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A randomized placebo-controlled trial on the effects of "*Pistacia atlantica*" on quality of life in patients with functional dyspepsia

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Background: **Functional dyspepsia (FD) is one of the most common problems in the world, which affects the quality of life (QoL). In Traditional Persian Medicine, *Pistacia atlantica* has beneficial effects on gastrointestinal disorders and on treating FD; therefore, it can improve QoL. *Objectives:* This study aimed to investigate the effects of "*Pistacia atlantica mutica*" (Baneh) on the improvement of the quality of life patients with Functional Dyspepsia. *Materials and Methods:* This randomized double blind placebo-controlled trial was carried out on 119 patients (18-60 years of age) with functional dyspepsia (between May 2016 and September 2016) in the research and referral center of gastroenterology and hepatology of Afzalipour Hospital affiliated to Kerman University of Medical Sciences. Subjects were randomly divided into intervention (n=61) and placebo (n=58) groups. Participants received the treatment twice a day (500 mg capsules containing 350 mg *Pistacia atlantica* resin plus 150 mg Sugar) in the intervention group, and 500 mg capsules of placebo containing 350 mg starch powder plus 150 mg sugar) in placebo group for 4 weeks and then were followed up for 1 month. The QoL was assessed using Nepean Dyspepsia Index (NDI) short questionnaire to evaluate tension, daily activities, eating, knowledge, and work in the fourth week intervention and 1 month after the intervention. *Results:* Fifty-three patients in the *Pistacia atlantica* group and 48 patients in the placebo group completed the study. There were no relevant differences in the baseline characteristics, chief complaint and provocation factors between the groups. Mean age was 38.30±12.57 and 44.85±13.08 years in *Pistacia atlantica* and placebo groups respectively (p=0.66). Tension, daily activities, eating/drinking, knowledge/control and work/study significantly improved in *Pistacia atlantica* group in the 4th and 8th weeks compared to the placebo group. Mean QoL score was (3.15±0.23 vs 5.24±0.34) at the 4th week and (3±0.18 vs 5.24±0.31) at the 8th week in pistica and placebo groups, respectively (p≤0.001). *Conclusions:* This study revealed that *Pistacia atlantica mutica* significantly improved QoL in patients with functional dyspepsia. No serious side effects were detected.**

INTRODUCTION

Quality of life (QoL) is a term used to refer to an individual's total well-being.[1] For people with chronic disease, measurement of QoL provides an appropriate path to determine the effect of health care when the cure is not complete.[2] As a matter of fact, the World Health Organization defined health as "the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Since then, QoL has become increasingly important in health-care practice and research.[3] Even though dyspepsia does not affect survival, it accounts for considerable health care costs and significantly affects the quality of life.[4] Functional dyspepsia (FD) is a common disorder with 10–15% prevalence in the general population that impairs the patient's quality of life.[4,5] The prevalence of FD in Iran varies from 2.2% to 29.9%.[6,7] Specifically, it has high prevalence in Shiraz (29.9%)[7] and moderate prevalence in Kerman (16.1%).[8] Nowadays, Rome criteria plays a pivotal role in creating diagnostic criteria of functional gastrointestinal disorders (FGIDs).[9] According to the Rome III criteria, functional dyspepsia is defined as the presence of early satiation, postprandial fullness, epigastric pain or epigastric burning in the last 3 months with the symptom onset appearing at least 6 months prior to the diagnosis regardless of the organic lesion (based on upper endoscopy).[10,11] FD is divided into postprandial distress syndrome (PDS) - comprising early satiety or meal-related fullness and epigastric pain syndrome (EPS).[12] Several treatments have been recommended for FD, but therapeutic options remain limited and are provided in most cases just as

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symptomatic options.[12] Pharmacological treatments can be considered acid suppressive drugs prokinetics, anxiolytics and antidepressants.[13] Unfortunately, the treatment of FD is not very satisfactory.[14] Therefore, other remedies such as complementary and alternative medications are suggested[15] Several herbal remedies such as *Apium graveolens*, *Trachyspermum copticom*[16] and *Pistacia atlantica* (Anacardiaceae) have been introduced as a treatment for FD in Traditional Persian Medicine[17] *Pistacia atlantica mutica* (from *Pistacia* species) is called "Baneh" in Iran whose resin has beneficial effects on gastrointestinal disorders. [18,19,20] In this regard, *Pistacia atlantica* improves dyspepsia symptoms and helps to eradicate H. pylori.[21] Likewise, it can be effective for ulcerative colitis.[22] Treatment of pain and discomfort can result in improved QoL in FD.[23] The aim of this study was to investigate the effect of "*Pistacia atlantica mutica*" on the improvement of the quality of life (QoL) of patients with Functional Dyspepsia.

