu regimen was offered only for afternoon or evening appointments (as this regimen is not suitable for morning appointments). In patients >70 years old or those with risk factors blood tests were checked and reviewed by a consultant to decide on the

most suitable regimen with split dose Moviprep given if estimated glomerular filtration rate was $<60\,\mathrm{mL/min/1.73\,m^2}$ as per the hospital standard operating policy.

On the day of the procedure, patients were invited to complete a bowel preparation experience questionnaire (see table 5). The procedures were performed by bowel cancer screening accredited colonoscopists. As part of the assessment of baseline characteristics we recorded any significant comorbidities.

During the procedure, fluid volumes (infused, suctioned, net [infused-suctioned]) and procedure times (insertion [intubation to ileocaecal valve reached], caecum [ileocaecal valve reached to ileocaecal valve left], withdrawal [ileocaecal valve left to extubation], total [intubation to extubation]) were recorded. Any cases where bowel preparation was inadequate to the extent a repeat procedure or CT colonography was required were documented. On withdrawal, the BBPS was scored by the endoscopist with a pictoral reference sheet shown to endoscopists to reduce variation. ¹⁶

We excluded any cases where a flexible sigmoidoscopy rather than a colonoscopy was performed. Patients with extended bowel preparation regimens were not invited to participate.

Outcomes

The primary outcome was BBPS score. The secondary outcomes were fluid volumes (infused and suctioned), procedure times (insertion, withdrawal and total), polyp detection (polyps per colonoscopy [PPC], polyp detection rate [PDR], adenoma detection rate [ADR], number of adenomas and sessile serrated polyps detected per 6 min withdrawal time at colonoscopy [SP6²⁹]) and bowel preparation experience evaluated using a patient experience questionnaire including assessment of taste, volume acceptability, completion and side effects.

Statistical analysis

Comparisons of demographics measured on a continuous scale between the bowel preparation groups were made using analysis of variance (ANOVA) if found to be normally distributed, and the Kruskal-Wallis if found to have a skewed distribution. Categorical demographic variables were compared between groups using the χ^2 tests.

Clinical outcomes were compared between the regimens with overall and pairwise comparisons. ANOVA and ANOVA post hoc tests were used to compare normally distributed outcomes, while the Kruskal-Wallis and Mann-Whitney U test was used for non-normally distributed continuous variables. The χ^2 test was used for categorical outcomes. Due to multiple comparisons between pairs of groups, and increased risk of finding a significant difference due to chance alone, a Bonferroni adjustment was made.

Questionnaire outcomes were mostly ordinal in nature. The Kruskal-Wallis test and Mann-Whitney test were used

Table 2 Participant characteristics								
	Moviprep 2 days	Senna & Citra 2 days	mag Plenvu 2days	Plenvu 1 day	P value			
Patients	218	108	152	75				
Gender								
Male	68 (31%)	36 (33%)	56 (37%)	24 (32%)	0.72			
Female	150 (69%)	72 (67%)	96 (63%)	51 (68%)				
Age (average)	66.4±11.3	65.1±5.4	65.0±4.3	63.5±8.9	0.07			

26.6 (23.3, 29.6)

0.47±0.68

Table 2 Participant characteristics

Summary statistics are: mean±SD, median (IQR) or number (percentage).

27.2 (24.3, 31.3)

0.83±1.00

P values reaching statistical significance are shown in bold.

BMI, body mass index.

Significant comorbidities

to compare between the groups overall and between pairs of groups, respectively.

RESULTS

BMI

Overview

There were 563 patients invited to participate with 10 exclusions (flexible sigmoidoscopies). Of 553 included patients there were: 218 Moviprep 2 days, 108 Senna & Citramag 2 days, 152 Plenvu 2 days and 75 Plenvu 1 day (see figure 1). Overall there were 184 female and 369 male patients with no significant difference in gender, age and body mass index (BMI) between the groups (see table 2). Those taking Moviprep had more significant comorbidities per patient compared with the other regimens as expected from the bowel preparation allocation process.

Clinical outcomes

Boston Bowel Preparation Scale

In terms of overall differences between the four bowel preparation regimens, there was a statistically significant difference in BBPS (p<0.001, see table 3). When pairwise comparisons were made (see table 4), BBPS scores were

significantly higher in both 1 and 2 day Plenvu regimens (7.8 ± 1.4 and 7.7 ± 1.6) compared with Senna & Citramag (7.0 ± 1.7 ; p=0.003 and 0.002, respectively) and Moviprep (7.1 ± 1.7 ; p=0.003 and 0.001, respectively). There was no significant difference in BBPS score between Plenvu 1 and 2 day regimens, and between Moviprep and Senna & Citramag.

