

Acupuncture for Chronic Severe Functional Constipation: A Randomized Trial

BACKGROUND:

- Chronic Severe Functional Constipation (CSFC) decreases quality of life in patients. Acupuncture has been used previously for constipation; however, concrete evidence does not exist to make a just recommendation for its use.

OBJECTIVE:

- To evaluate the efficacy of electroacupuncture (EA) versus Sham-acupuncture (SA) in the treatment of CSFC.

METHODS

- Randomized, parallel, sham-controlled trial, double blinding, but acupuncturists could not be blinded due to the nature of the procedure
- The treatment period was 8 weeks long, and there was a follow-up period of 12 weeks after that.
- Important inclusion/exclusion criteria
 - Inclusion Criteria:
 - Met the diagnosis of functional constipation based on the Rome III diagnostic criteria for functional gastrointestinal disorders, Had CSFC with 2 or fewer mean weekly CSBMs for 3+ months, Aged between 18 and 75, Had not taken constipation medication for a minimum of 2 weeks before enrollment except for rescue medicine (glycerol or sorbitol anal enema), Had not received acupuncture for constipation, Had not participated in any other trial in the previous 3 months
 - Exclusion Criteria:
 - Constipation caused by: IBS, medications, or the following disorders: endocrine, metabolic, neurologic, or postoperative.
 - Severe cardiac, hepatic, or renal dysfunction, Other listed comorbid conditions
- There were 536 patients in the EA group and 539 in the SA group.
- The treatments used were EA and SA. Each patient took part in 28 half-hour sessions. 5 per week for the first two weeks and 3 per week for the remaining six weeks.
- Outcomes:
 - Primary - Change from baseline in mean Complete Spontaneous Bowel Movements (CSBMs) weeks 1-8
 - Secondary – Change from baseline in mean CSBM weeks 9-20, Mean SBM week 1-8, Mean scores for stool consistency and straining of SBMs during weeks 1-8, Health-related quality of life, Proportion of patients with 3 or more CSBMs per week, Proportion of Participants using rescue medications, Mean weekly frequency of using rescue medications or defecation aids during weeks 1-4, 1-8, 9-20
- Power was above 95%
- Intention-to-treat data handling method was used

RESULTS

- Overall, 1021 patients completed the trial. 515 completed in the EA group and 506 completed in the SA group
- **Primary Outcome:** Change from baseline in mean CSBMs per week, weeks 1-8 (between group difference) was statistically significant – 0.9 (95% CI: 0.74 – 1.10), weeks 9-20 – 1.09 (95% CI: 0.94-1.31)

Secondary Outcomes: The following results were statistically significant: Participants with more than 3 CSBM per week (between group difference), weeks 1-8 – 19.3 (95% CI: 14.3 – 24.2), weeks 9-20 – 23.6 (95% CI: 18.5-28.7); Change in mean SBM per week during weeks 1-8 – 1.00 (95% CI: 0.81-1.21); change in mean Bristol Stool Form Scale score for stool consistency during weeks 1-8 – 0.24 (95% CI: 0.12-0.31); Change in mean score for straining during weeks 1-8 - -0.24 (95% CI: -0.29 - -0.15); Change in PAC-QOL Score: week 4 - -0.14 (95% CI: -0.20 - -0.09), week 8 - -0.31 (95% CI: -0.37 - -0.25). The following results were found to be not statistically significant: Patients using other measures for constipation: weeks 1-4: Rescue – 3.8 (95% CI: -2.1 – 9.8), other - -0.1 (95% CI: -5.8 – 5.6), weeks 1-8: rescue - -5.7 (95% CI: -11.8 - 0.5), other – 0.8 (95% CI: -6.5 – 8.0), weeks 9-20: rescue - -3.7 (95% CI: -10.3 – 2.9), other -0.3 (95% CI: -7.2 – 6.7).

- The authors of this journal article stated that electroacupuncture may normalize bowel function in some patients.

STRENGTHS

- This study had a large sample size.
- Assessed for unblinding
- Double-blind, sham-controlled trial
- Appropriate rationale for conducting the experiment
- Consistent hypothesis to answer the primary outcome

LIMITATIONS

- The study was not conducted long enough
- Did not explain the process for choosing who to evaluate for unblinding.
- Could not blind acupuncturists
- Exclusion criteria could have been hard to screen
- Patient responses in a diary are not always clinically reliable
- Not generalizable to the general population – mostly Han women were studied
- Did not discuss differences in practice sites
- Did not discuss or assess differences in acupuncturists
- Very wide range of time of having severe chronic functional constipation prior to randomization

CONCLUSIONS

- Electroacupuncture does provide some improvement in bowel movements and quality of life in patients with chronic severe functional constipation. However at this point the results cannot be generalized to the population.
- At this time the clinical significance of this treatment is questionable. The patients experienced only a small improvement in bowel movements and quality of life, but if the patient was severely constipated then this could be a major improvement for the patient. Due to the likely cost of this treatment it would not be listed as a first line treatment option, and may be patient specific to see improvement.
- To make a stronger recommendation for the use of this treatment more studies would be beneficial. Those studies would evaluate a longer time frame, have a more diverse patient population, and more uniform CSFC characteristics. The studies would also consist of standardization in the diary, practice sites, and acupuncturists.

References: 1: Liu Z, Yan S, Wu J, He L, Li N, Dong G, et. al. Acupuncture for Chronic Severe Functional Constipation: A Randomized Trial. *Ann Intern Med.* 2016;165(11):761-769.

Zachary Griffith, PharmD Candidate 12/9/16