

Split-dose vs same-day reduced-volume polyethylene glycol electrolyte lavage solution for morning colonoscopy

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Abstract

AIM: To compare same-day whole-dose vs split-dose of 2-litre polyethylene glycol electrolyte lavage solution (PEG-ELS) plus bisacodyl for colon cleansing for morning colonoscopy.

METHODS: Consecutive adult patients undergoing morning colonoscopy were allocated into two groups *i.e.*, same-day whole-dose or split-dose of 2-litre PEG-ELS. Investigators and endoscopists were blinded to the allocation. All patients completed a questionnaire that was designed by Aronchick and colleagues to assess the tolerability of the bowel preparation regime used. In addition, patients answered an ordinal five-value Likert scale question on comfort level during bowel preparation. Endoscopists graded the quality of bowel preparation using the Boston bowel preparation scale (BBPS). In addition, endoscopists gave an overall grading of the quality of bowel preparation. Cecal intu-

bation time, withdrawal time, total colonoscopy time, adenoma detection rate and number of adenomas detected for each patient were recorded. Sample size was calculated using an online calculator for binary outcome non-inferiority trial. Analyses was based upon intent-to-treat. Significance was assumed at P -value < 0.05.

RESULTS: Data for 295 patients were analysed. Mean age was 62.0 ± 14.4 years old and consisted of 50.2% male. There were 143 and 152 patients in the split-dose and whole-dose group, respectively. Split-dose was as good as whole-dose for quality of bowel preparation. The total BBPS score was as good in the split-dose group compared to the whole-dose group [6 (6-8) vs 6 (6-7), $P = 0.038$]. There was no difference in cecal intubation rate, cecal intubation time, withdrawal time, total colonoscopy time and adenoma detection rate. Median number of adenoma detected was marginally higher in the split-dose group [2 (1-3) vs 1 (1-2), $P = 0.010$]. Patients in the whole-dose group had more nausea (37.5% vs 25.2%, $P = 0.023$) and vomiting (16.4% vs 8.4%, $P = 0.037$), and were less likely to complete the bowel preparation (94.1% vs 99.3%, $P = 0.020$). Patients in the split-dose group were less likely to refuse the same bowel preparation regime (6.3% vs 13.8%, $P = 0.033$) and less likely to want to try another bowel preparation regime (53.8% vs 78.9%, $P < 0.001$).

CONCLUSION: Splitting reduced-volume PEG-ELS for morning colonoscopy is as effective as taking the whole dose on the same morning but is better tolerated and preferred by patients.

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Key words: Bowel preparation; Colonoscopy; Split-dose; Polyethylene glycol electrolyte lavage solution

Core tip: In this study of adult patients undergoing morning colonoscopy, split-dose administration of reduced-

volume polyethylene glycol electrolyte lavage solution (PEG-ELS) plus bisacodyl was found to be as effective but better tolerated than whole-dose taken on the same morning. To the best of our knowledge, this is the first time these regimes have been compared. Moreover, bowel preparation using split-dose reduced-volume PEG-ELS has not been reported before although there have been many studies comparing split-dose and previous-evening whole-dose regimes using larger volumes of PEG-ELS. We believe the findings of this study will be of interest to those in related fields.

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INTRODUCTION

The incidence of colorectal cancer has rapidly increased in the Asia-Pacific region^[1]. Colonoscopy remains the most accurate tool in diagnosing colorectal cancer and is advocated in many regions to be the modality of choice for screening and surveillance^[2]. However, the sensitivity depends largely on the quality of bowel preparation. Detection of neoplastic lesions is significantly reduced when bowel preparation is poor^[3,4]. Poor bowel preparation increases technical difficulty, prolongs procedure duration, decreases cecal intubation rate, and leads to greater costs associated with colonoscopy^[3,5,6].

A good bowel preparation regime is one that is not only effective in cleansing the colon but should be relatively small in volume and well-tolerated by patients with minimal adverse gastrointestinal symptoms^[7]. At our centre, reduced-volume 2-litre polyethylene glycol electrolyte lavage solution (PEG-ELS) plus bisacodyl and low fibre diet is used for bowel preparation for patients undergoing colonoscopy. Patients undergoing morning outpatient colonoscopy would normally ingest the PEG-ELS the day before. This regime is better tolerated by patients without compromising the quality of bowel preparation when compared with conventional 4-litre PEG-ELS^[8,9].