25.7 (23.2, 29.3)

 0.49 ± 0.76

0.06

<0.001

Fluid volumes

27.4 (24.2, 29.4)

0.49±0.72

Total suctioned fluid was significantly different (p=0.02), when assessing overall differences between the four bowel preparation regimens, as was net amount of fluid (p=0.04) but there was no difference in total fluid introduced. Plenvu 1 day had the highest volume of fluid suctioned which reached significance when compared with Moviprep (p=0.01). There were no other significant pairwise differences in fluid volume introduced or suctioned between the groups.

Procedure times

There was no overall difference in total procedure time, insertion time and caecum time between the groups. There was borderline overall difference

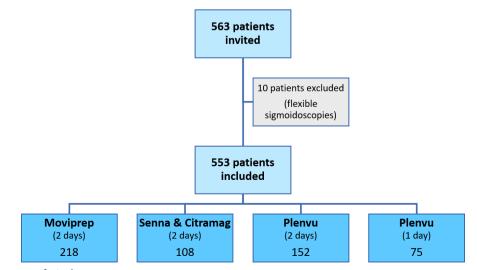


Figure 1 Flow diagram of study.

	Moviprep 2 days	Senna & Citramag 2days	Plenvu 2 days	Plenvu 1 day	P value
า	218	108	152	75	
Boston Bowel Preparation Scale	score				
Right	2.3±0.6	2.3±0.6	2.5±0.6	2.6±0.5	<0.001
Transverse	2.4±0.6	2.6±0.5	2.6±0.5	2.6±0.5	<0.001
Left	2.4±0.6	2.3±0.6	2.6±0.6	2.6±0.5	<0.001
Total	7.1±1.7	7.0±1.7	7.7±1.6	7.8±1.4	<0.001
Fluid volumes (mL)					
Total introduced	400 (250, 550)	400 (250, 653)	400 (250, 600)	450 (300, 650)	0.59
Total suctioned	500 (400, 700)	500 (400, 800)	550 (400, 800)	600 (450, 800)	0.02
Net amount	-100 (-200, 0)	-100 (-280, 0)	-150 (-300, 0)	-150 (-270 to -50)	0.04
Procedure times (minutes)					
Insertion time	7.2 (5.2, 9.9)	6.5 (4.6, 9.0)	7.3 (5.3, 9.6)	7.0 (5.0, 8.5)	0.24
Caecum time	1.8 (1.1, 2.6)	1.5 (1.0, 2.4)	1.7 (1.0, 2.5)	1.9 (1.0, 2.8)	0.55
Withdrawal time	15.0 (10.3, 20.3)	14.5 (10.1, 21.3)	15.6 (10.3, 23.0)	17.1 (11.4, 24.4)	0.05
Total time	25.1 (20.2, 31.5)	24.3 (18.5, 30.3)	25.4 (19.6, 33.3)	27.4 (21.0, 35.0)	0.10
Polyp detection					
Polyps per colonoscopy	2.5 (1, 5)	2 (1, 5)	3 (1, 6)	2 (1, 5)	0.28
Polyp detection rate (%)	83% (182/218)	80% (86/108)	84% (127/152)	84% (63/75)	0.81
Adenoma detection rate (%)	73% (159/218)	66% (71/108)	74% (112/152)	64% (48/75)	0.26
SP6	0.94 (0.49, 1.50)	0.86 (0.25, 1.39)	0.94 (0.43, 1.64)	0.64 (0.21, 1.36)	0.13
nadequate preparation requiring	repeat colonosco	ppy or CTVC (%)			
Inadequate prep	2% (5/218)	2% (2/108)	3% (4/152)	0% (0/75)	0.69

Summary statistics are: mean±SD, median (IQR) or percentage (number/total number). P values reaching statistical significance are shown in bold.

in withdrawal time (p=0.05). However, in pairwise comparisons, there were no significant differences in all procedure times (total, insertion, caecum and withdrawal).

Polyp detection

There was no difference in polyp detection between the groups.

Bowel preparation adequacy

There was no significant difference in proportion of cases classified as having inadequate bowel preparation between the groups (p=0.69).

Patient questionnaire

Patient questionnaire outcomes are summarised in table 5 with pairwise comparisons in table 6.

Taste was rated to be most pleasant in the Senna & Citramag group (76% agreed or strongly agreed), which achieved statistical significance when compared with Plenvu 1 day (45%, p=0.002), Plenvu 2 days (51%, p<0.001) and Moviprep 2 days (60%, p=0.04).

