ISSN: 0975-8585

Research Journal of Pharmaceutical, Biological and Chemical Sciences

The Effect of *Descureania Sophia L.* and *Prunus Domestica L.* in Prevention of Constipation among Iranian Hajj Pilgrims, Saudi Arabia

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ABSTRACT

It is still common for travelers to complain of gastrointestinal problems such as constipation. Different complementary and alternative modalities were reported to overcome constipation. This study investigated the effect of *Descureania sophia L.* and *Prunus domestica L.* in prevention of constipation among Iranian Hajj pilgrims in Kingdom of Saudi Arabia. In a randomized clinical trial among Hajj pilgrims who traveled from Shiraz, Iran to Saudi Arabia for their religious ceremony in November, 2010, 87 were considered as the case and 67 as the control group. In case group, each time, the participants received 10-15 g of flixweed (*Descurainia sophia L.)* seeds and 40-50 g of prune (*Prunus domestica L.)*. They consumed this daily medication before lunch and dinner for three weeks. During this period, the control group continued having daily meal without any intervention. Rome III criteria was used to define constipation. To evaluate the participants' health status in defecation, a ten-point Visual Analogue Scales (VAS) was used. No significant difference was noticed between the case and control groups regarding sex, age, body mass index (BMI) and cigarette smoking but there was a significant difference between the groups regarding improvement in frequency of feelings of pain, incomplete defecation, fullness, nausea, distention, reflux, the frequency of bowel movements bowel habits and the amount of daily fluid intake. Only for bleeding on defecation, no significant difference was noticed. As these herbals are inexpensive, available and without any complications, they can be safely administered in prevention of constipation especially among travelers.

Keywords: *Descureania sophia*, *Prunus domestica*, Constipation, Hajj, Traveler

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ISSN: 0975-8585

INTRODUCTION

Although not definitively correlated with travelling, it is common for travelers to complain of gastrointestinal problems such as constipation [1, 2]. Several etiologies, such as insufficient dietary fiber intake, fatigue, and jet lag have been reported for constipation [2-5]. Constipation is a widespread complaint among different age groups with various prevalence rates in different regions [5-8] while 20% of Americans were shown to suffer from constipation [5] and more than 2.5 million were reported the need to visit a physician [4, 8].

Constipation may cause psychological and social consequences such as anxiety, depression, and restlessness, which can affect the patients' quality of life [6-8]. Based on these complications, early management of the problem [5, 6, 8] seems necessary. Although, administration of laxative drugs are not always safe and a practical therapeutic measure [1, 5-8], a small number of patients may undergo invasive techniques such as surgery which may worsen their constipation [4]. Different complementary and alternative modalities were reported to overcome these complications [7, 8]. In Iran, Iranian traditional Medicine (ITM) has introduced multiple therapeutic measures for constipation, including dietary change, life style adjustment, and administration of herbal medicine [9-11]. The Hajj ceremony in Kingdom of Saudi Arabia is a mass gathering of more than one million Muslims traveling there from all of over the world which takes place every year. During the Hajj pilgrim, people are prone to communicable and non-communicable diseases [12-14] such as gastrointestinal symptoms, in which constipation has the highest rank especially among Iranian pilgrims, with an incidence of 588/10000 [15]. Therefore, a cost-effective strategy for management of this problem is needed [3]. ITM was previously demonstrated as a safe and favorable therapy for constipation [9, 10]. Flixweeds (*Descurainia sophia L.)* and prunes (*Prunus domestica L.)* are two herbal drugs mentioned in ITM with various components and efficacies [9, 10, 16-19] including laxative effects relieving constipation through a slipping and breaking mechanism [9, 10]. Therefore, this study evaluated the effects of *Descurainia sophia L.* and *Prunus domestica L.* in prevention of constipation among Iranian pilgrims who attended the Hajj ceremony in 2010 in Kingdom of Saudi Arabia.

MATERIALS AND METHODS

Two hundreds and seventy one eligible healthy Hajj pilgrims were randomly divided into two groups of case and control. Among participants 96 were excluded, 4 had failure to meet the inclusion criteria and 1 refused to participate until the end of the study. Among the remained 170 participants, 96 were considered as the case group while 3 were lost in the follow up study and the remained population was 87. For the control group the subjects were 80 but due to loss of follow up in 13 individuals, the remained subjects were 67. All pilgrims traveled from Shiraz, Iran to Kingdom of Saudi Arabia for their religious Hajj ceremony in November, 2010.