However, a previous study on patient satisfaction found that nearly half of the patients attending the outpatient colonoscopy service at our centre were dissatisfied with the bowel preparation regime used. Of the seven items considered in the evaluation of patient satisfaction, comfort level during bowel preparation was the main cause of unfavorable responses^[10]. Moreover, a separate study using the same bowel preparation regime at our centre found a high percentage of poor quality bowel preparation, which was associated with greater technical difficulty and patient discomfort during colonoscopy^[11]. There was clearly a need for a better bowel

preparation regime.

Current literature suggests that either taking reduced-volume PEG-ELS on the same morning instead of the previous evening^[12], or splitting the bowel preparation^[7], would enhance the quality of bowel preparation. However, it is uncertain which of these two regimes are better. The aim of our study was to compare the use of same-day whole-dose and split-dose reduced-volume PEG-ELS for colon cleansing in patients undergoing morning colonoscopy.

MATERIALS AND METHODS

The study included consecutive adult patients attending morning outpatient colonoscopy at the Endoscopy Suite of the University of Malaya Medical Centre from August 2012 to March 2013. The colonoscopy service is open-access, whereby patients are referred directly for colonoscopy from primary as well as secondary care clinics. The following subjects were excluded from the study: in-patients, patients scheduled for colonoscopy in the afternoon, patients who used other methods of bowel preparation than that assigned and patients who had an incomplete examination that was unrelated to quality of colon cleansing *e.g.*, obstructing tumour. The study was approved by the ethics committee of the institution. The study was registered with ClinicalTrials.gov. The protocol may be accessed at <http://clinicaltrials.gov/ct2/show/study/NCT01916564?term=chan+wah+kheong&rank=1>. All co-authors had access to the study data and had reviewed and approved the final manuscript.

Allocation and bowel preparation regime

Patients were assigned into two groups *i.e.*, split-dose or same-day whole-dose in a deterministic manner. Patients scheduled for colonoscopy on a particular day were listed by alphabetical order. Patients who were numbered odd were assigned to the same-day whole-dose group while patients who were numbered even were assigned to the split-dose group. The list did not reflect the sequence that patients would undergo colonoscopy. All patients were given instructions for bowel preparation through phone call 3-5 d prior to scheduled colonoscopy. In the whole-dose group, patients had to complete 2 L of PEG-ELS between 5 am and 6 am on the day of procedure. In the split-dose group, patients had to complete 1 L of PEG-ELS between 8 pm and 8.30 pm on the day before followed by another 1 L of PEG-ELS between 5.30 am and 6 am on the day of the procedure. All patients received 2 tablets of bisacodyl 5 mg on the two evenings prior to the procedure and were told to be on low residue diet on the day before the procedure. Patients were advised to drink clear liquids only after dinner at 6 pm and to keep nil orally once at the Endoscopy Unit. Adherence to instructions for bowel preparation was checked when patients arrived at the Endoscopy Unit. Allocation, providing instructions for bowel preparation and checking for adherence were carried out by a

trained research assistant who was not involved in other parts of the study.

Assessment of patient tolerability

All patients completed a questionnaire on tolerability of the bowel preparation regime used which was designed by Aronchick and colleagues^[13]. In addition, patients answered a question on comfort level during bowel preparation. This question was the same as that used in the earlier study on patient satisfaction of our colonoscopy service^[10]. This question has an ordinal five-value Likert scale (excellent, very good, good, fair, and poor). Patient response to this question was dichotomized to favourable (excellent, very good, good) and unfavourable (fair, poor) during analysis. An investigator who was blinded to the colon cleansing regime gathered other relevant information using a standard protocol. Completion of questionnaire and gathering of information were performed prior to patient undergoing the colonoscopy procedure. Patients were given Midazolam 2.5-5 mg and Fentanyl 50-100 mcg as sedation for the colonoscopy procedure.

