# Updates in Bowel Prep for 2022

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## Faculty/Presenter Disclosure

- **Faculty: Dr. Richard Sultanian**
- **Relationships with commercial interests:**
  - **Grants/Research Support:** None
  - **Speakers Bureau/Honoraria:** None
  - **Consulting Fees:** None
  - **Other:** Employee at the University of Alberta Hospital

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## Objectives

1. Review high level insights from the national B-CLEAN series of clinical trials on bowel preparation
   - Low volume vs. high volume split dose bowel prep
   - Same day vs. split dose bowel prep
   - Day before vs. split dose bowel prep
2. Learn an evidence-based approach to failed bowel preparation
3. Gain knowledge of a new bowel preparation product recently available in Canada

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## Why does a good bowel preparation matter?

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## Why does a good bowel preparation matter?

- Direct correlation with diagnostic accuracy and therapeutic safety of colonoscopy
- *Adequate bowel preparation is an essential quality indicator for colonoscopy*
- **Inadequate** bowel preparation leads to:
  - Higher complication rate
  - Incomplete colonoscopies
  - Decreased polyp detection (PDR) and adenoma detection rate (ADR)
  - Increased need to repeat/increase in cost

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## What are the clinically approved bowel preparation?

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## What are the clinically approved bowel preparation?

- FDA Approved Bowel Preps:
  - PEG Based
  - Sodium picosulfate
  - Oral sulfate
- In Alberta approved provincial preparations:
  - PEG 4L (Colyte, Peglyte)
  - Sodium picosulfate (Picosalax)
  - Oral Sulfate (KleanLyte)
  - PEG + bisacodyl (Bi-Peglyte)

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## Provincial Standardized Prep Info



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# What is the optimal prep?

- **Volume?**
- **Timing?**

- **Focus on PEG based preparations**
- **→ B-CLEAN**

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# B-CLEAN

- The Bowel CLEAnsing – A National Initiative (B-CLEAN) was a 10-centre nationwide 12-arm RCT aimed at answering multiple questions related to bowel preparation
  - University of British Columbia (Jennifer Telford)
  - University of Alberta (Richard Sultanian)
  - University of Calgary (Robert Hilsden)
  - University of Manitoba (Harminder Singh)
  - Western University (Michael Sey)
  - Ottawa University (Paul James)
  - McGill University (Alan Barkun) **(Principal Investigator)**
  - Université de Montréal (Daniel von Renteln)
  - Université Laval (Pierre Hallé)
  - Dalhousie University (Ian Epstein)

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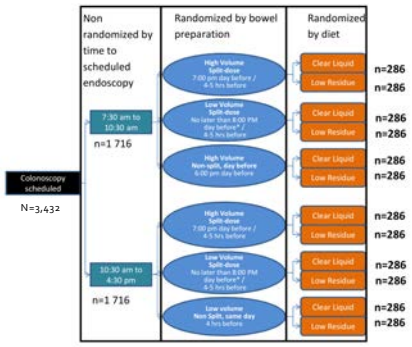
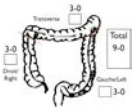



# OUTCOMES: CLEANLINESS

Boston Bowel Prep Scale (BBPS)

| Visual description | BBPS score |
|---|---|
| Entire mucosa of colon segment seen well with no residual staining, small fragments of stool, or opaque liquid | 3 |
| Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well | 2 |
| Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen because of staining, residual stool, and/or opaque liquid | 1 |
| Unprepared colon segment with mucosa not seen because of solid stool that cannot be cleared | 0 |




- High inter (ICC=0.91) and intra-rater (κ=0.78) reliabilities
- Adequate defined as segment scores ≥2 in each segment

Calderwood. Gastrointest Endosc 2010;72:686-92.
Calderwood. Gastrointest Endosc 2014;80:269-70.

