

Assessment of a Novel Nutritive Solution (NUTRIMOV) and Sodium Diatrizoate (Gastrografin) Booster for Bowel Cleaning Prior to Colonoscopy

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Abstract

Background: Sensitivity of colonoscopy in detecting pre-cancerous lesions depends on quality bowel preparation that is often negatively affected by low tolerability of patients to the different preparation protocols.

Aim of Study: To evaluate the efficacy and tolerability of a novel solution (NUTRIMOV) combining PEG and a carbohydrate-electrolyte solution for colonoscopy.

Patients and Methods: Fifty patients undergoing colorectal cancer (CRC) screening via colonoscopy. Split-dose of 4 L of NUTRIMOV were administered over a span of three days leading up to the colonoscopy.

Results: Fifty patients (26 males, mean age 55±8 years) were included in the final analysis. Excellent and good bowel preparation was achieved in 72% of patients. Patient's tolerability was reported as good in 43%, moderate in 42% and poor in 15%. Adverse effects were hunger (22%), fatigue (36%), abdominal pain (4%), bloating (24%), but no vomiting (0%).

Conclusion: NUTRIMOV is well tolerated by patients with low rates of adverse effects and results in high rates of adequate cleansing level.

Key Words: Colonoscopy – Preparation – Polyethylene Glycols.

Introduction

COLORECTAL cancer (CRC) is a leading cause of cancer-related mortality, and it is the third most common cancer in the USA. Early-stage CRC is often asymptomatic which necessitates sensitive screening modalities for early diagnosis. The gold standard of CRC screening is colonoscopy which allows for both early detection and treatment of pre-cancerous lesions [1].

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To optimize the detection of colorectal neoplasia, adequate bowel preparation is necessary. Previous studies have established the positive correlation between quality of bowel preparation and adenoma detection rate (ADR). A systematic review and meta-analysis concluded that low-quality bowel preparation resulted in the need for early repeat colonoscopy as ADRs were significantly higher in both intermediate-quality and high-quality preparation (odds ratio [OR], 1.39; 95% confidence interval [CI], 1.08-1.79) as compared to low-quality preparation (OR, 1.41; CI, 1.21-1.64) [2].

Factors that affect quality of bowel preparation can be categorized into product-related factors and patient-related factors. Product-related factors include tolerability, dosing regimen (split-dosing versus same day of colonoscopy) and timing of administration as related to the start of the procedure. Patient-related factors includes a combination of patient education, health literacy and motivation to complete the preparation [3].

Tolerability of bowel preparation depends on volume as well as the associated adverse events. Efforts to improve tolerability include the development of low-volume regimens and administering the solution in split-doses. While these adjustments result in improved tolerability, adverse effects include dehydration, fatigue, and electrolyte imbalances which ultimately affects patient compliance and the quality of bowel preparation [4,5].

This study aims to evaluate a novel nutritive solution in improving quality of bowel preparation, ultimately resulting in more sensitive colonoscopies.

Patients and Methods

Study setting and population:

Fifty patients were recruited from Gastroenterology Department and consultation at ROEYA Endoscopy Center, Egypt between January 2020, and March 2020. Each patient received full explanation of the study and signed an informed consent form.

Eligibility criteria:

Patients between the ages of 50-70 years old or with family history of colorectal cancer (first degree relatives with colorectal cancer less than 60 years old) were included.

Exclusion criteria:

- Patient has dysphagia or any swallowing disorder.
- Patient had Diabetes Mellitus.
- Patient has congestive heart failure.
- Patient is not eligible for colon preparation due to the presence of underlying conditions based on the clinical judgment of the investigator.
- Patient has any allergy or other known contraindication to the medications used in the study.
- Patient has had prior abdominal surgery of the gastrointestinal tract other than uncomplicated procedures that would be unlikely to lead to bowel obstruction based on the clinical judgment of the investigator.
- Patient has a cardiac pacemaker or other implanted electro medical device.
- Patient with gastrointestinal motility disorders.
- Patient suffers from life threatening conditions.
- Patient currently participating in another clinical study.

