

A new acupuncture method for management of irritable bowel syndrome: A randomized double blind clinical trial

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Background: Irritable bowel syndrome (IBS) is gastrointestinal functional disorder which is multifactorial with unknown etiology. There are several modalities for treatment of it. Acupuncture is increasingly used in numerous diseases, also in gastrointestinal disorders like IBS. The purpose of the study was to assess the effects of catgut embedding acupuncture in improving of IBS. **Materials and Methods:** A randomized double blind sham control clinical trial was designed. A total of 60 IBS patients assigned to three separated groups. The first group received clofac as drug only group (DO). The second one received catgut embedding acupuncture in special point (AP) and the last group received sham acupuncture (SA). Symptoms, pain, depression and anxiety assessed before and after two weeks at the end of study. **Results:** There was statistically significant difference between AP and SA and DO in constipation and bloating. Differences that were statistically significant favored acupuncture on pain ($F = 6.409, P = 0.003$), and depression ($F = 6.735, P = 0.002$) as the other outcomes. The average (standard deviation (SD)) of weight loss was 2 kg (0.88) in acupuncture group. **Conclusion:** Our finding showed a significant positive associated between acupuncture and IBS. Catgut embedding acupuncture is a new method which can eliminated IBS symptoms and can use as alternative therapeutic method for improvement of IBS.

Key words: Acupuncture, irritable bowel syndrome, randomized control trial

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INTRODUCTION

Irritable bowel syndrome (IBS) is one of the common gastrointestinal (GI) disorders that is defined as abdominal pain with abdominal discomfort which is not described as pain that associates with altered bowel habits.^[1]

It is so prevalent not only in GI clinics but also in general practice. The frequency of IBS in women is higher than men.^[2,3] The pathogenesis of it is unknown and many factors like diet, gene mutations, psychosocial factors and immunological pathways are hypothesized.^[4] The IBS symptoms like diarrhea, constipation, and bloating have impact on patients lifestyle, thus IBS caused patient's quality of life declination.^[5-8] On the other hand, the total cost of IBS is estimated \$200 billion worldwide.^[9]

All of aforementioned issue have been caused that there have been many treatment modalities for IBS from conventional pharmacotherapy to complementary

and alternative medicine (CAM). Acupuncture is one of the CAM options refereeing to Chinese traditional medicine which uses frequently in many chronic disease like bronchial asthma, angina pectoris, low back pain, inflammatory bowel disease, allergic rhinitis, and so on.^[9-17] One of the acupuncture common usage is in IBS treatment.^[18] The hypothesis of acupuncture for IBS is the influence of acupuncture on the serotonergic, cholinergic, and glutaminergic pathways on the brain-gut axis.^[19-21] However, there are some conflicts and controversies in effectiveness of acupuncture in treatment of IBS. There are also two systematic reviews that address this controversy.^[21,22] However, in this study a new method of acupuncture was used for the first time to decrease symptoms severity and relief pain of IBS patients.

MATERIALS AND METHODS

Participants

Our research question was regard to clinical implication of offering acupuncture as an alternative treatment

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for IBS. For this purpose we conducted a randomized, double-blind, sham control clinical trial to determine the impact of acupuncture for treatment of IBS. Sixty patients aged between 19 and 61 years who met Rome III criteria for IBS enrolled in study from January 2011 to April 2012 in two academic university clinic and a private GI clinic in Isfahan, Iran. They were included consequently and evaluated by a gastroenterologist. Patients with pregnancy, diabetes mellitus, scleroderma, inflammatory bowel disease (IBD), prior small intestinal surgery, and GI infections were not included. All of them signed a written informed consent to participate in study. Our research had been approved in research and ethical committee Islamic Azad University (research project number = 49005)

Interventions

They have been under observation for 2 weeks because of compliance evaluation and washout period. During this 2-week period, the gastroenterologist prescribed them standard regimen of drug which included colofac tablet 135 mg (Solvay Pharmaceuticals BV, the Netherlands). After that they were assigned in three treatment groups. Random allocation was performed by using random digit table. Drug administration was continued till the end of study. For the first group, acupuncture based on standard protocol was done. In the second group, sham acupuncture (SA) was done and third group as drug only (DO) treatment continued drug as standard regimen.

Standard acupuncture was catgut acupuncture. It is a new method of acupuncture which has developed in the recent 3 decades. Catgut is a type of cord that is made from the natural fibers of sheep or goat intestine. It is embedded in the acupuncture points and enhanced the point stimulation for 7-14 days. Catgut implantation is one kind of acupuncture, where specific acupuncture points are gently and continuously stimulated till the ailment is improved and designed results are achieved. AP was done in specific acupuncture points as followed; UB17, 23, 25, DU3, SP9, 15, ST25, 36, Ren12, and 4. Kid15. In contrast to AP group, SA was done the same as catgut embedded therapy in AP group in different points as; GB26, SP8, 1 inch ST25, UB22, and Ren5. All acupuncture treatment was done by a professional trained and experienced acupuncturist in catgut embedded therapy.

