

Improving Safety, Efficacy, and Tolerability of Preparation for Endoscopy



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Disclosures

- Ambu INC.

Types of Bowel Preparations

ISO-OSMOTIC

- PEG-ELS (Golytely, CoLyte) 4 L +/- Bisacodyl
- PEG-ELS + Ascorbic Acid (MoviPrep 3L, Plenvu 2L)
- PEG-ELS + Sulfate Free (NuLyteLy, TriLyte)

HYPEROSMOTIC

- Sodium Sulfate (SuPrep 3L, Sutab 3L)

COMBINATION AGENTS

- Sodium picosulfate/MgOx/Citric Acid (Prepopik 2L)

Preparation contents	Total volume ingested	Regimen	Safety
PEG-ELS	4 L	2 L solution evening prior 2 L solution morning of colonoscopy	- Needs to be ingested quickly - Safe in renal failure, congestive heart failure, and liver disease - Poor palatability and can cause nausea, vomiting, and bloating
PEG-ELS Bisacodyl 5 mg	2 L	Bisacodyl 5 mg with sip of water and 1 L PEG-ELS evening prior 1 L PEG-ELS morning of colonoscopy	- Low volume, better tolerated - Risk of ischemic colitis with increasing doses of bisacodyl ≥ 10 mg
PEG-ELS Sodium ascorbate ascorbic acid	2.95 L (99.6 oz)**	1 L preparation with 16 oz of water evening prior 1 L preparation with 16 oz water morning of colonoscopy	- Contains phenylalanine - Use with caution in glucose-6-phosphate dehydrogenase deficient patients
Sodium phosphate	1.89 L (64 oz)	20 tablets with 40 oz of water evening prior 12 tablets with 24 oz water morning of colonoscopy	- Lower volume - Avoid in diarrhea and IBD*** patients as can cause colonic mucosal architecture distortion and mimic colitis - Can cause acute phosphate nephropathy
Magnesium citrate	2.31 L (78 oz)	15 oz Mg citrate solution with 24 oz water evening prior 15 oz Mg citrate solution with 24 oz water morning of colonoscopy	- Avoid in elderly and patients with renal dysfunction - Patients may need to drink up to 64 oz of additional water with evening dose
Sodium sulfate potassium sulfate magnesium sulfate	2.84 L (96 oz)	16 oz preparation and water followed by 32 oz of water evening prior 16 oz preparation and water followed by 32 oz water morning of colonoscopy	- Avoid in patients with renal failure - Avoid in patients with gout as may cause increased uric acid levels
PEG 3350 without ELS gatorade	1.9 L (64 oz)	238-255 g Miralax with 1.9 L Gatorade with 0.95 L evening prior 0.95 L morning of colonoscopy	- Avoid in CHF and cirrhosis - Risk of hyponatremia - Does not work as well as PEG-ELS alone
Sodium picosulfate magnesium oxide citric acid	2.19 L (74 oz)	5 oz preparation and 40 oz of water evening prior 5 oz preparation and 24 oz of water morning of colonoscopy	- Avoid in renal failure
Sodium picosulfate magnesium oxide citric acid+magnesium citrate	2.3 L (78 oz)	2 sachets with 150 mL water followed by 1 L water evening prior 1 sachet with 150 mL water followed by 1 L water	- Avoid in renal failure - Avoid in elderly patients - More common in Japan and South Korea
Sodium phosphate	1.6 L (54 oz)	45 mL and 45 mL water evening prior 45 mL and 45 mL water morning of colonoscopy Must drink 6-8 8 oz clear liquid throughout preparation	- Avoid in renal failure, congestive heart failure, cirrhosis, and IBD - Risk of phosphate nephropathy - Not used much in United States and Europe
Sodium phosphate	1.66 L (56 oz)	4 tablets with 8 oz clear liquid every 15 min (total of 20 tablets) evening prior 4 tablets with 8 oz clear liquid every 15 min (total of 8 tablets) morning of colonoscopy	- Avoid in renal failure, congestive heart failure, cirrhosis, and IBD - Risk of phosphate nephropathy - Not used much in United States and Europe - Common clear liquid is ginger ale - Some add bisacodyl for improved efficacy



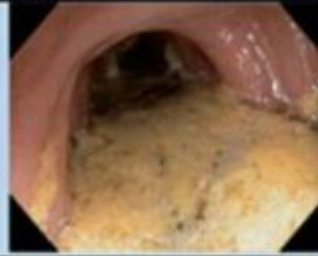
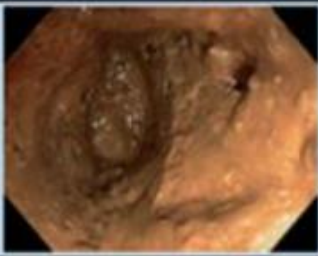
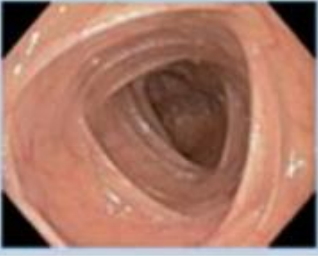



*PEG-ELS, polyethylene glycol with electrolytes; **oz, fluid ounces; ***IBD, inflammatory bowel disease

Non-FDA Approved Bowel Preparations

- “Miralax Prep”
 - Low volume PEG 3350 + sports drink with Bisacodyl = 2L
 - Inexpensive
 - Possible risk of electrolyte imbalance compared to 4L PEG-ELS (mixed data)
- Magnesium Citrate (~30oz Mg citrate with 6 cups water)
 - Hyperosmotic prep
 - Can cause fluid and electrolyte imbalance
 - Avoid in renal insufficiency, CHF, cirrhosis, electrolyte abnormalities

Table 3. Boston Bowel Preparation Score²⁰

Score	Definition
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.

BBPS	3	2	1	0
3=Excellent				
2=Good				
1=Poor				
0=Inadequate				

Introduction to Bowel Preparations: Timing

- Split Dose Prep
 - Half of the colon cleansing agent the evening prior
 - Second half the morning of the colonoscopy
 - ~5 hours pre-procedure
 - Best for AM colonoscopy patients
 - More effective, better tolerated, increased ADR
- Split Dose > Single Dose / Evening Before



Bucci C et al. Gastrointestinal Endoscopy 2014; 80(4):566-572.

Kilgore TW et al. Gastrointestinal Endoscopy 2011; 73(6):1240.

“Inadequate” Bowel Prep

- Inadequate in up to 25% of colonoscopy
- Poor prep:
 - Increased adverse events
 - Lengthens procedure time
 - Reduced interval times between procedures
 - Lower cecal intubation rates
 - Lower adenoma detection rates (ADR)
 - Healthcare cost



Frøehlich F et al. Gastrointestinal Endoscopy 2005; 61 (3):378.