People were excluded if they had any history of systemic disease such as diabetes mellitus, thyroid disease, hypertension, abdominal or gastrointestinal surgery (including

cesarean section and hernia), laxative and herbal drug consumption, chronic constipation, reactions or side effects during previous use of prune or flixweed, consumption of drugs which caused constipation (such as contraceptives and calcium channel blockers). Those not wishing to participate or who refused to sign the informed consent were also excluded. Informed consent was obtained from each pilgrim. Participants could withdraw from the study, at any time they wished. The Research Ethics Committee of Shiraz University of Medical Sciences (SUMS) approved this study. This trial was registered in the Iranian Registry of Clinical Trials as IRCT201009013074N2.

In the case group, each time, the participants received 10-15 g of flixweed (*Descurainia sophia L.)* seeds mixed in 250 ml of boiling water during a period of 30 min and also 40-50 g of prune (*Prunus domestica L.)*. They consumed this daily medication before lunch and dinner for a period of three weeks. During this period, the control group continued having daily meal without any intervention. We began the trial five days after arrival of the hajj pilgrims from Iran to Saudi Arabia to eliminate the effect of jet lag on the decrease in frequency of bowel movements.

Rome III criteria was used to define constipation as less than three times of defecation per/week, with straining, difficulty in defecation, unproductive urges, feeling of anorectal obstruction, hand maneuver to facilitate stool extraction and feeling of incomplete evacuation. All participants completed a questionnaire including their demographic data and information regarding their interview with a physician before and after the intervention to determine the gastrointestinal symptoms such as constipation, distention and reflux.

To evaluate the participants' health status and comfort in defecation, a ten-point Visual Analogue Scales (VAS) was used: 0-2 indicated poor health status and severe discomfort in defecation; 3-5 denoted to a fair health status and moderate discomfort in defecation; 6-8 showed good health status and mild discomfort in defecation; and 9-10 demonstrated a very good health status and complete comfort in defecation. The physician explained the participants how to interpret their VAS scores. During the study, both groups followed a similar diet prepared by the Iranian Hajj Organization. Subjects were asked not to use any additional herbal products, or change their meal dietary fibers or fluid intake and to also maintain their regular physical activity.

For statistical analysis the SPSS software (Version 16, Chicago, IL, USA) was used. Continuous variables were described using mean and, standard deviation (SD) for normally distributed data, or median and range for non-normally distributed data. Normal distribution was checked by a histogram and tested using the one-sample Kolmogorov-Smirnov test. Categorical variables were reported as frequencies and percents. For comparison of continuous variables in the two groups, an independent sample t-test was used for the normally distributed data and a non-parametric Mann-Whitney U test for skewed data. Paired sample t-test and Wilcoxon Signed Ranks test were used for comparison of continuous variables, and McNemar test was used to compare categorical variables before and after intervention in separate groups. Chi-square and Fisher's exact tests were used for comparison of qualitative variables in both groups. Two-tailed $p<0.05$ was considered statistically significant.

ISSN: 0975-8585

RESULTS

The numbers of excluded subjects were as follows: Gastrointestinal or abdominal surgeries (31), internal diseases (39), use of systemic drugs (40), use of laxative medications (7), history of constipation (1), and concomitant consumption of herbal drugs (4). Some pilgrims had more than one criterion for exclusion. No significant difference was noticed at the baseline between the case and control groups regarding sex, age, body mass index (BMI) and cigarette smoking (Table 1).

Table 1. Demographic data of the control and treatment groups.

	Control Group		Case Group		*P* value
Number	67		87		
Age (years)					
Mean±Standard deviation (SD)	53.55±12.59		54.87±12.94		0.52
Body Mass Index (BMI) (kg/m^2)	24.41±3.93		24.73±2.86		0.57
Gender					
Male (%)	35 (52.2)		52 (59.8)		0.35
Female (%)	32 (47.8)		35 (40.2)		
Cigarette smoking (%)	4 (6)		3 (3.4)		0.46

There was a significant difference at the baseline between the case and the control group regarding frequency of bowel habits and the amount of daily fluid intake. Self-assessment of a comfortable defecation and their health status which was determined by VAS before and after the intervention among both groups was summarized in Figures 1-4. Multiple complaints regarding constipation and function of the gastrointestinal system, including pain or bleeding on defecation, feeling of fullness or incomplete defecation, nausea, distention, and reflux before and after the intervention were evaluated in both groups. Our study indicated that in the case group, a combination of prune and flixweed had a significant effect on prevention of constipation and gastrointestinal symptoms, especially on the frequency of bowel movement, ease of defecation, health status, reflux, and feeling of fullness, when compared to the control group. Regarding the baseline in the case group, symptoms such as distention, nausea, pain and bleeding on defecation significantly improved (Table 2).