Assessment of quality of bowel preparation

Standard video-endoscopes (CF 160AL, Olympus, Tokyo, Japan) were used for the colonoscopy procedures. The endoscopists were considered as trainee if they had performed < 200 colonoscopies and as senior if they had performed ≥ 200 colonoscopies. The endoscopists were unaware of the regime used for bowel preparation. They graded the quality of bowel preparation using the Boston bowel preparation scale (BBPS)^[14]. According to the BBPS, three broad regions of the colon *i.e.*, the right colon (including the cecum and ascending colon), the transverse colon (including the hepatic and splenic flexures), and the left colon (including the descending colon, sigmoid colon, and rectum) are given a score of 0-3 as follows: 0 = unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared; 1 = portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid; 2 = minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well; and 3 = entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid.

In addition, endoscopists gave an overall grading of the quality of bowel preparation as follows: excellent = adequate visualization without flushing and suction; good = adequate visualization requiring minimal flushing and suction; fair = unsatisfactory visualization of all or part of the colon with coloured fluid requiring flushing and suction; poor = unsatisfactory visualization of all or part of the colon with coloured fluid and faeces requiring flushing and suction and repeat colonoscopy had to be considered. The overall quality of bowel preparation was then re-categorized as good (*i.e.*, excellent), inter-

mediate (*i.e.*, good and fair) and poor as this has been shown to have better inter-observer variability during the previous study on quality of bowel preparation at our centre^[11]. Good and intermediate quality bowel preparation were considered satisfactory while poor quality bowel preparation was considered non-satisfactory.

Other colonoscopy procedure details

The following information was obtained: cecal intubation time *i.e.*, time taken after the colonoscope was inserted through the anus until the cecum was reached, withdrawal time *i.e.*, time taken to pull back colonoscope from cecum till complete withdrawal from the anus, and total colonoscopy time *i.e.*, time from colonoscope insertion until complete removal from the anus. Times were recorded from the display screen during colonoscopy and adjustment was made for the time spent to carry out therapeutic work. Adenoma detection rate and number of adenomas detected for each patient (if detected) were also recorded. All adenomas were at least 0.5 cm in size and were followed by histological confirmation.

Statistical analysis

Sample size was calculated using an online calculator for binary outcome non-inferiority trial^[15]. The rate of satisfactory bowel preparation using same-day whole-dose reduced-volume PEG-ELS has been reported to be 93%^[12]. The rate of satisfactory bowel preparation using split-dose 4-L PEG-ELS has been reported to be 95.6%^[16]. As reduced-volume PEG-ELS plus bisacodyl has been shown to be as good as 4-L PEG-ELS, and as the rate of satisfactory bowel preparation using split-dose reduced-volume PEG-ELS plus bisacodyl has never been reported before, we assumed that the rate of satisfactory bowel preparation using split-dose reduced-volume PEG-ELS plus bisacodyl to be 93%. A sample size of 112 patients per group will have 90% power to detect a treatment difference of 10% at a significance level of 0.05.

Data were analysed using SPSS 16 (SPSS Inc., Chicago, Illinois, United States). Analyses was based upon intent-to-treat. Categorical variables were expressed as percentages and analysed using χ^2 test or Fisher exact test where appropriate. Continuous variables were expressed as means \pm standard deviations or median with inter-quartile range and analysed with student's *t*-test or Mann-Whitney test where appropriate. Significance was assumed at *P*-value < 0.05.

RESULTS

Three hundred and three patients attended outpatient colonoscopy in the morning during the study period. Eight patients were excluded for the following reasons: obstructing tumour *n* = 3, acute colonic angulation *n* = 2, patient used a different bowel preparation regime than that assigned *n* = 3. Data for 295 patients were analysed. Mean age of the study population was 62.0 \pm 14.4 years

