Efficacy of Low-residue diet versus Clear liquid diet for colonoscopy bowel preparation in Special populations (elderly,diabetics,chronic kidney disease and chronic liver disease patients): A Single-Blinded Randomized Non-inferiority Controlled Trial

A Research Protocol submitted to the

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PRECEPTOR'S COMMENT

Colortectal cancer is a preventable and treatable disease by removing pre-cancerous polyp/s and surveillance among susceptible individuals. Colonoscopy is the preferred screening and surveillance method which enables endoscopists to biopsy and remove polyps. Excellent quality of a bowel preparation is a must to visualize the colonic mucosa effectively and prevent premature repeat of a costly procedure. Safety and tolerance of bowel preparation is equally important to entice patients to subject for colonoscopy screening and good experience ensures subsequent examinations. Therefore, this study hopes to find a well-tolerated but of good quality diet as part of the bowel preparation to improve patients' experience with screening colonoscopy especially in special population with poor tolerance to fasting.

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Introduction

In the Philippines, colorectal cancer is gaining unwanted ground and is now the third leading type of cancer and the third most common cause of cancer related deaths (Globocan 2012). The Philippine Cancer Society (PCS) estimates at least 8,000 new cases of colorectal cancer to occur among Filipinos. Colorectal cancer (CRC) is preventable. With high statistical figures on colorectal cancer, understanding the disease could be the first step to winning our battle against this type of cancer.[2]

Colonoscopy is the preferred modality for CRC screening. Major advantages of colonoscopy includes that it is readily available, examines the entire colon, allows single session diagnosis and removal of pre-cancerous lesions or polyps .The completeness of the examination and the quality of the preparation should be taken into account for the timing of subsequent examinations. The evidence that colonoscopy prevents incident CRCs and reduces the consequent mortality from CRC is indirect but substantial.[3]

Regardless of indication, the success of colonoscopy is linked closely to the adequacy of preprocedure bowel cleansing. Quality of bowel preparation is based on ability to visualize the mucosa after retained stool and fluid have been suctioned away. The endoscopist should document the quality of the bowel preparation in each colonoscopy. [5] Unfortunately, up to 20%–25% of all colonoscopies are reported to have an inadequate bowel preparation. The reasons for this range from patient-related variables such as compliance with preparation instructions and a variety of medical conditions that make bowel cleansing more difficult to unit-specific factors (eg, extended wait times after scheduling of colonoscopy). Adverse consequences of ineffective bowel preparation include lower adenoma detection rates, longer procedural time, lower cecal intubation rates, increased electrocautery risk, and shorter intervals between examinations. [4]

Traditionally, patients are instructed to ingest only clear liquids the day before colonoscopy. Recent randomized trials report that a liberalized diet the day before colonoscopy is associated with better tolerance of the preparation and comparable or better bowel cleansing. [6]

A less restrictive low residue diet may improve colonoscopy bowel preparation quality compared with a clear liquid diet, according to interim randomized controlled trial data presented at Digestive Disease Week in May, 2016. The mean Boston Bowel Preparation Score was 7.98 with the low residue diet vs. 7.54 with the clear liquid diet, which was not statistically significant; however, the low residue diet group had significantly more adequate bowel preparations (91.3% vs. 75.7%; $P = .05$). The study also showed the low residue diet improved patient satisfaction and tolerability, and could help to increase patient participation in colorectal cancer screening programs. [7]

However,there are nopublished local guidelines on the use of low residue diet for bowel preparation. There is also insufficient evidence to recommend specific dietary regimens for special populations such as the elderly ,diabetes, chronic kidney disease, chronic liver disease patients.

Objectives

a. General:

   To determine the efficacy of low residue diet for colonoscopy bowel preparation in the special populations (elderly, diabetes mellitus,chronic kidney disase, chronic liver disease) versus clear liquid diet using the Boston Bowel Preparation Scale (BBPS).

b. Specific

   To determine the tolerability of low residue diet for colonoscopy bowel preparation in special populations (elderly, diabetes mellitus, chronic kidney disase, chronic liver disease) versus clear liquid diet.