There was no significant correlation before and after the intervention regarding all parameters mentioned in Table 2 for the control group, but in the case group, the feelings of pain, incomplete defecation, fullness, nausea, distention, reflux, and the frequency of bowel movements were significantly better after the intervention when compared to the baseline. Only bleeding on defecation had no significant change in this group. A comparison of both groups after the intervention showed significant changes between parameters such as the frequency of bowel movement, feeling of fullness and reflux (Table 2).

ISSN: 0975-8585

Figure-1: Ease of defication in the control group before and after the trial.

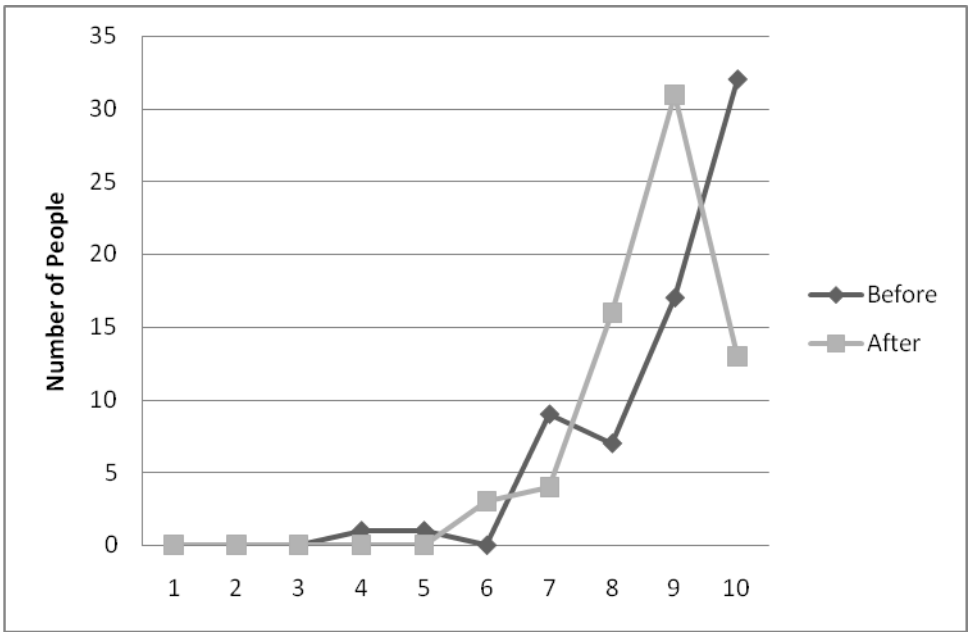
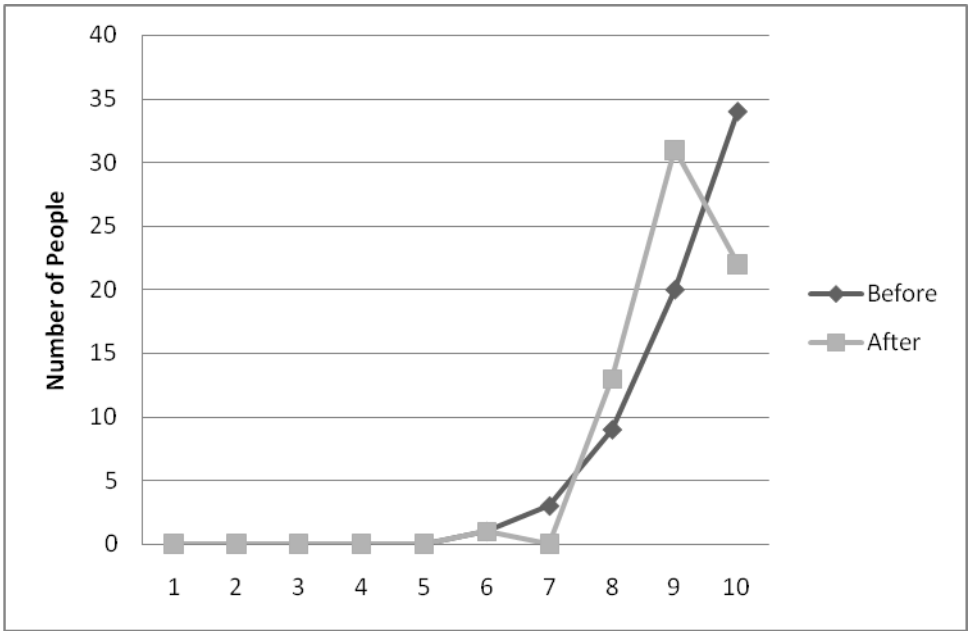