Outcome evaluation

After 2-week of under-observation period, independent researchers filled three data collection form for all patients. He was blinded regarding treatment groups. The first one was IBS symptoms check list which contained visual analog scale for pain, questions regarding bowel habits (diarrhea and constipation), and existence of abdominal bloating.

Second questionnaire was Beck depression inventory questionnaire to evaluate patients' depression and the last was Beck anxiety inventory questionnaire.^[8,23,24] After treatment all participants followed-up for 4 weeks and at the end all questionnaires were completed for them again as outcome evaluation.

Statistical analysis

Statistical Package for Social Sciences, version 20 (SPSS 20, IBM Chicago USA) was used for analyzing data. Three treatment groups (AP, SA, and DO) were considered as independent variable and symptoms frequency, score of pain, weight, depression, and anxiety were considered as independents. We used McNemar test for categorical data like symptom frequency and after obtaining analysis of covariance (ANCOVA) presumption, we used ANCOVA model to assess impact of acupuncture on pain mean score as main symptoms and depression and anxiety mean score as mental health issues. Statistical significant was set at $P < 0.05$.

RESULTS

We selected 60 IBS participants and allocated them randomly to three separated groups. Most of the patients (85%) were female with age range between 19 and 61 years. Table 1 displays these patient characteristics by treatment group. There were not any significant differences between treatment groups in demographic and baseline characteristics.

We had four main outcome variables; symptoms, pain, depression, and anxiety.

Results by McNemar test demonstrated the difference in declining of constipation and bloating in AP and SA groups; however, there was no significant difference in DO group [Figure 1].

The mean of pain score at the baseline in AP, SA, and DO were 7.5, 6.9, and 6.3 in contrary. However, ANCOVA test showed significant difference in final mean of pain score. Figure 2 presents this difference between three groups. Depression score was significantly lower comparison to baseline level. The ANCOVA analyses showed significant differences between AP, SA, and DO

Table 1: Demographic and baseline characteristics

	AP	SA	DO
Sex Male	3	4	4
Female	17	16	16
Age (mean ± SD)*	36.5±9.5	39.5±10	42.1±10.7
Weight (mean ± SD)*	68.9±11.2	69.4±10.4	69.5±12

*Not significant; AP = Acupuncture; SA = Sham acupuncture; OD = Only drug; SD = Standard deviation

treatment groups. The mean score of outcome variables is shown in Figure 3. Post hoc analysis demonstrated that main differences were between DO and AP treatment group.

Anxiety had been decreased, but it was not statistically significant. Figure 4 presents adjusted mean score of anxiety in different groups.

The average (standard deviation (SD)) of weight loss was 2 kg (0.88) in acupuncture group. The secondary weight at the end of study was lower than primary weight at the baseline in AP and this difference was significant in trial group in contrast to SA and DO treatment groups [Figure 5].