Review of Related Literature

CRC screening in average-risk persons should begin at age 50, except that in African Americans, screening should begin at age 45 years. A family history of polyps need not invoke earlier onset of screening or other adjustment in screening, unless there is convincing evidence that the polyps were advanced adenomas. [8]. Given the finding that adenomatous polyps are precursors to cancer and that polyps and early cancers are usually asymptomatic, there is a

strong rationale to support screening asymptomatic individuals for early cancer detection and prevention. [3]

Colonoscopy is the current standard method for imaging the mucosa of the entire colon. Large-scale reviews have shown rates of incomplete colonoscopy, defined as the inability to achieve cecal intubation and mucosal visualization effectively, between 10% and 20%, well over targets recommended by the U.S. Multi-Society Task Force on Colorectal Cancer.[6]

The diagnostic accuracy and therapeutic safety of colonoscopy depends, in part, on the quality of the colonic cleansing or preparation. Inadequate bowel preparation can result in failed detection of prevalent neoplastic lesions and has been linked to an increased risk of procedural adverse events. [6]

In clinical practice, preparation quality should be graded after efforts to remove residual effluent and fecal debris have been completed. Validated scoring systems that have been devised to rate the quality of colonoscopy preparation in clinical trials include the Aronchick Scale, the Ottawa Bowel Preparation Scale, and the Boston Bowel Prep Score .[5]

The BBPS is applied during the withdrawal phase of colonoscopy, after all washing, suctioning, and other cleaning maneuvers have been performed by the endoscopist. Good clinical practice dictates that the endoscopist should always clean as much as possible to obtain the highest possible score and ensure the best possible bowel cleanliness. Each of the three segments of the colon (right, including cecum and ascending colon; transverse, including hepatic and splenic flexures; and left, including descending colon, sigmoid and rectum) is given a score from 0–3. The BBPS demonstrated near-perfect inter-rater reliability (ICC=0.91) and substantial intra-rater reliability (weighted kappa 0.78; 95% CI 0.73–0.84). The BBPS is a valid and reliable instrument for assessing bowel cleanliness during colonoscopy. Segment scores may represent a standardized way to determine bowel preparation adequacy. The BBPS can be easily disseminated through the use of a brief instructional video. [5,9]

Clear liquid diet (CLD) is an established modified regime of normal diet, which do not include any solids, milk, and fruit juices non containing pulp. Traditionally, CLD is extensively adopted to perform bowel preparation on the day prior to colonoscopy. However, these shortages of the bowel preparation regime, such as too restrictive, containing insufficient calories and high risk of causing several adverse events (AEs), significantly impair the patient-based compliance.[10]

Nguyen and colleagues performed a study with meta-analysis to systematically assess the efficacy of LRD compared to CLD in implementing bowel preparation. These authors incorporated 5 eligible RCTs including 870 patients into their study. The satisfaction with bowel preparation, patient based tolerance, patient-based willing to repeat the same preparation regime in future, and AEs were listed to be as the outcomes of interesting in this study. This meta-analysis did not find difference between LRD and CLD in bowel preparation before colonoscopy. Although significant differences were not apparent in efficacy of colon cleansing, compliance with recommended bowel preparation regime and AEs, patient tolerance and willingness to repeat the same bowel preparation in future were improved in the LRD.[10]

Most colonoscopy preparation regimens require that the patient remain on a clear liquid diet for at least 24 h prior to their colonoscopy to reduce continued residue inflow into the colon from the small bowel. The most common problems leading to less than adequate colon cleansing include lack of compliance with the clear liquid diet and difficulty taking the preparation. [11]

In a study of M.'Delegge and R..Kaplan on the efficacy of bowel preparation with the use of a prepackaged, low fiber diet with a low sodium, magnesium citrate cathartic vs. a clear liquid diet with a standard sodium phosphate cathartic. This was a randomized, endoscopists' blinded comparison of the tolerability and efficacy of, low-residue diet (LRD) compared with a clear liquid diet(CLD). Outcome measures included efficacy of bowel preparation, patient preparation tolerability, side-effects and patient safety. A total of 506 patients completed the study, 222 randomized to CLD and 284 to LRD. The LRD regimen resulted in significantly better colon cleansing in terms of the proportion with good or excellent results (P 0.025) and in significantly better patient tolerance and willingness to repeat the cathartic preparation ($P < 0.01$).[11]

