

Efficacy and Safety of the 1-Liter NER1006 Bowel Preparation for Colonoscopy in Adults With Comorbid Conditions That May Impact Prep Quality

Brooks D. Cash, MD¹; David Poppers, MD, PhD²; Soo Han Yoon, PharmD³; Christopher Allen, MS³; Prateek Sharma, MD⁴

¹University of Texas Health Science Center at Houston, Houston, TX; ²NYU Langone Health, New York, NY; ³Salix Pharmaceuticals, Bridgewater, NJ; ⁴University of Kansas School of Medicine and VAMC, Kansas City, KS

INTRODUCTION

- For a successful colonoscopy, a high-quality, tolerable bowel preparation is imperative for lesion detection¹⁻⁴
- Patient-specific factors, such as certain comorbid conditions (eg, constipation, diabetes, and neurologic/neuropsychiatric disorders), can negatively impact bowel prep quality^{1,3}
- NER1006 is a low-volume (1 L) polyethylene glycol (PEG)-based bowel prep (Plenvu®, Norgine Ltd, Tir-Y-Berth Hengoed, United Kingdom) indicated for colon cleansing in preparation for colonoscopy in adults⁵
- Given that certain comorbid conditions are risk factors for inadequate bowel prep, a subgroup analysis was conducted to assess the cleansing quality of NER1006 versus 2L PEG plus ascorbate (2L PEG) in those at risk^{6,7}

AIM

- To evaluate the efficacy and safety of NER1006 versus 2L PEG in patients subgrouped by comorbid conditions and medical procedures (CCMPs) that can impact bowel prep quality

METHODS

- A pooled post hoc analysis was conducted of two phase 3 trials (NOCT⁸ and MORA⁹) of adults undergoing colonoscopy who were randomly assigned to receive a PM/AM split-dose regimen of NER1006 or 2L PEG (Figure 1)

Figure 1. Bowel Prep Dosing Regimens*^{16,7}

NOCT		MORA	
Day Before Colonoscopy	Day of Colonoscopy	Day Before Colonoscopy	Day of Colonoscopy
NER1006 (PM/AM)	NER1006 (PM/AM)	NER1006 (PM/AM)	NER1006 (PM/AM)
Dose 1: 6:00 PM	Dose 2: 6:00 AM	Dose 1: 6:00 PM	Dose 2: 6:00 AM
		2L PEG (PM/AM)	2L PEG (PM/AM)
		Dose 1: 6:00 PM	Dose 2: 6:00 AM

*2L PEG dietary restrictions were consistent with the summary of product characteristics/prescribing information. NER1006 regimens allowed a light breakfast and light lunch. 2L PEG regimen allowed for meals, including a light dinner, on the day before colonoscopy. [†]Trisulfate solution arm in NOCT study and NER1006 AM/AM split-dosing arm in MORA study were not included in the current analysis. MORA = morning arm; NOCT = nocturnal pause arm; 2L PEG = 2-liter polyethylene glycol plus ascorbate.

METHODS

- Patients were subgrouped based on medical history of CCMP of interest that included prior gastrointestinal surgery (ie, anal fistula excision/fistula repair, appendectomy, cholecystectomy, colon operation, gastric bypass, and small intestinal resection/operation), cerebrovascular accident, cirrhosis, constipation, dementia, diabetes mellitus, epilepsy, hysterectomy, major depressive disorder, parkinsonism, quadriplegia, schizoaffective disorder, and schizophrenia
- Overall colon cleansing success rates were assessed using the:
 - Boston Bowel Preparation Scale⁹ (BBPS; success defined as overall score ≥ 6 , with score ≥ 2 in each segment [right, transverse, and left colon]) and
 - Harefield Cleansing Scale⁹ (HCS; success defined as all 5 colonic segments scored 3 [clear liquid] or 4 [empty and clean] or ≥ 1 segment scored 2 [brown liquid/fully removable semi-solid stools] and other segments scored 3 or 4 [ie, good/excellent])
- Good/excellent cleansing quality for each segment (free of stool; score 3 or 4) using the HCS was also determined
- Adenomas were detected by site colonoscopists and confirmed by histopathology
- P values were determined using a Chi-square test

