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Cover Page Footnote

I would like to thank Dr. Susan Stevens and Dr. Tamera Schmidt for allowing me to rotate through their clinic.

Improved tolerability and efficaciousness of MiraLAX-Gatorade when compared to GoLYTELY in the outpatient setting

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ABSTRACT A clinical decision report using Gu P, Lew D, Jung OS, et al. Comparing the Real-World Effectiveness of Competing Colonoscopy Preparations: Results of a Prospective Trial. *Am J Gastroenterol.* 2019;114(2):305-314. <https://doi.org/10.14309/ajg.0000000000000057> for a patient reluctant to undergo colonoscopy screening due to concerns about GoLYTELY's tolerability.

Keywords: colonoscopy prep, MiraLAX, GoLYTELY

Clinical Context

Joan Smith (pseudonym) is 52-year-old Caucasian woman that presented to her PCP for an annual check-up. She had no complaints, but it was noted that she had not yet had her first colonoscopy. Mrs. Smith had been given referrals for the past two years, however, she never went. When asked what her concerns were, Mrs. Smith told us that she was embarrassed as she had concerns about the GoLYTELY bowel preparation, as several of her friends complained about its tolerability. One of her friends complained of a “disgusting drink that did not go down well” and another complained of “knowing what was coming after this drink making it hard to finish.” When asked what her biggest barrier with the colonoscopy preparation was, Mrs. Smith mentioned that the thought of having to drink something “gross” followed by diarrhea lessened her motivation and is the reason she doesn’t want the procedure. Mrs. Smith agreed that cancer screening was important, as her husband had polyps found when he had his procedure done, however, she was curious if she could use MiraLAX-Gatorade, a preparation that her husband had tolerated better during that time, instead.

Clinical Question

Is the MiraLAX-Gatorade colonoscopy preparation more tolerable and efficacious than GoLYTELY in an outpatient setting?

Research Article

Gu P, Lew D, Jung OS, et al. Comparing the Real-World Effectiveness of Competing Colonoscopy Preparations: Results of a Prospective Trial. *Am J Gastroenterol.* 2019;114(2):305-314. <https://doi.org/10.14309/ajg.0000000000000057>

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Related Literature

A search on UpToDate for “bowel preparation” provided a list of the FDA approved colonoscopy preparations. This included 4L polyethylene glycol with electrolyte solution (PEG-ELS), which includes GoLYTELY, 2L PEG-ELS, which includes Moviprep, and hyperosmotic agents such as Suprep. MiraLAX is a non-FDA approved OTC bowel preparation that works similarly to GoLYTELY. It is often mixed with 2L of Gatorade and used as bowel preparation. A PubMed search of “colonoscopy bowel preparation AND Gatorade” and colonoscopy bowel preparation AND MiraLAX provided several articles on this topic. There is conflicting literature on the bowel cleansing effectiveness of MiraLAX-Gatorade when compared to GoLYTELY. The Enestvedt and the Hjelkrem studies were among the first randomized controlled trials (RCTs) to study to efficacy of MiraLAX-Gatorade. They both concluded that it was inferior to GoLYTELY in bowel preparation quality, determined by the Boston Bowel Preparation Scale (BBPS) scores and Ottawa scores respectively.^{1,2} Another Enestvedt study later determined that MiraLAX-Gatorade also produced lower adenoma detection rates than GoLYTELY.³ This led to the conclusion that GoLYTELY should be used as first line for bowel preparation.

There were 2 RCTs that concluded MiraLAX-Gatorade was a non-inferior preparation when compared to GoLYTELY. The different result in the McKenna study was attributed to the lack of split dosing, which was used prior. The McKenna study also had independent researchers assign the BBPS score based off pictures of bowel, as opposed to by the endoscopists.⁴ The Samarasena study utilized the Ottawa score and the BBPS score, which was assigned by independent researchers observing a video of the procedure. In addition, MiraLAX-Gatorade consistently scored higher on patient tolerability surveys in this study, which asks about specific symptoms such as nausea, bloating, cramping, discomfort, and sleep disturbance.⁵ This was the first study where bowel preparation tolerability was assessed. Another article was a retrospective endoscopic database analysis at a community hospital, which concluded that MiraLAX-Gatorade-bisacodyl provided a statistically significant improvement to bowel cleansing.⁶ This was attributed to improved compliance when compared to GoLYTELY. The Govani study, which was a retrospective analysis, tested the impact of many different variables on bowel preparation efficacy. It found that MiraLAX-Gatorade preparations were associated with better bowel preparation, assessed by endoscopists.⁷ The first meta-analysis on MiraLAX-Gatorade effectiveness found that it was inferior to GoLYTELY.⁸ This analysis included 1418 patients and utilized 5 different studies, including the Enestvedt and Hjelkrem studies. A later meta-analysis by Zhang utilized regression with random effects on the same data and found that no significant difference existed between the groups, leading to the conclusion that many variables impact preparation efficacy.⁹

