Abstract Title: The use of senna with docusate for post-operative constipation after pelvic reconstructive surgery: a randomized, placebo-controlled trial

Investigators- Minita Patel, MD, Allison Forrest, RN, David M. O’Sullivan, PhD, Megan O. Schimpf, MD, Christine A. LaSala, MD

Purpose and Rationale: This study aimed to investigate whether a medication regimen using senna with docusate following surgery would decrease time to first bowel movement (BM). Post-operative constipation in patients after pelvic reconstructive surgery can lead to increased discomfort and possibly additional office visits for enemas or disimpaction.

Research Questions: Does the use of senna with docusate reduce the time to first bowel movement in patients undergoing pelvic reconstructive surgery?

Synthesis of Review of Literature: Senna with docusate was chosen for this study because of its prior benefit in the colorectal literature and in the absence of data to support the use of other types of medication for constipation after pelvic reconstructive surgery.

Methods: Institutional review board approval was obtained and all subjects signed informed consent for participation. Subjects completed a 7-day bowel diary and the validated Patient Assessment of Constipation Symptom Questionnaire (PAC-SYM) before surgery. After surgery, provided there was no unintentional bowel injury or resection, the subjects were randomized to either placebo or senna with docusate. The subjects received a standardized protocol to take the study medication. If no bowel movement occurred by post-operative day 4, the subject was instructed to use magnesium citrate.

Procedures: The subjects completed a 7 day bowel diary before surgery and post surgery to track the medication used (including the study medication) until first post-surgery bowel movement. All bowel diaries used the validated Bristol Stool Scale to rate appearance of BMs and a 10-point scale for pain and strain associated with BMs. As stated above, patients also completed a Patient Assessment of Constipation Symptom Questionnaire (PAC-SYM) before surgery.

Results: For this interim analysis, 72 subjects were randomized and completed post-operative diaries. The groups were not significantly different in terms of age, race, BMI, median parity, median stage of prolapse, prior prolapse surgery, and approach to surgery (abdominal vs. vaginal). There were no differences in PAC-SYM scores, baseline bowel frequency, pain or strain in the subjects. There was a significant difference in time to first BM in those receiving senna with docusate versus those receiving placebo (3.0 days versus 4.1, p<0.002). The placebo group was significantly more likely to use magnesium citrate to initiate a bowel movement (p<0.001). There was no difference in time to first bowel movement in those who underwent abdominal versus vaginal reconstructive surgery (3.5 days versus 3.4, p=0.80).

Discussion/Application to practice: The use of senna with docusate in this sample decreased time to first BM in those undergoing pelvic reconstructive surgery compared with placebo. There was also a significantly lower need for magnesium citrate with the use of senna with docusate.