Risks for Inadequate Preps

- Risk Factors for Inadequate Prep
 - Prior Inadequate Prep
 - History of Constipation
 - Constipation inducing medications (opioids)
 - Dementia / Parkinsons Disease
 - Male
 - Obesity
 - Diabetes Mellitus
 - Cirrhosis
 - Low health literacy / patient engagement
 - Procedure related: Later Procedures / Non-split dose prep



**Consider TWO DAY
PREP!!**

DDW ABSTRACT #1

Low volume bowel preparation is associated with reduced time to colonoscopy in hospitalized patients: a propensity matched analysis

Christopher L.F. Sun^{1,2}, Darrick K. Li³, Ana Cecilia Zenteno^{2,4}, Marjory A. Bravard^{5,6}, Peter Carolan^{5,7}, Bethany Daily^{2,4}, Sami Elamin^{5,6}, Jasmine Ha⁶, Amber Moore^{5,6}, Kyan Safavi^{2,4,5}, Brian J. Yun^{5,8}, Peter Dunn^{2,4,5}, Retsef Levi¹, James M. Richter^{5,7}

Massachusetts General & Massachusetts Institute of Technology

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Background

Adequate bowel cleansing is a critical component in the care of inpatients requiring diagnostic or therapeutic colonoscopy.

Inadequate bowel preparation is associated with worse clinical outcomes:

- Increased rates of complications
- Missed pathologic lesions
- Repeated bowel preparation medication administration
- Aborted colonoscopy procedures

Approximately 30-50% of inpatients undergoing colonoscopy suffer from inadequate colon cleansing

Among outpatients, low volume bowel preparations (LV-BPs), e.g., *sodium sulfate, potassium sulfate, and magnesium sulfate* (Suprep), has increased preparation quality and tolerability, compared to high volume bowel preparations (HV-BPs), e.g., *polyethylene glycol* (PEG)

Efficacy of LV-BPs in hospitalized patients is unclear, especially given their high medical acuity and comorbidities

Goal

Evaluate the impact of LV-BP, compared to HV-BP (split-dose PEG-based), on four clinical and operational outcomes:

- Time to colonoscopy after gastroenterology consultation
- Quality of bowel preparation
- Hospital LOS in hospitalized
- Bowel preparation completion after a single medication order

SUPREP[®] BOWEL PREP KIT

(sodium sulfate, potassium sulfate
and magnesium sulfate)
Oral Solution (17.5g/3.13g/1.6g)
per 6 ounces



[Visit Website](#)

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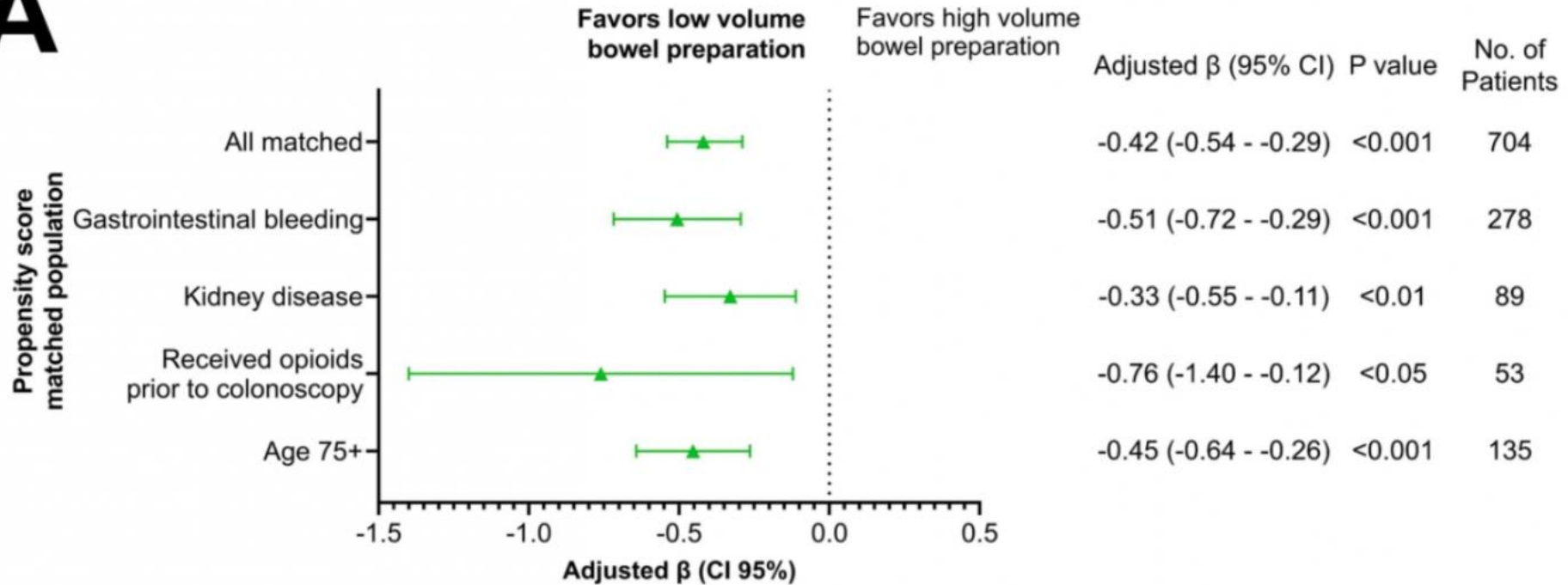


Methods

- Single Center, retrospective, observational study
- Included hospitalized adult (18+) patients from Jan 2018-Jan 2021 undergoing colonoscopy
 - LV BP available from June 2020 onward
- Statistical methods
 - propensity score matching
 - multivariate regression
 - secondary analysis