Patients found the volume to drink most acceptable with Senna & Citramag (92% agreed or strongly agreed) and this reached significance when compared with Moviprep 2 days (67%, p<0.001) and Plenvu 2 days (77%, p=0.002).

	Moviprep Senna & Senna &						
	2 days vs Senna & Citramag 2 days	Moviprep 2 days vs Plenvu 2 days	Moviprep 2days vs Plenvu 1day	Citramag 2 days vs Plenvu 2 day	Citramag 2days vs Plenvu 1day	Plenvu 2 days vs Plenvu 1 day	
Boston Bowel Preparation	Scale score						
Right	1.00	0.01	0.01	0.009	0.007	1.00	
Transverse	1.00	0.01	0.02	0.02	0.02	1.00	
Left	1.00	0.001	0.007	<0.001	0.004	1.00	
Total	1.00	0.001	0.003	0.002	0.003	1.00	
Fluid volumes (mL)							
Total introduced	1.00	1.00	0.93	1.00	1.00	1.00	
Total suctioned	1.00	0.28	0.01	1.00	0.97	1.00	
Net amount	1.00	0.10	0.11	1.00	1.00	1.00	
Procedure time (mins)							
Insertion time	0.43	1.00	1.00	0.70	1.00	1.00	
Caecum time	1.00	1.00	1.00	1.00	1.00	1.00	
Withdrawal time	1.00	1.00	0.07	1.00	0.08	0.79	
Total time	1.00	1.00	0.49	0.80	0.09	1.00	
Polyp detection							
Polyps per colonoscopy	1.00	1.00	1.00	0.42	1.00	1.00	
Polyp detection rate (%)	1.00	1.00	1.00	1.00	1.00	1.00	
Adenoma detection rate (%)	1.00	1.00	0.86	1.00	1.00	0.79	
SP6	1.00	1.00	0.32	0.97	1.00	0.26	
Inadequate preparation rec	quiring repeat c	olonoscopy or C7	Γ colonography (9	%)			
Inadequate prep	1.00	1.00	1.00	1.00	1.00	1.00	

There was no difference between the groups in terms of experience compared with previous bowel preparation taken and in ability to drink the total amount of preparation.

The highest volume of fluid consumed in addition to bowel preparation was in the Senna & Citramag group with 84% drinking >1 L. This achieved significance when compared with Moviprep 2 days (67%, p<0.001), Plenvu 2 days (71%, p=0.007) and Plenvu 1 day (66%, p<0.001).

Although a greater proportion of patients drank all preparation with Plenvu 1 day and 2 days compared with other groups this did not reach statistical significance.

There was a significant difference in rate of side effects between the groups. In pairwise comparisons, Plenvu 1 day had a significantly higher occurrence of side effects compared with Moviprep (48% and 29%, respectively, p=0.03). There were no other significant pairwise differences in side effects. There was also no difference in the occurrence of individual side effects between the groups (abdominal cramps, anal soreness, dizziness, nausea, vomiting, other).

DISCUSSION

Overview

A key test of the effectiveness of bowel preparation is whether mucosal visualisation is adequate to avoid the need for repeat colonoscopy or CT colonography. In this study, all four regimens showed no significant difference in the inadequate bowel preparation rate and no difference in polyp detection. In fact, for all regimens tested, including Plenvu 1 day, the rate of adequate bowel preparation surpassed the 90% threshold set by the European Society of Gastrointestinal Endoscopy (ESGE). 12 However, there were significant differences in BBPS score between the groups with 1 day and 2 days Plenvu (7.8±1.4 and 7.7±1.6) achieving a small but significant increase in score compared with Senna & Citramag (7.0±1.7; p=0.003 and 0.002, respectively) and Moviprep $(7.1\pm1.7; p=0.003 \text{ and } 0.001, \text{ respectively}).$

Several studies have evaluated Plenvu against higher volume PEG-based regimens.²⁴⁻²⁸ In a phase III multicentre, non-inferiority randomised trial of 849 patients, Bisschops et al assessed efficacy of 2 days Moviprep vs