An adequate bowel preparation is an important quality measure for optimal colonoscopy. From a patient standpoint, bowel preparation remains the biggest deterrent to an elective colonoscopy examination. Bowel preparations are generally poorly tolerated, which results in an important impediment to colorectal cancer screening and surveillance. Tolerability, often measured in clinical trials with ‘‘willingness to retake the preparation’’ or with respect to taste of the purgative solution, involves other factors that may lead to negative patient assessment. These include various dietary modifications or restrictions and important adjustments in work or social schedule that may affect the pre-procedural quality of life and directly influence adherence.[12]

Study done by Jennifer A Flemming et al on low-residue breakfast during the preparation for colonoscopy using a polyethylene glycol electrolyte solution: a randomized non-inferiority trial. On an intention-to-treat (ITT) basis, a total of 109 and 105 patients were included in the Clear fluid diet (CFD) and Low residue breakfast (LRB) arms, respectively, with 116 and 98 patients, respectively, for the per-protocol (PP) analysis. Although there was no difference in the mean total OBPS between the CFD or LRB arms in either the ITT or PP analysis, the threshold for non-inferiority was not met. Patient acceptance of the regimens was higher in the LRB arm than in the CFD arm in the ITT and PP analyses.[13]

Another study done by Stolpman et al entiltled :A randomized controlled trial comparing a low-residue diet versus clear liquids for colonoscopy preparation: impact on tolerance, procedure time, and adenoma detection rate. Overall, 96.5% of patients had a good or excellent bowel prep (BBPS=6, 7, 8, or 9). LRD prep quality was non-inferior to CLD prep quality (LRD 7.8 vs. CLD 8.1). Polyp detection rates were similar (68% vs. 65.4%, P=0.6899). Patient tolerance and acceptance did not differ. Withdrawal times were equivalent between both groups (16.2 vs. 16.5 min, P=NS).Patients allowed to have a limited low-residue diet before colonoscopy achieve a bowel prep quality that is noninferior to patients on a strict clear liquid diet limitation. Furthermore, polyp detection rates, patient tolerance, and patient acceptance were similar between the 2 groups. [14]

The success of colonoscopy is largely dependent on the level of bowel cleansing: a higher cleansing level being associated to a higher detection rate of clinically relevant neoplastic lesions. Thesubstantial adverse consequences of inadequate or suboptimal bowel preparation include: lower likelihood of detection of smaller large adenomas, longer procedure times and, in general, more difficulties during the exam [3–6]. This has inevitably a negative impact on the efficiency of colonoscopy, waiting lists and costs of screening programs. [15]

Significance of the Study

Ineffective bowel cleansing for colonoscopy results in missed precancerous lesions and increased costs related to early repeat procedures. Better tolerability of bowel preparation may

improve patients' compliance and experience and may potentially improve their future participation in colorectal cancer prevention programs without compromising examination quality . We want to test the hypothesis that the use of a low residue diet the day prior to colonoscopy was not inferior to consuming clear fluids alone in patients undergoing colonoscopy. It is the researcher's hope that a low residue diet may help alleviate patient concerns with bowel preparation experience and potentially improve patient participation in colorectal cancer prevention programs without compromising examination quality. It is also the researchers hope to determine the efficacy of low residue diet in special populations (ie,diabetes mellitus, CKD,CLD and elderly)

Methodology

Study Area

The study will be conducted at the out-patient department (OPD), wards and endoscopy unit of Veterans Memorial Medical Center until target population is reached

Study Design

Thisstudy is a prospective single-blinded, randomized controlled non-inferiority trial. All eligible patients will be included in the study. Patients will be randomized using block randomization.There are no benefits or compensations that will be provided for the patients in this study.

Intervention

All eligible patients subjected for screening colonoscopy at the OPD and wards will be included in the study. Medical risk evaluation, if necessary, will be done even prior to enrollment. As in everyprocedure , the risks and complications of colonoscopy will be highly explained. Outmost care and safety during the procedurewill be assured to the patients as this will all be done with the assistance of service consultants.

All the procedures will be done by the GI consultants and fellows in-training with the assistance of service consultant for the day (see Appendix A for the list of service consultants per day). The patients will be randomized into two groups: those following the low residue diet regimen, and those on the clear liquid diet regimen. Each patient will receive oral and written instructions regarding the diet and cathartics to be ingested prior to scheduled colonoscopy.