Table 1 Patient characteristics

Characteristics	Whole-dose same-morning <i>n</i> = 152	Split-dose <i>n</i> = 143	<i>P</i>
Age, yr	61.3 ± 14.9	62.8 ± 13.9	0.378
Male	51.3%	49.0%	0.685
Race			
Chinese	56.6%	60.1%	0.434
Malay	21.7%	18.9%	
Indian	21.7%	19.6%	
Others	0%	1.4%	
Education level			
None or primary	28.9%	23.8%	0.314
Secondary or higher	71.1%	76.2%	
Appointment waiting time			
Less than 16 wk	52.6%	48.3%	0.452
16 wk or longer	47.4%	51.7%	
Medical condition			
Diabetes mellitus	23.7%	19.6%	0.393
Chronic constipation	7.9%	8.4%	0.876
Neurological condition	2.0%	2.8%	0.716
Others	52.6%	55.2%	0.514
Previous abdominal surgery	39.5%	38.5%	0.859
Previous colonic resection	21.1%	13.3%	0.078
Indication			
Surveillance	30.3%	32.9%	0.263
Screening	16.4%	27.3%	
Altered bowel habit	13.8%	14.0%	
Per rectal bleeding	12.5%	9.8%	
Abdominal pain	11.2%	6.3%	
Anemia	5.3%	3.5%	
Chronic diarrhoea	3.9%	1.4%	
Chronic constipation	3.3%	3.5%	
Others	3.3%	1.4%	
Diagnosis			
Normal colonoscopy	53.0%	46.5%	0.233
Colonic polyp	23.2%	26.8%	
Diverticular disease	9.3%	11.3%	
Colorectal carcinoma	4.0%	0.7%	
Others	10.6%	14.8%	
Seniority of endoscopist			
Senior	34.2%	39.9%	0.315
Trainee	65.8%	60.1%	

old and consisted of 50.2% male. There were 152 patients in the whole-dose group and 143 patients in the split-dose group. Patient characteristics were comparable between the two groups (Table 1). A higher proportion of patients in the whole-dose group had previous colonic resection but this was not statistically significant.

Data on technical performance of colonoscopy, quality of bowel preparation and patient tolerability of the bowel preparation regimes are presented in Table 2. Cecal intubation rate (98.6% *vs* 98.7%), cecal intubation time [657 (480-980) *s vs* 600 (432-900) *s*], withdrawal time [244 (180-348) *s vs* 298 (180-418) *s*] and total colonoscopy time [960 (720-1304) *s vs* 960 (660-1320) *s*] were similar between the two groups. Although adenoma detection rates were similar between the two groups (30.1% *vs* 31.6%), the number of adenoma that were detected was marginally higher in the split-dose group [2 (1-3) *vs* 1 (1-2), *P* = 0.010].

Using the BPSS, there was a trend towards a better score for the right colon in the split-dose group [2 (2-3)

vs 2 (2-2), *P* = 0.060]. Scores for the transverse and left colon were similar between the groups. The total BBPS score was as good in the split-dose group compared to the whole-dose group [6 (6-8) *vs* 6 (6-7), *P* = 0.038]. Similarly, there was a trend towards a higher proportion of patients graded as having good or intermediate quality bowel preparation in the split-dose group (97.2% *vs* 92.1%, *P* = 0.071).

A greater proportion of patients in the split-dose group were able to complete the prescribed bowel preparation regime (99.3% *vs* 94.1%, *P* = 0.020). When enquired about willingness to repeat the type of bowel preparation regime, patients in the split-dose group were less likely to refuse the same bowel preparation regime (6.3% *vs* 13.8%, *P* = 0.033) and less likely to want to try another bowel preparation regime (53.8% *vs* 78.9%, *P* < 0.001). With regard to adverse symptoms, more patients in the whole-dose group had nausea (37.5% *vs* 25.2%, *P* = 0.023) and vomiting (16.4% *vs* 8.4%, *P* = 0.037). Other adverse effects were similar between the two groups. There was a trend towards higher proportion of unfavourable responses for level of comfort during bowel preparation in the whole-dose group (28.3% *vs* 18.9%, *P* = 0.058).