RESULTS

- 248 patients were included in the analysis (Table)
 - The most common CCMPs of interest in the overall population (n=248) were hysterectomy (33.9%), appendectomy (30.6%), cholecystectomy (23.4%), diabetes (21.4%), and constipation (15.7%)
 - A higher percentage of patients in the NER1006 group compared with the 2L PEG group had diabetes mellitus and/or constipation; in the 2L PEG group, a higher percentage had a prior hysterectomy and/or appendectomy

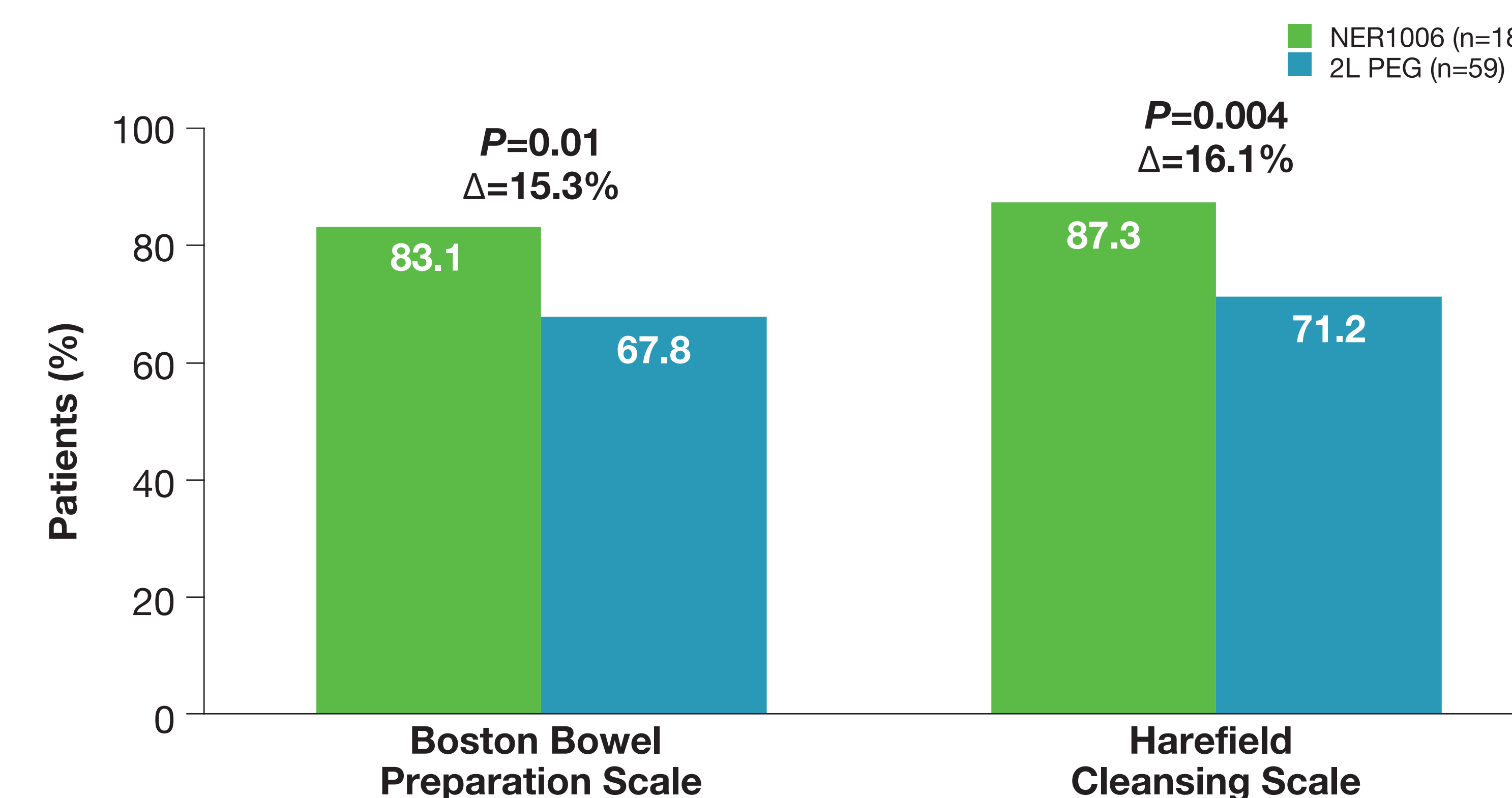
Table. Demographics and Baseline Characteristics