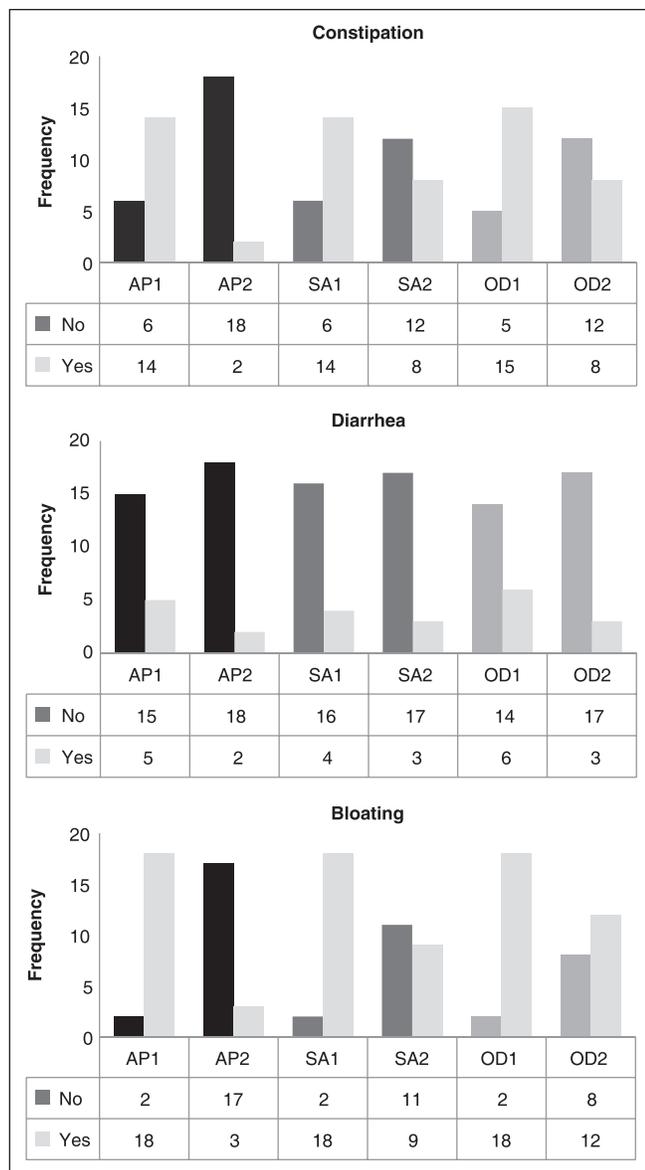


Figure 1: Frequency of symptoms at the first compared to the end of study after 2 weeks; AP = Acupuncture, SA = Sham acupuncture, OD = Only drug

DISCUSSION

Because of chronic and tormenting nature of IBS and low levels of treatment satisfaction in IBS patients, they turn to CAM therapies. Complementary medicine refers to the use of CAM as an adjunct to conventional medicine; whereas, alternative medicine refers to the use of CAM as a substitute for conventional medicine. Acupuncture is one of the common manipulative and body-based practices of CAM used for IBS treatment.^[25]

The current investigation is the first report on the use of embedding acupuncture for IBS from Iran in special care setting. We have determined an appropriate effect size, with clinically and statistically significant differences, between the outcomes in the acupuncture group and those receiving usual drug treatment and SA. Our finding demonstrated decrease in colonic symptoms (constipation and bloating) and abdominal pain by acupuncture against SA and DO trials. A secondary benefit was effect of acupuncture on non-colonic symptoms of IBS (depression and anxiety). Our additional finding was significant weight loss in AP group.

There are many controversies regarding to acupuncture treatment for IBS. Manheimer and colleagues have reviewed studies around acupuncture for IBS. They have reported two groups of studies. The first one was from the western countries which were sham control randomized clinical trials. None of these studies found a statistically significant benefit of acupuncture relative to SA for the outcomes symptom.^[26-28] Similarly, pooling the data from these articles did not result in statistically significant benefits of acupuncture for either outcome.^[29] In contrast five Chinese trials found that patients receiving acupuncture reported greater improvements in IBS symptoms compared to patients receiving drug for IBS.^[19,29-33] Schneider and coworkers reported another systematic review that demonstrated the same data but they declared quality of life

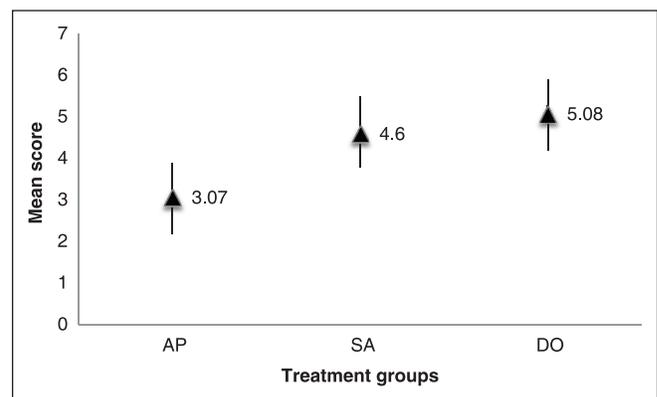


Figure 2: Mean of pain score in treatment groups. Analysis of covariance (ANCOVA) test; $F = 6.409, P = 0.003$. AP = Acupuncture, SA = Sham acupuncture, OD = Only drug

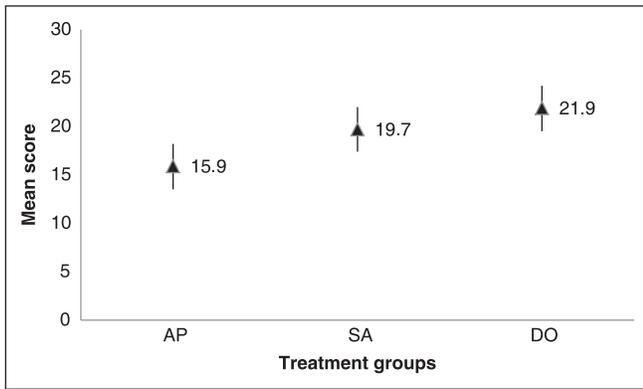


Figure 3: Mean of depression score in treatment groups. ANCOVA test; $F = 6.735$, $P = 0.002$. AP = Acupuncture, SA = Sham acupuncture, OD = Only drug