Study design:

Enrolled patients were scheduled for a colonoscopy. Prior to the colonoscopy, the patients began a novel bowel preparation consisting of a combination of polyethylene glycol solution and carbohydrate oral solution (NUTRIMOV; Table 1). Two days prior to the colonoscopy procedure, patients were instructed to begin the regimen as follows: A fiber free diet and 1 L of NUTRIMOV solution taken at 20:00. One day before the colonoscopy procedure, patients were instructed to ingest 1 L of NUTRIMOV solution in the morning at 8:00 and another liter in the evening at 20:00. On the day of the colonoscopy, the patients ingested a final liter of NUTRIMOV solution four hours before the procedure. Two hours before the procedure, 30mL of sodium diatrizoate (Gastrografin)

were administered as a booster. After the procedure, patients were advised to consume clear fluids two hours after the procedure and were allowed to eat a total of three hours after the procedure.

Table (1): Combined solution (NUTRIMOV) description. NUTRIMOV is offered in packs of 1000mL after dilution.

Carbohydrates (g)	120-140	g
Minerals		
K Cl	1.13	g
Na Cl	2.19	g
NaHCO ₃	2.52	g
PEG (MACROGOL 3350)	88.5	g
Na ₂ SO ₄	8.52	g
Ca	<5	mg
P	<5	mg
Mg	<5	mg
Water	1000	ml
Total Energy Level	500	Kcal

Colon cleansing for colonoscopy procedures was rated based on investigators readings at each site: Rectum, sigmoid, left colon, transverse colon, right colon, and cecum. Colon cleansing will be graded using the following 4-point scale grading system (excellent, good, fair and poor) for each segment of the colon (cecum, right colon, transverse colon, left colon and recto-sigmoid colon) and overall, for the entire colonoscopy (Table 2) [6].

Table (2): Grading system for colon cleansing.

Grade	Comments
Excellent	No more than small bits of adherent feces
Good	Small amount of feces or dark fluid without interfering with examination
Fair	Enough feces or dark fluid present to preclude a completely reliable examination
Poor	Large amount of fecal residue

Patient tolerability was assessed on a scale of "poor", "moderate" or "good". Tolerability of the solution was assessed after ingestion of each of the 4 liters of NUTRIMOV. Overall tolerability was calculated by averaging tolerability status for the patients over the span of the 3 days of bowel preparation.

Any adverse events, including hunger, fatigue, abdominal pain, bloating, sleep disturbance and vomiting were assessed and documented. Assessment occurred during each of three days of preparation.

Data analysis/calculations:

Continuous variables were reported as mean (SD) while categorical variables were summarized as proportions. Comparisons between two groups were performed using chi-squared test. *p*-values <0.05 was considered significant. Statistical analyses were performed using SPSS (V.27.0).

Results

Fifty patients (26 male, mean age 55±8 years) were enrolled. All the patients were eligible for CRC screening. None of the patients were excluded from the final analysis.

Quality of bowel preparation:

During the analysis, colon cleansing grades of “excellent” and “good” were combined and “fair” and “poor” were combined (Table 3).

Table (3): Quality of bowel cleansing for each colon segment expressed as number of patients (percentage).

	Male	Females	<i>p</i> -value
<i>Cecum:</i>			
Excellent/Good	25 (50%)	18 (36%)	0.0313
Fair/Poor	1 (2%)	6 (12%)	
<i>Right colon:</i>			
Excellent/Good	23 (48%)	17 (35%)	.3000
Fair/Poor	3 (6%)	5 (10%)	
<i>Transverse colon:</i>			
Excellent/Good	23 (50%)	13 (28%)	0.0558
Fair/Poor	3 (7%)	7 (15%)	
<i>Left Colon:</i>			
Excellent/Good	21 (53%)	13 (33%)	0.1940
Fair/Poor	2 (5%)	4 (10%)	
<i>Rectum:</i>			
Excellent/Good	17 (50%)	10 (29%)	0.2515
Fair/Poor	3 (9%)	4 (12%)	
<i>Overall:</i>			
Excellent/Good	23 (46%)	13 (26%)	0.0070
Fair/Poor	3 (6%)	11 (22%)	

Patient tolerability:

Overall tolerability was the average of the reported. Overall tolerability was “good” in 43% of the patients, “moderate” in 42% and poor in 15%.