Parameter	NER1006 (n=189)	2L PEG (n=59)
Age		
Mean (SD), y	58.9 (10.7)	56.6 (11.4)
Range, y	23-86	22-75
>65 years of age, n (%)	51 (27.0)	10 (16.9)
Female, n (%)	126 (66.7)	41 (69.5)
Race, n (%)		
White	164 (86.8)	59 (100)
Black	21 (11.1)	0
Asian	4 (2.1)	0
Most common CCMPs, n (%)*		
Hysterectomy	60 (22.8)	24 (29.6)
Appendectomy	53 (20.2)	23 (28.4)
Cholecystectomy	46 (17.5)	12 (14.8)
Diabetes mellitus	47 (24.9)	6 (10.2)
Constipation	33 (12.5)	6 (7.4)
Anal fistula excision	0	2 (2.5)
Cerebrovascular accident	2 (0.8)	0

* >1 patient per treatment arm. Patients may have had >1 CCMP of interest. 2L PEG = 2-liter polyethylene glycol plus ascorbate; CCMPs = comorbid conditions and medical procedures.

RESULTS

Figure 2. Overall Cleansing Success Rates in Patients With a CCMP of Interest



2L PEG = 2-liter polyethylene glycol plus ascorbate; CCMP = comorbid condition and medical procedure.

- NER1006 was significantly more effective than 2L PEG in overall colon cleansing success rates when assessed using the BBPS or HCS (Figure 2)
- High-quality (good/excellent) cleansing in each colonic segment was significantly higher with NER1006 compared with 2L PEG using the HCS, except for the sigmoid colon (Figure 3)
- In addition, a higher percentage of patients had an adenoma detected in the ascending colon in the NER1006 versus 2L PEG groups, but the difference was not statistically significant (14.3% vs 6.8%, respectively; $P=0.13$)
- NER1006 and 2L PEG bowel preps were well tolerated
 - No patients in NER1006 group and 1 patient in the 2L PEG group failed to complete the bowel prep due to an adverse event
 - There was 1 serious adverse event of ileus in the NER1006 group; this event was not considered to be treatment-related

