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Research Article

Plenvu Improve Bowel Preparation in Outpatients Undergoing Colonoscopy in a Cost Effective Manner

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Abstract

Background: The efficacy and safety of colonoscopy depend on quality of bowel cleansing. Inadequate preparation require to repeat procedures and increase costs. Objective: To compare the quality of bowel cleansing of Plenvu and standard oral purgatory preparation, to identify risk factors for inadequate preparation and to calculate added costs and repeated procedures.

Methods: Analysis of prospectively collected data of consecutive outpatients undergoing colonoscopy at our center during 3 months.

Results: We included 624 colonoscopies. Plenvu patients were more commonly female (56.6% vs. 51.4% $p < 0.001$) and significantly older [66.5 vs. 57.6 years old, $P < 0.0001$]. Quality of preparation was excellent, good/fair, poor or inadequate in 54.5 vs 26.4%, 32.4 vs 21.6%, 7.8 vs. 25.2% and 5.3 vs 26.8% in Plenvu vs. other PEG prep, respectively ($P < 0.0001$). Multivariate logistic regression showed that age [OR 1.008 per year] male gender [OR 1.407] and constipation as indication [OR 1.401] were independent risk factors for poor preparation while female gender [OR 0.71] were protective. 2-way sensitivity analysis demonstrated Plenvu preparation to be highly cost-effective.

Conclusions: There is a significant economic burden associated with an inadequate bowel cleansing. Use of Plenvu for colon preparation is much more cost effective compared to traditional preparation when considering both direct and indirect costs.

Keywords: *Plenvu; Colonoscopy; Bowel Preparation*

Introduction

Adequate bowel preparation is crucial for high quality colonoscopy [1-4]. Two of the most important quality indicators in colonoscopy, adenoma detection rate (ADR) and cecal intubation rate are influenced by the quality of the bowel preparation [5,6]. Notably Inadequate bowel cleansing poor preparation has been related with increased risks and complications for colonoscopy [6,7]. Inadequate bowel preparation also represents a huge cost to the healthcare system [8]. This cost is attributable to increased duration of the examination and the need for repeated procedures. Numerous bowel cleansing agents are in use for this purpose; however there is a noticeable limitation to their effectiveness due to variations in their tolerability and side effect profile. An ideal bowel cleansing agent should not only be effective in cleansing the bowel, but also well tolerated and convenient to use, with minimal side effect profile. Over the past decade, several new oral preparations have come to market [9]. Many of the newer formulations are being advertised as a "low volume solution" and while they do contain lower volumes of cathartic consumption, in reality the recommended additional fluid intake may approach the usual 4-liter volume for optimal preparation. Recently, a novel bowel preparation for colonoscopy has been made available in Italy marketed as Plenvu (1-L polyethylene glycol (PEG) bowel preparation, NER1006).

Aim of the Study

The aim our study was to compare this new modality of bowel preparation for colonoscopy to standard oral purgatory preparation in outpatients undergoing to colonoscopy, to identify risk factors for inadequate preparation and to calculate added costs in a "real life" set-up.

Methods

Patients

We included 624 consecutive colonoscopies for any indication performed over a period of 3 months looking particularly at the type of prep used, quality of bowel cleansing and if any repeat investigation was required due to poor cleansing. Patients assigned to a standard bowel preparation strategy underwent bowel preparation using a 4 L, 2-day split dose of polyethylene glycol with electrolyte solution (PEG-ELS), as recommended by expert consensus guidelines [10]. All commercially available PEG bowel preparation were acceptable. The alternative to conventional bowel preparation is use of Plenvu. The database was elaborated automatically from the electronic medical records of the patients during regular, real life clinical practice. Collected data includes age, sex, indication for colonoscopy (screening or surveillance, rectal bleeding, anemia, weight loss, abdominal pain, change of bowel habits, suspected inflammatory bowel disease or after a positive occult blood stool test). The efficacy of bowel cleansing was rated using the Boston Bowel Preparation Scale (BBPS) [11], a validated scoring systems applied to each of the three broad regions of the colon: 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). The points assigned 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.
- 3 = Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid. The wording of the scale was finalized after incorporating feedback from three colleagues experienced in colonoscopy.

The endoscopist determined the preparation immediately at the end of each procedure.