DISCUSSION

Several factors are recognized to influence the quality of colon cleansing in adults undergoing colonoscopy, and the timing of colon cleansing is one such determinant^[17]. In this study, we have found that split-dose reduced-volume PEG-ELS is as effective as, but better tolerated and preferred by patients, compared to whole-dose reduced-volume PEG-ELS taken on the same day. To the best of our knowledge, this is the first time these regimes have been compared. Moreover, bowel preparation using split-dose reduced-volume PEG-ELS has not been reported before, although there have been many studies comparing split-dose and previous-evening whole-dose regimes using larger volumes of PEG-ELS^[7]. In contrast to recent studies at our centre that used previous-evening whole-dose reduced-volume PEG-ELS^[10,11], both bowel preparation regimes in the current study were superior.

Chiu *et al*^[12] have already reported that a significantly greater proportion of patients had satisfactory bowel preparation when reduced-volume PEG-ELS was taken in the morning of colonoscopy instead of the previous evening (93% *vs* 72%, *P* = 0.003). Similarly, we found that 92.1% of our patients had satisfactory bowel preparation with same-morning reduced-volume PEG-ELS in this study. In contrast, only 69.9% had satisfactory bowel preparation with previous-evening reduced-volume PEG-ELS in an earlier study^[11]. Same-morning as opposed to a previous-evening PEG-ELS is superior due to a shorter interval between completion of bowel preparation and the colonoscopy procedure. The quality of bowel preparation has been shown to decline with an increasing interval between completion of bowel preparation and the colonoscopy procedure^[18]. Church *et al*^[19] hypothesized

Table 2 Comparison of technical performance of colonoscopy, quality of bowel preparation and patient tolerability between groups

Technical performance	Whole-dose same-morning <i>n</i> = 152	Split-dose <i>n</i> = 143	<i>P</i>
Completed colonoscopy	98.7%	98.6%	1.000
Cecal intubation time, s	600 (432-900)	657 (480-980)	0.510
Withdrawal time, s	298 (180-418)	244 (180-348)	0.235
Total colonoscopy time, s	960 (660-1320)	960 (720-1304)	0.888
Adenoma detection rate	31.6%	30.1%	0.779
Number of adenoma detected	1 (1-2)	2 (1-3)	0.010
Boston bowel preparation scale			
Right	2 (2-2)	2 (2-3)	0.060
Transverse	2 (2-3)	2 (2-3)	0.119
Left	2 (2-3)	2 (2-3)	0.176
Total	6 (6-7)	6 (6-8)	0.038
Overall grading of quality of bowel preparation			
Good or intermediate	92.1%	97.2%	0.071
Poor	7.9%	2.8%	
Completed bowel preparation	94.1%	99.3%	0.020
Difficult to complete bowel preparation	61.2%	29.4%	< 0.001
Will try another preparation	78.9%	53.8%	< 0.001
Refuse the same preparation	13.8%	6.3%	0.033
Barely tolerable or unacceptable taste	7.9%	5.6%	0.432
Nausea	37.5%	25.2%	0.023
Vomiting	16.4%	8.4%	0.037
Abdominal pain	19.7%	13.3%	0.137
Bloating	32.2%	30.1%	0.688
Chest pain	3.9%	5.6%	0.506
Dizziness	10.5%	9.8%	0.834
Level of comfort during bowel preparation			
Unfavourable response	28.3%	18.9%	0.058
Favourable response	71.7%	81.1%	

that there is a window period following bowel preparation, after which the quality of bowel preparation begins to decline due to increasing entry of small bowel content into the colon.

In this study, the percentage of patients with an unfavourable response to a question on comfort level during bowel preparation with same-morning reduced-volume PEG-ELS was 23.7%. This is much lower than that found in an earlier study using previous-evening reduced-volume PEG-ELS (48.6%)^[10]. The reason for this is unclear. We hypothesize that the better response for same-morning PEG-ELS could be related to the shorter interval between completing bowel preparation and the colonoscopy procedure itself.

Although reduced-volume PEG-ELS plus bisacodyl has been shown to be as good as conventional 4-liter PEG-ELS^[8], it was uncertain if splitting an already lower volume of PEG-ELS would compromise its efficacy. We have demonstrated in this study that split-dose reduced-volume PEG-ELS was as effective as whole-dose same-morning reduced-volume PEG-ELS in terms of quality of bowel preparation. Importantly, splitting the dose resulted in significantly less side effects (nausea and vomiting), was more tolerable and resulted in more patients being able to complete the bowel preparation. This may have compensated for any negative effect of splitting the dose and would explain the quality of bowel preparation seen in the split-dose group.

