



The effect of oral Psyllium Herbal Laxative Powder in Prevention of Hemorrhoids and Anal Fissure during Pregnancy, a Randomized Double Blind Clinical Trial

Leila Ghahramani¹, Seyed Vahid Hosseini¹, Salar Rahimikazerooni¹, Alimohammad Bananzadeh⁵, Bahia Namavar Jahromi², Alamtaj Samsam², Abbas Rezaeianzadeh³, Ali Reza Safarpour¹, Ali Bagherpour Jahromi¹, Seyed Hesamaddin Banihashemi⁴

¹ Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, IR Iran

² Department of Obstetrics and Gynecology, Shiraz University of Medical Sciences, Shiraz, IR Iran

³ Department of Epidemiology, Shiraz University of Medical Sciences, Shiraz, IR Iran

⁴ Department of Surgery, Hormozgan University of Medical Sciences, Bandar Abbas, IR Iran

⁵ Laparoscopy Research Center, Shiraz University of Medical Sciences, Shiraz, IR Iran

*Corresponding Author: Ali Reza Safarpour, Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, IR Iran, Tel.: +98-7112357282, Fax: +98-7112307594, E-mail: asafarpour@sums.ac.ir

ABSTRACT

Background: Pregnancy and delivery make susceptible women to hemorrhoidal disease and fissure during pregnancy because of an increase in abdominal pressure and constipation.

Objectives: We aimed to determine the preventative effect of psyllium powder (herbal laxative) on constipation, anal fissure and hemorrhoidal diseases during pregnancy.

Patients and Methods: Regarding the properties of oral psyllium powder, in this study, we aimed to determine the preventative effect of psyllium powder on constipation, anal fissure and hemorrhoidal diseases during pregnancy. This is a randomized clinical trial. All primigravid women, aging 20 - 30, at the onset of 3rd trimester who referred to OB clinic of Shiraz university of medical sciences were divided into two groups. Treatment group received psyllium powder twice daily while control group received placebo. All cases were evaluated two times before delivery and occurrence of constipation and fissure and hemorrhoid were assessed by a single team.

Results: The mean and SD of age in group A (psyllium consumption group) was 29.9 ± 2.24 and in group B (placebo group) was 29.5 ± 2.48 . Comparison between three outcome variables (hemorrhoid, fissure and constipation) revealed significant difference in group A and group B, $P < 0.001$.

Conclusions: According to our study psyllium powder consumption during the third trimester of pregnancy could significantly prevent constipation, hemorrhoid anal fissure.

Keywords: Laxatives; Hemorrhoid; Fissure; Pregnancy; Psyllium powder

► Article type: Research Article; Received: 25 Feb 2013, Revised: 15 Mar 2013, Accepted: 08 Apr 2013; DOI: 10.17795/acr-11488

► Implication for health policy/practice/research/medical education:

This article is about the preventive effect of psyllium powder (herbal laxative) on constipation, anal fissure and hemorrhoidal diseases during pregnancy. It is helpful for gastroenterologist, obstetricians, Gynecologist and prenatal care physicians.

► Please cite this paper as:

Ghahramani L, Hosseini SV, Rahimikazerooni S, Bananzadeh A, Namavar Jahromi B, Samsam A, Rezaeian Zadeh A, Safarpour AR, Bagherpour Jahromi A, Banihashemi SH. The Effect of Oral Psyllium Herbal Laxative Powder in Prevention of Hemorrhoids and Anal Fissure During Pregnancy, A Randomized Double Blind Clinical Trial. *Ann Colorectal Res*; 2013;1(1): 23-7. DOI: 10.17795/acr-11488

► Copyright © 2013, Colorectal Research Center and Health Policy Research Center of Shiraz University of Medical Sciences. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/3.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

1. Background

Hemorrhoidal disease and anal fissure are known as one of the prevalent clinical problems in women (1). The prevalence is different in various places and the level of its outbreak was reported 24.8% (2). Pregnancy and delivery make susceptible women to hemorrhoidal disease and fissure during pregnancy because of an increase in abdominal pressure and constipation (2).