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# OUTCOMES: TOLERABILITY

- Willingness to repeat preparation
- % of bowel preparation consumed
- Validated Bowel Preparation Tolerability Questionnaire[1]

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1. Lawrence. Dig Dis Sci 2013;58:926-35.

# PATIENT CHARACTERISTICS

| | All patients N=3473 |
|---|---|
| Age | 56.3 ± 13.3 |
| Female | 53.2% |
| BMI | 27.8 ± 14.4 |
| Help required for preparation directive | 1.0% |
| Known IBD | 7.3% |
| Received colonoscopy in the past | 58.1% |
| Previous failed colonoscopy | 4.0% |
| Narcotic use in the last 24 hours | 3.3% |
| Chronic laxative use or known medication induced constipation | 9.5% |
| Functional constipation* | 9.8% |
| Indication | |
| Non screening | 37.8% |
| Screening | 37.4% |
| Surveillance | 24.8% |

'Table 1' for entire trial population but patient characteristics for the cohort that defines each group comparison are comparable

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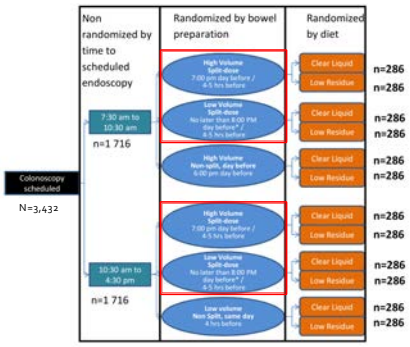
# HIGH VS. LOW VOLUME SPLIT DOSE

# HIGH VS. LOW VOLUME SPLIT DOSE

- 2,314 patients randomized to:
  - 1,157 to high volume split dose
    - 2L PEG night before
    - 2L PEG morning of procedure
  - 1,157 to low volume split dose
    - 15 mg bisacodyl 2 PM day before
    - 1L PEG night before
    - 1L PEG morning of procedure


*

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*All boxing references courtesy of Dr. M. Sey!

# EFFICACY

| Variable | PegLyte Split-dose High-volume N=1,157 | BiPegLyte Split-dose Low-volume N=1,157 | p-value |
|---|---|---|---|
| Primary outcome | | | |
| Adequate*-no. (%) | 966 (90.1%) | 936 (88.1%) | 0.02 |
| BBPS total score-mean (SD) | 7.37 ± 1.66 | 7.15 ± 1.78 | <0.01 |
| BBPS score right mean (SD) | 2.37 ± 0.64 | 2.31 ± 0.66 | 0.02 |
| BBPS score transverse mean (SD) | 2.51 ± 0.61 | 2.44 ± 0.66 | 0.01 |
| BBPS score left mean (SD) | 2.48 ± 0.63 | 2.37 ± 0.72 | <0.01 |
| | | | |
| Adequate ≥5-no. (%) | 1010 (94.9%) | 985 (92.7%) | 0.02 |
| Adequate ≥7-no. (%) | 706 (66.4%) | 663 (62.4%) | 0.03 |

Barkun. Clin Gastroenterol Hepatol 2021;Online ahead of print

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# EFFICACY

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| Adequate ≥7-no. (%) | 706 (66.4%) | 663 (62.4%) | 0.03 |

