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Is Acupuncture an Effective Treatment for Patients with Irritable Bowel Syndrome?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this systematic review is to determine whether or not acupuncture is an effective treatment for patients with Irritable Bowel Syndrome.

STUDY DESIGN: Review of three, English language studies published in 2007, 2009 and 2009.

DATA SOURCES: Randomized, placebo-controlled trials comparing the effects of acupuncture to “sham” acupuncture in relieving the symptoms of IBS were found using Cochrane Databases.

OUTCOMES MEASURED: Self-reported IBS symptoms: abdominal bloating, discomfort, intestinal gas, stool consistency, daily activity-related anxiety, diet, sleep, health perception, coping with disease and quality of life. Outcomes were measured data gathered in patients “symptoms diaries” as well as administration of symptom scales and questionnaires. Clinical Global Impression Scale was used to measure the patient-perceived severity at baseline and again at the completion of the treatment. Other scales used in the studies include: The IBS Global Severity Scale, The IBS Adequate Relief scale, The IBS Quality of Life scale and the Functional Digestive Diseases Quality of Life Questionnaire.

RESULTS: In the three RCT’s included in this review none found a significant difference in improvement of symptoms of IBS when comparing the acupuncture treatment group to the “sham” acupuncture control group. However all patients showed some reduction in symptoms from baseline and significant improvement of symptoms compared to the “wait list” control group.

CONCLUSION: The results of the RCT’s reviewed demonstrated that patients treated with acupuncture and “sham” acupuncture experience an improvement in symptoms of IBS. The data however, did not prove enough statistical significance to claim that acupuncture is more effective in the treatment of IBS versus “sham” acupuncture.

KEYWORDS: IBS, Irritable Bowel Syndrome, Acupuncture

INTRODUCTION

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder characterized by recurring symptoms of abdominal pain or discomfort associated with altered bowel habits such as constipation, diarrhea or both. IBS is a chronic GI disorder that greatly interferes with the patients' quality of life and leads to significant healthcare costs. The current treatments used for IBS are aimed at symptomatic relief and lack the ability to cover the full spectrum of IBS symptoms. In addition to the lack of efficacy, the medications used for IBS treatment have potential side effects⁵. This systematic review paper used three randomized-controlled trials to evaluate whether acupuncture is an effective treatment for patients with Irritable Bowel Syndrome.

IBS is a common health problem, which makes it likely for practitioner in all specialties to have patients who suffer from IBS. According to a community survey of IBS prevalence, the current point prevalence ranges from 12-30%. IBS is 1.5 to 2 times more common in women compared to men. It is usually diagnosed in patients under the age of 50 years old. IBS generates a substantial workload for both primary and secondary care. It is estimated that only 10-50% of patients experiencing symptoms of IBS consult their primary care provider. Of those patients 17-30% will require a referral to a gastroenterology specialist. Leading IBS to account for 20-50% referrals of gastroenterology clinics⁶. IBS leads to significant cost for the individual, employer and health services. The estimated total direct cost per year/person range from \$348-\$8750. The total days of missed work range from 8.5-21.6 day/year³.

IBS differs from other GI disorders as it is a functional disorder of gut motility and there are no anatomical or structural abnormalities present. The exact cause of

dysfunction in IBS is unknown. The symptoms appear to be caused by motor-sensory dysfunction or an up-regulation in neural processing between the gut and brain. This pathway is referred to as the “brain-gut-axis.” GI motility and visceral sensitivity are exaggerated by luminal and environmental factors including inflammation, gut distention, bacteria, meals, and stress. Despite common belief IBS is not solely a psychosomatic disorder. Stress and anxiety do not cause IBS. Rather they are provocative factors, which invoke an exaggerated neural response on the brain-gut-axis in patients with IBS³.

There is no definitive treatment available for IBS. Most conventional therapies are aimed at symptomatic relief by altering GI motility and sensory function or CNS processing. Some common medications include: stimulant laxatives, fiber supplementation, smooth muscle relaxants/antispasmodics, loperamide, tegaserod, and antidepressants. RCTs have shown little benefit from lactose restriction, fiber supplementation and stimulant laxatives³. Conventional therapies can cause significant side effects if not administered correctly. These therapies only work on one area of dysfunction and lack the ability to cover the full spectrum of IBS symptoms.