MATERIALS AND METHODS

Trial design

This study was a double blind randomized clinical trial conducted between May 2016 and September 2016.

Participants

This trial was carried out on patients (18-60 years of age) with Functional Dyspepsia at Afzalipour Hospital which is a research and referral center of gastroenterology and hepatology affilated to Kerman University of Medical Sciences in Iran.

Selection criteria

In this study, participant inclusion criteria were based on Rome III criteria including: 1) the presence of early satiation, 2) postprandial fullness, and 3) epigastric pain, or epigastric burning for the last 3 months with symptom onset appearing at least 6 months prior to diagnosis. The exclusion criteria were organic or structural evidence (including in upper endoscopy), history of peptic ulcer or reflux, underlying diseases (such as heart failure, renal failure, cirrhosis, diabetes, hypothyroidism) and also history of abdominal surgeries after examining by a gastroenterologist. It is noteworthy that participants who used the chemical and herbal drugs and those who drank alcohol and abused opiates were also excluded; pregnant or lactating women were excluded as well.

Randomization and blinding

Random allocation was performed in blocks of four using random number tables. Randomization was done by one of the researchers who did not have a role in the treatment of the participants. Neither the patients nor the researchers were aware of the treatment assignment. Drugs were identically packaged and coded. The person coding the drugs was not involved in the study. The examinations and follow-up assessments were done by someone who was unaware of the coding procedure. A third person, who was unaware of research objectives, divided the patients into two groups (*Pistacia atlantica* and placebo) and gave them the medications based on their initial descriptions. The statistical analysis was also carried out by a fourth person who was unaware of the grouping.

Interventions

Subjects were randomly divided into two groups: one group received *Pistacia atlantica mutica* capsules and another group received placebo capsules. Participants received capsules twice a day (after lunch and dinner) for 4 weeks; they were followed up for 1 month. QoL index was assessed on arrival, at the forth week and also 1 month after intervention. The Nepean Dyspepsia Index (NDI) short questionnaire -a standard tool for evaluating QoL in the patients with FD- was used to evaluate QoL in this study. The questionnaire was completed by a researcher who was not aware of the drug content. Moreover, any adverse effects of intervention were assessed in participants.

Outcomes

At the first baseline, demographic features (sex, age and body mass index "BMI"), chief complaint (postprandial fullness, bloating, nausea, pain and burning) and provocation factors (fasting, stress and eating) of patients were recorded. Nepean Dyspepsia Index (NDI) short questionnaire (that is a standard tool for evaluating QoL in the patients with FD) was used to assess QoL in this study. QoL was filled in for each patient at the baseline and the 4th and 8th weeks. The questionnaire which included 10 questions designed in the form of 5 subsets (tension, interference with daily activities, eating/drinking, knowledge/control, work/study) was assessed by the 5-point Likert scale: 1 (not at all or not applicable), 2(a little), 3 (moderately), 4 (quite a lot) to 5 (extremely).[24] Lower scores were in favor of better QoL. The Persian translation of this questionnaire whose validity and reliability were investigated by Azimi and et al was used in this study.[25]

Preparation of *Pistacia atlantica* and placebo capsules

In this study, resin of *Pistacia atlantica mutica* was gathered from Rabor town (in Kerman Province located in Iran) with herbarium code KF1136_3 and was also dried. Then, it was powdered and prepared as 500 mg capsules. Capsules contained 350 mg *Pistacia atlantica mutica* resin plus 150 mg Sugar. The qualitative and microbial control steps of this study were carried out by Barij Essence Pharmaceutical Company. Microbial contamination was conducted based on the United States Pharmacopeia guideline (USP38). The Capsules were standardized using gas chromatography based on α-pinene.[20,26,27] The amount of α-pinene was about 60%. Placebo capsules were prepared as 500 mg capsules containing 350 mg starch powder plus 150 mg sugar. The pistica and placebo capsules were identical in the same physical form, packaging and labeling.

Safety evaluation

Patients were assessed for any possible side effects of the herbal medicine at every visit; moreover, routine physical examinations were done.

Sample size

We calculated that 47 patients in each group would be required to provide 80% power to detect a difference of 25% in the average score of QoL at an alpha level of 0.05.

Statistical methods

To compare quantitative and qualitative data (patients' demographic data), independent t-test and Chi-square were used, respectively. Two way repeated measures ANOVA was used to compare the outcome of treatment between the two groups across the weeks. SPSS software, version 21 was used and P-value < 0.05 was considered significant.

