

The Affect of Low-Volume
Bowel Preparation for
Hospitalized Patients
Colonoscopies

NCT#01978509

December 03, 2015

The Affect of Low-Volume Bowel Preparation for Hospitalized Patients Colonoscopies-Final

Jennifer Horsley-Silva, MD; Laura Koepke, NP; Sameer Islam, MD; Kevin Ruff, MD; Francisco Ramirez, MD

Colonoscopic examinations are frequently performed in hospitalized patients for a number of indications. There are, however, significant limitations that prevent an endoscopist from performing a high quality examination, necessitating delaying the procedure or even cancelling it. One such challenge is in the adequacy of bowel cleansing. Inpatient status has been shown to be a predictor of poor bowel preparation as these patients are older, less mobile, and have more co-morbidities than outpatient populations. Though studies in outpatient populations have demonstrated that timing and choice of cathartic medication affects the cleanliness of the bowel preparations, currently, no standardized (or optimized) bowel preparation regiment administration exists for inpatient populations undergoing colonoscopy.

The purpose of this study is to compare the efficacy of a low-volume bowel preparation versus a high-volume bowel preparation for bowel cleansing on hospitalized patients undergoing colonoscopies.

Primary Outcome:

To determine if using a split-dose low volume prep (Prepopik ® or Moviprep ®) prior to colonoscopy would improve bowel preparation in hospitalized patients based on a Boston Bowel Prep Score (BBPS).

Secondary Outcomes:

1. Delayed colonoscopy if bowel prep deemed inadequate
2. Procedure cancelled if bowel prep deemed inadequate
3. Patient tolerance
4. Able to completely finish prep
5. Side effects of low volume preparation
6. Cecal intubation time
7. Withdrawal time
8. Total time of colonoscopy
9. Willingness to repeat colonoscopy in future

Inclusion Criteria:

1. Inpatient colonoscopies
2. Age 18 years and older
3. Able to give consent
4. Split dose colonoscopies for all patients

Exclusion Criteria:

1. No consent obtained

2. Pregnancy or lactating
3. Renal impairment
4. Ileus
5. Ascites
6. Toxic megacolon
7. Gastrointestinal obstruction
8. Allergy to study drug
9. Toxic colitis
10. Not able to split the dose

Methods:

We plan of performing a single blinded (endoscopist), prospective, randomized control trial on whether using a split-dose low volume bowel preparation would improve bowel preparation in hospitalized patients at our institution.

Currently at Mayo Clinic Arizona, there are two bowel preps available in hospitalized patients: Golytely ® and Moviprep ®. They are 4-liter and 3-liter preparations taken the night prior to colonoscopy or in a split-dose fashion.

After informed consent, we will randomly select patients to take the 4-liter split-dose prep (Golytely ®) or the low volume split-dose preps (Moviprep ® or Prepopik ®). The randomization will be carried out using a computer-generated random numbers, with the group assignments placed in sealed, consecutively numbered,

opaque envelopes. Instructions will be provided prior to the colonoscopy for the common side effects and administration instructions for both arms. Bowel prep orders will be done by a Nurse Practitioner, who will not inform the endoscopists of which prep is being used (i.e. the endoscopists will be blinded). Additionally, the patients will be told to not inform the endoscopy nurse and performing endoscopists which bowel prep regimen they took.

During the colonoscopy, various metrics will be obtained. After colonoscopy is completed, patients will be given a questionnaire about their experiences with the bowel preps.

Data Collection:

1. All enrolled patient will be asked:
 - a. Details of how purging agents were used
 - b. Start of bowel prep time
 - c. Side effects of preparation
 - d. Sleeping quality
 - e. Willingness to repeat bowel preparation

2. Colonoscopy demographics
 - a. Prep quality, based on the Boston Bowel Prep Score
 - b. Cecal intubation
 - c. Terminal ileum intubation

- d. Total colonoscopy time
- e. Adenoma detection rate

3. Patient demographics

- a. Sex
- b. Age
- c. BMI
- d. Primary symptoms
- e. Purgative type

Confidentiality of Data

The cases will be indexed by medical record to protect the privacy of the patients.

All electronic data will be stored in a password-protected database. The data storage will be restricted to facility computers that are password protected.

Relevant clinical information will be reported only with collective data with no identities revealed.

Bowel Preparations:

Prep Types	Volume of Prep	Ingredients	Administration (full dose regiment)
Golytely ®	4 liters	Polyethylene glycol, sodium sulfate, sodium bicarbonate, sodium chloride, potassium chloride	3L of water and Golytely and taken in the evening before the colonoscopy, 1 L of water and Golytely taken the morning of the colonoscopy
Moviprep ®	3 liters	Polyethylene glycol, sodium sulfate, sodium chloride, potassium chloride, sodium ascorbate and ascorbic acid	1.5L of water and Moviprep taken in the evening before the colonoscopy, 1.5 L of water and Moviprep taken the morning of the colonoscopy
Prepopik ®	74 ounces (2.2 liters)	Sodium picosulfate, magnesium oxide, anhydrous citric acid	1) Drink 5-ounce cold water mixed with one packet of Prepopik 2) This is followed by 5 8-ounces of water within the next 5 hours the night prior to the colonoscopy 3) Drink second 5-ounce cold water mixed with packet in the morning 4) This is followed by 3 8-ounces of water within the next 5 hours

References:

1. Hendry PO, Jenkins JT, Diament RH. The impact of poor bowel

preparation on colonoscopy: a prospective single centre study of 10571 colonoscopies. *Colorectal Dis* 2007;9:745–8.

2. Froehlich F, Wietlisbach V, Gonvers JJ, et al. Impact of colonic cleansing on quality and diagnostic yield of colonoscopy: the European Panel of Appropriateness of Gastrointestinal Endoscopy European multicenter study. *Gastrointest Endosc* 2005;61:378–84.

3. Spiegel BMR, Talley J, Shekelle P, et al. Development and validation of a novel patient educational booklet to enhance colonoscopy preparation. *Am J Gastroenterol* 2011;106:875–83.

4. Golytely ®, Moviprep ®, and Prepopik ® Prescribing Information and Patient Instructions.