Comparing the Effect of Golghand and Psyllium on Constipation among the Elderly: A Randomized Clinical Trial

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Received: 27 Apr. 2017 **Accepted:** 4 Sep. 2017

Abstract

Background: Constipation is a common problem among the elderly which would decrease their quality of life. One of the solutions for improving this problem is using medicinal plants.

Objective: The present study was conducted to compare the effect of Golghand and Psyllium on constipation among the elderly.

Methods: In this clinical trial, 70 older adults with constipation were selected and randomly allocated into two groups on Golghand and Psyllium. The Golghand group, consumed one tablespoon of Golghand potion three times a day half an hour after meals. The Psyllium group consumed a sachet of Psyllium powder with a glass of water three times a day after meals. The intervention lasted for two weeks. Data gathering tools were demographic questionnaire and a researcher-made checklist about bowel habits. Data were analyzed using SPSS 18.

Results: According to the results, there was a significant difference between the mean numbers of defecation in each group before and after the intervention (paired t-test, $P < 0.05$); but in comparison between the two groups mean number of defecation was significantly higher in the Psyllium group (independent t-test, $P < 0.001$). The mean numbers of vomiting in each group had no significant difference before and after the intervention (paired t-test, $P > 0.05$).

Conclusions: Results of the present study showed that both medications could be used as supplementary non-medicinal methods for treating constipation among the elderly.

Keywords: Constipation, Elderly, Golghand, Psyllium

Introduction

The increased population of the elderly has drawn the attentions toward their health, comfort and well-being, and also, resolving their needs and problems [1]. The necessity of comprehensive care for the elderly comes from that this population has various health issues and is the major user of healthcare services [2]. Constipation is one of the problems of this population. Studies have shown that dietary habits, physical activities, economic-social status, psychological parameters, drugs, age and gender could be effective on the development of constipation [3].

The prevalence of constipation would increase by age; about 50% of the over 80 years old, 40% of the under 80 elderly and 60% of those living in care institutions are suffering from constipation [4]. Due to the risk factors such as disability and long-term drug consumption for diseases such diabetes, hypothyroidism, dementia, Parkinson and etc. the prevalence of constipation is 17% to 40% among the elderly, 26% of men and 34% of women and this rate would increase to 80% among those living at care institutions and hospitals [5, 6].

Constipation has rarely been regarded as a significant problem because its hospitalization and mortality rates are not high, while it could be a symptom of a disease [7]. On the other hand, due to shame and embarrassment, this problem would not be discussed with the physicians or health personnel by the elderly and it usually would be encountered as a normal aging process [8]. But this disease would decrease the quality of life among the patients and it is of great importance because it could lead to long term complications such hemorrhoid, fissure and psychological problems [9].

To prevent and treat constipation, The American Digestive Disease Society has recommended a well-balanced diet including bran, grains, fresh fruits and vegetables, and drinking sufficient amount of fluids and also physical activity. If these recommendations would not be effective, the physician might also prescribe laxatives. Bulk-forming laxatives, stimulants, stool softeners, lubricants and osmotic are some of the recommended drugs for treating constipation [10]. But, it worth noting that, by aging physical activity would be decreased in most of the elderly and due to digestive problems or loosing teeth, their fruit and vegetable consumption would also be limited. On the other hand, decreased cardiac, liver and renal outputs and hemostatic changes in the elderly would increase drug accumulation in their bodies and increase medicinal complications among the elderly [11].

Chemical drugs all have side effects and could become health threatening factors for the elderly or have interactions with other consumed medicines [12]. One of the solutions for this problem is using herbal medicines and drugs, which have been used in our traditional medicine for centuries and are more preferred than the chemical drugs in the Iranian culture, especially among the elderly. Different national and international studies have evaluated the effects of herbal medicines such as ginger [13], kiwi powder [10], flaxseeds, prunes and yoghurt [14] on treatment of constipation and reported various results.

Psyllium or fleawort is a plant of Plantagi Nacea family which is named *Planta ovata*. Psyllium is an herbal laxative which would increase the bulk of the intestinal contents

through absorbing water and would lead to stool defecation by increasing peristalsis motions [15]. The role of Psyllium in treating constipation [16-18], obesity in children and teenagers [19] and high blood cholesterol [20-22] has been approved through various studies.