Statistically significant but perhaps not clinically meaningful

Barkun. Clin Gastroenterol Hepatol 2021;Online ahead of print

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# TOLERABILITY

| Variable | PegLyte Split-dose High-volume N=1,157 | BiPegLyte Split-dose Low-volume N=1,157 | p-value |
|---|---|---|---|
| Willingness to repeat the preparation | 602 (66.9%) | 891 (91.9%) | <0.01 |
| Tolerance (scale of 1-10) mean +/- Std | 7.2 ± 2.3 | 8.1 ± 1.9 | <0.01 |
| Symptoms | | | |
| Unpleasant taste | 433 (41.1%) | 425 (39.6%) | 0.50 |
| Excessive thirst | 109 (10.4%) | 79 (7.4%) | 0.02 |
| Nausea | 175 (16.6%) | 127 (11.9%) | <0.01 |
| Vomiting | 62 (5.9%) | 32 (3.0%) | <0.01 |
| Bloating | 218 (20.8%) | 141 (13.2%) | <0.01 |
| Abdominal pain - Cramp | 113 (10.8%) | 91 (8.5%) | 0.08 |
| Headache | 157 (14.9%) | 129 (12.1%) | 0.06 |
| Dizziness | 41 (3.9%) | 36 (3.4%) | 0.53 |
| Sleep disturbance | 164 (15.7%) | 124 (11.6%) | <0.01 |
| Perianal irritation | 187 (17.9%) | 109 (10.3%) | <0.01 |
| Chills | 323 (30.7%) | 191 (17.9%) | <0.01 |
| Compliance | | | |
| 100% compliance | 781 (72.9%) | 931 (84.9%) | <0.01 |
| 85% compliance | 938 (87.6%) | 1046 (95.4%) | <0.01 |
| 80% compliance | 962 (89.8%) | 1056 (96.3%) | <0.01 |

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## TAKE HOME MESSAGE

- Split dose low volume PEG (BiPegLyte™) has comparable clinical efficacy to high volume split dose PEG (PegLyte™) but is much better tolerated
- Consider PegLyte™ or BiPegLyte™ as 1st line bowel preps

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## SPLIT DOSE VS. SAME DAY PREP


## SPLIT DOSE VS. SAME DAY PREP

- 1,750 subjects randomized to:
  - 583 to same day bowel prep
    - 15 mg bisacodyl 2 PM day before
    - 2L PEG morning of procedure
  - 585 to low volume split dose
    - 15 mg bisacodyl 2 PM day before
    - 1L PEG night before
    - 1L PEG morning of procedure
  - 582 to high volume split dose
    - 2L PEG night before
    - 2L PEG morning of procedure


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## EFFICACY

| Variable | "Same day prep" Low-volume same-day | "Split dose 4L PEG" High-volume split-dose | P value | "Split dose BiPegLyte" Low-volume split-dose | P value | "Split dose 4L PEG or BiPegLyte" Combined high-/low-volume split-dose | P value |
|---|---|---|---|---|---|---|---|
| Primary outcome | | | | | | | |
| Adequate,* no. (%) | 478 (90.5%) | 495 (92.2%) | 0.34 | 474 (87.9%) | 0.17 | 969 (90.1%) | 0.76 |
| BBPS total score, mean (SD) | 7.50 ± 1.70 | 7.44 ± 1.59 | 0.52 | 7.11 ± 1.78 | <0.01 | 7.27 ± 1.69 | 0.01 |
| BBPS score right, mean (SD) | 2.45 ± 0.64 | 2.39 ± 0.62 | 0.12 | 2.30 ± 0.66 | <0.01 | 2.34 ± 0.64 | <0.01 |
| BBPS score transverse, mean (SD) | 2.56 ± 0.62 | 2.53 ± 0.60 | 0.51 | 2.43 ± 0.66 | <0.01 | 2.48 ± 0.61 | 0.02 |
| BBPS score left, mean (SD) | 2.47 ± 0.68 | 2.52 ± 0.60 | 0.30 | 2.37 ± 0.70 | <0.01 | 2.44 ± 0.66 | 0.36 |
| Adequate ≥5, no. (%) | 499 (94.5%) | 517 (96.3%) | 0.17 | 500 (92.8%) | 0.24 | 1,017 (94.5%) | 0.99 |
| Adequate ≥7, no. (%) | 379 (71.8%) | 361 (67.2%) | 0.11 | 337 (62.5%) | <0.01 | 698 (64.9%) | <0.01 |

BBPS, Boston Bowel Preparation Scale.
*Defined as a BBPS cutoff of ≥6 with all segment scores ≥2.