Those patients randomized to the clear liquid regimen will be asked to take only clear liquids the entire day before their procedure. The low residue diet regimen group will consume the prescribed low residue diet until 6 pm the day before the procedure or 12 hours prior to scheduled colonoscopy.

Bowel cleansing regimen

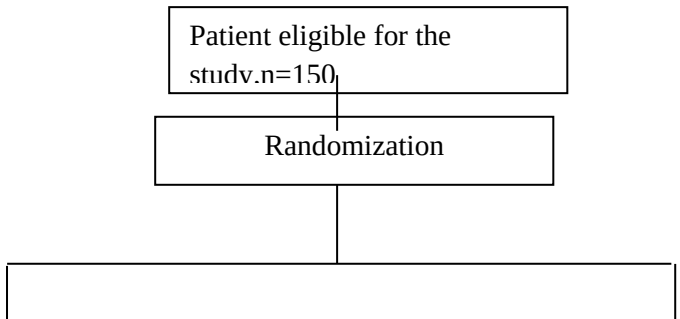
All patients will be instructed to ingest the standard operating procedure (SOP) bowel cleansing agent of VMMC. Patients whose colonoscopy was scheduled at 8 AM will be instructed to take lactulose 60cc followed by 4-5 glasses of water at 1pm, 3pm and 5pm the day before the procedure. They will also be instructed to take bisacodyl 5mg/tab, 2 tablets followed by 4-5 glasses of water at 7pm. Those patients schedule after 8am will follow the same regimen. They will be instructed to take the lactulose and bisacodyl 15 hours and 12 hours respectively prior to colonoscopy.

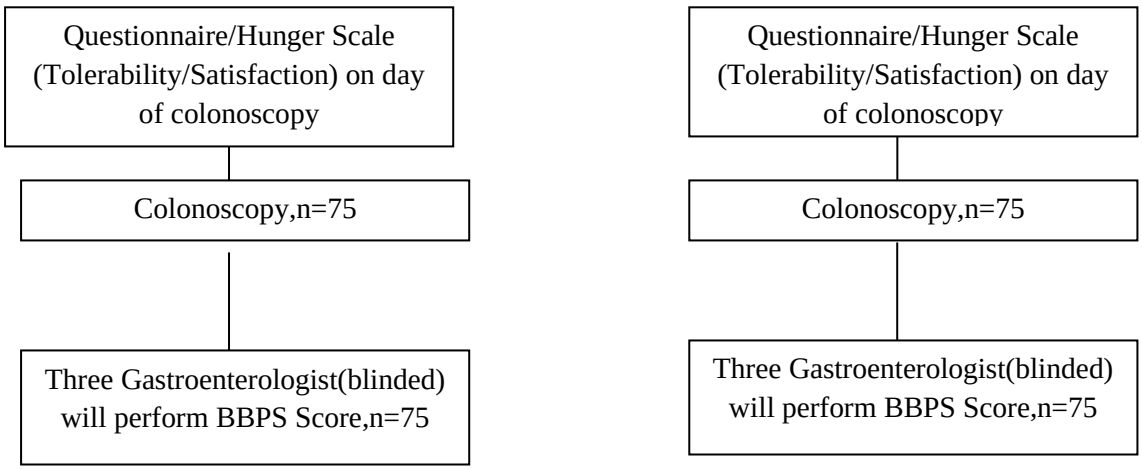
Outcomes

The primary outcome is the efficacy or adequacy of bowel preparation.It will be measured by the Boston Bowel Preparation Scale (BBPS), which is a validated and reliable scale.Secondary outcomes such as patient's tolerability of the regimen will be assessed by inquiring on the occurrence of gastrointestinal symptoms related to the dietary regimen, i.e, nausea, vomiting, bloatedness, abdominal cramps/discomfort. Other outcomes such as cecal intubation rate, polyp detection rate and insertion/withdrawal time will also be measured.

The efficacy of bowel preparation will be assessed by three gastroenterology consultants blinded to the bowel preparation . An adequate bowel preparation will be given a BBPS score of ≥ 6. The secondary outcomes will also be assessed on the day of the procedure. Before colonoscopy patients will be asked to complete a questionnaire to assess their tolerability, hunger score and satisfaction with the dietary regimen. A subgroup analysis to assess the efficacy of bowel preparation on special population will also be conducted.