It was shown that hemorrhoidal diseases may be caused by a backflow of venous blood in order to transient increase in intra abdominal pressure (3, 4). Constipation in pregnancy results from a change in diet, a decline in physical activity, hormonal alterations, and a decrease in digestive system function (5, 6). In different studies, the prevalence of anorectal diseases (hemorrhoidal diseases and anal fissure) and constipation in the third gestational period was reported 11% to 38% (2, 5). Thus, using therapeutic measures without any side effects for the patients and the fetus are clinically important (7). Recently, the use of some herbal medicines like flavonoid acid extracted from the citrus has been taken into account. *Plantago psyllium* (psyllium as the seed of fleawort) is also one of these herbs whose remedial effect appears by absorption of water by chelating agent in the crust of its seed (8). When powder is used with adequate water, it will result into an additional bulk in the stool, increase the water content, and trap it in the mucin within the stool. So psyllium granule would increase the peristalsis movement (5, 7, 9).

2. Objectives

Regarding the properties of psyllium, in this study, we aimed to determine the preventative effect of psyllium powder on constipation, anal fissure and hemorrhoidal diseases during pregnancy.

3. Patients and Methods

This study was a prospective randomized control trial to compare the effect of psyllium powder on preventing constipation and its' associated diseases with placebo in pregnant women who referred to Pregnancy Care Clinics of Shiraz University of Medical Sciences from July 1, 2010 to July 1, 2011. The study was submitted to Iranian Registry of Clinical Trials and its' approval code is 201212119936N3.

All (3136) primigravid women ageing between 20 and 30, at the onset of third trimester of pregnancy were asked to take part in the program and 2412 of them accepted our invitation (724, declined) and signed the written consent form. The inclusion criteria were first pregnancy, being at the beginning of third trimester of gestational period and age between 20 and 30. At the same time, positive medical history of anorectal diseases and signs of current anorectal disease were determined as exclusion criteria.

As a consequence 303 participants were excluded from the study. The remaining 2109 participants were divided randomly into two groups. The random sequence was assigned by Blocked Randomization Method and use of standard random number tables. We lost 17 participants during follow-up after allocation.

A package containing 180 small packs of 10 mg powder was delivered to each participant. They were requested to mix a pack in a glass of water and drink it twice daily. In the follow-up under such circumstances, group A with 1015 participants received Psyllium Powder and group B with 1077 participants received placebo. Both placebo powder and Psyllium Powder were provided by Shiraz School of Pharmacy and were just labeled A and B. We arranged two follow up sessions for all cases. The first, 45 days after intervention and the second, seven days before expected delivery date. A surgeon with two assistants who were general practitioners (GP) evaluated the participants in follow-up sessions and recorded information in prepared questionnaires.

All of the persons involved in the study were blinded to intervention including both participants and care providers such as physicians, nurses and the clerks.

Constipation which was the primary outcome was defined as feelings of incomplete or uncomfortable defecation as well as defecation less than three times per week. Obviously, these pieces of data were acquired through the subjective history of participants. Hemorrhoid and anal fissures were regarded as secondary outcomes. They were diagnosed on the basis of history and Physical Examination. The entire process was completed by the same team including a surgeon and two GP assistances.

Statistical analyses were performed with SPSS 20.0 software (SPSS, Chicago, IL, USA). Comparisons between treatment and placebo groups on outcome variables were conducted using chi-square tests for categorical variables. P values below 0.05 were considered significant (Figure 1).

4. Results

The mean and SD of age in group A (treatment group) was 29.9 ± 3.24 and in group B (placebo group) the mean \pm SD was 29.5 ± 3.48 . In group A 14 participants had less than three times defecation per week, 12 of them had hard stool and 26 had positive history of uncomfortable defecation. Consequently, 52 patients were classified as cases of constipation which eight of them were suffering from fissure and two of them were diagnosed as hemorrhoid cases.

In group B, 92 patients had less than three times defecation per week, 62 of them had hard stool and 56 women had positive history of uncomfortable defecation. As a result all of them (190) classified as cases of constipation. The evaluating team diagnosed 127 of them as fissure cases while 11 of them were suffered from hemorrhoid.