The lack of efficacy had lead up to 43% of patients to seek alternatives and complementary therapies for the management of IBS symptoms³. Acupuncture is currently gaining more acceptances in Western medicine however there is no clear evidence to support acupuncture as an effective treatment for IBS. Acupuncture holds an end on conventional therapies because the basic principle of TCM is to treat the underlying root cause of disease and restore balance within the body. Therefore, the use of acupuncture aims to improve the full range of symptoms in a patient with IBS. TCM

takes a vary individualized approach to evaluating and treating a patient with makes it very hard to simplify and standardize treatment plans for randomized control trials¹.

OBJECTIVE

The objective of this systematic review is to determine whether or not acupuncture is an effective treatment for patients with Irritable Bowel Syndrome.

METHODS

The following criteria were used in the selection of the three studies found in this review. The three studies used in this review were a randomized-controlled trial, a pilot randomized-control trial and a randomized-placebo controlled trial. The population included adults, >18 years old, with a diagnosis of IBS based on the ROME II criteria. The type of intervention was acupuncture treatment over a period of several weeks. Each study had a fixed protocol of acupuncture points used to treat all patients. Optional points were also allowed at the discretion of the acupuncturist based on the individual's Chinese Medicine diagnosis. The Anastasi study included the use of moxibustion in addition to acupuncture. Moxibustion, another Chinese Medicine therapy, involves the burning of a small moxa-pole over the acupuncture point to help stimulate the flow of qi. The studies used "sham" acupuncture and "wait-list" groups as comparisons to the acupuncture treatment. The "sham" acupuncture uses "Streitberger" needles that are identical to traditional acupuncture needles but do not actually penetrate the skin. The sham points were chosen 2-3 cm from the traditional points to avoid acupressure effects on the meridians or energy channels. The primary outcomes measured in the studies were patients' perception of an improvement in quality of life (QOL) and improvement in self-reported IBS-related symptoms including abdominal pain/discomfort. Intestinal gas,

bloating, stool consistency were grouped as secondary outcomes as well as IBS Symptom Severity Scale and IBS Adequate Relief.

I researched the studies in this review using the Cochrane Database from December 17, 2009 through February 2010. I selected the most recent and relevant articles based on outcomes that would matter most to patients (POEMS). All the studies were published in peer-reviewed journal and written in the English language. The following keywords were used: Irritable Bowel Syndrome, IBS, and Acupuncture. Inclusion criteria for this review were RCT studies published after 2006 and studies with outcomes that would be important to patients with IBS. Excluded from this review were studies that were in previous systematic reviews (Meta Analysis from 2008.) Table 1 includes the demographics and characteristics of the included studies. The statistics utilized in the studies were *p*-values, relative benefit increase (RBI), absolute benefit increase (ABI), and numbers needed to treat (NNT).

OUTCOMES MEASURED

The outcomes in Anastasi's study include participants' self-reported IBS symptoms in "symptom diaries." Abdominal pain and discomfort were primary outcomes measured. Secondary outcomes include intestinal gas, bloating, and stool consistency. The Clinical Global Impression Scale (CGIS) was used to measure the patient-perceived severity symptoms with a 7-point Likert-type scale. The CGIS was administered at baseline and again after the completion of a 4-week of treatment.