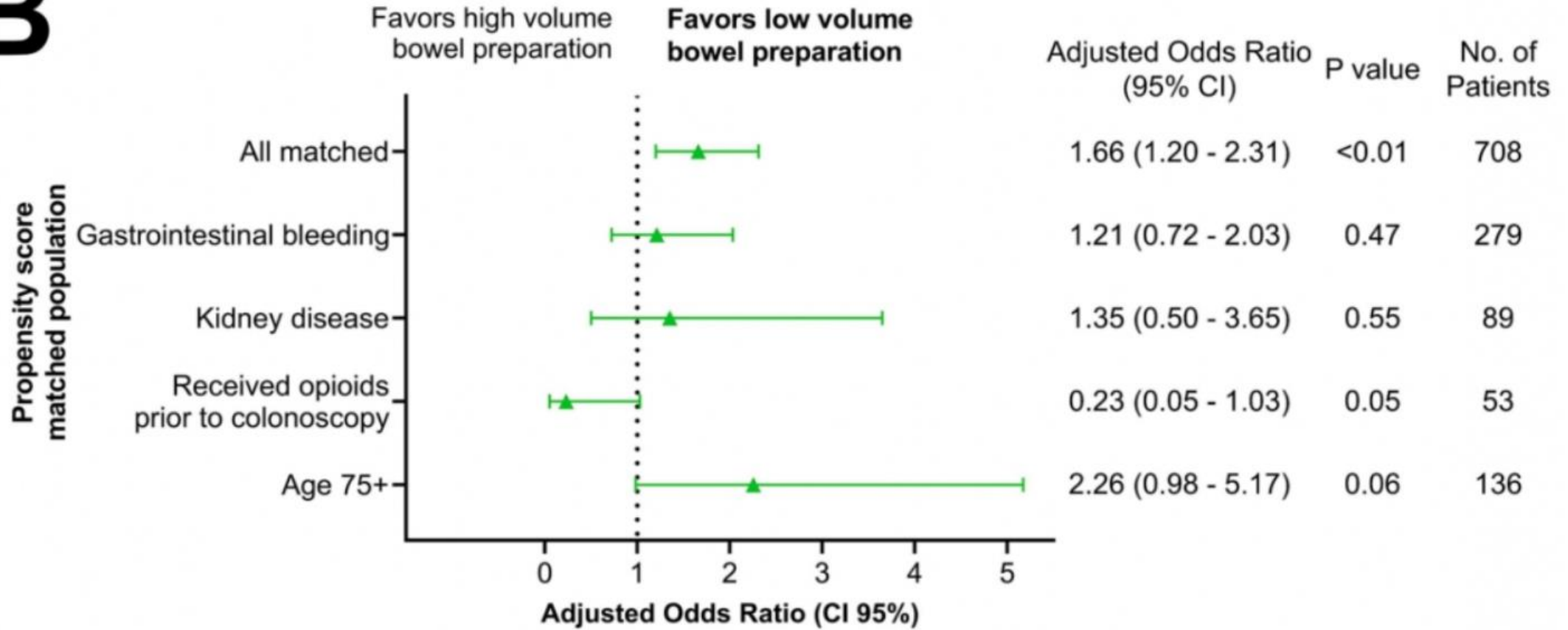
Results

Outcomes	Full population, n = 1,807			1:2 Propensity score matched population, n = 708		
	Low volume, n = 293	High volume, n = 1514	P-value	Low volume, n = 249	High volume, n = 459	P-value
Duration of time from first bowel preparation order administration to colonoscopy (days), median (IQR)	1.1 (0.9 - 1.9)	1.5 (1.0 - 2.1)	<0.001	1.2 (0.9 - 1.9)	1.2 (1.0 - 2.1)	<0.05
Completion of bowel preparation with one preparation order, % (N)	58.7% (172)	46.6% (705)	0.11	58.2% (145)	46.6% (214)	0.25
Hospital LOS (days), median (IQR)	5.7 (3.8 - 9.8)	5.9 (3.7 - 11.4)	0.17	5.7 (3.8 - 9.0)	5.8 (3.6 - 9.7)	0.46
Aronchick Scale Rating						
1 (Excellent), % (N)	31.1% (73)	15.7% (182)	<0.001	29.1% (58)	15.7% (54)	<0.001
2 (Good), % (N)	31.1% (73)	42.9% (498)	<0.001	31.2% (62)	43.7% (150)	<0.01
3 (Fair), % (N)	11.9% (28)	13.0% (151)	0.73	12.1% (24)	12.0% (41)	0.92
4 (Poor), % (N)	14.5% (34)	15.4% (179)	0.79	15.1% (30)	16.3% (56)	0.79
5 (Inadequate), % (N)	11.5% (27)	13.0% (151)	0.60	12.6% (25)	12.2% (42)	0.98