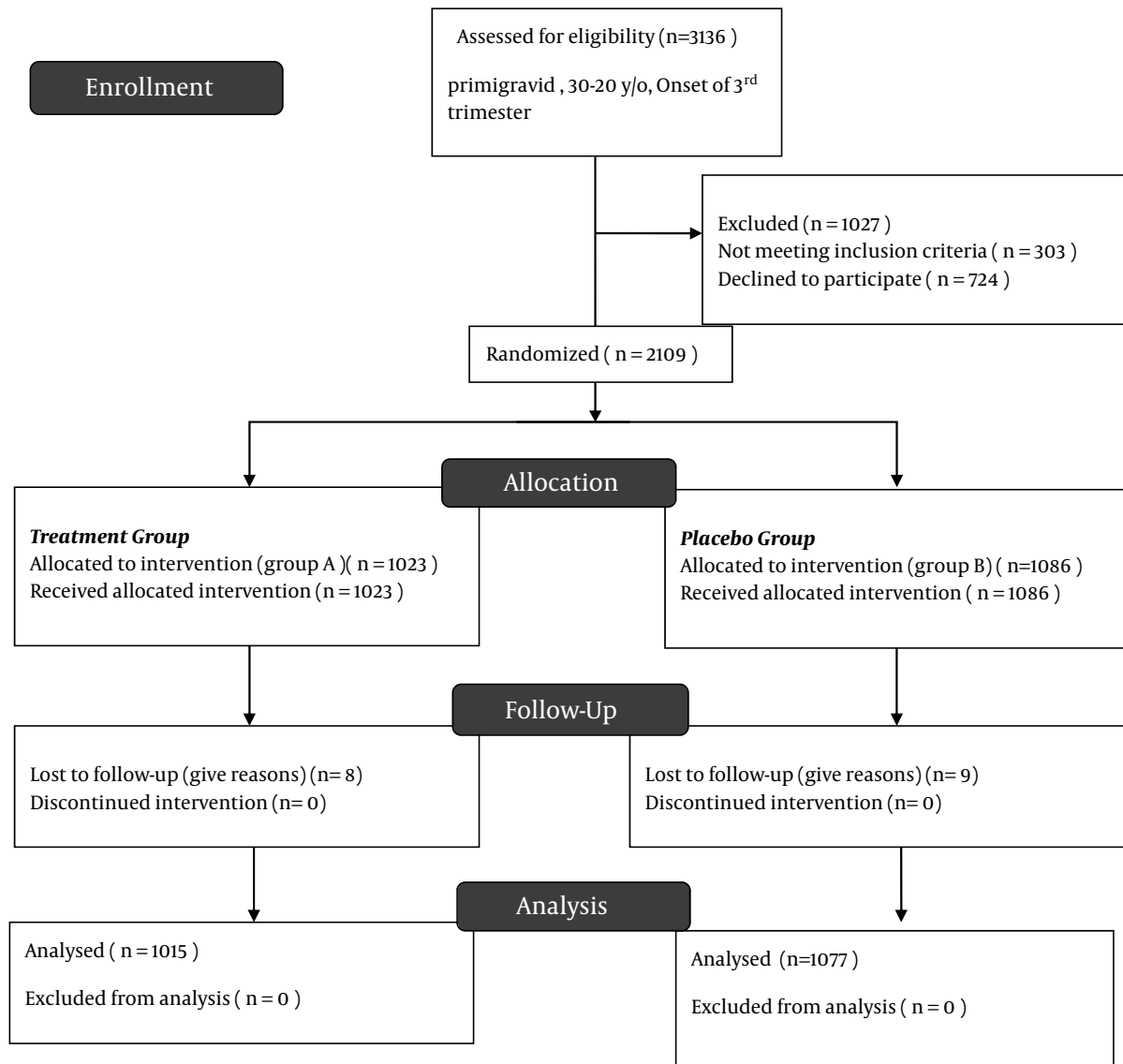


Figure 1. CONSORT 2010 Flow Diagram

Chi-square test for independence indicated significant association between consumption of psyllium powder and decrease rates of constipation, hemorrhoid and fissure, in group B compare with group A ($P < 0.001$).

