Author’s response to reviews

Title: Electroacupuncture for postoperative pain and gastrointestinal motility after laparoscopic appendectomy (AcuLap trial): study protocol for a prospective randomized controlled trial with three-arm, parallel-group (electroacupuncture versus sham acupuncture versus control)

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Author’s response to reviews: see over
Dear Editors-in Chief, Dr. Doug Altman, Dr. Curt Furberg and Dr. Jeremy Grimshaw

I appreciate your kind interest in my manuscript and the valuable and detailed comments provided by Prof. Fan-Rong Liang. I am pleased to submit the revised manuscript titled “Electroacupuncture for postoperative pain and gastrointestinal motility after laparoscopic appendectomy (AcuLap trial): study protocol for a prospective randomized controlled trial with three-arm, parallel-group (electroacupuncture versus sham acupuncture versus control)” by Gangmi Kim to Trials.

I provide my point-by-point responses following the reviewer’s comments below.

Response to comments:

Reviewer's report: The authors designed an interesting randomized controlled study to investigate the efficacy of EA for postoperative pain and gastrointestinal motility after laparoscopic appendectomy. However, the authors should consider the following comments for the improvement of the manuscript before resubmission.

1. In the intervention group I, about electroacupuncture treatment, firstly, how did you set the frequency as twice a day, and a maximum of 4 session of acupuncture treatment were given? Was there any evidence to supported? Or there were other reasons can you specify please?

Response: We searched literature in medical research engines including Pubmed to set the acupuncture protocol, however not so many supporting evidences from the English literature were found to set the frequency of acupuncture for postoperative pain and ileus after laparoscopic appendectomy. We found a well designed randomized controlled trial of acupuncture for reduction of post colectomy ileus by Dr. Dengie et al. from Memorial Sloan-Kattering Cancer Center [1]. They performed 30 minute of true or sham acupuncture twice a day for 3 days postoperatively to evaluate the efficacy of acupuncture for postoperative ileus.

In Korean oriental medicine, acupuncture is performed normally twice a day for acute diseases or once per two to three days for chronic diseases. In this study, the eligible criteria are patients with acute appendicitis which is
acute disease. And patients undergoing laparoscopic appendectomy are usually discharged in 2 days after surgery. For these reasons, we made the schedule twice a day with maximum of 4 sessions.

Reference


Secondly, since it is the disorder of gastrointestinal, why the acupoints on the stomach meridian(ST36, ST37, ST39 et al.) or spleen meridian were not selected?

Response: As Prf. Liang mentioned, it is correct that either stomach meridian or spleen meridian can be used for the gastrointestinal disorders. And there are many other acupoints other than those meridians known for treating gastrointestine. We selected LI4, PC6, KI6, and LR3 among those because they are well known meridians for treating gastrointestinal disorders including low abdominal pain and are currently employed in our Korean oriental medical clinic.

Thirdly, the EA versus sham acupuncture, park sham device was used to resemble acupuncture, how about the electric stimulation?

Response: Park sham device has PG-306 electric pulse generator which is the same as in true acupuncture. In Park sham device, the internal wire inside PG-306 is cut so as not to deliver the electric pulse to patients and the patients only hear continuous sound (fake sound) which resembles the electrostimulation.

2. In the control group, patients were given routine standard postoperative care, it was a positive control or blank control? In the sham group, they were not given routine standard postoperative care, whether it was ethical or not.

Response: The control in this study is blank control. All three groups are given the same routine standard postoperative care after laparoscopic appendectomy. The only difference is that the control group is not given acupuncture, which makes it a blank control, and the other two groups are given acupuncture or sham acupuncture. It is described in study outline on page 5 as “After laparoscopic appendectomy, routine postoperative care is equally given to all patients except for interventions (electroacupuncture or sham acupuncture).”. And routine postoperative care for all patients is described on page 6~7.
3. About the timeline, the quality of life, readmission, medical costs and protocol failure will be assessed on the first visit day after discharge, when is the first visit?

**Response:** The first visit day is usually postoperative day 7.

4. As for the statistical methods, what would you do to handle the missing data?

**Response:** For missing data less than 5% of sample, they will be dropped out. For missing data more than 5%, analysis will be carried out with missing data imputation by last observation carried forward and maximum likelihood estimation method.

5. In the discussion part, would you please add the strength and limitation of your study protocol?

**Response:** We believe that the strength of this study is to prove the true effect of acupuncture on postoperative recovery by comparing patients receiving true acupuncture or sham acupuncture and control group without acupuncture treatment. If the true acupuncture group shows better outcome compared to the sham group, true effect of acupuncture can be justified on postsurgical patients. However if the true acupuncture group fails to show superior outcome to the sham group, even though the acupuncture group shows better recovery compared to the control group, a placebo effect of acupuncture should be considered. And it will be the first published protocol in English to investigate the efficacy of acupuncture on postoperative pain and ileus after laparoscopic appendectomy. We hope to share this protocol with investigators whoever are interested in the acupuncture and recovery of postsurgical patients.

On the other hand, it is possible that the study may not reveal statistically significant positive or negative conclusions because laparoscopic appendectomy is minimally invasive surgery and patients undergoing laparoscopic appendectomy mostly show fast recovery after surgery. However, we hope to design our next study in other surgical procedures with experiences from this study.

I hope this would be a sufficient response to Prf. Liang’s comment. Please do not hesitate to contact me if you have additional questions or suggestions on improving the manuscript. Thank you.

Sincerely yours,

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