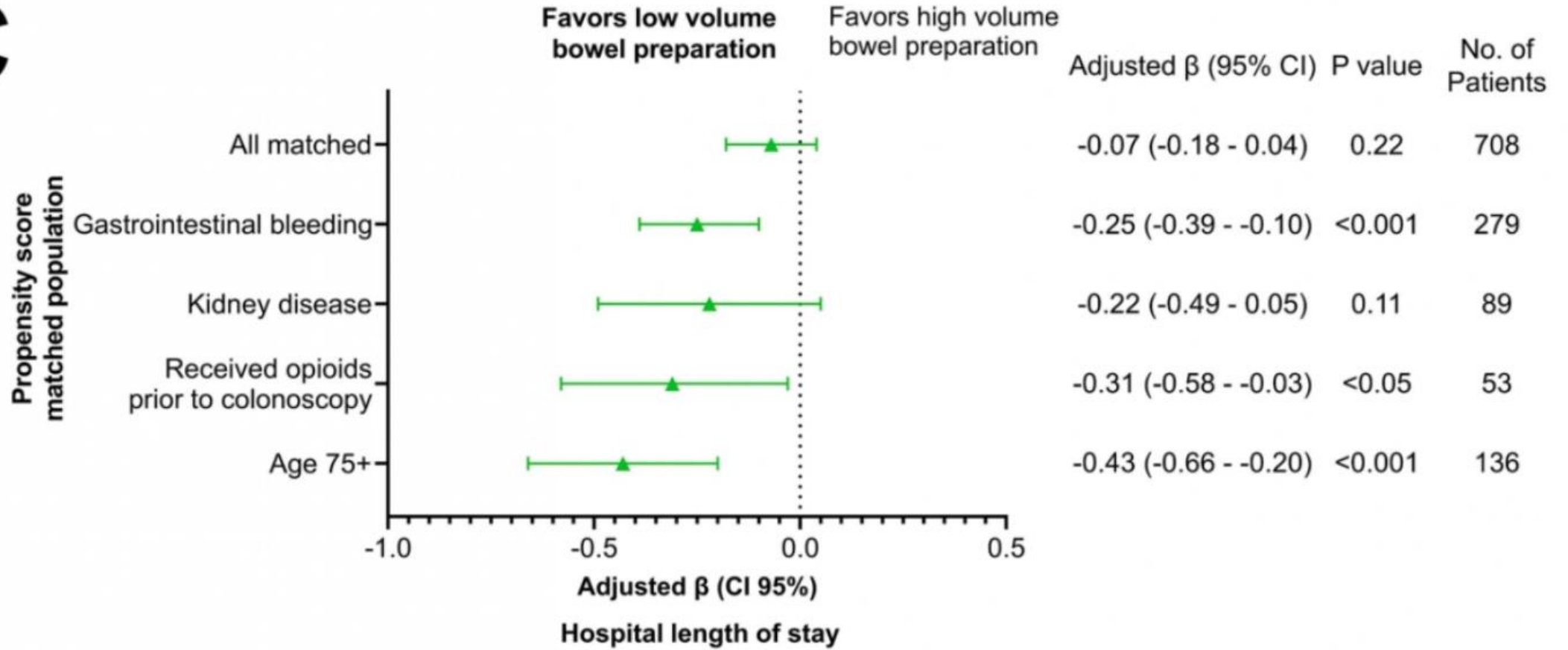
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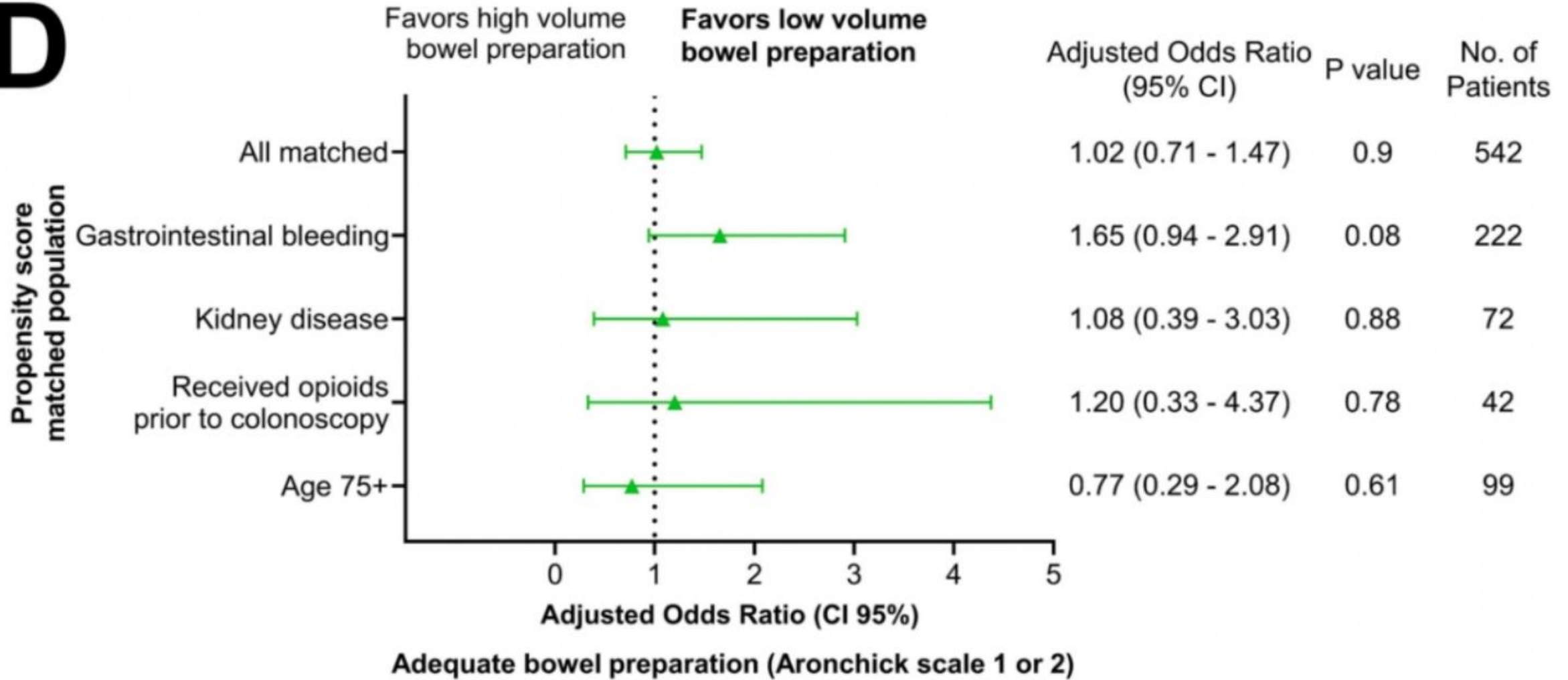
Duration of time from the administration of the first bowel preparation order to the colonoscopy

B



Bowel preparation completion with one bowel preparation medication order

C

D

DDW CONCLUSION

LV-BP use among inpatient populations significantly reduces the time from bowel preparation to colonoscopy and thus may decrease avoidable hospital bed days and excess healthcare costs.

- Suggests that LV-BPs may be better tolerated with a similar degree of bowel preparation quality compared to traditional HV-BPs.
- Cost-effectiveness analyses and randomized controlled trials can provide support to decisions regarding the wide adoption of LV-BPs for inpatients

DDW ABSTRACT #2

Efficacy and safety of very low-volume bowel preparation with 1 L Plenvu® comparison with 2 L polyethylene glycol + ascorbate: Multicenter, randomized, endoscopist-blinded study

Sung Noh Hong, Chang Kyun Lee, Jong Pil Im, Chang Hwan Choi, Jeong-Sik Byeon, Young-Seok Cho, Sung-Ae Jung, Tae Il, Kim, Yoon Tae Jeon

AIM

: To evaluate the **efficacy and safety** of lower-volume **1L PEG-based bowel preparation (Plenvu)** compared with the **2L PEG + ascorbate (Clicool)** bowel preparation in **Korean population**.

INTRODUCTION

Polyethylene glycol (PEG)-based bowel preparation regimens
→ **Effective & Safe, however ...**

Large-volume (2–4 L)



Patient compliance



Impact on efficacy

Plenvu®
1L very low volume PEG-based
bowel preparation agents

- 3 RCTs (MORA, DAYB, NOCT)
- : Non-inferior to 2L PEG with ascorbate, triphosphate, and pico-sulfate
- : European & North American countries

Methods

- Multi-center (9 Korean Hospitals), randomized, endoscopist blinded study
- Adults (18-80) undergoing colonoscopy (screening+diagnostic)

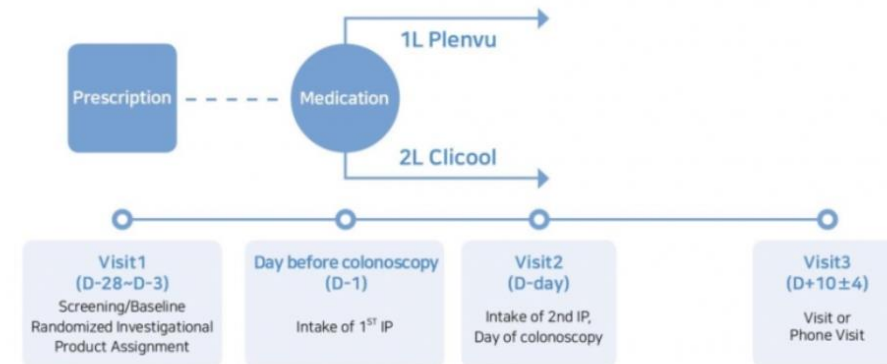
Primary End Point: “overall bowel cleansing success”
BBPS >2 per segment