Adverse effects:

Overall occurrence of adverse effects was calculated out of 150 since each of the 50 patients were assessed three times (Table 4).

Table (4): Occurrence of adverse effects expressed as sum of occurrences each of the three days (percentages).

	Yes	No
Hunger	38 (25%)	112 (75%)
Fatigue	52 (35%)	98 (65%)
Abdominal pain	15 (10%)	135 (90%)
Bloating	33 (22%)	117 (78%)
Vomiting	2 (1%)	148 (99%)
Sleep disorder	13 (9%)	137 (91%)

Discussion

Studies suggest that inadequate bowel preparation occurs in about 15-35% of colonoscopies [7-9]. Additionally, bowel preparation is one of the main reasons that colonoscopies are avoided [10]. The present study showed that a new regimen for colonoscopy preparation results in adequate cleansing level.

As recommended by the European Society of Gastroenterology and Endoscopy (ESGE), patients were instructed to follow a low fiber diet [11]. Patients were provided with four packs of NUTRIMOV (4L of solution) to be taken in a split-dose regimen. In a meta-analysis including 13,487 patients, comparing the efficacy of split-dose colon preparation regimens versus other regimens, split-dose preparation provided significantly better colon cleansing than day-before preparations. Additionally, PEG split-dose preparations of 3L or more resulted in greater quality of bowel preparation in terms of bowel cleanliness as compared to low-volume split-dose regimens (OR, 1.89; CI, 1.01-3.46) [12]. This is in agreement with other studies confirming the superiority of split-dose high volume PEG as compared to split-dose low volume PEG [13].

Regarding quality of bowel preparation, colon cleanliness was graded as “Excellent/Good” in most of the patients. While only the transverse colon segment showed a borderline significant difference between males and females (*p*=0.0558), overall assessment of colon cleanliness throughout the segments showed a highly significant difference between males and females (*p*=0.0070). Most patients rated the tolerability of the solution as “good” or “moderate” (85%) while only 15% of the patients reported the regimen to be of “poor” tolerability. No major adverse events occurred in any of the patients. Fatigue was the most commonly reported side effect as 35% of the included patients complained of fatigue.

Conclusion:

Overall, colonoscopy preparations tend to be disliked which present a significant barrier to colonoscopy screening, an essential procedure for early detection of pre-cancerous lesions. NUTRIMOV is well tolerated by patients undergoing colonoscopy screening with low rates of adverse events and adequate quality of colon cleansing.

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تقييم محلول مغذي جديد (NUTRIMOV) والصوديوم (Gastrografin) الداعم لتنظيف الأمعاء قبل تنظير القولون

الخلفية: حساسية تنظير القولون في الكشف عن الآفات ما قبل السرطانية تعتمد على تحضير الأمعاء الجيد الذي غالباً ما يتأثر سلباً بانخفاض تحمل المرضى لبروتوكولات التحضير المختلفة.

هدف الدراسة: لتقييم فعالية وتحمل محلول جديد (NUTRIMOV) يجمع بين PEG ومحلول من الكربوهيدرات والكهارل لتنظير القولون.

المرضى والطرق: خمسون مريضاً يخضعون لفحص سرطان القولون والمستقيم (CRC) عن طريق تنظير القولون. تم إعطاء جرعة مقسمة من 4 لترات من NUTRIMOV على مدى ثلاثة أيام قبل تنظير القولون.

النتائج: تم تضمين خمسين مريضاً (26 ذكر، متوسط العمر 8±5 سنوات في التحليل النهائي). تم تحقيق تحضير جيد وجيد للأمعاء لدى 72% من المرضى. تم الإبلاغ عن قدرة تحمل المريض جيدة في 43%، ومعتدلة في 42% والفقيرة في 15%. كانت التأثيرات الضارة هي الجوع (22%)، التعب (36%)، آلام البطن (4%)، الانتفاخ (24%)، ولكن لا يوجد قي (0%).

الخلاصة: NUTRIMOV جيد التحمل من قبل المرضى الذين يعانون من معدلات منخفضة من الآثار الضارة ويؤدي إلى معدلات عالية من مستوى التطهير المناسب.