Golghand potion is a traditional medicine product that could be used for treating constipation. Golghand is a medicinal product which is derived from the petals of the rose or as it is known in Iran, the Damask rose. Golghand has been used in Greek, Chinese and Ayurvedic medicine and it has recently drawn the attention of traditional medicine experts. This drug is also a laxative but it does not have the side effects of other chemical and herbal laxatives such as Bisacodyland Sana products [23]. Also considering that the main component of this drug is Damask rose and this plant has a holy place in the Iranian culture and Iranians are usually willing to use this flower and its combinations in their foods, especially for religious events, and since no studies about the effect of this drug especially on the elderly have not been conducted nationally or internationally, the present study was conducted to evaluate the effect of Golghand and comparing its effect with Psyllium on constipation among the elderly.

Materials and methods

The present study was a clinical trial that has been registered on the Iranian Registry for Clinical Trials by No. IRCT2016012423190N2. Study population consisted of all elderly referred to Traditional Medicine School Clinic of Ardakan, Yazd, Iran in 2016. Inclusion criteria were diagnosis of constipation based on the Rome III criteria and willing to participate in the study. The exclusion criteria were disability to move and perform physical activity, having addiction to narcotics, having diagnosed metabolic disorders like diabetes, consuming drugs for treating psychiatric disorders, not using the drugs based on the prescribed plan (missing four times during one week), receiving any kind of treatment for constipation during the recent two week, having the symptoms of acute gastroenteritis like vomiting, nausea, and diarrhea during the study, and unwillingness to participate in the study.

Sample size was calculated using the mean comparison formula with a standard deviation of 0.5, based on the number of defecations from the previous articles [14], effect size of 0.4, test power of 90%, confidence interval of 95% and sample loss, to be 35 participants for each group and a total of 70. From all of the participants, one person from the Psyllium group was excluded due to not tolerating the drug.

Random allocation of the participants was carried out using the minimization method [24]. Initially, the patients were categorized based on key variables, such as age and gender. Afterwards, from the patients who met the inclusion criteria, the first participant was placed in the intervention or control group by coin flip, and other participants were allocated to the study group with lower total of variables (age and gender). In case of equality, random allocation was repeated.

Data gathering tools included demographic characteristics questionnaire (age, gender, job…) and a researcher-made checklist which was developed based on previous articles for

evaluating bowel habits and the number of defecations, vomiting, flatulence, stomach ache or discomfort, and pain while passing. For gaining more accurate information, a table was developed based on the checklist to be completed by the patient daily and was handed to the researcher after the two-week period of the study and so, the bowel habits were calculated.

To perform the study, the researcher (first author) referred to the clinic and completed the demographic characteristics questionnaire and the constipation checklist based on the Rome III criteria through personal interviews. After selecting the participants according to the inclusion and the exclusion criteria and taking informed consent, they randomly allocated to the groups of Psyllium and Golghand. In the Golghand group, the participants consumed one tablespoon of Golghand potion three times a day half an hour after meals for two weeks. In the Psyllium group, one sachet of Psyllium powder was consumed after each meal three times a day for two weeks (Figure 1). Sufficient information was provided to the participants about the correct method of drug consumption, visiting with the researcher, completing the tools. To remind the patients about taking their drugs, the researcher contacted them daily and answered their question. If their drugs were finished, the researcher would provide them with more drugs.

Ethical considerations of this study were taking permission for performing the study from Rafsanjan University of Medical Sciences, taking ethics code from the Ethics Committee of Rafsanjan University of Medical Sciences (IR.RUMS.REC.1394.177), taking consent from the participants and justifying them about the study and their goals, keeping their information confidential, regarding the principle of secrecy in publishing the information, and regarding the rights of the writers in using articles and published and electronic sources. Eventually, after gathering the data, data were analyzed using descriptive statistics (mean and standard deviation) and analytic statistics (independent t-test, paired t-test and Mann-Whitney test) using SPSS software version 18. The significance level was considered less than 0.05.

Results

Demographic results revealed that most of the participantsin both groups were women, from 60 to 70 years old and had an educational level of under diploma and all the participants were similar regarding all of the characteristics of their disease (Table 1).

According to the results, before the intervention, the mean number of defecations per week in the Psyllium group was 1.20 ± 0.53 and in the Golghand group was 1.20 ± 0.63 and their difference was not significant (independent t-test, $P = 1$). Two weeks after the intervention, the difference in the mean of defecations per week was significant between both groups (independent t-test, $P = 0.001$); the Psyllium group had a higher mean of defecations per week. The difference between both groups regarding the number of vomiting before the intervention was not significant (independent t-test, $p = 0.37$). After the intervention, the difference between both groups regarding the number of vomiting was still not significant (independent t-test, $P = 0.21$).