Research Ethics

This research was conducted based on the last version of Helsinki ethical points approved in October 2013 and also the Ethics Committee

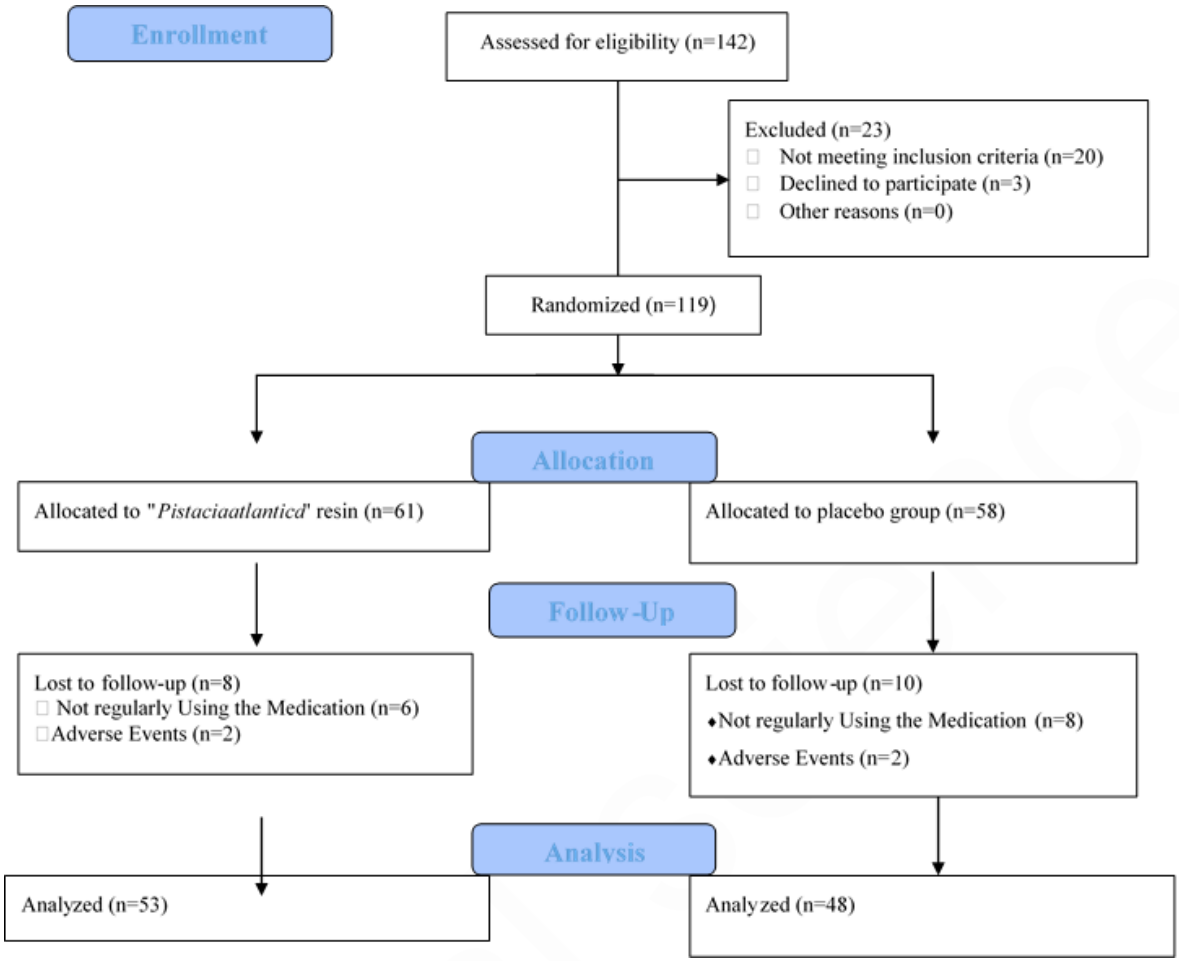


Figure 1 CONSORT flow diagram of the trial

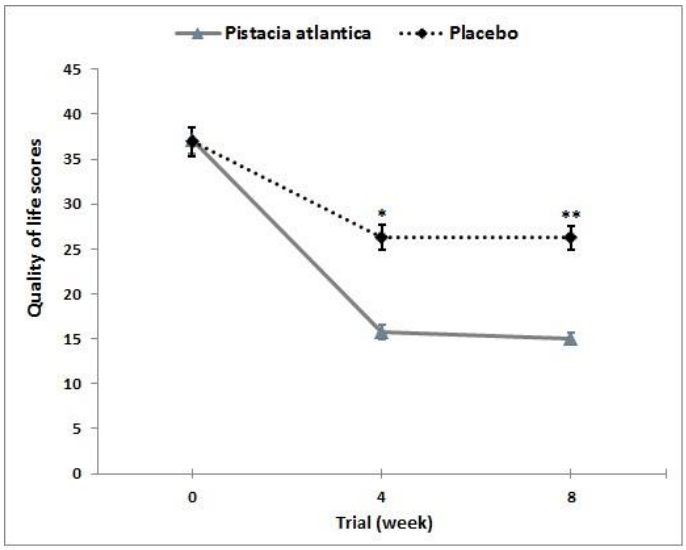
Table 1 Demographic and clinical characteristics at the baseline in "*Pistacia atlantica mutica*" (Baneh) and Placebo groups

characteristics		"*Pistacia atlantica*" group		Placebo group		P-value
Age	Mean ± SD	38.30±12.57		44.85±13.08		p= 0.66
BMI	Mean ± SD	24.67±4.75		27.04±4.69		p= 0.49
		N	%	N	%	
Sex	male	19	35.8	13	27.1	0.344
	female	34	64.2	35	72.9	
Chief Complaint	Postprandial Fullness	1	1.9	3	6.3	0.491
	Bloating	16	30.2	15	31.3	
	Nausea	1	1.9	3	6.3	
	Pain	33	62.3	24	5.	
	Burning	2	3.8	3	6.3	
Provocation factors	Fasting	4	7.5	8	16.7	0.142
	Stress	30	56.6	22	45.8	
	Eating	16	30.2	18	37.5	
	Other cases	3	5.7	0	0	

of Kerman University of Medical Sciences, which approved this trial, by ethic number IR.KMU.AH.REC.1395.10. Researchers explained the potential use of the drug or placebo with the patients' consent. All patients were fully aware of the objectives and details of the study through the information form; the signed written consent forms were taken from them. Each participant could withdraw from the study at any moment. During the study, the patients were visited at the baseline, the 4th and the 8th weeks. Moreover, the presenter's contact number was given to the patients from the beginning of the study. The patients were closely monitored and excluded from the study in the case of serious side effects.

RESULT

In this study, 119 patients were recruited and randomized into two groups. Of them, fifty-three patients in the *Pistacia atlantica mutica* and 48 ones in the placebo group completed the study. Eight patients in the