Category	Moviprep 2 days	Senna & Citramag 2days	Plenvu 2 days	Plenvu 1 day	P value	
1: The bowel preparation was p	leasant to taste					
Strongly agree	18 (9%)	13 (12%)	8 (5%)	7 (10%)	<0.001	
Agree	106 (51%)	68 (64%)	69 (46%)	25 (35%)		
Neither agree or disagree	27 (13%)	6 (6%)	9 (6%)	10 (14%)		
Disagree	26 (13%)	11 (10%)	33 (22%)	16 (23%)		
Strongly disagree	30 (14%)	8 (8%)	30 (20%)	13 (18%)		
2: The volume (amount of prepa	ration) to drink was	acceptable				
Strongly agree	15 (7%)	17 (16%)	11 (7%)	14 (20%)	<0.001	
Agree	124 (60%)	81 (76%)	103 (70%)	39 (55%)		
Neither agree or disagree	12 (6%)	2 (2%)	8 (5%)	3 (4%)		
Disagree	48 (23%)	4 (4%)	22 (15%)	11 (15%)		
Strongly disagree	8 (4%)	2 (2%)	4 (3%)	4 (6%)		
3: The instructions were easy to	follow					
Strongly agree	133 (64%)	69 (65%)	115 (77%)	55 (77%)	0.02	
Agree	69 (33%)	31 (29%)	30 (20%)	15 (21%)		
Neither agree or disagree	3 (1%)	2 (2%)	3 (2%)	1 (1%)		
Disagree	2 (1%)	4 (4%)	0 (0%)	0 (0%)		
Strongly disagree	0 (0%)	0 (0%)	1 (1%)	0 (0%)		
4: If you have taken bowel prepa	aration before, did yo	ou rate if better tha	n last time?			
Yes/better	29 (41%)	17 (38%)	19 (46%)	6 (38%)	0.94	
Same	21 (30%)	16 (36%)	9 (22%)	4 (25%)		
No/worse	20 (29%)	12 (27%)	13 (32%)	6 (38%)		
5: Did you manage to complete	(drink) all the prepar	ation?				
Yes	193 (94%)	101 (96%)	147 (99%)	64 (98%)	0.08	
No	13 (6%)	4 (4%)	2 (1%)	1 (2%)		
6: Since starting the bowel prep	aration, how much o	ther fluid did you d	rink?			
None	5 (2%)	1 (1%)	1 (1%)	2 (3%)	<0.001	
Less than 1 L	18 (9%)	4 (4%)	11 (7%)	6 (8%)		
About 1L	45 (22%)	12 (11%)	32 (21%)	16 (23%)		
1–2L	71 (34%)	29 (27%)	43 (29%)	29 (41%)		
More than 2L	68 (33%)	60 (57%)	62 (42%)	18 (25%)		
7: Did you experience any side e	effects*?					
Yes	61 (29%)	37 (35%)	64 (43%)	34 (48%)	0.01	
No	146 (71%)	69 (65%)	85 (57%)	37 (52%)		

1 or 2days Plenvu regimens in people aged 18–85 in a screening/surveillance/diagnostic colonoscopy setting. Bowel cleansing efficacy was significantly higher with 1 and 2 days Plenvu (6.6 and 6.7) compared with 2 days Moviprep (6.3, p=0.006 and p<0.001). In our study, we also showed an enhanced BBPS with 1 and 2 days Plenvu versus Moviprep.

*Nausea/vomiting, abdominal cramps, dizziness, anal soreness and other.

High-quality right colon cleansing is particularly important to detect flat or subtle proximal lesions

such as sessile serrated polyps.³⁰ Bischopps *et al* showed right colon BBPS scores were significantly higher with 1 and 2 days Plenvu vs 2 days Moviprep (2.2 and 2.2 vs 2.0; p=0.013 and p<0.001). We also found a significant improvement in right colon BBPS scores with 1 and 2 days Plenvu (2.6 and 2.5, respectively) when compared with Moviprep (2.3; p=0.01 and 0.01, respectively) and Senna & Citramag (2.3; p=0.007 and 0.009, respectively).

Table 6 P values from pairwise group comparisons for questionnaire outcomes

Question	Moviprep 2days vs Senna & Citramag 2days	Moviprep 2days vs Plenvu 2days	Moviprep 2days vs Plenvu 1day	Senna & Citramag 2days vs Plenvu 2days	Senna & Citramag 2 days vs Plenvu 1 day	Plenvu 2 days vs Plenvu 1 day
1	0.04	0.17	0.44	<0.001	0.002	1.00
2	<0.001	0.41	0.24	0.002	0.68	1.00
3	1.00	0.07	0.24	0.18	0.38	1.00
4	1.00	1.00	1.00	1.00	1.00	1.00
5	1.00	0.13	0.78	1.00	1.00	1.00
6	<0.001	0.80	1.00	0.007	<0.001	0.38
7	1.00	0.05	0.03	1.00	0.50	1.00

The first reported phase IV multicentre randomised study of Plenvu in an Asian population (South Korea) assessed cleansing in 346 patients with either 2 days Plenvu or 2L PEG and also showed 2 days Plenvu was non-inferior, had improved high-quality bowel cleansing, particularly in the right colon compared with 2L PEG. ²⁸

P values reaching statistical significance are shown in bold.

