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A New "Pill Prep" for Colonoscopy: An Effective Alternative for Individuals Who Won't Drink GoLytely®

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This article reviews DiPalma JA, Bhandari R, Cleveland M, et al A Safety and Efficacy Comparison of a New Sulfate-Based Tablet Bowel Preparation Versus a PEG and Ascorbate Comparator in Adult Subjects Undergoing Colonoscopy. Am J Gastroenterol 2021; 116: 319-28 PMID: 33165006

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STRUCTURED ABSTRACT

Question: For colonoscopy bowel preparation, does an oral, tasteless, sulfate-based tablet (SUTAB®; Braintree Laboratories, Braintree, MA) cleanse as well as a 2-liter solution containing PEG3350, electrolytes, and ascorbate (MoviPrep®; Salix Pharmaceuticals, Morrisville, NC)?

Design: Randomized, single-blind (investigator) noninferiority trial of SUTAB® vs MoviPrep® with 24-48 hours of follow-up after colonoscopy for safety assessment.

Setting: Twenty-two United States study sites including hospital-based and stand-alone gastroenterology practices.

Patients: There were 515 adult outpatients (mean age: 57.9 years, 56% women, 78% White) requiring a colonoscopy for colorectal cancer screening, colon polyp surveillance, or GI symptoms. In addition to routine exclusions from bowel prep (e.g., suspected ileus or obstruction), patients were excluded if they had severe renal, liver, or cardiac insufficiency.

Intervention: SUTAB® prep requires intake of 12 oral sulfate tablets (OST) taken the evening before colonoscopy with a minimum of 16 ounces/473 ml of water. A second 12-tablet dose (with minimum of 16 ounces/473 ml of water) is taken 5-8 hours before colonoscopy. Additional

hydration with 32 ounces/946 ml of water was required with each dose. Thus, the minimum total liquid intake was approximately 3 liters of water with prep. Participants in the comparator arm received a split-dose of MoviPrep®, which is a 2-liter bowel prep solution containing PEG3350, electrolytes, and ascorbate with an additional 500ml of clear liquid intake with each 1-liter dose of prep.

Outcomes: The primary efficacy endpoint was global colon cleansing using a new US FDA bowel prep scoring scale which also accounts for work of endoscopist cleansing. Specifically, *excellent*: no more than small bits of feces/fluid which can be suctioned easily; achieves clear visualization of the entire mucosa; *good*: feces and fluid requiring washing and suctioning, but still achieves clear visualization of the entire mucosa; *fair*, enough feces even after washing and suctioning to prevent clear visualization of the entire colonic mucosa; *poor*, large amounts of fecal residue and additional bowel prep required. Grades of good or excellent for global cleansing of the colon were considered successful. Secondary efficacy endpoints included: number of excellent preparations, segmental cleaning score, adequacy of cleansing and need for repreparation, adenoma detection rate, duration of colonoscopy, volume of intraprocedural water needed to irrigate the colon, and cecal intubation rate.

Data Analysis: Intention-to-treat analysis.

Funding: Braintree Laboratories, part of Sebela Pharmaceuticals, Inc.

Results: Study results are summarized in **Table 1**.

COMMENTARY

Why Is This Important?

For some patients, the bowel prep is worse than the colonoscopy procedure itself! In a survey of individuals that declined a colonoscopy even after a positive stool-based screening test, some based their decision on the discomfort associated with the bowel preparation.[1] However, even reluctant patients need to be compliant with prep instructions because a high-quality bowel preparation is necessary to optimize the adenoma detection rate and cecal intubation rate. In addition, suboptimal or inadequate bowel prep leads to increased procedure duration, incomplete colonoscopies, missed lesions, and higher costs.[2]