Secondary End Point:

- Segmental bowel cleansing success rate
- High Quality Bowel Cleansing
- ADR
- Tolerability + Acceptability

METHOD

- Multicenter, randomized, endoscopist-blinded study



- **Patient baseline characteristics**

	mITT		<i>p</i>	PP		<i>p</i>
	Plenvu group (n=174)	2L PEG group (n=172)		Plenvu group (n=159)	2L PEG group (n=162)	
Age, Mean ± SD	51.05 ± 13.28	50.68 ± 13.48	0.768	50.74 ± 13.37	50.78 ± 13.32	0.952
Gender						
Male, n(%)	84(48.28)	73(42.44)	0.276	78(49.06)	67(41.36)	0.166
Female, n(%)	90(51.72)	99(57.56)		81(50.94)	95(58.64)	
Weight, Mean ± SD	67.93 ± 12.56	65.91 ± 12.28	0.124	67.79 ± 12.53	65.93 ± 12.53	0.164

- Primary outcome
: Overall bowel cleansing efficacy

mITT analysis : 93.10% (162/174) vs. 91.86% (158/172)



Each colonic seg BBPS score ≥ 2

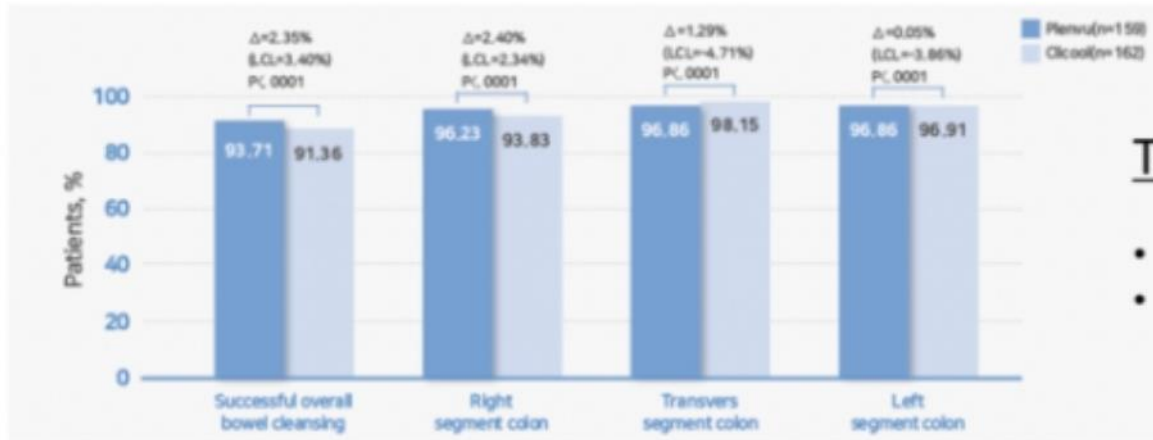
Total BBPS score

- Plenvu group : 7.85 ± 1.45
 - 2L PEG group : 7.58 ± 1.37
- $p = 0.0302$

1L PEG-Asc showed non-inferiority in successful bowel cleansing compared with 2L PEG-Asc

- Primary outcome
: Overall bowel cleansing efficacy

PP analysis : 93.71% (149/159) vs.91.36% (148/162)



Total BBPS score

- Plenvu group : 7.83 ± 1.45
- 2L PEG group : 7.58 ± 1.40

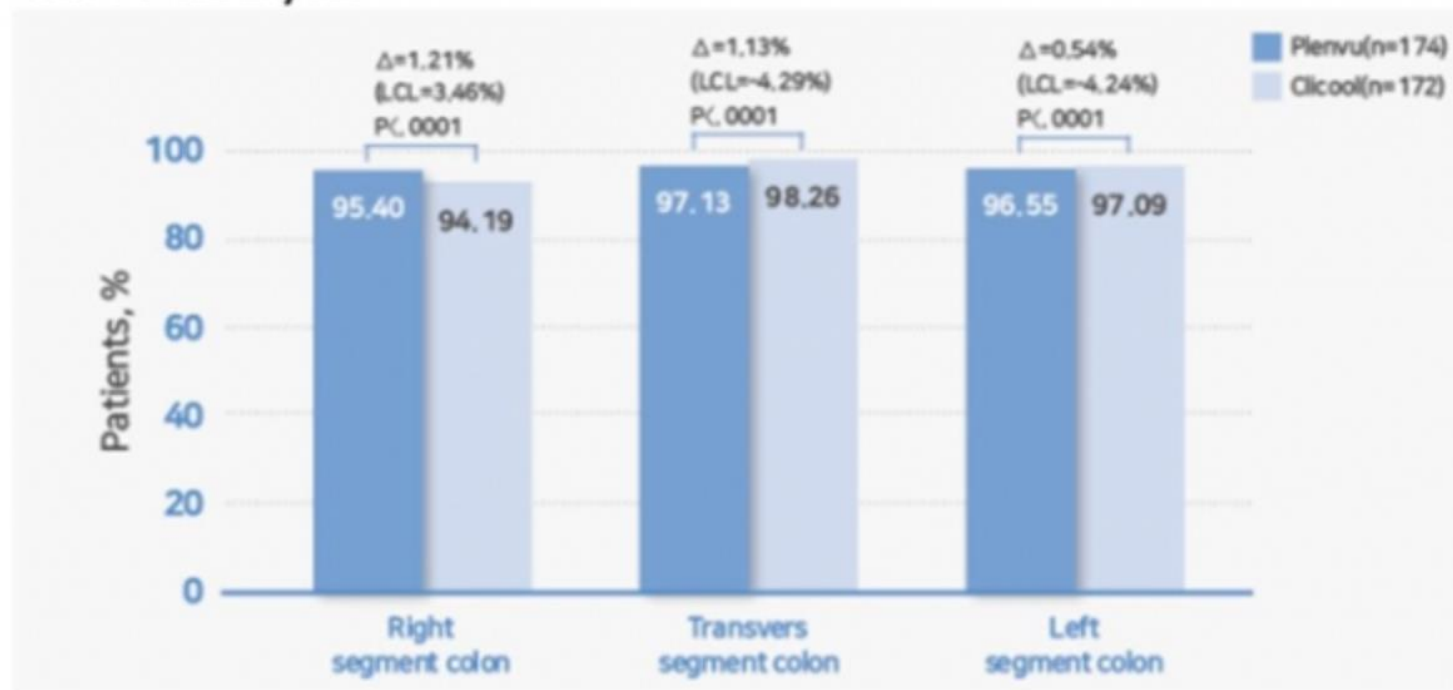
$p = 0.0689$

1L PEG-Asc showed non-inferiority in successful bowel cleansing compared with 2L PEG-Asc