Figure-2: Health status self-assessment in the control group before and after the trial.



ISSN: 0975-8585

Figure-3: Ease of defication in the treatment group before and after the trial.

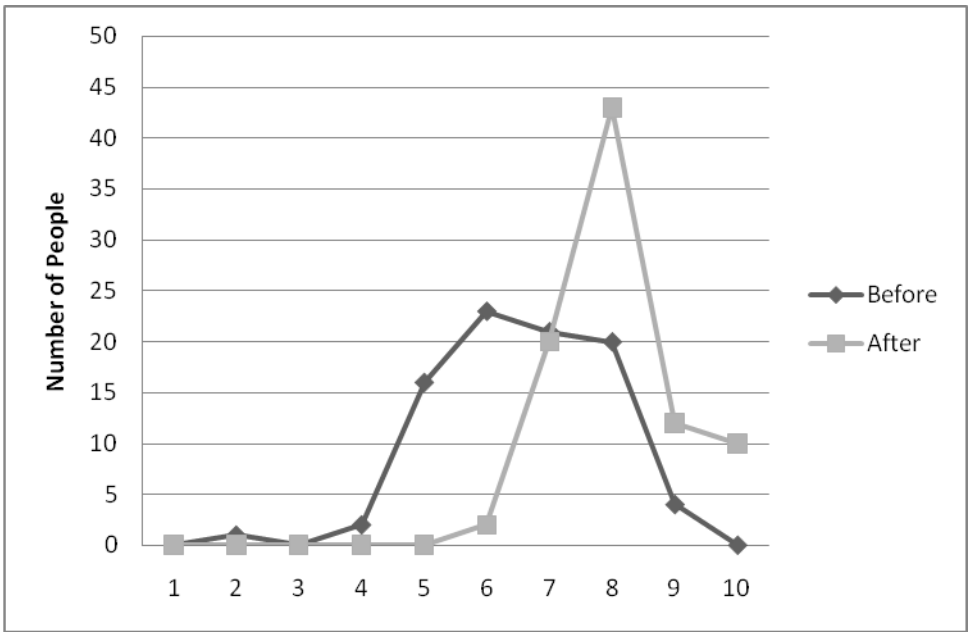
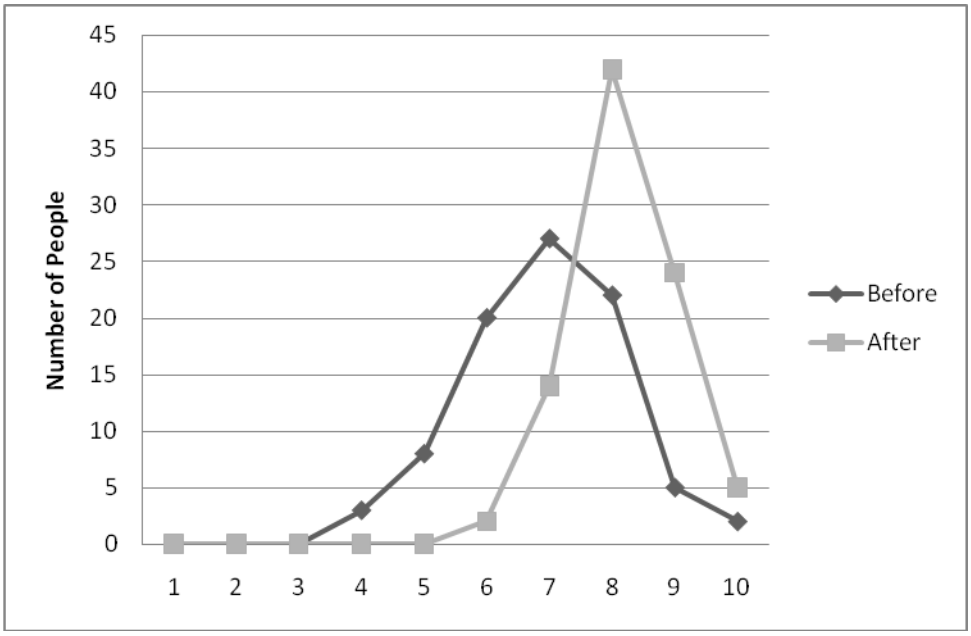