* p<0.001
** p<0.001

Figure 2 Comparing the Quality of Life change in *Pistacia atlantica mutica* and placebo group at the first day, the 4th week and 1 month follow-up period

Table 2 Comparing tension, daily activities, eating/ drinking, knowledge/control and work/study changes in *Pistacia atlantica mutica* and placebo group at the baseline, the 4th& the 8th week

	Baneh			Placebo			p-value	P-value	P-value
	baseline	4W	8W	baseline	4W	8W	baseline	4w	8w
Tension	8.26±0.37	3.56±0.29	3.41±0.23	8.06±0.39	6.20±0.38	6.43±0.38	0.712	<0.001	<0.001
Daily activities	6.45±0.43	2.45±0.13	2.43±0.10	6.68±0.44	4.66±0.36	4.64±0.32	0.710	<0.001	<0.001
Eating/drinking	8.07±0.32	4.20±0.29	4.33±0.27	8.37±0.39	6.68±0.36	6.68±0.33	0.552	<0.001	<0.001
Knowledge/ control	7.20±0.44	2.49±0.16	2.30±0.13	7.29±0.46	4.02±0.30	3.95±0.28	0.897	<0.001	<0.001
Work/study	7.05±0.42	3.07±0.29	2.54±0.20	6.52±0.44	4.68±0.33	4.5±0.28	0.388	<0.001	<0.001
Total	7.40±0.39	3.15±0.23	3±0.18	7.38±0.42	5.24±0.34	5.24±0.31	0.956	<0.001	<0.001

pistica group and ten in the placebo group were not followed up. The main reason was the lack of regular drug use or concurrent use of herbal medicine or other chemicals (6 patients in the drug and 8 in placebo group). Four patients experienced side effects and thus discontinued medication (in *Pistacia atlantica* group: one due to severe bloating and irritation, one because of bloating and constipation; in the placebo group: one because of severe diarrhea and one due to severe pain), (Figure 1). Concerning chief complaint and provocation factors of subjects, the baseline characteristics were shown in Table 1.