- Segmental Bowel Cleansing Efficacy

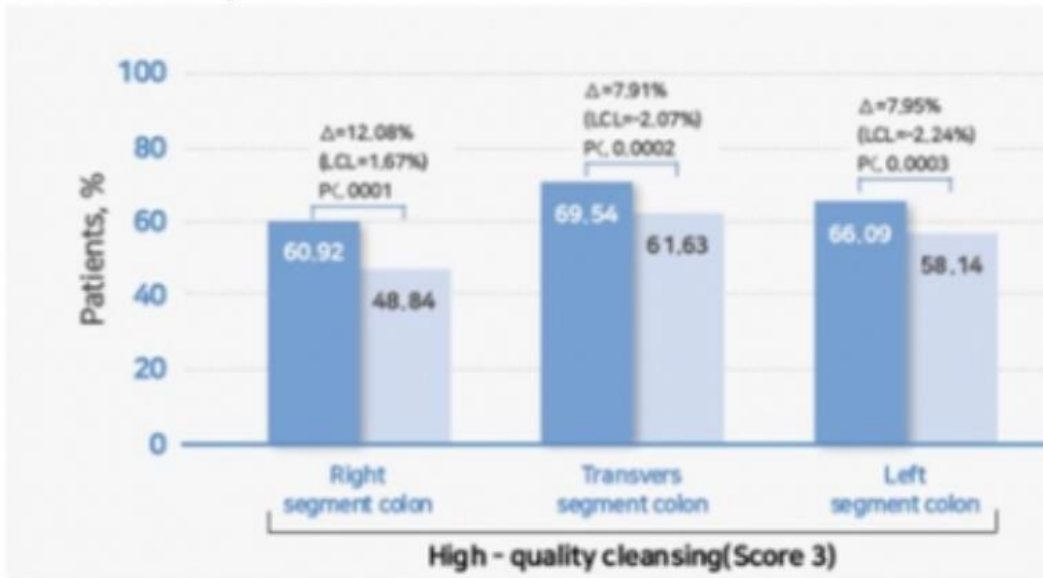
mITT analysis

Each colonic seg BBPS score ≥ 2

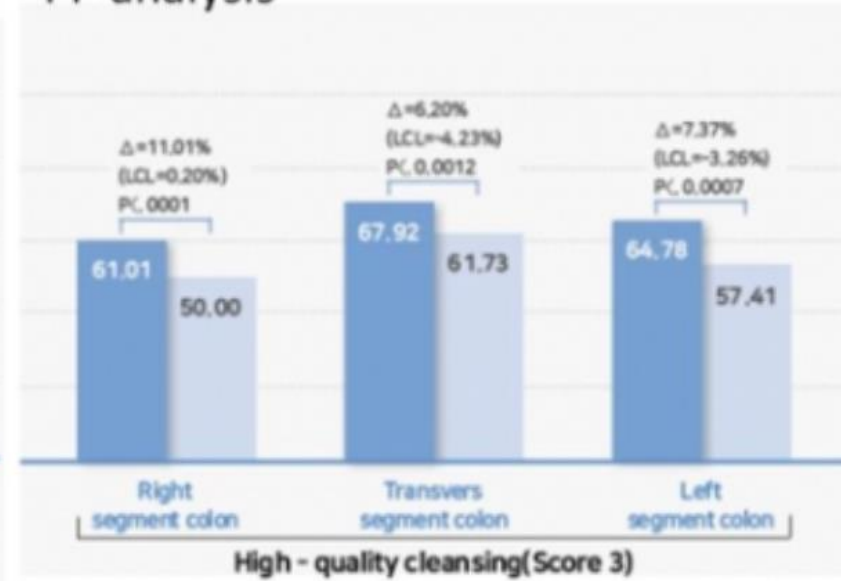


- **High quality bowel cleansing (BPPS = 3)**

MITT analysis

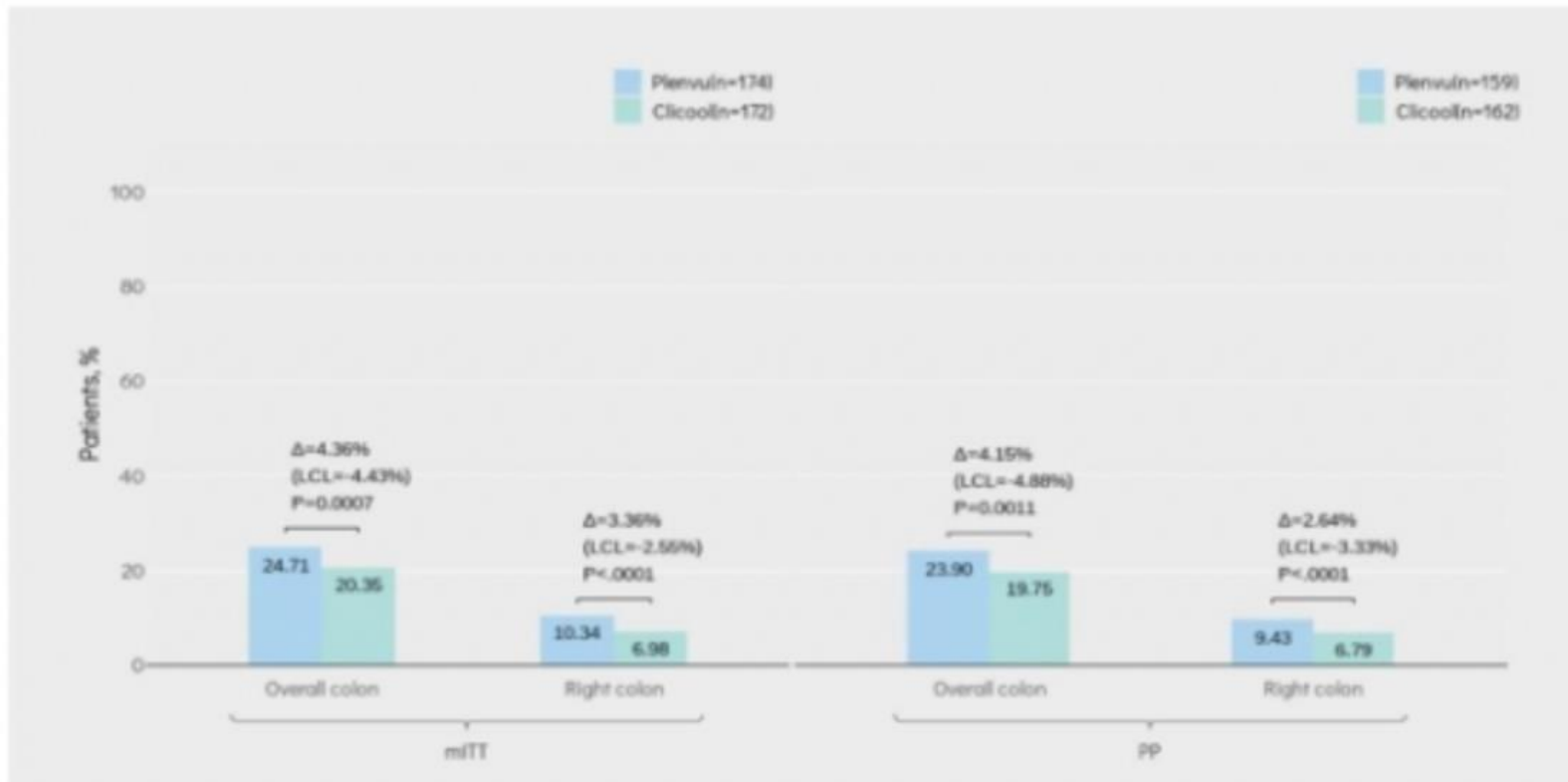


PP analysis



→ 1L PEG-Asc showed non-inferiority in high quality bowel cleansing at each colonic segment compared with 2L PEG-Asc

- **Adenoma detection rate**



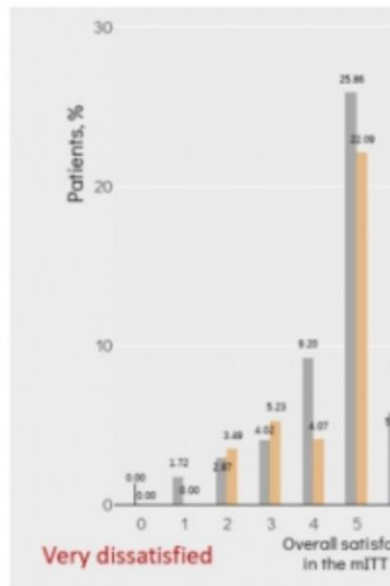
→ **ADR** of Plenuvu group was numerically higher than that of 2L PEG group (24.71% vs. 20.35%, p = 0.3314).

Adherence

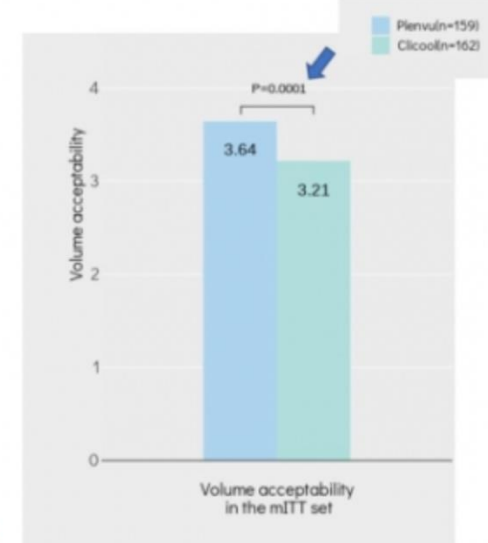
- How much did you take yesterday and today with the 1st and 2nd medications (including water)?

Total dose ordered	Plenvu 2L PEG
3/4 degree	Plenvu 2L PEG

Overall satisfaction



	Total TEAE (n=519)		Plenvu group (n=302)		2L PEG group (n=217)	
	N	%	N	%	N	%
Gastrointestinal system	396	76.30%	225	74.50%	171	78.80%
Abdominal distension	126	24.28%	62	20.53%	64	29.49%
Abdominal pain	67	12.91%	34	11.26%	33	15.21%
Nausea	142	27.36%	86	28.48%	56	25.81%
Vomiting	60	11.56%	42	13.91%	18	8.29%
Toothache	1	0.19%	1	0.33%	0	0.00%