Definitions

For the purpose of this study we considered inadequate preparation if less than 90% of the mucosa was seen. For the purpose of cost analysis we defined a procedure as ineffective (i.e. generating costs and exposing patients to risks without benefit) if the preparation was inadequate and the procedure was repeated for the same indication within 30 days of the index colonoscopy. If the preparation was inadequate but the procedure was not repeated, the index procedure was not considered futile and its cost was not calculated.

Statistical analysis

Patients' data and clinical parameters were given as means with 95% confidence intervals in parenthesis, for normally distributed variables. For categorical variables, results were reported as absolute numbers with population proportions (percentages) in parenthesis. To analyze differences in the distribution of categorical data, chi-square test or Fisher exact test was used, as appropriate. Mean differences in continuous variables between the two patient groups (traditional PEG and Plenvu) were analyzed by t-test. Logistic regression with backward stepwise variable selection was used to identify the independent predictors of inadequate bowel preparation. Odds ratios was provided in brackets and 95% confidence intervals in parenthesis. Two-tailed tests with a significance level of 5% were used in all analyses. All calculations were performed using IBM statistics SPSS, Chicago IL.

Results

The complete cohort consisted of 624 colonoscopies; 454 (75%) of the patients had Plenvu prep while 150 (25%) had other PEG preparation. Patients that had Plenvu were more commonly female (56.6% vs 51.4%, *P* < 0.001), significantly older [66.5 (95% CI 66.7 - 69.4) vs 57.66 (95% CI 57.3 - 57.9) years old, *P* < 0.0001], and the main indication for colonoscopy was screening (38% vs 10.5%, *P* < 0.001). In other PEG prep patients the main indication was surveillance (45% vs 8.6%, P< 0.001) (Table 1).

Variable	Plenvu prep (n = 454)	other PEG prep (n = 150)	P value
Mean age (SD)	66.5 (15.45)	57.66 (17.05)	< 0.0001
Gender (% of females)	56.6	51.4	< 0.001
Indication (%)			
Screening/ surveillance	38	10.5	
Rectal bleeding	9.5	37.0	
Abdominal pain	12.1	8.3	
Occult blood	6.0	0.2	
Constipation	4.1	2.1	
Anemia	6.6	13.1	
Weight loss	1.3	0.8	
Diarrhea	2.1	3.7	
Suspected IBD	3.5	1.6	
Other	3.6	10.3	
Unspecified	13.2	12.4	
			< 0.001
Quality of bowel prep (%)			
Excellent	54.5	26.4	
Good/fair	32.4	21.6	
Poor	7.8	25.2	
Inadequate	5.3	26.8	
			< 0.0001

Table 1: *Characteristic of the cohort.*

Quality of preparation: Visibility was rated by the endoscopist as excellent, good/fair, poor or inadequate in 54.5 vs 26.4%, 32.4 vs 21.6%, 7.8 vs 25.2% and 5.3 vs 26.8% in Plenvu vs other PEG prep, respectively (*P* < 0.0001) (Table 1). When the quality of preparation was dichotomized as adequate (more than 90% of mucosa seen) or inadequate (less than 90% of mucosa seen) only 48% of other PEG patients had adequate bowel cleansing compared to 86.9% of Plenvu patients (*P* < 0.0001).

Risk Factors for poor preparation (Table 2): Variables associated with poor preparation at unadjusted logistic regression were, age [OR 1.016 (1.013 - 1.019) per increment in one year], and female gender [OR 0.682 (0.620 - 0.749)]. In univariate analysis, indications associated with poor preparation were rectal bleeding [OR 1.376 (1.195 - 1.858)], occult blood in stool [OR 1.277 (1.053 - 1.548)],

constipation [OR 1.558 (1.256 - 1.932)], and anemia [OR 1.329 (1.116 - 1.583)]. Indications negatively associated with poor preparation were screening or surveillance [OR 0.749 (0.679 - 0.827)], abdominal pain [OR 0.818 (0.704 - 0.951)], and suspected IBD [0.692 (0.521 - 0.920)]. Multivariate logistic regression showed that age [OR 1.008 (1.005 - 1.012) per increment in one year] male gender [OR 1.407 (1.272 - 1.555)] and constipation as indication [1.401 (1.059 - 1.168)] were identified as independent risk factors for poor preparation while female gender [OR 0.711 (0.643 - 0.787)] were protective.