Barkun. Am J Gastoenterol 2020;115:2068-76.

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# EFFICACY

"Split dose 4L PEG" "Split dose BiPegLyte" "Split dose 4L PEG or BiPegLyte"

"Same day prep"

| Variable | Low-volume same-day | High-volume split-dose | *P* value | Low-volume split-dose | *P* value | Combined high-/low-volume split-dose | *P* value |
|---|---|---|---|---|---|---|---|
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# EFFICACY

"Split dose 4L PEG" "Split dose BiPegLyte" "Split dose 4L PEG or BiPegLyte"

"Same day prep"

| Variable | Low-volume same-day | High-volume split-dose | *P* value | Low-volume split-dose | *P* value | Combined high-/low-volume split-dose | *P* value |
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# EFFICACY

"Split dose 4L PEG" "Split dose BiPegLyte" "Split dose 4L PEG or BiPegLyte"

"Same day prep"

| Variable | Low-volume same-day | High-volume split-dose | *P* value | Low-volume split-dose | *P* value | Combined high-/low-volume split-dose | *P* value |
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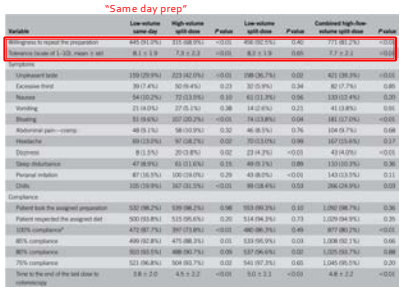
# TOLERABILITY

"Same day prep"



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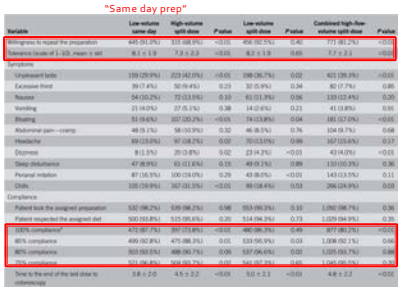
## TOLERABILITY

"Same day prep"



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## TAKE HOME MESSAGE

- Same day prep is roughly equivalent to low volume split dose and high volume split dose in achieving adequate bowel prep
- Same day prep and high volume split dose may be a bit better at achieving a cleaner colon beyond 'adequate'
- Same day and low volume split dose bowel preps are better tolerated than high volume split dose prep

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## DAY BEFORE VS. SPLIT DOSE PREP


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## DAY BEFORE VS. SPLIT DOSE PREP

- 1,726 subjects randomized to:
  - 579 to 'day before' bowel prep
    - 4L PEG night before
  - 572 to low volume split dose
    - 15 mg bisacodyl 2 PM day before
    - 1L PEG night before
    - 1L PEG morning of procedure
  - 575 to high volume split dose
    - 2L PEG night before
    - 2L PEG morning of procedure


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# EFFICACY

| | Day before high-volume N=579 | Split-dose high-volume N=575 | p-value | Split-dose low-volume N=572 | p-value | (High or Low) split-dose N=1147 | p-value |
|---|---|---|---|---|---|---|---|
| BBPS Adequate* | 71.8% | 89.4% | <0.001 | 88.1% | <0.001 | 88.8% | <0.001 |
| Total BBPS | 6.2 ± 2.0 | 7.3 ± 1.7 | <0.001 | 7.2 ± 1.8 | <0.001 | 7.2 ± 1.8 | <0.001 |
| Boston ≥ 7 | 42.9% | 65.5% | <0.001 | 66.2% | <0.001 | 63.8% | <0.001 |
| Patient willing to repeat the preparation | 59.6% | 64.8% | 0.107 | 91.2% | <0.001 | 78.5% | <0.001 |
| Patient Tolerance (1-10 scale) | 7.0 ± 2.3 | 7.2 ± 2.4 | 0.106 | 8.0 ± 1.8 | <0.001 | 7.6 ± 2.1 | <0.001 |