In terms of polyp detection, Bisschops *et al* showed the ADR and PDR in both right and overall colon was non-inferior in both 1 and 2 days Plenvu groups. In the right colon PDR group, Plenvu 2 days was superior compared with 2L PEG (23.3% vs 16.2%; p=0.024). Hong *et al* also showed improved PDR for Plenvu vs 2L PEG but there was no difference in ADR. In our study, we found no significant difference in PPC, PDR, ADR and SP6 between the groups.

We also assessed fluid volumes infused and suctioned during the procedure to assess if any particular regimen required more fluid to achieve adequate BBPS scores. Use of water during the procedure could also affect procedure time and have environmental implications due to sterile water used. However, in pairwise comparisons, we found no difference in fluid volume suctioned or introduced during colonoscopy except a higher volume suctioned with 1 day Plenvu compared with 2 days Moviprep (600 mL vs 550 mL, p=0.01).

The patient survey showed no difference between the regimens in the proportion of patients who completed the bowel preparation. However, a significantly higher proportion of patients reporting their bowel preparation was 'pleasant to taste' with Senna & Citramag (76%) compared with Moviprep (60%), 2 days Plenvu (51%) and 1 day Plenvu (45%). Although Plenvu is already available in two flavours (mango [dose 1] and tropical punch [dose 2]) alternative flavours may improve patient experience, although the underlying 'salty' taste of all PEG-based preparations remains an issue for many patients.

Regarding safety and tolerability, Bisschops *et al* showed this was comparable for 1 L vs 2 L PEG groups. However, both Bisschops and Hong show overall significantly

higher treatment-related adverse events with Plenvu 1 day compared with 2L PEG but these were generally mild and rarely required intervention. We found, across all regimens evaluated, patients experienced side effects (such as nausea/vomiting, abdominal cramps, dizziness and anal soreness) in 29%–48% of cases. There was a significant increase in side effects with 1 day Plenvu vs 2 days Moviprep (48% vs 29%, p=0.03) with no other significant difference in pairwise comparisons.

Concerns about the safety of hyper-osmotic low-volume bowel preparations with a risk of hypernatraemia and dehydration have been reported emphasising the importance of ensuring an appropriate volume of clear fluid is taken in addition to the active ingredient. We did not assess changes in electrolyte balance in this service evaluation but there were no instances of severe clinical dehydration or detected cardiac arrhythmia. The patient experience survey showed the majority of patients taking Plenvu consumed >1 L of clear fluid to avoid dehydration risk.

Strengths and limitations

In this study, we assessed real-life experience of bowel preparation regimens, using a validated bowel cleansing score, within a bowel cancer screening setting. Apart from an earlier more limited evaluation in our unit, CLEANSE is the first substantial study to evaluate Senna & Citramag against 1 and 2 days Plenvu. ²⁵ We also provide further data on the use of Plenvu 1 day which has had limited previous evaluation.

As a non-randomised study, there is a risk of subjective allocation of bowel preparation regimens. Moviprep was given preferentially to patients with significant cardiac, liver or renal disease. Previous studies have shown significant comorbidities and polypharmacy are risk factors for poor bowel preparation. ^{32–34} The Plenvu 1 day group had a lower number of patients compared with the other groups as only afternoon and evening appointments were eligible for this regimen. In addition, Plenvu 1 day was the



only bowel preparation regimen licensed for same day use with all other regimens given over 2 days. A potential advantage of 1 day preparation is that the right colon does not have a chance to accumulate stool contents due to close proximity of procedure time to bowel preparation. However, we did not find a significant difference in BBPS scores for all segments in pairwise comparisons between the Plenvu 1 and 2 days regimens.

Further work

Further studies are required to evaluate the economic impact of using Plenvu versus other regimens.

CONCLUSION

In this service evaluation, there was a significantly improved BBPS score for both 1 day and 2 days low volume Plenvu regimens, compared with Senna & Citramag and Moviprep. Plenvu may offer both enhanced cleansing and improved efficiency, particularly when administered as a same day preparation for afternoon and evening appointments by significantly reducing patient preparation time. However, Plenvu same day was associated with more minor side effects and the taste was not rated as highly as Senna & Citramag.

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Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information.

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