Outcomes		OST	PEG-EA	*P*-value
Overall cleansing rating	Successful cleansing (defined as excellent or good), n (%)	257 (92.4%)	241 (89.3%)	0.217*
Secondary endpoints	Cecal intubation rate, n (%)	271 (98.2%)	261 (97.8%)	0.824
	Adenoma detection rateΨ, n (%)	92 (33.1%)	94 (34.8%)	0.532
	Procedure duration, mean (SD)	15.8 (9.6)	15.9 (8.1)	0.909
	Intraprocedural water in mls, mean (SD)	88.4 (128.1)	93.8 (126.2)	0.632
Tolerance	Abdominal pain	17%	19%	0.655
	Abdominal distension	30%	22%	0.052
	Nausea	49%	26%	**<0.001**
	Vomiting	23%	6%	**<0.001**
Experience consuming bowel preparation	Very easy or easy	65.1%	39.5%	**<0.001**

Table 1. Outcomes
**P*-value for treatment difference, successful=excellent or good
Ψ Observed during screening and disgnostic colonoscopies
OST, oral sulfate tablets (SUTAB®, Braintree Laboratories, Braintree, MA)
PEG-EA, PEG3350, electrolytes, and ascorbate (MoviPrep®, Salix Pharmaceuticals, Morrisville, NC)

Since many patients dislike the taste and volume of current bowel preparations, a tablet-based formulation is very appealing. Although oral sodium phosphate tablets (OsmoPrep®, Salix Pharmaceuticals, Morrisville, NC) are available, this formulation has traditionally been avoided because acute phosphate nephropathy is a rare complication. Oral sodium sulfate tablets do not have this risk. This is the first published randomized controlled trial (RCT) to assess efficacy and safety compared to an FDA-approved bowel preparation, and a second similar RCT comparing OST vs a sodium picosulfate-based oral solution (Prepopik®, no longer marketed) showed similar results.[3]

Key Study Findings

In the SUTAB® arm, 92% of participants had successful cleansing (defined as a score of excellent or good on the global cleansing score) compared with 89% of patients that used MoviPrep® (Table 1), which established non-inferiority. Similar results were achieved in both arms for all secondary efficacy endpoints. Study participants in the SUTAB® group reported more nausea and vomiting than those in the MoviPrep® group,

and this difference was statistically significant (Table 1). However, fewer than 5% had severe symptoms. Interestingly, patient surveys indicated better overall experience with SUTAB® vs MoviPrep® even among participants that had used a previous prep in the past for colonoscopy. In fact, more participants that used SUTAB® (78%) would request it again as compared to those that used MoviPrep®(67%).

Caution

The authors acknowledge that even though adenoma detection rates were comparable between both treatment groups, generalization of this important metric may be limited because the population in this trial was heterogenous as it included patients undergoing colonoscopy for non-screening indications. Another limitation was the choice of cleansing grading scale, which was different from the more common, Boston Bowel Prep Scale. Most importantly, this is a hyperosmolar bowel preparation, so there could be increased risk for adverse events among patients with congestive heart failure, renal insufficiency, or electrolyte disturbances. Therefore, it would be helpful to see more data in patients with cardiac and renal insufficiency.

My Practice

I am yet to prescribe SUTAB®. However, based on these results, I intend to offer it to my patients particularly those hesitant to proceed with colonoscopy because of concern with the large volume and taste of traditional bowel prep formulations. OST may also have a role to play in patients with a history of poor bowel prep because of failure to completely consume large volume bowel prep. Until we have more safety data, I will probably avoid OST in patients with moderate renal insufficiency or congestive heart failure. In addition, as I adopt SUTAB in my clinical practice, out-of-pocket cost for the patient will be a critical factor. For most patients with Medicare Part D or commercial insurance, the maximum cost would be $40 when using a coupon from the SUTAB website, but GoLytely® should not cost more than $15 with a GoodRx coupon or even have a copay less than $5.

For Future Research

Since this study was exclusively performed in an outpatient population, there may be some utility in studying the efficacy of OST in the inpatient setting.

In addition, cost-effectiveness analyses particularly from a payer and societal perspective would be important to explore given the attendant costs of poor bowel preparation. Data from these cost-effectiveness studies can inform third-party payers which will improve insurance coverage for OST among patients that prefer this new pill prep for colonoscopy.

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