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Safety of MiraLAX/Gatorade Bowel Preparation Has Not Been Established in Appropriately-Designed Studies

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To the Editors

I commend Enestvedt and colleagues for their meta-analysis comparing the efficacy and tolerability of different bowel preparations (1). This is a well-designed meta-analysis of randomized controlled trials and it clearly demonstrates the superiority of 4-Liter Split-Dose (PM/AM) Polyethylene Glycol (PEG) for efficacy of colon cleansing versus 4-Liter PM-only dosing of 4-Liter PEG. They also demonstrated its superiority versus 64 ounces Split-Dose (PM/AM) of MiraLAX/Gatorade. Furthermore, they noted no difference between these bowel preparations for tolerability or compliance. Based on these results, 4-Liter Split-Dose PEG would appear to be the preferred bowel preparation, but 64 ounces of MiraLAX/Gatorade is the preferred bowel preparation in many settings because it is perceived as better tolerated compared to the higher volume 4-Liter PEG prep. When choosing therapies, clinicians consider efficacy, tolerability, and safety of the therapy (e.g., frequency of serious adverse events). Discussion of the safety of different bowel preparations would be a helpful addition to the study by Enestvedt and colleagues.

This issue is particularly important to consider when discussing the use of 238 grams MiraLAX mixed in 64 ounces of Gatorade as a bowel preparation. Ultimately, endoscopists should remember that MiraLAX/Gatorade: (a) is not an osmotically balanced solution; (b) is not FDA-approved for use as a pre-colonoscopy bowel preparation ; and, (c) has not been evaluated in appropriately large safety studies. The 64 ounce MiraLAX/Gatorade preparation is hyperosmolar compared to osmotically balanced, FDA-approved PEG bowel preparation, and MiraLAX is only FDA-approved for the treatment of occasional constipation at doses of 17 grams per day.

An RCT by Samarasena and colleagues was published 2 months before this meta-analysis and concluded that MiraLAX/Gatorade was a safe bowel preparation among the low-risk patients partly due to the absence of clinically important electrolyte abnormalities based on pre- and post-bowel preparation laboratory studies (2). However, only 114 patients were assigned MiraLAX/Gatorade, which is insufficient to identify infrequent severe

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hyponatremia (serum Na⁺ < 130 mEq/L). I suspect that Enestvedt and colleagues did not define frequency of serious adverse events as a secondary outcome because they knew that the sample size of RCTs in their meta-analysis is also insufficient to comment on this.

Endoscopists should also note that a recent case series identified 14 low-risk patients who used MiraLAX/Gatorade bowel preparations and then suffered severe hyponatremia and serious adverse events, including cardiac arrhythmias and ICU admissions (3). Furthermore, an endoscopic database study of over 8400 patients found a strong trend for an increased incidence of severe hyponatremia with MiraLAX/Gatorade vs osmotically balanced PEG bowel preparations (OR = 3.98; 95% CI: 0.66-23.8, p = 0.10) (4).

There are not many reports of serious adverse events with MiraLAX/Gatorade after several years of use. However, this is similar to another agent for occasional constipation, Fleet's Phospho-soda, which was also used off-label as a bowel preparation although it was not FDA-approved for this use, not osmotically balanced, and had not been the subject of appropriate safety studies. Of course, after many years of use, phosphate nephropathy and renal failure were associated with this product. Although Fleet's Phospho-soda and MiraLAX/Gatorade combinations are quite different products chemically, let's not repeat our mistake with the off-label use of Fleet's Phospho-soda and subject MiraLAX/Gatorade bowel preparation to appropriately designed and sufficiently large safety studies.

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