Table 1 - Demographics & Characteristics of included studies							
Study	Type	#Pts	Age	Inclusion Criteria	Exclusion Criteria	W / D	Interventions
Anastasi, 2009	Pilot RCT	29	18-70 yo	Sx >6mo Based on Rome Criteria, Dx confirmed by medical provider and absence of pathology	Hx of lactose intolerance, abdominal surgery(except appendix, uterus or GB); GI/GU,gyno pathology. Iron supp., Abx,narcs,bile acid sequestering, &stool/gut motility altering agents >3d/wk, Acupuncture w/in 6mos	2	4 weeks of 1-hour, twice-weekly treatments of acupuncture with moxibustion or sham acupuncture(contr ol)
Lembo, 2009	RCT	262	>18 yo	Pt met Rome II criteria from IBS, Dx confirmed by GI specialist, pt allowed to continue IBS meds, but ask not to change dose	Received acupuncture earlier, abdominal surgery(excluding cholecystectomy, appendectomy, hysterectomy, hernia repair) narc or other pain meds	3 / 2	3 wk “run-in” w/Sham AC in “augmented” or “limited” pt-dr interaction. After 3 wk blinded re-randomized to either continue “Sham” or start “true” AC. A 3 rd arm, “wait-list” never received treatment.
Schneider, 2007	Ran domized, placebo controlled trial	43	Me an age 41-46y o	Met Rome II criteria	insufficient diagnostic work-up, AC tx within the last 3 mo, 5-HT3 antagonists and spasmolytics or pregnant	9	Pt w IBS reived Acupuncture or sham-acupuncture(streit berger needles) for a total of 10 sessions, twice a week for a total of 5 wks

In the Schneider trial the outcomes addressed were the symptomatic improvements in IBS as a result of acupuncture. Symptoms include daily activity-related anxiety, diet, sleep, discomfort, health perception, coping with disease, and impact of stress. The outcomes were measured by patients completing Quality of Life (QoL) questionnaire and assessed using the functional quality of life diseases quality of life questionnaire (FDDQL).

The outcomes measured in the Lembo study included participants perception of global improvement in symptoms of IBS. The primary endpoint of the study utilized the IBS Global Improvement Scale (IBS-GIS). Secondary outcomes were measured using IBS Symptom Severity Scale (IBS-SSS), the IBS Adequate Relief (IBS-AR), and the IBS Quality of Life (IBS-QOL).

RESULTS

The primary outcome measured in all three studies pertained to the overall improvement in patient-perceived symptoms of IBS. Each study used a different scale to measure the participants' improvement of symptoms from baseline to the completion of the study. Table 2 lists the studies with measurements scales used in their respective study. Table 2 also describes the change in symptoms between the treatment and control groups. In addition to the comparison of baseline and post-treatment results, table also included the "between group differences." This information is important to note because although none of the studies showed a statistically significant improvement when comparing the acupuncture group to the "sham" acupuncture group, all participants showed some improvement in symptoms from baseline.

In the Lembo study a wait-list control group was also used in addition to the acupuncture and “sham” acupuncture group. There was no statistically significant difference in IBS-GIS between the acupuncture treatment group vs. the sham acupuncture group with a p-value=0.25. However, there was a significant improvement after 3 weeks of treatment when comparing the acupuncture and sham acupuncture groups to the wait-list group p-value<0.001.

In Anastasi’s 4-week study, the difference in improvements between the acupuncture group and the sham group was not statistically significant based on a p-value=0.77. However, both groups experience some reduction in symptom score which was the primary outcome being measured. The CGIS (measurement of patient-perceived IBS symptoms) improved during the 4-week study from 3.86(95% CI 3.51-4.20) to 2.08(95% CI 1.27-2.90) in the acupuncture treatment group and from 3.73(95%CI 3.37-4.09) to 1.73 (95%CI 0.96-2.51) for the sham-acupuncture group.

According to the Schneider study, based on the FDDQL (functional quality of life diseases quality of life questionnaire) scores, there was a significant increase in the Quality of Life for IBS patients receiving acupuncture and sham acupuncture p-value <0.001. However, there is no significant difference in the extent of improvement in symptoms after the 5-week intervention between the two treatment groups based on p-value=0.327.

