Author's response to reviews

Title: A randomized controlled trial: Can acupuncture reduce drug requirement during propofol sedation for colonoscopy? A study protocol

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Author's response to reviews: see over
Dear reviewers,

Thank you very much for your comprehensive advice on our manuscript. Realising that you put a lot of time and effort in this revision I tried to correct and improve the manuscript in the way you suggested.

Review 1:

We added the acupuncture points used in the study by Ni et al.
We removed “prospective” out the description of the trial design.
We removed “retrospective” out the description of sample size calculation.

Review 2:

We rewrited the title more clearly: A randomized controlled trial: Can acupuncture reduce drug requirement during analgosedation with propofol and alfentanil for colonoscopy? A study protocol
We reworded our statement about LI4 in the chapter intervention and discussed it in the chapter discussion.

Intervention:
There are no specific acupuncture points known for their sedative effect. Large intestine 4 (LI4), Pericardium 6 (P6) and Stomach 36 (ST36) is the most used combination to reduce gastrointestinal discomfort and pain [5][7] with a consecutive sedation side effect. [15]

Discussion
Another point of discussion comes up with the question: Does acupuncture really have a sedative effect or is this effect the consequence of its analgesic properties.
Fanti et al. studied three groups of patients scheduled for colonoscopy. [5] Group 1 got acupuncture, group 2 sham-acupuncture and group 3 placebo. All groups were premedicated with 0.02-mg/kg midazolam before, and no analgesic agent was used. If patients complained about pain during procedure they received additional boluses of midazolam. To medicate a patient moaning about pain with a sedative and to conclude that acupuncture can decrease the demand for sedatives during colonoscopy is not the correct conclusion.
So the question whether acupuncture can reduce the dosage of sedative, and be implemented into the clinical routine as a complementary sedative method has still to be answered. [21]
Statistics: We rewrited the discussion with an explanation why we considered a non-inferiority approach, but in the end decided not to use it:

One might discuss to analyse the data using a non-inferiority approach because sedation quality after application of acupuncture should be at least as good as using medication only.
However, our motivation in the end to choose for the superiority approach was: During this trial acupuncture is performed by only one experienced acupuncturist. Implementing acupuncture in our daily anaesthesia sedation praxis would mean additional engagement of anaesthesia personal to learn and perform acupuncture. This investment will only be cost-effective if the dosage of propofol is reduced or - in case of the dosage of propofol is not influenced, there is an improvement of satisfaction among patients and endoscopist.
Alongside, safety concerns of deep sedation performed with propofol still remain. Cote et al. showed that hypoxemia occurred in 12.8% of 799 patients sedated for endoscopic procedures with propofol applied by trained anaesthesia nurses. [20] In 14.4% of the patients airway manoeuvres were necessary to prevent hypoxemia. In our own previous study looking at 180 patients undergoing colonoscopy, 47% of all patients with propofol sedation experienced at least one respiratory incident and 87% had at least one hypotensive event. [13] Minimizing those propofol related risks by means of a superior sedation form is therefore an important goal to make sedation procedures safer.
Aside these considerations all groups receive propofol sedation and therefore using placebo needles is not an unethical treatment.

I have tried to act on your questions and suggestions exactly. Hopefully this will be sufficient.

Kind regards
Susanne Eberl