Study Process





Study Population

Inclusion Criteria:

1. All adults≥18 years of age scheduled for colonoscopy at VMMC and willing to sign informed consent were eligible for ourstudy

Exclusion Criteria:

1. Patients with bowel obstruction and/or bowel perforation
2. Presence of a colostomy and/or history of a partial colon resection
3. Active gastrointestinal bleeding
4. Pregnancy
5. Inflammatory bowel disease
6. Diverticulitis

Sample Size:

At 95% confidence interval and 80% power of test, the minimum required sample size is 75 patients per group. This is also based on the previous proportion of adequate bowel preparation of 91% among low residue diet while 76% for clear liquid diet.

Statistical Analysis:

Baseline characteristics of the patients will be described as mean and standard deviation among continuous variables while percentage will be utilized for categorical data. In comparing the two groups, t-test will be used to compare means such as BBPSscore, while chi square test will be utilized for categorical variables such as proportion of adequate bowel preparation. All significant test will be done at 5 % level. A non inferiority margin of 0.05 was set. Medcalc statistical calculator will be utilized to carry out statistical computations.

Results

Patients Demographics

A total of 75 patientseach from low residue diet and clear liquid diet group were included in this study whose average age is 67.9 and 64.9 respectively (p=.0515). (Table 1).It also showed that around 82.7% of the patients in low residue are elderly, which is not significantly different from the resulting proportion of elderly patients in clear liquid diet group (72%). (Table 1) Moreover, both group is composed mostly of male (61% vs 75%, Low Residue vs Clear liquid), while proportion of occurrence of diabetes mellitus, chronic kidney disease and chronic liver disease is also not significantly different for the two groups.(Table 1). There were also no differences in terms of cecal intubation rate, withdrawal time, out patients and in patient's number.(Table 1).

Table 1. Patient Baseline Demographic Information

Profile	Low Residue Diet (n=75)	Clear Liquid Diet (n=75)	p value
Age (years), mean±sd	67.9 ± 9.5	64.9 ± 9.0	0.0515^{ns}
Elderly (>60), n,%	62 (82.7)	54 (72.0)	0.1200^{ns}
Sex, n,%			
Male	46 (61.3)	56 (74.7)	0.0811^{ns}

Female	29 (38.7)	19 (25.3)	
Comorbidities, n,%			
Diabetes Mellitus	32 (42.7)	29 (38.7)	0.6192 ^{ns}
Chronic Kidney Disease	11 (14.7)	6 (8.0)	0.1993 ^{ns}
Chronic Liver Disease	5 (6.7)	5 (6.7)	1.0000 ^{ns}
Others			
Cecal intubation rate	75 (100)	75(100)	1.0
Withrawal time	8.6±2.2	8.95±2.5	0.3642
In patients	44(58.7)	39(52)	0.4131
Out patients	31(41.3)	36(48)	

Adequacy of Bowel Preparation

The mean Boston Bowel Preparation Score was 7.00 ± 1.12 with the low residue diet(LRD) vs. 6.90 ± 1.12 with the clear liquid diet(CLD), which was not statistically significant. LRD bowel preparation quality was non inferior to CLD bowel preparation quality (LRD 7.0 vs. CLD 6.9) (Table 2). Bowel preparation was considered adequate if the BBPS score was equal or higher than 6. Both colon preparation regimens were adequate for colon cleansing (92% vs 90.7%). No significant differences were observed between the treatment groups(92% vs 90.7%, p=0.7724). Likewise, same conclusion can be derived from patients with Diabetes, Chronic Kidney Disease, chronic liver disease, and among elderly patients.(Table 2b-2e).

Table 2a. Boston Bowel Preparation Scale (BBPS) Scores

Outcome	Low Residue Diet (n=75)	Clear Liquid Diet (n=75)	p value
BBPS Score, mean±sd	7.00 ± 1.12	6.90 ± 1.12	0.6095^{ns}
BBPS Score≥6, n, %	69 (92.0)	68 (90.7)	0.7724^{ns}
BBPS Score<6, n,%	6 (8.0)	7 (9.3)	

Table 2b. Boston Bowel Preparation Scale (BBPS) Scores for Diabetes

Outcome	Low Residue Diet (n=32)	Clear Liquid Diet (n=29)	p value
BBPS Score, mean±sd	6.89 ± 1.17	7.01 ± 1.14	0.6722^{ns}
BBPS Score≥6, n, %	27 (84.4)	27 (93.1)	0.2894^{ns}