According to the results, there was a significant difference between the mean numbers of defecation in each group before and after the intervention (paired t-test, P = 0.001); but the mean numbers of vomiting in each group had no significant difference before and after the intervention (paired t-test, P > 0.05) (Table 2).

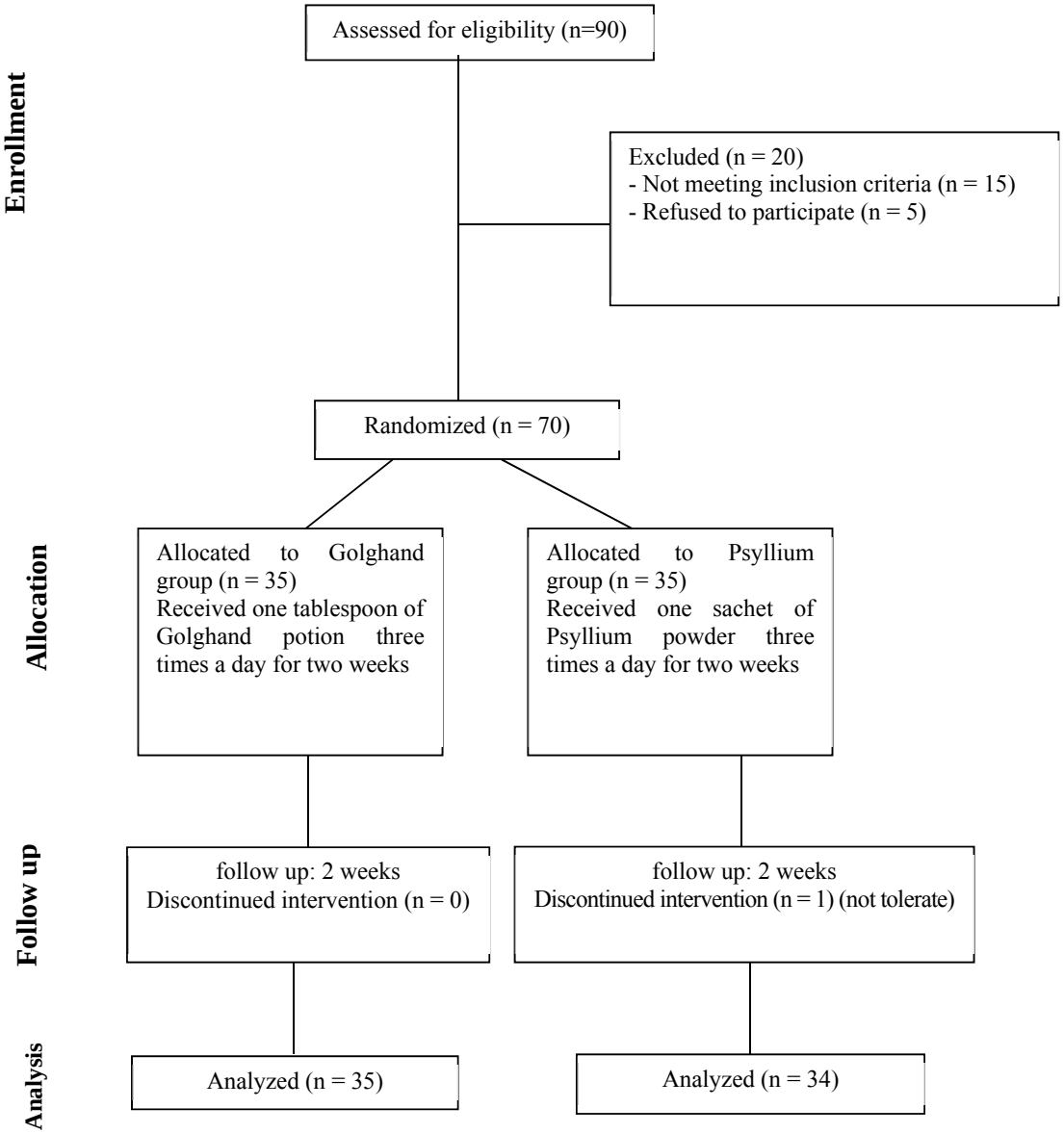

Figure 1- CONSORT chart

Table 1- Comparing the demographic characteristics of the patients between the Psyllium and Golghand groups

Variable		Group		Test results
		Psyllium	Golghand	
Gender	Male	10 (28.6)	10 (28.6)	P* = 1
	Female	25 (71.4)	25 (71.4)	
Age (years)	60-70	21 (60)	23 (65.7)	P** = 0.71
	71-80	13 (37.1)	11 (32.5)	
	> 80	1 (2.9)	1 (2.9)	
Educational level	Illiterate	13 (37.1)	17 (48.6)	P** = 0.12
	Under diploma	14 (40.0)	16 (45.7)	
	Diploma and higher	8 (22.9)	2 (5.7)	

