

Rates of Hospitalization and Repeat Procedures in Patients Receiving Sodium Picosulfate/Magnesium Citrate Bowel Preparation Prior to Colonoscopy

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BACKGROUND

- Colorectal cancer (CRC) is the third most common cancer among men and women in the United States (US), with 132,700 new cases and 49,700 deaths expected per year^{1,2}
- Colonoscopy is the gold standard for CRC screening and is the most sensitive method for the detection of CRC and adenomatous polyps³
- Adherence to colonoscopy screening guidelines has been shown to decrease CRC incidence and mortality rates^{4,5}
- Adequate bowel preparation is critical for a safe and effective CRC-screening colonoscopy.⁶ Inadequate bowel preparation is associated with an increased adenoma miss rate and may require an early repeat colonoscopy⁷
- High-volume (HV) preparation products typically require patients to consume up to 4 L of solution and are often poorly tolerated; many patients are unable to consume the entire solution, increasing the risk of a poor preparation. Low-volume (LV) products are better tolerated and have shown similar cleansing quality when compared with HV agents^{6,8,9}
- Prepopik® (Ferring Pharmaceuticals, Inc., Parsippany, NJ) is a sodium picosulfate and magnesium citrate (P/MC) bowel preparation approved in the US for colon cleansing prior to colonoscopy since 2012¹⁰
 - For each dose of P/MC, patients are required to consume 5 oz of medicine followed by 3 or 5 8-oz cups of clear liquids within 5 hours¹⁰
 - P/MC has been shown to be safe and effective when administered in either split-dose or day-before bowel cleansing regimens^{11–13}

OBJECTIVE

- The objective of this retrospective cohort study was to evaluate the incidence of 2 high-cost events (repeat colonoscopy and hospitalization) associated with bowel preparation prior to colonoscopy, and to compare P/MC event rates with those of other LV products, HV products, and other bowel preparation agents

METHODS

- This was a retrospective study of adult colonoscopy or sigmoidoscopy patients identified using the Truven Health Analytics MarketScan database from July 1, 2012, to June 30, 2014
- The study used healthcare encounter records from the MarketScan Commercial Database for patients with private insurance and the MarketScan Medicare Supplemental Database for patients with Medicare and employer-paid supplemental coverage

Inclusion Criteria

- Age ≥18 years
- ≥1 identified colonoscopy or sigmoidoscopy between the study dates
- Medical and pharmacy data available ≥6 months prior to and ≥3 months following the colonoscopy or sigmoidoscopy
- Patient health status was estimated using the Charlson Comorbidity Index (CCI) score¹⁴
 - To minimize potentially confounding comorbidities, patients determined to be at high risk for colon cancer based on medical claims were excluded

Screening Procedures

- Colonoscopies and sigmoidoscopies were identified using claims data for physicians and/or facilities
- For each identified procedure, claims data were used to identify patient demographics, geographic location, patient health status, bowel preparation agent, presence of a repeat procedure, and an associated hospitalization
- The bowel preparation agent associated with each procedure was identified through pharmacy records of the closest filled prescription within 90 days prior to the colonoscopy or sigmoidoscopy
- All solution-based bowel preparations were classified as HV (≥4 L solution) or LV (<4 L solution) based on their approved labeling and directions for use (**Table 1**)
- Tablet-based agents were categorized as “other bowel preparations”

Table 1. Classification of Bowel Preparations

LV Products	HV Products	Other Bowel Preparations
HalfLyte ^{®a}	Colyte ^{®c}	OsmoPrep ^{®b}
MoviPrep ^{®b}	GaviLyte ^{™d}	Visicol ^{®b}
Suclear ^{®a}	GoLYTELY ^{®a}	
Suprep ^{®a}	NuLYTELY ^{®a}	
	TriLyte ^{®e}	

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HV, high-volume; LV, low-volume.