BBPS Score<6, n,%	5 (15.6)	2 (6.9)	

Table 2c. Boston Bowel Preparation Scale (BBPS) Scores for CKD

Outcome	Low Residue Diet (n=11)	Clear Liquid Diet (n=6)	p value
BBPS Score, mean±sd	6.79 ± 1.21	7.11 ± 1.19	0.6034^{ns}
BBPS Score≥6, n, %	10 (90.9)	6 (100.0)	1.000^{ns}
BBPS Score<6, n,%	1 (9.1)	0 (0.0)	

Table 2d. Boston Bowel Preparation Scale (BBPS) Scores for CLD

Outcome	Low Residue Diet (n=5)	Clear Liquid Diet (n=5)	p value
BBPS Score, mean±sd	7.33 ± 1.45	6.47 ± 1.50	0.3802^{ns}
BBPS Score≥6, n, %	4 (80.0)	4 (80.0)	1.000^{ns}
BPPS Score<6, n,%	1 (20.0)	1 (20.0)	

Table 2eBoston Bowel Preparation Scale (BBPS) Scores for Elderly (Age≥60)

Outcome	Low Residue Diet (n=62)	Clear Liquid Diet (n=54)	p value
BBPS Score, mean±sd	7.06 ± 1.15	6.90 ± 1.09	0.4333^{ns}
BBPS Score≥6, n, %	57 (91.9)	49 (90.7)	0.8199^{ns}
BBPS Score<6, n,%	5 (8.1)	5 (9.3)	

Patient Tolerance and Satisfaction

The proportion of patients who developed nausea and vomiting were not statistically significant between the two groups(5.35 vs 12 %,p=0.148)(Table 3a). However, the occurrence of abdominal pain/cramping/discomfort (34.7%) and bloatedness (44%) are significantly higher in clear liquid diet group compared to low residue diet group(16% and 26.7% respectively, p=0.0088 and0.0269) (Table 3a). Moreover, patients in the LRD group were less hungry before colonoscopy as compared to CLD group(4.16 vs 3.72, p=0.0027). Patient's satisfaction with the diet showed a higher proportion of patients in the LRD group rated the procedure easy(12%) and fair (78.7 %) compared to CLD group (3% and 72% respectively, p=0.0178). Likewise, in terms of willingness to repeat the procedure, patients who said yes is significantly higher for low residue diet group (93%) as compared to only 81.3% for Clear liquid diet group. On the other hand, among patients with Diabetes Mellitus, Chronic

Kidney Disease, and Chronic liver disease showed no significant difference between the two groups in terms of symptoms, hunger score, satisfaction with diet and willingness to repeat procedure.(Table 3b-3d).

Table 3e showed that among elderly patients, proportion of patients with abdominal pain(37%) was higher for Clear liquid diet group compared to LRD group (12%, p=0.0343). Finally, in terms of willingness to repeat the procedure, elderly patients who said yes is significantly higher for low residue diet group (93.5%) as compared to only (81.5%) for Clear liquid diet group.

Table 3a Patients Tolerability (Gastrointestinal Symptoms)

	Low Residue Diet (n=75)	**Clear Liquid Diet (n=75)**	**p value**
GI Symptoms			
Nausea/Vomiting,n,%	4 (5.3)	9 (12.0)	0.1481^{ns}
Abdominal Pain/Cramping/Discomfort, n, %	12 (16.0)	26 (34.7)	0.0088*
Bloatedness,n,%	20 (26.7)	33 (44.0)	0.0269*
Hunger Score, mean±sd	4.16 ± 0.81	3.72 ± 0.95	0.0027*
Satisfaction with Diet, n, %			
Easy	9 (12.0)	3 (4.0)	0.0178*
Fair	59 (78.7)	54 (72.0)	
Difficult	7 (9.3)	18 (24.0)	
Willingness to Repeat Procedure, n, %			
Yes	70 (93.3)	61 (81.3)	0.0277*
No	5 (6.7)	14 (18.7)	

