Author's response to reviews

Title: Acupuncture is a feasible treatment for post-thoracotomy pain: Results of a prospective pilot trial

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Response to referees

Referee: Macpherson

Comment: The abstract should include the number invited, showing the number (proportion) who participate, which is also a measure of acceptability that will impact on recruitment to a large-scale RCT.
Response: As pointed out below, patients could be approached for trial by a number of different individuals and so formal recording of refusal rate was logistically complex. At the end of the trial, we asked all referring clinicians to reflect on patient refusals: refusal rate was very low (we state in the text that fewer than five patients refused).

Comment: In the Methods, the rationale for using these specific locations of acupuncture points is not well covered. And the association between these points and traditional acupuncture points is not discussed. The role of Kotani’s study in informing this one is not properly discussed in the Methods, though Kotani’s study is mentioned in passing in the Comments section regarding the length of time of which acupuncture was provided. Really this should be set out in the Methods section.
Response: We have specified the points using both Chinese and, where appropriate, western anatomical descriptions. We have also given a rationale for the points used.

Comment: The last sentence of the first paragraph on page 7 discusses the use of metal balls, arguing that they are used for the reason that they do not penetrate the skin. This is not a good argument, as logically it could be applied to all points at all times in the trial. The authors need to provide a better rationale for using metal balls that does not undermine the case for using auricular needles earlier on in the study.
Response: We have clarified the key point with respect to the metal balls: patients did not see an acupuncturist after the metal balls were placed, and there was therefore no check on whether they had been removed. Metal balls are safer than needles in this context.

Comment: A “modified” pain inventory (BPI) was used, but no explanation of how the BPI was modified, and the implications of this modification in term of validity and reliability of data.
Response: The only modification we made was to omit the diagram of pain site (which is similar in all patients). All the scored questions were identical. Hence we feel that reference to a "modified" BPI was misleading and just use the term "BPI" without specifying "modified".
Comment: Page 11, first paragraph, it should be reiterated here that the decreasing severity of pain over time is possibly due to a number of factors, such as natural history, and that this study explicitly does not demonstrate that the improvement is due to the acupuncture.
Response: This change has been made.

Comment: The title of the Tables should be more self-explanatory. This applies particularly to Table 2 and 3 where the actual scale used should be provided, and the units given, with a note to say that reduction is related to improvement.
Response: This change has been made.

Referee: Karakaya

Comment: The authors should check that they have covered all the reporting requirements of the STRICTA guidelines
Response: We have checked our manuscript against STRICTA and made several changes to confirm to these guidelines.

Comment: In my opinion anesthesia technique and also the drug(s) given through the epidural catheter, postoperative pain management for analgesia should be given in the manuscript.
Response: Descriptions of these aspects of the trial have been added.

Comment: Alternative therapies if pain VAS scores >5 should be mentioned in the text.
Response: This change has been made: we describe treatment of patients with "poor analgesia"

Reviewer: Dagnino

Comment: The aims of the study are not clear, both in the abstract and then in the Introduction … in the Introduction, aims are stated as 1) … 4) . After this, further objectives are added as “to determine the optimal timing of outcome assessments”, “to provide data to aid trial design”. Optimal timing of assessments are not addressed later. This lack of clarity ends with conclusions not clearly related to aims nor supported by the results.
Response: We have re-written the introduction to clarify our aims. All are listed in numerical order with no additional aims added. Each of these aims is explicitly flagged up in the conclusions.

Comment: Second paragraph in p.10 is confusing: there were no data on needle retention for two patients and a further four retained fewer than half the needles. This jeopardizes one definition of feasibility and is in direct contradiction with the starting line of the next paragraph.
Response: We have added that 82% of patients retained more than half the applied needles, our specified target for “tolerating” the intervention.

Comment: Safety cannot be evaluated with just 25 patients and even less with the 19 that retained more than half the needles after 30 days (Hanley JA, Lippman-Hand A. JAMA 1983;249:1743).  
Response: Although safety is typically evaluated initially in a small number of patients, as in this study, we accept that safety cannot be demonstrated in such a small group (as we stated in our conclusion). We have therefore changed references to “demonstrated to be safe” to “no important adverse events”.

Comment: Method and parameters used for sample size calculation should be stated  
Response: The sample size calculation is now explained in detail

Comment: Use of means and SD for analysis of VAS scores has been validated but it can be misleading in the lower and upper regions (ie. Mean of 1.72 and SD of 1.76 BPI pain intensity at 60 days). It might be preferable to use median values.  
Response: The median can be useful for summarizing data but not for planning research, which is the main aim of the tables.

Comment: 1) The title is appropriate but the Running head adds the word effective, conclusion that is not supported by this trial.  
Response: This has been changed.

Comment: 2) In the Abstract, conclusions declare the trial to be feasible but no results are given to support this. The same applies to conclusions on acceptability and interference with surgery.  
Response: The discussion section has been changed to clarify these points.

Comment: Line 4 of the Methods states that “all needles were kept in place for four weeks” but this was not the case.  
Response: This has been changed to “all needles were removed after four weeks”.

Comment: 3) In Methods. The epidural insertion and management technique should be described … 4) Pain management after epidural catheter removal should be described  
Response: Full descriptions have been added

Comment: 5) P.7, l.4 “in place in place”; p.7.l 18 “wanted insure”; p.8, l.3 “operation surgery”.  
Response: These typographical errors have been corrected
Comment: 6) Pain relief as part of BPI should be explained as is the fact that fewer patients have evaluable data when compared to BPI intensity and interference (Table 3).
Response: We have added text to table 3 to explain these points.

Comment: 7) On patient acceptance, stating that “fewer than five patients refused” suggests that this parameter was not evaluated prospectively.
Response: Patients could be approached for trial by a number of different individuals and so formal recording of refusal rate was logistically complex. At the end of the trial, we asked all referring clinicians to reflect on patient refusals.

Comment: 8) Why use acupuncture in a pre-emptive fashion?
Response: Use of medication before the noxious insult is standard practice in anesthesia.

Comment: 9) How do the 30 day results predict longer-term outcome? In particular, chronic post thoracotomy pain?
Response: We draw this conclusion on the basis of the findings of the current study and the results reported in reference 11.

Comment: 10) Adverse events should be described to let the reader judge that they had clearly had no relationship to acupuncture.
Response: We respectfully disagree: the only way to judge the relationship with acupuncture is to give a medical history and a detailed description of the time course of the adverse event.

Comment: 11) Could change of needles alter the results?
Response: We do not believe that there are any important differences between the needles other than that one is easier to apply.

Comment: 12) Table 2. Add VAS to title. Explain why Pain on cough was obtained in fewer patients.
Response: These points have been addressed.

Comment: 13) Table 3. Add BPI to title and Mean and SD. Explain why BPI relief was obtained in fewer patients.
Response: These points have been addressed.