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A PROPHYLACTIC CONSTIPATION REGIMEN PRIOR TO PELVIC SURGERY: INTERIM ANALYSIS OF A RANDOMIZED CONTROLLED TRIAL.

Hypothesis / aims of study

The anticipation and prevention of peri-operative complications is often as crucial as the actual surgical procedure. Constipation, already prevalent in the aging population, too frequently hinders adequate management of our patients after pelvic reconstructive surgery[1]. The primary aim of this project was to investigate the effect of advanced pre-operative regulation of bowel movements with oral Docusate sodium on the incidence of postoperative constipation among our patient population.

Study design, materials and methods

This was an IRB-approved randomized controlled trial started in October 2008 with continued current enrollment. After informed consent, patients scheduled for prolapse reconstructive surgery and not on any medication for constipation were recruited. They were assigned to two arms using a computer-generated randomization. Group I was started on Docusate sodium 100 mg twice daily for fourteen days prior to their scheduled surgery and continued their regimen post-operatively . Group II was only allowed to initiate Docusate sodium on the first day following their surgery as it had been our standard practice for post-operative prevention of constipation.

Objective assessments were obtained both pre-operatively and within 2 weeks of surgery using the validated Wexner Constipation Questionnaire and the Bristol stool chart. Constipation was defined as any two of the following 3 assessment methods:

- A decrease in the Wexner score of ≤ 3 points
- Any stool reported to be of type 1or 2 from the Bristol chart
- The need for laxative use within the 1st post-operative week

Patients' subjective self-assessment of constipation and adverse events related to their use of Docusate sodium were recorded. Any telephone call to our office during the peri-operative period regarding constipation symptoms was documented.

Unpaired t-test, Fischer's exact test and Wilcoxon matched-paired signed rank test were used as indicated.

Our power analysis generated a sample size of 70 patients, assuming a standard deviation of 50 % (15 % response from the post-operative Docusate group and a 30% response rate in the pre-operative intervention group) and using an unpaired t test to detect a 35% treatment difference with 80% power at a significance level of 0.05. We chose to enroll 100 patients anticipating about 30% of our patient population would not complete all required questionnaires and/or follow the medication instructions.

Results

We present the results of the initial 50 patients enrolled as of December 2009.

24 and 26 patients were assigned to group I and II respectively.

Demographics data included age, parity, BMI, menopausal status and history of hysterectomy and showed no statistical difference (*p = 0.432; 0.744; 0.331; 0.639; 0.372).*

	Wexner Score				**Bristol**			**Laxative**	**CONSTIPATION**
Objective Outcomes	*N*	Pre	Post	*p*	Pre	Post	*p*	*N*	*2 of 3 assessments*
Docusate	**22**	5.81 ± 0.75	3 (2-6)	***0.01***	3.46 ± 0.37	4 (1-4)	*0.687*	4	2/22 (9.1%)
No Docusate	**25**	7.28 ± 0.91	4 (1-6)	***0.001***	3.89 ± 0.25	4 (2-4)	*0.449*	10	7/25 (28 %)
p		*0.213*	*1.0*		*0.329*	*0.90*		*0.203*	*0.151*

		Constipation			**Telephone Call**		
Subjective Outcomes	***N =***	**Yes**	**No**	**%**	**Yes**	**No**	**%**
Docusate	22	7	15	46.70%	4	18	18.20%
No Docusate	26	7	19	36.80%	9	17	34.60%
p		*0.7583*			*0.328*		

2 patients from the Group I cancelled their surgery for health reasons. 2 additional patients discontinued Docusate sodium within a week of surgery due to new onset fecal incontinence and diarrhea. 2 patients from the non-intervention group had allergic reactions (rash and hives) that dissipated upon discontinuation of the medication. 1 patient reported a metallic taste but continued Docusate sodium for the two weeks.

Interpretation of results

All patients objectively and subjectively demonstrated a general trend towards improvement in constipation post-operatively. The Wexner questionnaire was the only parameter that showed a statistically significant decrease in the peri-operative scores.

The type 4 stool, described as “normal” on the Bristol chart, was the median stool type in both groups post-operatively. All other assessment methods resulted in comparable outcomes between the two groups at the cost of 2 significant adverse events amongst Docusate users.
The perioperative care of patients using Docusate sodium pre-operatively was subjectively enhanced since they were able to manage their bowel issues without the assistance of our ancillary staff as represented by the lower number of telephone calls in comparison to those who did not.

Concluding message

In this interim analysis, advanced pre-operative prophylactic constipation treatment with Docusate sodium demonstrated no objective benefit in preventing constipation over initiation post-operatively. The reduction in telephone calls by half suggests a subjective enhanced ability for the patients to solely manage this common perioperative issue.

References

1. Soligo M, et al. Patterns of constipation in urogynecology: clinical importance and pathophysiologic insights. AJOG (2006) 195, 50-55

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Cleveland Clinic Florida's Institutional Review Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**