There are some concerns with taking part of or the

whole dose of a bowel preparation solution in the same morning for a morning colonoscopy procedure. For example, bowel movements during transit to the Endoscopy Unit may inconvenience patients. A randomized study comparing a split-dose and a whole-dose bowel preparation regime found slightly more toilet stops on the way to the hospital for patients in the split-dose group. However, patients in the split-dose group found it easier to complete their bowel preparation, were more satisfied, and had better quality of bowel preparation compared to the whole-dose group^[20]. Another concern is aspiration of bowel preparation solution from the stomach into the lung following administration of sedation for the procedure. However, a randomized study found no difference in residual gastric volume between patients who fasted for 2 h and patients who fasted for 6-23 h^[21].

Approximately 40% of colonoscopy patients in our centre are direct referrals from primary care clinics^[22]. Hence, data from this study may be generalized to populations scheduled for colonoscopy at large. However, the study was specifically on patients attending morning outpatient colonoscopy. The findings may be different for patients attending afternoon outpatient colonoscopy and for in-patients. Recently, Longcroft-Wheaton and colleagues reported that same-day bowel preparation produced better quality bowel preparation compared to split-dose bowel preparation for afternoon colonoscopy and was preferred by patients^[23]. However, the same-day group had to take less amount of bowel preparation

and completed bowel preparation closer to the colonoscopy procedure, both factors which were in favour of the same-day group. Moreover, the colonoscopy was performed by the same endoscopist and there was no information regarding randomization and blinding. Hence, further studies are needed to elucidate which bowel preparation regime is better for afternoon colonoscopy.

In summary, patients scheduled for morning colonoscopy preferred a split-dose to the whole-dose same-morning of reduced-volume PEG-ELS for colon cleansing. Patients given split-dose experienced significantly less nausea and vomiting, and were more likely to complete the regime. The quality of bowel preparation using split-dose was as good as using whole-dose same-morning reduced-volume PEG-ELS. For endoscopy units using a PEG-ELS-based bowel preparation regime, we recommend a split-dose reduced-volume PEG-ELS plus bisacodyl as the regime of choice for patients undergoing morning colonoscopy (ClinicalTrials.gov Identifier: NCT01916564).

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COMMENTS

Background

A good bowel preparation regime is one that is not only effective in cleansing the colon but should be relatively small in volume and well-tolerated by patients with minimal adverse gastrointestinal symptoms.

Research frontiers

Current literature suggests that either taking reduced-volume polyethylene glycol electrolyte lavage solution (PEG-ELS) on the same day instead of the previous evening, or splitting the bowel preparation, would be better for patients undergoing morning colonoscopy. However, whether the former or the latter is better, is unknown.

Innovations and breakthroughs

In this study of 295 patients undergoing morning colonoscopy, the authors found split-dose reduced-volume PEG-ELS plus bisacodyl to be as effective as, but better tolerated and preferred by patients than, a same-morning whole-dose regime. To the best of our knowledge, this is the first time these regimes have been compared. Moreover, bowel preparation using split-dose reduced-volume PEG-ELS has not been reported before although there have been many studies comparing split-dose and previous-evening whole-dose regimes using larger volumes of PEG-ELS.

Applications

Split-dose should be considered when reduced-volume PEG-ELS is used for colon cleansing for patients undergoing colonoscopy in the morning.

Peer review

This is an interesting, generally well-written study. The authors presented an interesting method of providing bowel preparation prior to endoscopy. They have split the dose of PEG-ELS, and demonstrated no discernable deterioration in quality of bowel preparation, with an improvement in patient-reported symptoms compared to standard single-dose bowel preparation. The findings may be different for patients attending afternoon outpatient colonoscopy and for in-patients and further studies are needed to elucidate which bowel preparation regime is better for afternoon colonoscopy.

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