General symptoms	48	9.25%	28	9.27%	20	9.22%
Chills	46	8.86%	26	8.61%	20	9.22%
Temperature intolerance	1	0.19%	1	0.33%	0	0.00%
Thirst	1	0.19%	1	0.33%	0	0.00%
Nervous system	69	13.29%	45	14.90%	24	11.06%
Dizziness	66	12.72%	44	14.57%	22	10.14%
Headache	2	0.39%	1	0.33%	1	0.46%
Lethargy	1	0.19%	0	0.00%	1	0.46%
Cardiovascular system	2	0.39%	2	0.66%	0	0.00%
Hypertension	1	0.19%	1	0.33%	0	0.00%
Palpitations	1	0.19%	1	0.33%	0	0.00%
Musculoskeletal systems	2	0.39%	0	0.00%	2	0.92%
Arthralgia	1	0.19%	0	0.00%	1	0.46%
Musculoskeletal pain	1	0.19%	0	0.00%	1	0.46%
Psychiatric symptoms	1	0.19%	1	0.33%	0	0.00%
Insomnia	1	0.19%	1	0.33%	0	0.00%
Respiratory system	1	0.19%	1	0.33%	0	0.00%
Hemoptysis	1	0.19%	1	0.33%	0	0.00%



Efficacy and safety of very low-volume bowel preparation with 1 L Plenvu® comparison with 2 L polyethylene glycol + ascorbate: Multicenter, randomized, endoscopist-blinded study

Sung Noh Hong, Chang Kyun Lee, Jong Pil Im, Chang Hwan Choi, Jeong-Sik Byeon, Young-Seok Cho, Sung-Ae Jung, Tae Il, Kim, Yoon Tae Jeon

DDW Conclusion: 1L PEG-Asc was as effective as 2L PEG-Asc in bowel cleansing and polyp detection rate in this study.