Unpublished results

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# TOLERABILITY

| | Day before high-volume N=579 | Split-dose high-volume N=575 | p-value | Split-dose low-volume N=572 | p-value | (High or Low) split-dose N=1147 | p-value |
|---|---|---|---|---|---|---|---|
| BBPS Adequate* | 71.8% | 89.4% | <0.001 | 88.1% | <0.001 | 88.8% | <0.001 |
| Total BBPS | 6.2 ± 2.0 | 7.3 ± 1.7 | <0.001 | 7.2 ± 1.8 | <0.001 | 7.2 ± 1.8 | <0.001 |
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Unpublished results

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# TAKE HOME MESSAGE

- Split dose bowel prep results in a cleaner colon and better patient tolerability
- There is little role for 4L day before bowel prep as a first line agent in routine outpatient colonoscopy

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# B-CLEAN Conclusion

- Split-dose high-volume PEG (2L+2L) compared to split-dose low-volume PEG (1L+1L) with bisacodyl (15mg)

- **Split-dose high-volume PEG - Independent of time of procedure (AM or PM) or diet (clear liquid or low residue diet)**
  - Improved bowel cleansing according to the BBPS
  - Improved cecal intubation
  - Improved polypectomy rates
- **However,**
  - Lower patient willingness to repeat the bowel preparation
  - Lower patient tolerance

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## B-CLEAN Conclusion

- Same-day low-volume PEG (2L) compared split-dose high-volume PEG (2L+2L) and/or split-dose low-volume (1L+1L) PEG with bisacodyl (15mg)

- **Low volume PEG given the day of the colonoscopy - independent of diet (clear liquid or low residue)**
  - Similar bowel cleanliness compared to split-dose high-volume PEG
  - Better bowel cleanliness compared to split-dose low volume PEG
- **Same-day low-volume PEG**
  - Greater willingness-to-repeat compared to split-dose high-volume PEG
  - No different willingness-to-repeat compared to split-dose low-volume PEG

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## B-CLEAN Conclusion

- Day before high-volume PEG (4L) versus split-dose high-volume PEG (2L+2L) and/or split-dose low-volume PEG (1L+1L) with Bisacodyl (15mg)

- **Day before high-volume PEG - independent of diet (clear liquid or low residue)**
  - Worse bowel cleanliness compared to split-dose high volume PEG
  - Worse bowel cleanliness compared to split-dose low volume PEG
  - Lower patient willingness to repeat compared to the split-dose low-volume PEG
  - Not significantly different patient willingness to repeat compared to the split-dose high-volume PEG
  - Inferior cecal intubation and polyp detection vs split-dose high-volume PEG

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## WHAT ABOUT FAILED BOWEL PREP?

## WHAT ABOUT FAILED BOWEL PREP?

- The Bowel CLEAnsing: A National Initiative - Repeat Colonscopy (B-CLEAN(R) was a 4-centre RCT comparing two regimens for use after an initial failed attempt at bowel preparation
  - University of Alberta (Richard Sultanian)
  - Western University (Michael Sey) **(Principal Investigator)**
  - McGill University (Alan Barkun)
  - Université de Montréal (Daniel von Renteln)

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## ELIGIBILITY CRITERIA: B-CLEAN(R)

- Inclusion criteria
  - Anyone who failed outpatient on label bowel preparation requiring a repeat colonoscopy
- Exclusion criteria
  - Non-compliance with index bowel preparation
  - Intolerance to PEG based bowel prep
  - Used off-label bowel preparation
  - Inpatient index colonoscopy
  - Increased risk for fluid/electrolyte disturbances
  - History of ischemic colitis

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## RANDOMIZATION: B-CLEAN(R)