Table 2. Summary of Improvement of Symptoms of IBS When Treatment with Acupuncture is Compared with Sham-Acupuncture from Baseline to Post-treatment Scales

Study	Types of measurement used	Tx Group	Baseline Scale scores	Post treatment	P-value	Between-group tx difference
Anastasi	Clinical Global Impression Scale	AC	3.86(3.51-4.20)	2.08(1.27-2.90)	<0.05	P=0.77
		SAC	3.73(3.37-4.09)	1.73(0.96-2.51)		
Lembo	IBS Global Improvement Scale %responders:	AC	*	41%	=0.25	P<0.001 (comparing AC&SAC to the WL)
		SAC		32%		
		WL		4%		
Schneider	FDDQL	AC	57.7	64.6	=.001	P=0.327
	Global scores:	SAC	55.3	60.6		

AC=acupuncture treatment group
 SAC=sham-acupuncture treatment group
 WL=wait-listed group

Two studies used in this review presented data in dichotomous format which allowed for further calculations including Relative Benefit Increase (RBI); Absolute Benefit Increase (ABI); and Numbers Needed to Treat (NNT). Number Needed to Harm (NNH) was not of interest in this review because of the relative low incidence of adverse events due to treatment with acupuncture. One study mentioned reports of foot cramps, nausea and hip pain, all of which were ruled out of being related to the study procedure.

The lack of any serious side effects suggests that acupuncture is a relatively safe treatment. Table 3 reflects the ABI, RBI and NNT from the Lembo and Anastasi studies which both show a modest benefit increase from acupuncture treatment. Based on the NNT from these to studies, 10 to 12 patients would need to be treated with acupuncture for one to have an improvement in symptoms. The 3 studies totaled 334 patients, only 39 of which were lost to follow up. Most were reportedly due to time constraints.

Table 3. Analysis of Outcomes and NNT in order to Improve the Symptoms in IBS Patients Treated with Acupuncture v.s Sham-Acupuncture

Study	#completed the study	RBI	ABI	NNT
Anastasi	27	30%	10%	10
Lembo	230	28%	9%	12
Schneider	34	*	*	*

DISCUSSION

There was great amount heterogeneity between the trials including method of intervention (length of trial and style of acupuncture), controls used, and outcomes measured. The trials ranged in length from 4-6 weeks which may not have been enough time to see results from treatment. Acupuncture is traditionally based on individual assessment that makes it hard to replicate in the structured setting of a randomized controlled study. A confounding variable in this type of study could be “handling” which is a result of the innate increase in doctor-patient interaction. In both the acupuncture and sham-acupuncture group it is difficult to control for the interaction between the provider and patient that may offer some therapeutic effect to the patient.

Although the efficacy of acupuncture remains up for debate, the safety of acupuncture surpasses the risks associated with other medical treatments used for IBS. None of the studies in this review reported dropout due to adverse effects from the treatment. However, the time commitment required for acupuncture treatment did lead to a number of participants withdrawing from the study. It was mentioned in the results section that ten to twelve patients need to be treated in order for one patient to benefit from acupuncture treatment. Although it may seem like a waste of time for the 9 patients who may not have benefitted from acupuncture it should be noted that there was minimal risk for them participating in the treatment. The same cannot be said about medical treatments used for IBS management, many of which have multiple side effects. Patients demand for alternative therapies continues to drive research on acupuncture as well as reimbursement from insurance companies.

CONCLUSION

The studies reviewed do not statistically support acupuncture as an effective treatment for IBS. However, at this time no recommendations should be made against acupuncture because an improvement in symptoms was seen across all trials. More high quality trials are necessary to make recommendations on the use of acupuncture in IBS. Future trials should seek alternate control groups other than “sham”-acupuncture. Some studies on “sham”-acupuncture have suggested that the “Streitberger” needles used can have some physiological or analgesic effect. There are meridians (or acupuncture points) at almost every area of the skin and the needle does not have to puncture the skin to have energetic effects. This may be why there is a lack of difference between the two groups. There is no way to validate that “sham” acupuncture did not have “true”

acupuncture effects. The studies did not use Traditional Chinese Medicine (TCM) diagnoses that are typically used for acupuncture treatments. It is essential in future studies involving TCM therapy, such as acupuncture, to use a TCM approach for the evaluation of the patient. These studies lacked individual diagnosis and lack of specified techniques based on the diagnosis, which is the typical nature of TCM. Also researchers should use standard outcome measurements such as FDDQL or IBS-QoL to evaluate the treatments for IBS. It is difficult to compile data from multiple sources when each study has its own method for evaluating the treatment.

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