5. Discussion

Constipation in pregnancy is related to change in life style, poor oral fluid intake because of nausea and vomiting, hormonal alteration (especially progesterone), some medication such as iron supplement. About 11% to 38% of

pregnant women have suffering of constipation. Treatment has to leasd on softy without incontincy risk of congenital malformation (9).Some drugs like senna PEG use for treatment of constipation and related complication sally during pregnancy. Although, some laxative usage like castor oil and mineral oil should be limited. There is no evidence to use prophylactic any laxative agents in pregnancy (10-12).

However, some data have shown similarity of prevalence for constipation during pregnancy among women from the same geo graphic area (13). Our results showed

that in the case group, psyllium powder could significantly decrease the number of surgeries resulting from anorectal complications, hemorrhoidal diseases, anal fissure and constipation. It is in concordance of several other studies which emphasized the effect of fiber in diet on preventing constipation in the course of pregnancy (1). Considering the type of delivery, psyllium powder led to the significantly decrease in surgical complications, constipation and fissure in women who had normal delivery. However this decline was observed only for constipation and fissure in women who underwent cesarean section. In other words, psyllium powder had a significant effect on reducing the anorectal complications in normal deliveries, which is justifiable in regard to the additional pressure on the true pelvis during the normal delivery and the effect of psyllium laxative against the increase of pressure in internal anal sphincter. Several studies have already done hemorrhoidal diseases and anal fissures during pregnancy. In one study in Spain by 'Alonso Coello' et al on the effect of laxatives during pregnancy in seven subjects, it was shown that fiber could decrease the hemorrhoidal symptoms and bleeding (7). In another study in France in women during pregnancy until delivery, anal fissure was visible in 15.2% of the subjects and hemorrhoidal diseases in 20% (14).

In Thailand, trihydroxy ethyl rothoside was used for treatment of hemorrhoidal diseases during pregnancy and the patients' signs were evaluated two weeks after medication (15). In another study in Indonesia, the effect of Hydroxy ethyl rothoside in treatment of hemorrhoidal diseases during pregnancy was studied that shown pain, bleeding, secretion and itching (16). In another study in Italy, the effect of betahydroxy ethyl rothoside to treat hemorrhoidal diseases during pregnancy was studied and a considerable clinical recovery was noticed (17).

In another study in Argentina, conservative measures were practiced for hemorrhoidal diseases during pregnancy such as changes in food habits and the effect of hydroxyl ethyl rothoside in decreasing of hemorrhoidal symptoms was studied during pregnancy showing, however more attention needed to ensure the safety of this drug during pregnancy (18). In another study in India, micronized flavonoic was used for treatment of hemorrhoidal diseases during pregnancy which resulted into a significant decline in symptoms, bleeding, pain and anal discharge in patients (19). During pregnancy anal sphincter pressure is slightly higher than normal level and laxative medications like psyllium can not reduce the resting pressure of the anal sphincter checked by manometry. The laxatives can prevent the rise of pressure in internal anal sphincter only (20, 21). We can conclude that psyllium powder consumption during the third trimester of pregnancy could significantly prevent constipation, hemorrhoid anal fissure.

Acknowledgements

We would like to thank Colorectal Research Center of Shiraz University of Medical Sciences for their supports.

Authors' Contribution

Dr. Ghahramani and Dr. Hosseini proposed the main idea of the manuscript. Data have been collected by Dr. Rahimikazerooni, Dr. Bananzadeh, Dr. Namavar Jahromi, Dr. Samsam, Dr. Bagherpour Jahromi, Dr. Banihashemi. The data analyzed by Dr. Rezaeian Zadeh and Dr. Safarpour. Dr. Ghahramani, Dr. Hosseini, Dr. Rezaeian Zadeh, Dr. Safarpour have contributed in the design and writing of the manuscript.

Financial Disclosure

Non declared

Funding/Support

The manuscript has been supported by the Colorectal Research Center of Shiraz University of Medical Sciences.