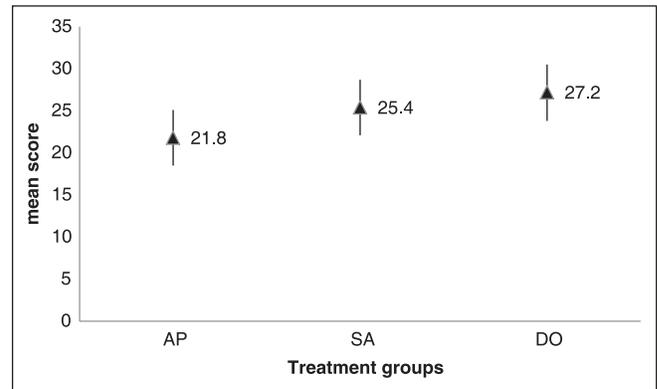


Figure 4: Mean of anxiety score in treatment groups. ANCOVA test; $F = 2.796$, $P = 0.077$. AP = Acupuncture, SA = Sham acupuncture, OD = Only drug

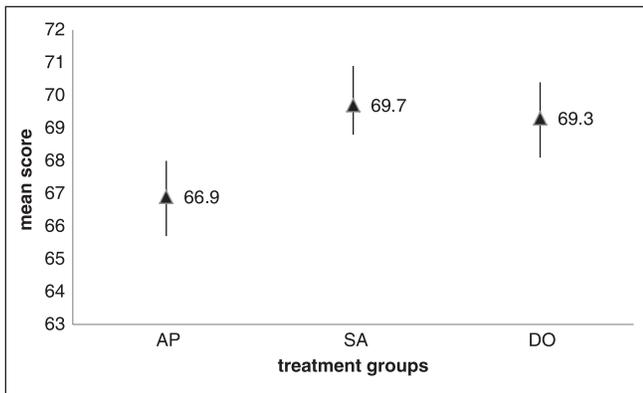


Figure 5: Mean of weight (kg) in treatment groups. ANCOVA test; $F = 6.897$, $P = 0.002$. AP = Acupuncture, SA = Sham acupuncture, OD = Only drug

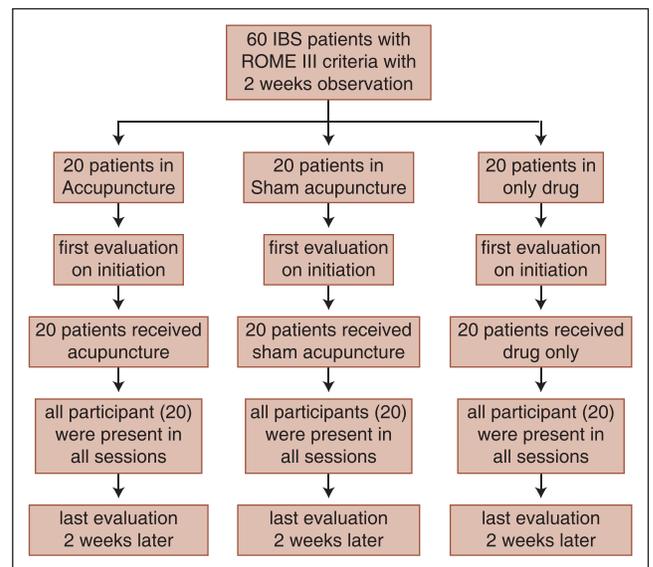


Figure 6: The design of participants' deviation into 3 groups: Acupuncture, Sham acupuncture and only drug

increase with acupuncture in IBS.^[34] The inference that our finding in recent study showed that acupuncture is useful for symptom relief in IBS. Our study had many advantages the first one was the exact design and performance. We conducted double blind randomized sham control method and tried to control confounders. The other new issue of our study was the method of acupuncture. We performed catgut embedding therapy and use the catpoint which were selected for weight loss.^[31,35] This was an innovation and new approach to acupuncture therapy of IBS. We assessed not only IBS symptom relief but also non-colonic situation like depression and anxiety. Both of them decreased by acupuncture; however, the anxiety difference was not statistically significant declination.

Our study had some limitation, too. The main limitation of our study was not to assess quality of life. We could not find available and standard Persian questionnaire to evaluate quality of life in IBS. Although we estimated sample size with statistical formula, it was better to extend our sample size to improve study power. One of our patients had bulging in her leg after embedding therapy that been cause her unsatisfaction.

CONCLUSION

We established the acceptability of acupuncture. Though our analysis showed a significant positive associated between acupuncture and IBS, the study sample was small. Therefore, there is a need for more definitive research into acupuncture for IBS, such that the results can be generalized more widely.

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AUTHORS' CONTRIBUTIONS

All authors have contributed in designing and conducting the study. All authors have assisted in preparation of the first

draft of the manuscript or revising it critically for important intellectual content. All authors have read and approved the content of the manuscript and confirmed the accuracy or integrity of any part of the work.

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