DDW ABSTRACT #3

NER1006 1 Liter Polyethylene Glycol–Based Bowel Preparation Safety Profile in Patients With Mild or Moderate Renal Impairment: a Pooled Analysis of Two Phase 3 Trials

Brooks D. Cash, MD¹; Christopher Allen, MS²; Prateek Sharma, MD³

INTRODUCTION

- NER1006 (Plenvu[®], Salix Pharmaceuticals, Bridgewater, NJ), a 1 L polyethylene glycol (PEG)-based bowel preparation, was approved in the United States in 2018 for colon cleansing in preparation for colonoscopy in adults^{1,2}
- Two randomized, phase 3 studies evaluating the US-indicated dosing regimens (2-day evening/morning [PM/AM] split dosing or 1-day morning [AM/AM] split dosing) demonstrated that NER1006 was efficacious and well tolerated^{2,3}
- In patients with decreased renal function, bowel preparations may increase the risk of electrolyte imbalances or worsen renal function^{1,4}
- Due to their iso-osmotic nature, PEG-based bowel preparations are generally preferred in patients with renal insufficiency^{5,6}
- Data are limited on the safety profile of low-volume PEG products (eg, 1 L) in patients with renal insufficiency

OBJECTIVE: EVALUATE SAFETY PROFILE OF NER1006 IN PATIENTS WITH RENAL IMPAIRMENT UNDERGOING COLONOSCOPY

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METHODS

- Data were pooled from two phase 3, randomized studies (NOCT and MORA)
- Patients (aged 18–85 years) undergoing colonoscopy were randomly assigned to NER1006 as a 2-day evening/morning (PM/AM) or 1-day morning/morning (AM/AM) split-dosing regimen^{2,3}
- Per protocol, mild renal insufficiency was defined as creatinine clearance (CrCl) ≥ 60 to < 90 mL/min/1.73 m² and moderate as CrCl ≥ 30 to < 60 mL/min/1.73 m²
 - Moderate renal insufficiency was an exclusion criterion in NOCT, and severe disease (CrCl < 30 mL/min/1.73 m²) was an exclusion criterion in both trials
- Safety (adverse events [AEs] and clinical lab testing) was assessed, per protocol, through 7 ± 1 days post-colonoscopy
- In a post hoc analysis, worsening renal function (ie, increase from baseline in creatinine > 0.3 mg/dL or decrease from baseline in calculated CrCl of $> 25\%$) definition was derived from RIFLE (risk, injury, failure, loss, end-stage kidney disease) criteria
- The intent to treat (ITT) population included all patients randomly assigned to treatment; the safety population included those in the ITT population for whom it could not be ruled out that they had received ≥ 1 dose of NER1006 (based on patient diary)

RESULTS

- 524 and 269 adults were included in the NER1006 PM/AM and the NER1006 AM/AM groups, respectively (**Table 1**)
 - The majority of patients in each treatment group had mild-to-moderate renal insufficiency (67.6%–73.6%)
- To assess a risk of worsening renal function, patients who showed an increase from baseline in creatinine >0.3 mg/dL or a decrease from baseline in calculated CrCl of >25% were identified
 - The number of patients, subgrouped by renal insufficiency, meeting 1 or both of these criteria was low, with no signal of renal injury related to NER1006 observed
- In addition, these changes did not persist; only 1 patient (baseline mild renal insufficiency; AM/AM split dose) with a change in renal function at Day 2 ± post-colonoscopy met the same criteria (for CrCl) at Day 7 ± 1 days post-colonoscopy

Table 1. Demographic and Baseline Characteristics (Safety Population)

Parameter	NER1006 PM/AM (n=524)	NER1006 AM/AM (n=269)
Age, y, mean (SD)	57.0 (11.1)	54.9 (13.2)
Age >65 y, n (%)	118 (22.5)	60 (22.3)
Sex, n (%)		
Male	243 (46.4)	124 (46.1)
Female	281 (53.6)	145 (53.9)
Race, n (%)		
White	477 (91.0)	266 (98.9)
Black	39 (7.4)	3 (1.1)
Asian	7 (1.3)	0
Other	1 (0.2)	0
BMI, mean (SD), kg/m²	28.4 (5.3)*	26.9 (4.3)
Reason for colonoscopy, n (%)		
Screening	287 (54.8)	136 (50.6)
Surveillance	143 (27.3)	57 (21.2)
Diagnostic	94 (17.9)	76 (28.3)
Renal insufficiency status, n (%)		
Mild	340 (64.9)	184 (68.4)
Moderate	14 (2.7)	14 (5.2)
None	166 (31.7)	68 (25.3)
Unknown	4 (0.8)	3 (1.1)

*n=523.

BMI = body mass index; SD = standard deviation.



Table 2. AE Profile of Patients Treated With NER1006, by Renal Insufficiency Status (Safety Population)*

Patients, n (%)	Renal Insufficiency					
	NER1006 (PM/AM) Split-Dosing Regimen			NER1006 (AM/AM) Split-Dosing Regimen		
	Mild [†] (n=340)	Moderate [‡] (n=14)	None (n=166)	Mild [†] (n=184)	Moderate [‡] (n=14)	None (n=68)
Any AE	77 (22.6)	5 (35.7)	36 (21.7)	28 (15.2)	4 (28.6)	17 (25.0)
Drug-related AEs	48 (14.1)	3 (21.4)	19 (11.4)	24 (13.0)	4 (48.6)	12 (17.6)
AEs leading to discontinuation	0	0	0	0	0	1
Most common AEs[§]						
Nausea	22 (6.5)	1 (7.1)	10 (6.0)	11 (6.0)	1 (7.1)	2 (2.9)
Vomiting	18 (5.3)	0	9 (5.4)	12 (6.5)	2 (14.3)	4 (5.9)
Other AEs of interest						
Abdominal pain	1 (0.3)	1 (7.1)	1 (0.6)	1 (0.5)	0	0
Dehydration	7 (2.1)	0	2 (1.2)	2 (1.1)	0	2 (2.9)
Dry mouth	2 (0.6)	1 (7.1)	0	2 (1.1)	0	1 (1.5)
Fatigue	2 (0.6)	0	2 (1.2)	0	0	0
Feeling cold	0	0	0	0	0	1 (1.5)
Headache	6 (1.8)	0	3 (1.8)	2 (1.1)	0	0
Thirst	2 (0.6)	0	0	2 (1.1)	1 (7.1)	2 (2.9)

*All patients randomized to treatment in whom it could not be ruled out that they received NER1006 at least once, per patient diary.

[†]CrCl ≥60 to <90 mL/min/1.73 m².

[‡]CrCl ≥30 to <60 mL/min/1.73 m².

[§]Most common AEs reported in overall population of the NOCT and MORA studies.

AE = adverse event; CrCl = creatinine clearance.

NER1006 1 Liter Polyethylene Glycol–Based Bowel Preparation Safety Profile in Patients With Mild or Moderate Renal Impairment: a Pooled Analysis of Two Phase 3 Trials

Brooks D. Cash, MD¹; Christopher Allen, MS²; Prateek Sharma, MD³

CONCLUSION

- Data support the overall safety profile of 1 L PEG-based NER1006 as a bowel preparation, including in patients with mild-to-moderate renal insufficiency

THANK YOU

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