Many of the previously listed studies tested the effectiveness of MiraLAX-Gatorade in a controlled setting with monitored protocols; however, the clinical effectiveness of MiraLAX-Gatorade in a “real-world” setting has not been extensively studied. Gu et al. provided a prospective, naturalistic comparative effectiveness study to assess the effectiveness and tolerability of different colonoscopy preparations.¹⁰ This makes it more applicable to the outpatient setting, as patient tolerability can determine preparation effectiveness and was Mrs. Smith’s primary concern. The level of evidence of this study is 2 using the SORT algorithm, as it is an observational study. Despite this, a study that mimicked outpatient colonoscopies and measured both efficacy and tolerability was required to answer the clinical question, making this paper ideal.

Critical Appraisal

This study was conducted at Cedars-Sinai Hospital in Los Angeles, California. To be eligible, patients had to have an outpatient colonoscopy from August 4th, 2016 to July 31st, 2018 and be ≥ 18 . Age, BMI, race/ethnicity, sex, language, opioid/tricyclic antidepressant use, and comorbidities of patients were noted. Patients were primarily Non-Hispanic white (2952) and 51% female, with the majority aged 50-64 (1763). Bowel cleansing was assessed using the routine BBPS score, which is assigned by a nurse during the colonoscopy. Adequate bowel cleansing was defined as a total BBPS score of ≥ 6 . Bowel preparation tolerability was assessed through a question asked to each patient. Prior to the procedure, the nurse asked each patient “How much of the bowel prep did you ingest,” with answer options being all (100%), 75-99%, <75%, or unsure. This was further categorized into “fully completed” and “not fully completed” groups. Endoscopists were free to give any preparation and dose, and patients were asked which preparation they used prior to the procedure. GoLYTELY, Colyte, NuLYTELY, Trilyte, MoviPrep, MiraLAX-Gatorade, Suprep, Suclear, Prepopik, OsmoPrep, and magnesium citrate were all used; however, Colyte, NuLYTELY, and Trilyte were grouped with GoLYTELY due to similar formulation.

Overall, 5253 outpatient colonoscopies were completed, with 914 cases excluded either due to age < 18 (257), using two day preparations or unknown dosing (184), absent colons or procedure termination other than suboptimal preparation (93), or missing



scoring data (383). The study included 4339 colonoscopies, performed by 75 different independent providers. The results showed that MiraLAX-Gatorade had a 92.6% completion rate, whereas GoLYTELY had an 82.9% completion rate. Upon adjusting for preparation, provider, and patient-related variables using multivariable logistic regression analysis with random effects, patients using MiraLAX were significantly more likely to finish the preparation, with a rate of 62.3% compared to 11.8% for GoLYTELY ($p < 0.001$). MiraLAX-Gatorade also had the highest adjusted completion rate when compared to the other preparations. With regards to the bowel cleansing efficacy, MiraLAX-Gatorade had an average BBPS score of 7.09 ± 1.64 whereas GoLYTELY had an average score of 6.67 ± 1.87 after multivariable regression analysis, which was significant ($p < 0.001$). Patients using MiraLAX-Gatorade also had higher odds for adequate cleansing when compared to GoLYTELY (OR, 1.76; 95% CI, 1.24-2.49). MoviPrep and Suprep also had higher completion rates and BBPS scores than GoLYTELY. Patients told to use split-prep dosing also had higher total BBPS scores.

Several characteristics contributed to the strength of this study. This was the largest prospective study analyzing both the tolerability and efficacy of various bowel preparations, with over 4300 colonoscopies included. In addition, because there were over 75 providers that could prescribe any regimen, this study can compare many different bowel preparations. Patients were also not excluded for having chronic conditions such as chronic opioid use, inflammatory bowel disease, chronic kidney disease, congestive heart failure, and cirrhosis.¹⁰ This is in contrast to the RCTs previously listed, which typically include fewer, more controlled regimens and excluded patients with chronic conditions.^{1,4,5} This study was also free of the Hawthorne effect and remuneration, as it was not a RCT. Multiple RCTs have found GoLYTELY to have superior efficacy when compared to MiraLAX-Gatorade^{1,2,3}; however, patients may be more willing to fully ingest GoLYTELY, despite its lower tolerability, due to these biases. This makes prospective, naturalistic trials like the Ru study more closely reflect outpatient clinical care. Regression analysis with random effects also improves the strength of these results, as it controlled for unobserved heterogeneity.