References

1. Heidi Nelson . *Sabiston Text book of surgery*.
2. Hyams L, Philpot J. An epidemiological investigation of hemorrhoids. *Am J Proctol*. 1970;**21**(3):177-93.
3. Haas PA, Fox TA, Jr, Haas GP. The pathogenesis of hemorrhoids. *Dis Colon Rectum*. 1984;**27**(7):442-50.
4. Loder PB, Kamm MA, Nicholls RJ, Phillips RK. Haemorrhoids: pathology, pathophysiology and aetiology. *Br J Surg*. 1994;**81**(7):946-54.
5. Corman ML. *Colon and Rectal Surgery*.
6. Simmons SC. Anorectal disorders in pregnancy. *Proc R Soc Med*. 1972;**65**(3):286.
7. Alonso-Coello P, Guyatt G, Heels-Ansdell D, Johanson JF, Lopez-Yarto M, Mills E, et al. Laxatives for the treatment of hemorrhoids. *Cochrane Database Syst Rev*. 2005(4):CD004649.
8. Greenhalf JO, Leonard HS. Laxatives in the treatment of constipation in pregnant and breast-feeding mothers. *Practitioner*. 1973;**210**(256):259-63.
9. Trottier M, Erebara A, Bozzo P. Treating constipation during pregnancy. *Can Fam Physician*. Canada: 2012. p. 836-8.
10. Horn JR, Mantione MM, Johanson JF. OTC polyethylene glycol 3350 and pharmacists' role in managing constipation. *J Am Pharm Assoc (2003)*. United States: 2012. p. 372-80.
11. Acs N, Banhidly F, Puho EH, Czeizel AE. Senna treatment in pregnant women and congenital abnormalities in their offspring-a population-based case-control study. *Reprod Toxicol*. United States: 2009. p. 100-4.
12. Acs N, Banhidly F, Puho EH, Czeizel AE. No association between severe constipation with related drug treatment in pregnant women and congenital abnormalities in their offspring: A population-based case-control study. *Congenit Anom (Kyoto)*. Japan: 2010. p. 15-20.
13. Ponce J, Martinez B, Fernandez A, Ponce M, Bastida G, Pla E, et al. Constipation during pregnancy: a longitudinal survey based on self-reported symptoms and the Rome II criteria. *Eur J Gastroenterol Hepatol*. England: 2008. p. 56-61.
14. Abramowitz L, Batallan A. [Epidemiology of anal lesions (fissure and thrombosed external hemorrhoid) during pregnancy and post-partum]. *Gynecol Obstet Fertil*. France: 2003. p. 546-9.

15. Titapant V, Indrasuksri B, Lekprasert V, Boonnuch W. Trihydroxyethylrutosides in the treatment of hemorrhoids of pregnancy: a double-blind placebo-controlled trial. *J Med Assoc Thai.* 2001;**84**(10):1395-400.
16. Wijayanegara H, Mose JC, Achmad L, Sobarna R, Permadi W. A clinical trial of hydroxyethylrutosides in the treatment of haemorrhoids of pregnancy. *J Int Med Res.* 1992;**20**(1):54-60.
17. Benzi G, Vanzulli A, Pozzi E, Acerboni S. [Clinical study for the evaluation of the tolerability of O-(beta-hydroxy-ethyl)-rutoside in the treatment of hemorrhoids during the 3d trimester of pregnancy and in the postpartum period]. *Minerva Ginecol.* 1992;**44**(11):591-7.
18. Quijano CE, Abalos E. Conservative management of symptomatic and/or complicated haemorrhoids in pregnancy and the puerperium. *Cochrane Database Syst Rev.* 2005(3).
19. Buckshee K, Takkar D, Aggarwal N. Micronized flavonoid therapy in internal hemorrhoids of pregnancy. *Int J Gynaecol Obstet.* Ireland:1997. p.145-51.
20. Singer AJ, Brandt LJ. Pathophysiology of the gastrointestinal tract during pregnancy. *Am J Gastroenterol.* 1991;**86**(12):1695-712.
21. Gattuso JM, Kamm MA. Adverse effects of drugs used in the management of constipation and diarrhoea. *Drug Saf.* 1994;**10**(1):47-6.5