Table 3b Patients Tolerability (Gastrointestinal Symptoms) for DM

	Low Residue Diet (n=32)	**Clear Liquid Diet (n=29)**	**p value**

GI Symptoms			
Nausea/Vomiting,n,%	2 (6.2)	5 (17.2)	0.1822 ns
Abdominal Pain/Cramping/Discomfort, n, %	7 (21.9)	12 (41.4)	0.1033 ns
Bloatedness,n,%	10 (31.2)	13 (55.2)	0.0613 ns
Hunger Score, mean±sd	4.22 ± 0.94	3.76 ± 0.91	0.0578ns
Satisfaction with Diet, n, %			
Easy	6 (18.8)	2 (6.9)	0.2500ns
Fair	22 (68.7)	20 (69.0)	
Difficult	4 (12.5)	7 (24.1)	
Willingness to Repeat Procedure, n, %			
Yes	29 (90.6)	22 (75.9)	0.1229ns
No	3 (9.4)	7 (24.1)	

Table 3c Patients Tolerability (Gastrointestinal Symptoms) for CKD

	Low Residue Diet (n=11)	**Clear Liquid Diet (n=6)**	**p value**
GI Symptoms			
Nausea/Vomiting,n,%	0 (0.0)	0 (0.0)	1.000ns
Abdominal Pain/Cramping/Discomfort, n, %	1 (9.1)	1 (16.7)	1.000 ns
Bloatedness,n,%	3 (27.3)	1 (16.7)	1.000 ns
Hunger Score, mean±sd	4.27 ± 0.65	4.00 ± 0.89	0.4781ns
Satisfaction with Diet, n, %			
Easy	1 (9.1)	1 (16.7)	0.3167 ns
Fair	10 (90.9)	4 (66.7)	
Difficult	0 (0.0)	1 (16.7)	
Willingness to Repeat Procedure, n, %			
Yes	11 (100.0)	5 (83.3)	0.3529 ns
No	0 (0.0)	1 (16.7)	

Table 3d Patients Tolerability (Gastrointestinal Symptoms) for CLD

	Low Residue Diet (n=5)	**Clear Liquid Diet (n=5)**	**p value**

GI Symptoms			
Nausea/Vomiting,n,%	0 (0.0)	1 (20.0)	1.000[ns]
Abdominal Pain/Cramping/Discomfort, n, %	0 (0.0)	3 (60.0)	0.1667 [ns]
Bloatedness,n,%	0 (0.0)	3 (60.0)	0.1667 [ns]
Hunger Score, mean±sd	4.20 ± 0.84	3.60 ± 1.34	0.4208[ns]
Satisfaction with Diet, n, %			
Easy	0 (0.0)	0 (0.0)	0.4444 [ns]
Fair	5 (100.0)	3 (60.0)	
Difficult	0 (0.0)	0 (0.0)	
Willingness to Repeat Procedure, n, %			
Yes	5 (100.0)	4 (80.0)	1.000 [ns]
No	0 (0.0)	1 (20.0)	

Table 3e Patients Tolerability (Gastrointestinal Symptoms) for Elderly

	Low Residue Diet (n=62)	**Clear Liquid Diet (n=54)**	**p value**
GI Symptoms			
Nausea/Vomiting,n,%	4 (6.5)	9 (16.7)	0.0832 [ns]
Abdominal Pain/Cramping/Discomfort, n, %	12 (19.4)	34 (37.0)	0.0343*
Bloatedness,n,%	19 (30.6)	25 (46.3)	0.0845 [ns]
Hunger Score, mean±sd	4.21 ± 0.83	3.83 ± 1.06	0.0345*
Satisfaction with Diet, n, %			
Easy	6 (9.7)	3 (5.6)	0.0845[ns]
Fair	50 (80.6)	38 (70.4)	
Difficult	6 (9.7)	13 (24.1)	
Willingness to Repeat Procedure, n, %			
Yes	58 (93.5)	44 (81.5)	0.0475*
No	4 (6.5)	10 (18.5)	

Table 4. Hunger Scale

Hunger Scale	**Low Residue Diet (n=75)**	**Clear Liquid Diet (n=75)**	**p value**
1=starving,dizzy,irritable	0 (0.0)	0 (0.0)	0.0002*
2=very hungry,unable to concentrate	0 (0.0)	0 (0.0)	