The authors chose to exclude patients less than 18 years old, those with surgically absent colons, those that were unable to complete the BBPS due to reasons other than bowel prep, and those with missing data. These patients were eliminated because they could not be scored using the BBPS, which was used as the primary measure for the manuscript. While this could have had an impact on the final outcome, the overall sample size was large enough that the conclusions can still be seen as a generalized outcome for a broader population. In addition, MiraLAX-Gatorade was found to have superior BBPS scores and tolerability, the impact of this is not clear because the minimum score before which the adenoma detection rate decreases and interval colorectal carcinoma development increases has not been determined. Because this study was conducted at a single site, there were also concerns about generalizability. This was somewhat offset by the large sample size and diverse patient cohorts. With regards to the assessment of bowel cleansing efficacy, since BBPS scores are assigned by the nurse who participated in the procedure, variability in scoring exists. This was addressed through the in-service training that was given to the nurses participating. The lack of blinded reviewers of the BBPS scores could also be a flaw, but this made the study better reflect clinical practice and eliminate observer bias. Providers selecting regimens may have been biased but having 75 participating helps lessen this. Regression analysis with random effects accounted for differences in the providers such as endoscopic skills and experience, personal bowel cleansing thresholds, and patient population. Finally, the study was unable to account for patients who missed or canceled their procedure. Patients with intolerable preparations may have been part of this group, meaning tolerability and bowel cleansing effects of GoLYTELY may have been overestimated. There were no significant conflicts of interest, although the authors received a consulting fee from Bayer, which makes MiraLax. This should not affect the results as providers chose the regimens.

Clinical Application

The authors concluded that MiraLAX-Gatorade, MoviPrep, and Suprep have superior tolerability and are associated with better bowel cleansing in patients aged ≥ 18 when compared to GoLYTELY. They also noted that split dosing was associated with superior cleansing. Because this study used outpatient data and Mrs. Smith fit the majority demographic of a Caucasian female aged 50-64 with BMI < 25 without any comorbidities, split dose MiraLAX-Gatorade was recommended. In addition, Mrs. Smith had the greatest likelihood of tolerating the MiraLAX-Gatorade, which was her biggest concern. We explained to her that while GoLYTELY was found to be superior in a controlled setting, when you consider people's real-world concerns and limitations with finishing the bowel preparation, MiraLAX-Gatorade had better bowel cleansing outcomes due to its better tolerability. Each of the factors mentioned could have changed the clinical decision making, but for Mrs. Smith, they solidified the choice that we made. We are confident in our decision to have Mrs. Smith have a split dose of MiraLAX-Gatorade, even though it was not found to be the most effective treatment in other manuscripts because in this clinical context it

fit her needs the best. Mrs. Smith had been nervous and embarrassed about not having had the colonoscopy done sooner and was thankful that we listened to her concerns and found something that would work for her.

New Knowledge Related To Clinical Decision Science

Screening for malignancy only works if the patient is actually screened. This report highlights a common clinical problem. In the clinical setting, convincing a patient who would otherwise decline screening depends on understanding and accepting the patient’s perspective. Clinical Decision Science asks multiple questions related to this patient. How many patients are never screened because of concerns related to the bowel prep? What other types of screening are available and acceptable to the patient? In this case, the patient herself suggests a solution to her personal barrier for screening.

This report is a good example of using evidence that best fits a patient’s concerns. Had we only used the older RCTs in deciding what to recommend to Mrs. Smith, we would have recommended GoLYTELY due to superior bowel preparation and adenoma detection rates.^{1,2} While this would work in inpatient settings where you can monitor if a patient finishes the bowel preparation, in outpatient settings this is unrealistic. Newer studies have since included tolerability and have shown that better tolerability plays a major role in showing that Miralax-Gatorade has either non-inferior or even superior cleansing. The Gu study is relevant to Mrs. Smith as she had concerns about the preparation’s taste and adding Gatorade would help with that. Including tolerability, the large sample size that fits Mrs. Smith’s demographic, and use of outpatient data are the main reasons this article is superior to other articles and is the reason that recommending Miralax-Gatorade was the best decision for her. Because of the contradictory data, it is important to look at the patient demographics of each article and who the findings best apply to before applying their conclusions to your patients, as each patient’s backgrounds and concerns are unique.

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