Predictors	Unadjusted OR (95% CI) for poor preparation	P value	Adjusted# OR (95% CI) for poor preparation	P value
Age	1.016 (1.013 - 1.019)*	< 0.0001	1.008 (1.005 - 1.012)*	< 0.0001
Gender (females)	0.682 (0.620 - 0.749)	< 0.0001	0.711 (0.643 - 0.787)*	< 0.0001
Indication (%)				
Screening/surveillance	0.749 (0.679 - 0.827)	< 0.0001	0.822 (0.676 - 1.0)	0.05
Rectal bleeding	1.376 (1.195 - 1.858)	< 0.0001	1.112 (0.889 - 1.362)	
Abdominal pain	0.818 (0.704 - 0.951)	0.009	0.883 (0.702.1.111)	
Occult blood	1.277 (1.053 - 1.548)	0.013	1.171 (0.901 - 1.52)	
Constipation	1.558 (1.256 - 1.932)	< 0.0001	1.401 (1.059 - 1.168)	0.017
Anemia	1.329 (1.116 - 1.583)	0.001	1.05 (0.819 - 1.346)	
Suspected IBD	0.692 (0.521 - 0.920)	0.011	0.83 (0.591 - 1.168)	

Table 2: *Risk factors for inadequate bowel cleansing at logistic regression analysis.*

**: For every increment of one year in age.*

#: Adjusted for age, gender and indication.

Costs: We performed the baseline analysis by taking into account both the direct and indirect costs (i.e. loss of productivity by both the patient and the family, and the cost of travel-related to the procedure) related to colonoscopy. In a baseline analysis, Plenvu proved to be more expensive when compared to traditional PEG preparation (€19.40 vs €16.90, respectively). A 2-way sensitivity analysis using cost of Plenvu preparation and probability of adequate cleansing using the variables input the model. 2-way sensitivity analysis demonstrated Plenvu preparation to be highly cost-effective.

Discussion

Inadequate bowel preparations are the leading cause of failed colonoscopy, which results in delayed diagnosis, repeat procedures, and any accelerated inherent risk associated with procedures. Inadequate bowel cleansing is common; rates of poor preparation were reported to be between 20 and 25% of all colonoscopies [3]. Inadequate visualization of the mucosa is a major drawback on colonoscopy and is associated with multiple negative outcomes [1-13]. The issue of poor preparation in all patients has been extensively studied, the main risk factors are considered to be poor adherence to preparation instructions, incorrect timing of bowel purgative administration, previous inadequate bowel preparation, being single, inpatient status, polypharmacy, obesity, older age, male sex, lower health literacy and multiple comorbidities [6,13,14]. There have been several changes made to traditional preparations in order to overcome its pitfalls (e.g. palatability, lower volumes, etc.) over the past several years, however approximately up to a ¼ of patients undergoing a colonoscopy will have an inadequate preparation. Beyond the immediate disadvantages of an inadequate exam (e.g. delay in diagnosis, unnecessary repeat procedures, and an increase risk of procedure-related complications) the direct and indirect costs to both the patient and the family are evident and considerable. Choosing an optimal bowel preparation requires attention to details such as the patient's medical

history (for example, constipation), ability to understand and comply with instructions, and preference of choice of laxative. Hassan., *et al.* [13] proposed a predictive model based on patients' demographics and comorbidities that could hypothetically decrease the inadequate preparation rate from 33% to 13%. In practice, most endoscopy units prescribe a standard bowel preparation to all patients because individualizing colon preparations can be resource intensive. Recently a low-volume oral preparation has become available as an alternative to traditional purgatory preparations. In the current study, we performed the baseline analysis by taking into account both the direct and indirect costs related to colonoscopy. It should be noted that our database allowed us to calculate only a small portion of the total cost, based only on repeated colonoscopies while only the price of futile procedure was calculated. This in conjunction with the strict pre-specified definition for futility led us to an underestimation of the "real" economic burden of the problem; which in our opinion is substantially higher. The main strengths of our study are the prospectively collected data, the large sample size; therefore this can be considered as a population based "real life" study of prospectively collected data. In this study low quality preparation for colonoscopy was associated with repeated procedures leading to unnecessary risks and increased costs. Even whilst removing indirect costs and analyzing the direct cost of both standard PEG preparation and Plenvu, Plenvu preparation was significantly more cost effective. Currently, however, Plenvu is not being reimbursed by insurance carriers.

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Disclosures

The author declares that she has no financial, personal or professional conflicts of interest relevant to this work.

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