* Chi-square
** Man-Whitney

Table 2- Comparing the mean and standard deviation of the number of defecations and vomiting before and after the intervention between the Psyllium and Golghand groups

Variable	Group	Before the intervention (Mean ± SD)	After the intervention (Mean ± SD)	Comparison within groups (paired t-test)
Number of defecations	Psyllium	1.20 ± 0.53	12.94 ± 4.55	P = 0.001
	Golghand	1.20 ± 0.63	6.05 ± 1.92	P = 0.001
		P = 1	P = 0.001	
Number of vomiting	Psyllium	0.11 ± 0.32	0.20 ± 0.47	P = 0.1
	Golghand	0.11 ± 0.40	0.25 ± 0.50	P = 0.57
		P = 0.37	P = 0.21	

According to the results, no significant difference was observed between both groups regarding the variables of flatulence (Mann-Whitney, P = 0.26), stomach ache (Mann-Whitney, P = 0.46), and pain while passing (Mann-Whitney, P = 0.97) after the intervention and none of these drugs had no effect on these symptoms.

Discussion

According to the results, after two weeks of consuming Golghand and Psyllium, although the mean number of defecations was increased in both groups compared to before the intervention, but the increase in the Psyllium group was more and the difference between both groups was significant. Golghand is an herbal medicine which is produced in Iran but no national or international studies were found about its effect on constipation or its comparison with other drugs; but some studies were previously conducted about the effect of Damask rose (which is the main ingredient of Golghand). For example, results of the studies by Marofi et al., and Gharebaghi et al., indicated the effect of rose extract on decreasing the intensity of pain after surgery [25, 26]. Results of studies by Sadraei et al., and Kim et al., revealed the role of Damask rose extract in decreasing the intensity of dysmenorrhea pain [27, 28]. Results of a study by Ezzati et al., also confirmed the positive effect of hydroalcoholic extract of Damask rose on intra-abdominal adhesions after laparotomy in rats [29].

Honey which is another combination of this drug has been approved to have a role in

decreasing ulcers and gastritis, treating intestinal infections, and treating constipation and liver and gallbladder diseases, which is in line with the results of the present study [30].

Psyllium is a drug with longer history and many studies have been conducted about its effects. For example McRorie et al., in a study compared the effect of Psyllium and Sodium Docusate in treating chronic constipation and reported that Psyllium significantly increased the stool fluids, total stool defecation and number of bowel movements; which is in line with the results of the present study regarding the positive effects of Psyllium on constipation [31].

Results of a study by Attaluri et al., which compared the effect of dried plums and Psyllium on constipation revealed that in the plum consuming group, the number of bowel movements and stool consistency were significantly improved, which was not similar to the results of the present study [16]. Besides the differences between the study populations of both studies and the differences in the age range of the participants, the compared drug to Psyllium was also different between both studies; therefore it is recommended to design a study for comparing the effect of Golghand and dried plum. Results of a study by Singh [15] which was similar to the present study showed that Psyllium as a high-fiber source and a natural active polysaccharide has a direct relation with bowel movements and would increase the stool bulk and lubricate it through more absorption of water and its mucilage nature. This would facilitate the defecation of stool. This drug would increase the number of bowel movements and decrease the duration of passing the stool through the bowels.

According to the results of the present study, no significant difference existed between both groups regarding the variables of number of vomiting, flatulence, stomach ache and pain while passing the stool after the intervention ($P > 0.05$) and none of these drugs had no effect on these symptoms. It is recommended to perform more studies with longer durations to have a more definite opinion in this regard. Performing the study on the elderly for only two weeks were the limitations of this study which would limit the generalization of its results. Thus it is recommended to perform this study with longer duration on populations with different age range.

Conclusion

According to the results, although psyllium was better in comparison with Golghand, but Golghand could increase the number of defecation too. Our findings suggest that Golghand also can use as a non-medicinal therapy for constipation. Although further studies are required in this field.

Acknowledgement

This article was extracted from a master's thesis (Research Number: 20/1237) approved in Rafsanjan University of Medical Sciences and was financially sponsored by this university. Hereby, we extend our gratitude to the authorities of the university for supporting this study. We are grateful to all of participants who participated in our study.

Conflict of interest

The authors declare no conflict of interest related to this work.

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