- Regimen A
  - 15 mg bisacodyl at 2 PM the day before colonoscopy
  - 2L PegLyte the night before colonoscopy
  - 2L PegLyte the morning of colonoscopy
- Regimen B
  - 15 mg bisacodyl at 2 PM the day before colonoscopy
  - 4L PegLyte the night before colonoscopy
  - 2L PegLyte the morning of colonoscopy
- Both preceded by a low fiber diet 3 and 2 days before colonoscopy and clear fluids day before and day of the procedure

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≈ BiPegLyte x 2 boxes – 15 mg bisacodyl
OR
≈ PegLyte 4L + 15 mg bisacodyl

- Regimen B
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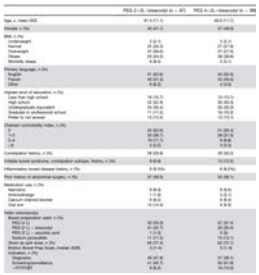
# TABLE 1: PATIENT CHARACTERISTICS



N=196

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# EFFICACY

| | PEG 2+2L+bisacodyl (n = 97) | PEG 4+2L+bisacodyl (n = 99) | RR (95% CI) | *P* value |
|---|---|---|---|---|
| Adequate preparation, n (%) | | | | |
| BBPS definition | 83 (91.2) | 78 (87.6) | 0.96 (0.87–1.06) | .44 |
| USMSTF definition | 82 (91.1) | 76 (85.4) | 0.94 (0.85–1.04) | .24 |
| BBPS, median (IQR) | | | | |
| Total score | 7 (6–9) | 7 (6–9) | – | .95 |
| Right colon | 2 (2–3) | 2 (2–3) | – | .33 |
| Transverse colon | 2 (2–3) | 2 (2–3) | – | .51 |
| Left colon | 2 (2–3) | 3 (2–3) | – | .56 |
| Detection rates, n (%) | | | | |
| Adenoma | 34 (37.4) | 28 (31.5) | 0.84 (0.56–1.26) | .41 |
| Advanced adenoma | 17 (18.7) | 10 (11.2) | 0.79 (0.55–1.13) | .19 |
| Sessile serrated lesion | 8 (8.8) | 5 (5.6) | 0.64 (0.22–1.88) | .41 |
| Polyp | 53 (58.2) | 49 (55.1) | 0.94 (0.73–1.22) | .66 |
| Adenoma/colonoscopy | 0.99 (1.88) | 0.64 (1.15) | – | .13 |
| Polyp/colonoscopy | 1.54 (2.29) | 1.25 (1.93) | – | .36 |
| Cecal intubation, n (%) | 87 (96.7) | 82 (92.1) | 0.95 (0.89–1.02) | .19 |

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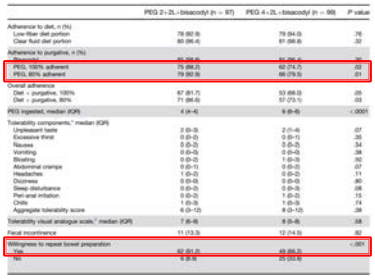
# TOLERABILITY



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# TAKE HOME MESSAGE

- In patients who fail first line bowel preparation:
  - Assess adherence
    - If non-adherence, provide education/alternate preparation
  - Assess tolerance
    - If PEG intolerant, switch to sodium picosulfate based (Pico-Salax® or Purg-odan™) or oral sulfate solution (KleanLyte™) based bowel preparation
    - If sodium picosulfate intolerant, switch to low volume PEG (BiPegLyte®) or oral sulfate solution (KleanLyte™) based bowel preparation
  - If adherent and tolerant, use:
    - Low fiber diet 3 and 2 days before procedure and clear fluids day before and day of procedure
    - 15 mg bisacodyl at 2 PM day before colonoscopy
    - 2L PegLyte between 8-10 PM night before colonoscopy
    - 2L PegLyte started 4-6 hours before colonoscopy and consumed over 2 hours

*Do not take antacids within 1 hour of bisacodyl

*Patients with contraindications to PEG, bisacodyl, or colonoscopy were excluded from the trial

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Questions?
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