3= hungry, ready to eat	15 (20.0)	38 (50.7)	
4=Beginning signals of hunger	37 (49.3)	27 (36.0)	
5=Comfortable, neither hungry nor full	19 (25.3)	5 (6.7)	
6=comfortably full	4 (5.3)	3 (4.0)	
7=Very full,feel as if you have overeaten	0 (0.0)	2 (2.7)	
8=Uncomfortably full	0 (0.0)	0 (0.0)	
9=Very uncomfortably full, needed to loosen you belt	0 (0.0)	0 (0.0)	
10 Stuffed to the point of feeling sick,in a food coma	0 (0.0)	0 (0.0)	

Table 5. Patient Satisfaction

Satisfaction	Low Residue Diet (n=75)	Clear Liquid Diet (n=75)	p value
How easy or difficult was it to consume the diet regimen			
Easy	9 (12.0)	3 (4.0)	0.0178*
Fair	59 (78.7)	54 (72.0)	
Difficult	7 (9.3)	18 (24.0)	
Were you able to consume the entire preparation as instructed			
Yes	73 (97.3)	71 (94.7)	0.4062^{ns}
No	2 (2.7)	4 (5.3)	
Please describe your overall experience of the study preparation			
Easy	9 (12.0)	3 (4.0)	0.0178*
Fair	59 (78.7)	54 (72.0)	
Difficult	7 (9.3)	18 (24.0)	
Would you ask your doctor for this preparation again if you needed another colonoscopy in the future			
Yes	70 (93.3)	61 (81.3)	0.0277*
No	5 (6.7)	14 (18.7)	
Would you refuse the same preparation again if it were to be prescribed to you in the future			
Yes	5 (6.7)	14 (18.7)	0.0277*
No	70 (93.3)	61 (81.3)	

Discussion

The adequacy of bowel preparation is an important quality measure for optimal colonoscopy. The efficacy of bowel preparation is vital to guarantee the accuracy and proper visualization of colonoscopy test and treatment. Conventionally, the clear liquid dietary regime

was commonly selected to perform the bowel preparation; however, apparentrestrictions such as patients tolerability and satisfaction limits this approach.

In this study, we examined the effect of low residue diet onthe adequacy of bowel preparation using the BBPS compared to clear liquid diet. It showed that low residue diet is non-inferior to clear liquid diet in the efficacy of bowel preparation. Our findings suggested that LRD did not compromise the adequacy of bowel preparation relative to CLD. This is consistent with the results of most studies.

From a patient standpoint, bowel preparation remains the biggest deterrent to an elective colonoscopy examination. Bowel preparations are generally poorly tolerated, which results in an important impediment to colorectal cancer screening and surveillance. Tolerability, often measured in clinical trials with ‘‘willingness to retake the preparation’’ or with respect to taste of the purgative solution, involves other factors that may lead to negative patient assessment. These include various dietary modifications or restrictions and important adjustments in work or social schedule that may affect the pre-procedural quality of life and directly influence adherence.

Overall, patient’s tolerability and satisfaction were better in the LRD group than the CLD group. The present study showed that the proportion of patients having abdominal pain/cramping/discomfort and bloatedness are significantly lower in LRD group compared to CLD group. In addition, the proportion of patients in the LRD group was less hungry before colonoscopy as compared to CLD group. Our study also showed a higher proportion of patients in the LRD group rated the procedure easy and fair compared to CLD group.These results were parallel to other studies.

However, in our subgroup analysis,no difference was found among diabetics, chronic kidney disease and chronic liver disease patients when the two groups were compared with regards to patient’s tolerability and satisfaction.

The present study has some limitations. It is a single-center study with arelatively small sample size. In addition, another limitation of the study is the sample size included in the chronic kidney disease(total of 17) and chronic liver disease(10) were small compared to elderly population(116) and diabetics(61),hence we cannot totally assessed their impact on the adequacy of bowel preparation.

Conclusion

Patients on a low residue diet for bowel preparation achieved an adequate bowel preparation that is non-inferior to patients on a clear liquid diet. Furthermore, the study showed that patients tolerability and overall satisfaction were better on the low residue diet group. Patients

in the LRD group would be more willing to repeat the same bowel regimen as compared to CLD group. However, the study also showed no statistical significance on patient's tolerability and satisfaction among diabetics, chronic kidney disease and chronic liver disease patients.

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