Figure-4: Health status self-assessment in the treatment group before and after the trial.



ISSN: 0975-8585

Table 2. Gastrointestinal symptoms for constipation evaluation.

		Control group		Case group			
		Before trial	After trial	Before trial	After trial	*p* value*	*p* value**
Pain on defecation	Nothing	65 (97)	67 (100)	81 (93.1)	87 (100)		
	1-3 times	2 (3)	0	5 (5.7)	0	0.02	0.28
	> 3 times	0	0	1 (1.2)	0		
Feeling of incomplete defecation	Nothing	66 (98.5)	67 (100)	71 (81.6)	81 (93.1)		
	1-3 times	1 (1.5)	0	16 (18.4)	6 (6.9)	0.02	0.052
	> 3 times	0	0	0	0		
Bleeding on defecation	Nothing	67 (100)	67 (100)	82 (94.2)	86 (98.9)		
	1-3 times	0	0	5 (5.8)	1 (1.1)	0.21	0.14
	> 3 times		0	0	0		
Feeling of fullness	Nothing	59 (88.1)	58 (86.6)	61 (70.1)	81 (93.6)		
	1-3 times	8 (11.9)	9 (13.4)	25 (28.7)	6 (6.9)	<0.001	0.001
	> 3 times	0	0	1 (1.2)	0		
Nausea	Nothing	61 (91)	64 (95.5)	83 (95.4)	87 (100)		
	1-3 times	3 (4.5)	3 (4.5)	4 (4.6)		0.04	0.68
	> 3 times	3 (4.5)	0	0	0		
Distention	Nothing	48 (71.6)	50 (74.6)	70 (80.5)	79 (90.8)		
	1-3 times	18 (26.9)	17 (25.4)	13 (14.9)	7 (8)	0.005	0.25
	> 3 times	1 (1.5)	0	4 (4.6)	1 (1.2)		
Reflux	Nothing	59 (88)	59 (88)	56 (64.4)	72 (82.7)		
	1-3 times	5 (7.5)	8 (12)	26 (29.9)	14 (16.1)	0.001	0.02
	> 3 times	3 (4.5)	0	5 (5.7)	1 (1.2)		
Frequency of bowel habit (daily)	0 - 1 time	10 (14.9)	10 (14.9)	75 (86.2)	13 (14.9)	<0.001	<0.001
	2-3 times	57 (85.1)	56 (83.6)	12 (13.8)	74 (85.1)		
	> 3 times	0	1 (1.5)	0	0		

*Comparison in treatment group, before and after the trial. (There was no significant change between control group before and after trial in all measured parameters); **Comparison between control and case groups after the trial; All figures are presented as No. (%).

DISCUSSION

Gastrointestinal disorders may affect many travelers[1] while several treatment modalities were reported in management of these disorders using different complementary and alternative medicine [7, 8, 20]. In our study, there was a significant difference regarding frequency of bowel habits between the case and the control group after administration of herbal medicines in the case group showing the importance of regularity of bowel habits in self-assessment of gastrointestinal function.