Concerning avarage score of the quality of life, there was no statistically significant difference between the two groups of *Pistacia atlantica mutica*" resin and placebo at the baseline (i.e., the zero week) (P = 0.96). A significant improvement in QoL was seen in the intervention group comparing to the placebo group in both 4th and 8th weeks (P <0.001) (Figure 2).

In the zero week, there was no significant difference between the two groups of "*Pistacia atlantica mutica*" resin and placebo in terms of the avarege score of tention, interference with daily activities, eating/drinking, knowledge/control, daily work/study (P>0.05). There were significant differences between the two groups in the 4th and 8th weeks (P <0.001) (Table 2).

DISCUSSION

In this study, the QoL of 98 patients with functional dyspepsia was investigated using the NDI questionnaire. The present study demonstrated that *Pistacia atlantica* significantly improved tension, daily activities, eating, knowledge and work in the 4th and the 8th week ($p \leq 0.001$). No other clinical trials were found about the assessment of *Pistacia atlantica* on QoL in patients with FD. However, there are some studies about the effects of other plants on the quality of life of these patients. Holtmann et al., assessed the effects of a combination of peppermint oil and caraway oil capsule (FPCO) on QoL in patients suffering from FD in double blind clinical trial. Their results demonstrated that NDI total score improved significantly in FPCO compared to placebo ($p<0.05$).[28] Like our study, their results showed that medicinal plants were effective on QoL in FD. They used combination of two plants for their intervention, but we used only a single herb. In another double-blind randomized controlled trial, Holtmann et al., investigated the efficacy of artichoke leaf extract (ALE) on symptoms and QoL in patients with FD. Their results revealed that ALE improved QoL significantly compared to placebo in patients with functional dyspepsia.[29] Similarly, their results showed effectiveness of herbal remedies on QoL. Nevertheless, their trial period was 6 weeks

and our study period was as long as 8 weeks. Their sample size was more than our trial (244 patients). Moreover, they used intention-to-treat method for statistical analysis, but we used per protocol method. Like our study, there were not serious adverse events in their trial. In another study, Raveendra et al evaluated the efficacy of GutGard, an extract of Glycyrrhiza glabra, in patients with FD. The Nepean dyspepsia index decreased significantly in the GutGard group compared to placebo ($P \leq 0.05$).[30] They evaluated QoL as a secondary outcome, and the period of trial was 30 days and was shorter than our trial; in addition, the number of participants was 50 (lower than our study). No treatment-related adverse effects were reported during their study. Azimi et al investigated the effectiveness of combination of Apium graveolens and Trachyspermum copticum (AT) with comparison to placebo and omeprazole on the QoL of patients with FD. According to their results, AT could improve QoL more than omeprazole or placebo.[31] They used a combination of two plants, but we used one plant. The period of two trials was 8 weeks. Side effects in AT group slightly increased in bowel movements during the first 3 days of intervention; in our study four patients had side effects and discontinued medication and other drugs used in *Pistacia atlantica* group (one due to severe bloating and irritation, and one due to bloating and constipation). Babaeian et al examined the effects of *Mentha longifolia* on improving the quality of life (QoL) in patients with functional dyspepsia from the subgroup of postprandial distress syndrome. *Mentha longifolia* significantly improved the scores of QoL.[32] Their intervention period was 4 weeks, but the patients were followed-up for 12 weeks which was longer than ours. Like our study, their study was single center. They found no significant side effects. In thier study, Mohtashami *et al* assessed the effects of the honey-based formulation of *Nigella Sativa* on QoL of FD patients. Their results revealed that this formulation significantly improved the QoL in comparison to the placebo group.[33] Their intervention period was longer than our period (8 weeks). In another trial, Kim et al assessed the effects of *Hyangaa-Pyeongwi san*- the most well known description in Traditional Chinese Medicine for treating functional gastrointestinal disorders- on QoL in FD. Their results showed a significant difference in some subsets such as eating/drinking and interference.[34,35] Their intervention and follow up periods were the same as our study. Our study had some limitations such as short follow-up period, small sample size and also we did not carry out intention-to-treat (ITT) analysis in the presence study. One of the strengths of this trial was using domestic and safe medication.

CONCLUSIONS

This study indicated that *Pistacia atlantica mutica* had significant effects on Quality of Life in patients with functional dyspepsia compared to placebo. The authors suggest that further studies must investigate the effects of *Pistacia atlantica mutica* on symptoms and QoL in patients with FD along with larger sample size and longer follow up periods. Moreover, making use of the extract of the active ingredient of the *Pistacia atlantica mutica* can be recommended for further research.

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Conflict of interest
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