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Letter to Editor Concerning the Article: The Effect of Oral Psyllium Herbal Laxative Powder in Prevention of Hemorrhoids and Anal Fissure During Pregnancy

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Dear Editor,

We have read the interesting article of Ghahramani et al., entitled "The Effect of Oral Psyllium Herbal Laxative Powder in Prevention of Hemorrhoids and Anal Fissure During Pregnancy" published in your journal (1). The authors have compared two groups of primigravida pregnant women, who were taking and not taking Psyllium powder, in terms of evaluation of its effect on the outcomes, such as hemorrhoid, fissure and constipation, during pregnancy. The study had clear and specific questions and PICO has been well described. The randomization procedure has been used for assigning pregnant women into the two treatment and placebo groups and, also, the blindness has been observed in both researchers and subjects. However, four important questions are raised by this study:

1. Precise Definition of Outcomes:

It seems that the study lacks a specific and standard definition of primary and secondary outcomes. For example, the mentioned criteria for the diagnosis of constipation, hemorrhoids or fissure are not based on specific scientific reference (2). In addition, no specific scientific reference has been declared for considering hemorrhoids as one of the complications of constipation, while, according to the results of Johanson and Sonnenberg (1994), diarrhea and not constipation is among the risk factors leading to hemorrhoids (3).

2. Intention to Treat Analysis:

The intention-to-treat analysis means to compare any two or more groups treated in a study, meaning that it investigates all those subjects who were allocated to the groups, at the beginning of the study and after randomization. This investigation is performed regardless of whether or not the studied participants end the study or take the specified medication. This type of analysis is proposed in superiority trials to prevent bias.

3. Per-Protocol Analysis:

With the per-protocol analysis, we compare only those participants who have been present from the beginning of the study and have ended it and also those who have consumed only the medicines they have been supposed to take from the beginning and have not taken the medicines of the other group. If this analysis is performed alone, it would lead to bias. The study of Ghahramani (1) did not specify the type of analysis among the mentioned types and whether or not one or both analyses (recommended) have been performed.

4. Management of Missing Data:

In addition, no information about the missing data has been presented to the reader. This is one of the most important cases in the analysis of clinical trial data. Since patients who left the study usually either have considered the treatment as ineffective or have suffered the side effects of the medicine, assessing missing data is often directly related to efficacy or safety of the studied medication. One of the important methods for handling missing data is using the last observation carried forward method.

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