We began the trial five days after arrival of the hajj pilgrims from Iran to Saudi Arabia to eliminate the effect of jet lag on the decrease in frequency of bowel movements even it was shown that destination and duration of trip were not associated with gastrointestinal problems [2]. For constipation, there was no need for laxative consumption in the case group, but 7

subjects in the control group consumed a laxative (either bisacodyl, milk of magnesium, or both). Insufficient dietary fiber intake, inadequate fluid intake, decreased physical activity, side effects of drugs, hypothyroidism, sex hormones, stress and psychological factors, the elderly, irregular toilet habits, prolonged bed rest, jet lag, and obstruction due to colorectal malignancies were shown to play an important role in pathogenesis of constipation during traveling explaining the multiple complaints reported by our participants including constipation and function of the gastrointestinal system such as pain or bleeding on defecation, feeling of fullness or incomplete defecation, nausea, distention, and reflux before and after the intervention shown in Table 2 [2, 3, 5, 21]. These factors may be the leading cause of traveler's constipation during the Hajj ceremony either alone or in combination with other symptoms, as most were easily experienced by pilgrims. It could be hypothesized that traveling fatigue (jet lag) might manipulate bowel movements in the course of the brain-gut axis too [2].

Mearin *et al.* reported a prevalence of 38% for traveler's constipation which is about eight times more than the prevalence of traveler's diarrhea [2], while Tuteja *et al.*'s showed a prevalence of 9% for traveler's constipation and 63% for diarrhea [1]. In our study, just one case of diarrhea was noticed in the case group due to bacterial dysentery and 12 (17.9%) cases of diarrhea in the control group due to viral infections. Our data did not confirm Mearin *et al.* and Tuteja *et al.*'s studies as diarrhea was scarce in our case group which may be due to the antibacterial and antifungal properties of prune which has polycyclic components [1, 2, 19]. Prune and flixweed are two Iranian herbal medicines mentioned in traditional resources, and many of their characteristics such as their laxative effect and gastrointestinal support were previously studied [9, 10, 18, 22, 23]. Prune and flixweed are domestic herbals in Iran, and multiple products have been derived from these plants [10, 16, 18, 19, 24, 25], having antioxidant, phenolic, fiber and simple sugar constituents. Prune was shown to have preventive effects on osteoporosis and colon cancer both *in vivo* and *in vitro* conditions [17, 21, 26, 27]. The laxative effects of prune and flixweed in our study originate from presence of fiber and simple sugars in these plants such as sorbitol, neochlorogenic, and chlorogenic acids (phenolic compounds) [16, 18, 19]. Although we did not find any side effects for these two herbal medicines, we excluded the participants with any history of internal systemic diseases (diabetes, thyroid dysfunction, heart disease, etc.). It is worthy to note that prune has also beneficial effects in patients who suffer from heart disease, diabetes, and cancer [22] but we did not encounter any side effects during our study.

The use of new methods and medications for decreasing or eliminating gastrointestinal symptoms is not new for different complementary and alternative medicine systems [7, 8, 20]. These methods are believed to be helpful in different gastrointestinal symptoms, although some methodological flaws are obvious in some of these surveys [3, 5]. Increasing bowel movement is one of the most important symptoms that all studies have accurately considered. This symptom significantly improved during our trial in the treatment group.

Our study focused on treatment of constipation symptoms among Hajj pilgrims while some gastrointestinal symptoms (feeling of fullness and reflux) significantly improved similar to the studies of Lin *et al.* and Li *et al.* [7, 8] who showed the effectiveness of natural remedies in

treatment of similar disorders. There have been several studies during Hajj among Iranian and non-Iranian pilgrims but they have not paid attention to all aspects of gastrointestinal symptoms [15, 28, 29].

There were some limitations during our study, although the control and case groups were adjusted for many factors but the frequency of bowel movements and daily fluid intake were significantly higher in the control group compared to the case group. Other limitations of our study were our inability to conduct the research as a double blind study because the herbal medicines used in this trial were completely familiar for all participants and also, we could not change the appearance of these herbals to look different that were emphasized in other studies [9-11], but the statistician that analyzed the data was blind to both groups.

CONCLUSION

Our study indicated that a combination of prune and flixweed had a more significant effect on prevention of constipation and gastrointestinal symptoms in the case group, especially on the frequency of bowel movement, ease of defecation, health status, reflux, and feeling of fullness, when compared to the control group. Moreover, in the case group regarding the baseline, symptoms such as distention, nausea, pain and bleeding on defecation improved significantly. As these herbals are inexpensive, available and without any complications, so they can be safely administered in prevention of constipation especially for travelers.

ACKNOWLEDGMENT

This study was financially supported by the Shiraz University of Medical Sciences. The authors would like to thank the Iranian Hajj Organization, in particular Dr. Dandebor, for their executive support.

Conflict of interest

The investigators received no external funding and no competing financial interests exist.

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