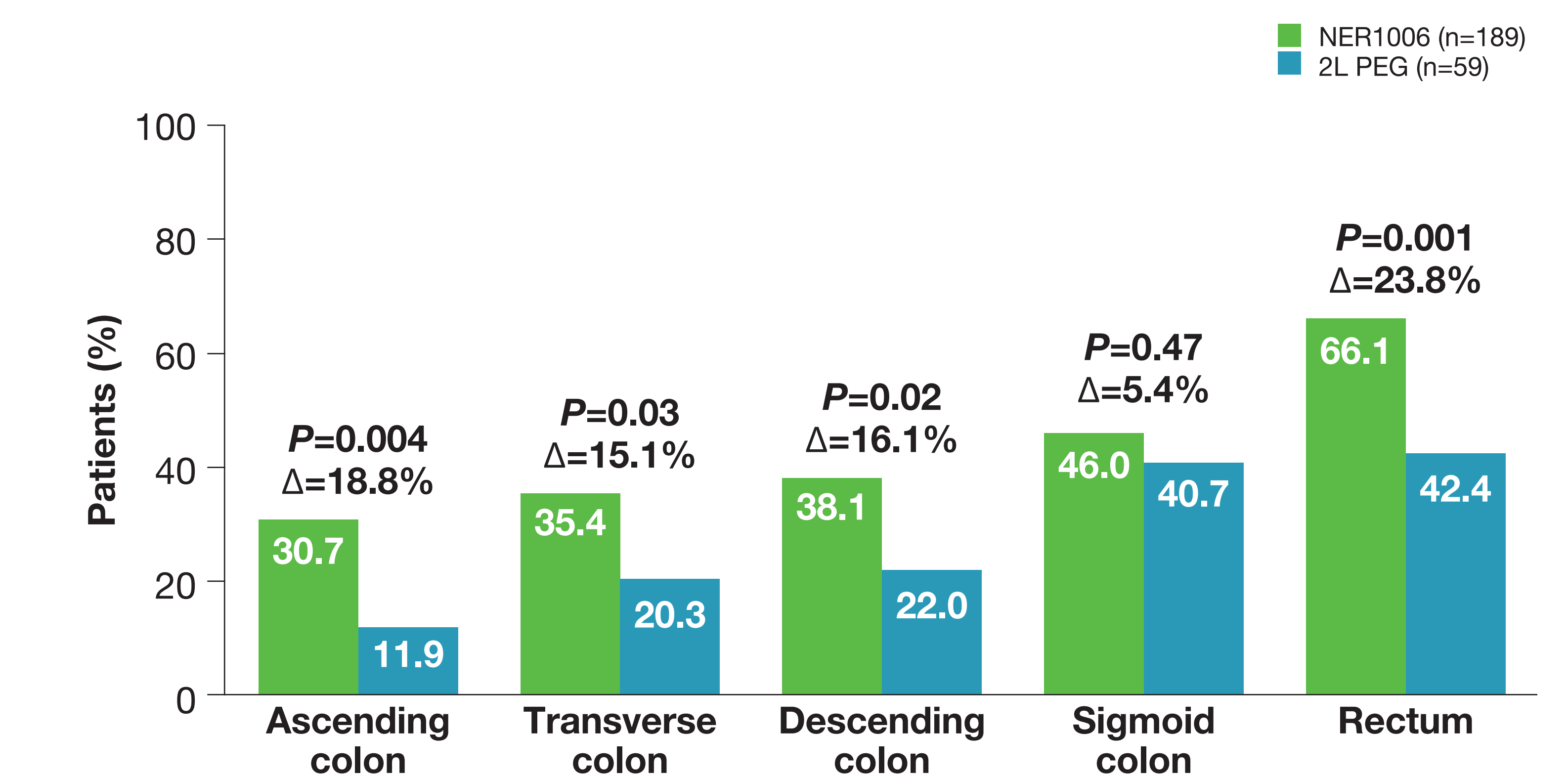
REFERENCES: 1. Feng L, et al. *J Evid Based Med*. 2024;17(2):341-350. 2. Sharma P, et al. *Endosc Int Open*. 2020;8(5):E673-E683. 3. D'Souza SM, et al. *Br J Gastroenterol*. 2019;1(1):106-115. 4. Froehlich F, et al. *Gastrointest Endosc*. 2005;61(3):378-384. 5. Plenvu® [polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride for oral solution] [package insert]. Amsterdam, The Netherlands: Norgine BV; 2023. 6. DeMicco MP, et al. *Gastrointest Endosc*. 2018;87(3):677-687. 7. Bisschops R, et al. *Endoscopy*. 2019;51(1):60-72. 8. Lai EJ, et al. *Gastrointest Endosc*. 2009;69(3 Pt 2):620-625. 9. Halphen M, et al. *Gastrointest Endosc*. 2013;78(1):121-131.

ACKNOWLEDGMENTS: The phase 3 trials were supported by Norgine BV and the post hoc analyses were supported by Salix Pharmaceuticals. Medical writing and technical editorial assistance were provided under direction of the authors by Mary Beth Moncrief, PhD, Synchrony Medical Communications, LLC, West Chester, PA. Funding for this assistance was provided by Salix Pharmaceuticals.

DISCLOSURES: BDC reports serving on the speakers' bureau, as a consultant, or as an advisory board member for Salix Pharmaceuticals. DP reports being a consultant and serving on the speakers' bureau for Salix Pharmaceuticals. SY and CA are employees of Salix Pharmaceuticals. PS reports being a consultant for Salix Pharmaceuticals.

PLENVU® is a registered trademark of the Norgine group of companies used under license.

Figure 3. High-Quality Bowel Cleansing (HCS) in Patients With a CCMP of Interest, by Colonic Segment



2L PEG = 2-liter polyethylene glycol plus ascorbate; CCMP = comorbid condition and medical procedure.

CONCLUSION

- 1L NER1006 provided superior cleansing (good/excellent) compared with 2L PEG as a bowel preparation for colonoscopy in adults with comorbid conditions that can impact bowel prep quality