

A comparison of efficacy, safety, and adherence profiles of bowel regimens in pregnancy-related constipation

Yen H. Dang, PharmD, CTTS-M¹, Yinyin Li, Student Pharmacist¹

¹ School of Pharmacy and Health Professions, University of Maryland Eastern Shore, Princess Anne, Maryland



UNIVERSITY of MARYLAND
EASTERN SHORE

School of Pharmacy and Health Professions

Background

- Constipation is a common complaint in 40% of all pregnancies.
- Pregnancy-related constipation is highest in the first and second trimester and decreases in the third trimester to the post-partum period.
- Factors for constipation include changes in the hormonal levels in the GI tract, mechanical effects with advancing gestation, changes in dietary habits, and lower levels of physical activity.
- Commonly prescribed bowel regimens for refractory episodes, along with diet and exercise, include lactulose, senna, docusate, bisacodyl and polyethylene glycol 3350 (PEG 3350).
- Since there are little reports about optimal treatment for pregnancy-related constipation after failure of non-pharmacological therapy, specific guideline has not yet been established for refractory episodes.

Objective

The purpose of this study was to determine efficacy, safety, and adherence profiles of commonly prescribed laxatives in pregnancy-related constipation.

References

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Methods

This is a prospective study approved by the institutional review board of the University of Maryland Eastern Shore.

Inclusion Criteria:

- Pregnant women of all trimesters who were diagnosed with constipation and were prescribed either lactulose, docusate, senna, bisacodyl, or PEG 3350 for at least 3 days.

Exclusion Criteria:

- Pregnant women less than 18 years old,
- Those without a permanent address on file, and
- Those who do not speak English or were illiterate.

After 2 weeks of laxative initiation, patients were given a Patient Assessment of Constipation (PAC) instrument to assess efficacy endpoints and quality-of-life measures. Additionally, safety endpoints and medication adherence was assessed via a self-reported questionnaire.

Primary endpoint: the difference in the total Patient Assessment of Constipation Symptoms (PAC-SYM) score among different laxatives.

- PAC-SYM measures the patient's constipation over the past 2 weeks on laxative therapy based on 3 domains: stool symptoms, rectal symptoms, and abdominal symptoms.
- A 5-point-likert scale will be given on responses of these symptoms.
- The lower the final score, the lower the symptom severity and the higher the efficacy of the laxative.

Secondary endpoints: the differences between the adherence score, rectal symptoms, stool symptoms, and abdominal symptoms of the PAC-SYM questionnaire.

Adherence endpoints: were measured by the Medication Adherence Questionnaire (MAQ, Morisky 4). The higher the total score, the lower the adherence to laxative therapy.

Side-effect profiles of laxatives: was assessed by self-report on a 5-point-likert scale. Rash, diarrhea and nausea will be assessed with the respective prescribed laxatives. The higher the total score, the more the side effects to the laxative therapy.

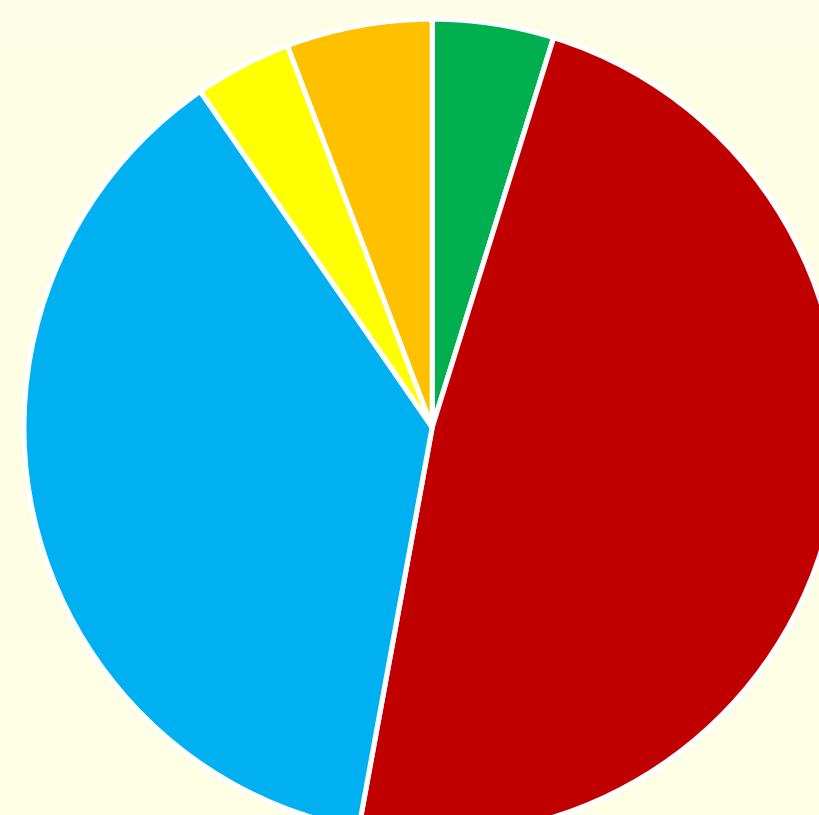
The Mann-Whitney U Test was used to calculate nonparametric data. P-values were 2-sided at a 95% confidence interval.

Results

- A baseline demographic assessment was completed for study eligibility by collecting data for pregnant women receiving care from January 2015 to September 2015 in the regional OB/GYN clinic. Screening was done with a sample size of 104 subjects. However, the senna, bisacodyl and PEG 3350 group had very small sample size so that these data were discarded.

Different Laxatives in Sample Size of 104

- Biscodyl
- Docusate
- Lactulose
- PEG 3350
- Senna



	N
Lactulose	39
Docusate	50
Bisacodyl	5
Senna	6
PEG 3350	4

Results

- Difference in mean Adherence score, the mean stool, rectal and abdominal symptoms and the mean total PAC-SYM score between Lactulose vs. Docusate

	Lactulose	Docusate	P-value
Adherence, mean	0	0	0.1754
Stool sx, mean	2	0	0.2487
Rectal sx, mean	1	0	0.04338
Abdominal sx, mean	1	0	0.1251
Total, mean	3	2	0.0703

- Constipation Score Before and After use of Lactulose or Docusate

	Before	After	P-value
Lactulose, mean	1	0	0.0053
Docusate	1	0	0.0002

- Constipation Score After use of Lactulose vs. Docusate

	Lactulose	Docusate	P-value
After scores, mean	0	0	0.13104

- Side-effect Profiles of Lactulose vs. Docusate

	Lactulose	Docusate	P-value
Rash, mean	0	0	0.41794
Diarrhea, mean	0	0	0.97606
Nausea, mean	0	0	0.81034

Conclusion

Overall, both docusate and lactulose significantly improved constipation symptoms in pregnant women. While patients on docusate complained of less rectal symptoms from constipation, there were no major overall differences in efficacy, safety, or adherence between docusate and lactulose. Future studies should be done to compare the effects of other laxatives such as senna, bisacodyl, and polyethylene glycol in pregnancy-related constipation.

Disclosure

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

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