Study Endpoints

- An early repeat screen was identified as any colonoscopy within 90 days of the initial procedure, which is much sooner than current guidelines recommend¹⁵
- An associated hospitalization was defined as any hospitalization with an admission date within 10 days of an identified procedure
- The total number and proportion of repeat screening examinations were compared between patients who received P/MC and those who received other LV products, HV products, and other bowel preparations
- Total hospitalizations and the proportion of non-CRC hospitalizations were compared between patients who received P/MC and those who used other LV products, HV products, and other bowel preparations

Statistical Methods

- Patient demographics, patient health status, presence of repeat procedures, and associated hospitalizations were summarized using descriptive statistics
- Multivariate logistic regression was used to evaluate the association between preparation agent and the likelihood of a repeat screen or hospitalization, with adjustment for age, sex, geography, and CCI score

RESULTS

Patient Population

- Applying the inclusion criteria to the database yielded 566,628 total procedures (**Table 2**)
- Mean age for all patients was 56.4 years, and 53.5% were female
- CCI scores indicate the patient population had a relatively low comorbidity burden

Table 2. Population Characteristics

	Bowel Preparation Products				
	P/MC	Other LV ^a	HV	Other	All Agents
Number of procedures	33,574	391,063	123,853	18,138	566,628
Mean age, years (SD)	55.1 (10.6)	56.0 (10.8)	58.1 (11.2)	55.0 (10.7)	56.4 (10.9)
Female, %	58.2	53.3	51.4	64.1	53.5
Mean CCI (SD)	0.49 (1.07)	0.54 (1.16)	0.69 (1.35)	0.45 (1.05)	0.56 (1.19)
Geographic region, %					
Northeast	23.6	19.8	15.7	18.9	19.1
Midwest	11.6	19.1	23.7	19.2	19.7
South	49.8	41.1	27.4	43.8	38.9
West	13.0	18.0	31.1	15.3	20.5
Other	2.0	1.6	2.2	2.8	1.8

^aLVs except P/MC.

CCI, Charlson Comorbidity Index; HV, high-volume; LV, low-volume; P/MC, sodium picosulfate and magnesium citrate; SD, standard deviation.

Repeat Screening Events

- The rate of repeat colonoscopy or sigmoidoscopy in patients receiving P/MC was not different compared with other patients overall (1.8% vs. 1.8%, respectively) (**Table 3**)

Table 3. Early Repeat Screening Events

	Bowel Preparation Products				
	P/MC	Other LV ^a	HV	Other	All Agents
Number of procedures	33,574	391,063	123,853	18,138	566,628
Repeat screenings, n (%)	613 (1.8)	6,495 (1.7)	2,913 (2.4)	362 (2.0)	10,383 (1.8)

^aLVs except P/MC.

HV, high-volume; LV, low-volume; P/MC, sodium picosulfate and magnesium citrate.

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*Precision Health Economics is a division of Precision for Value.

Hospitalizations

- A total of 3,433 hospitalizations were identified. The rate of non-CRC hospitalization (per 1,000 screens) was 3.78 for P/MC, 5.01 for other LV bowel preparation products, and 6.13 for HV products
- There were no hospitalizations for hyponatremia or dehydration in patients receiving P/MC (**Table 4**)
- The logistic regression model found no significant relationship between P/MC and these hospitalizations ($P=0.32$)

Table 4. Number of Hospitalizations

	Bowel Preparation Products				
	P/MC	Other LV ^a	HV	Other	All Agents
Number of procedures	33,574	391,063	123,853	18,138	566,628
Total hospitalizations	154	2,298	888	93	3,433
CRC-related	27	338	129	11	505
Non-CRC-related	127	1,960	759	82	2,928
Diverticulitis	10	199	56	8	273
Hyponatremia	0	13	1	1	15
Dehydration	0	7	1	0	8
Other ^b	117	1,741	701	73	2,632

^aLVs except P/MC; ^bHospitalization for any cause other than CRC, diverticulitis, hyponatremia, or dehydration.

CRC, colorectal cancer; HV, high-volume; LV, low-volume; P/MC, sodium picosulfate and magnesium citrate.

CONCLUSIONS

- In a real-world study of outcomes associated with bowel cleansing agents, P/MC compared favorably with other LV products, HV products, and other bowel preparations
- Patients who received P/MC had no hospitalizations with a diagnosis of hyponatremia, dehydration, or other fluid disorders within 10 days of a colonoscopy/sigmoidoscopy
- Repeat procedure rates for patients who received P/MC were not significantly different from rates for those who used other bowel preparation products

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