Reviewer’s report

Title: Adverse events following acupuncture: a survey of 1968 cases in China

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Reviewer: Dugald Seely

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The issue of adverse events when considering acupuncture is important and deserves attention. In some jurisdictions, the use of acupuncture is common and likely potential risks are well understood allowing for better prevention and treatment when they occur. That said, the advent or possibility of this therapy been used in conventional settings in the West would require a greater understanding of inherent risk, foreseeable, and possibly preventable adverse events. As such, the topic of the paper and decision to assess for all adverse events in three large, and purportedly, well conducted clinical trials in China that employ acupuncture is laudable. There are a few major compulsory revisions suggested for this paper and a few minor issues to consider.

In addition to evaluation of both incidence and type of adverse reactions one of the strengths of this analysis is the use of logistic regression to evaluate for contributors to risk. For instance the contribution of patient characteristics (i.e. age, gender, education, and previous acupuncture exposure) were evaluated in the regression analysis.

Major Compulsory Revisions

The biggest substantive concern I had in reviewing this paper was a lack of information and clarity on the three trials that were assessed to collect the data on adverse events (AEs). Specifically the section on Methods begins with describing all the cases coming from two program(s) but then goes on to define three registered RCTs. This is confusing and clouds the ability to effectively review the remainder the paper.

Related to this issue, it would be helpful to provide more information on each of the trials especially with regard to the frequency and site of acupuncture application in each trial. Were all points standardized, was there any blinding attempted, was point selection up to the individual practitioners, what were the locations (per trial) of the points used, what were the general characteristics of the patients per trial, etc...? This detail is necessary to better understand the intervention and what kind of AEs might be expected.

Providing a chart that details point location generalized by body area (ie. thorax, extremities, face, etc...) and associated AEs would allow a better sense of the data. For instance if there were very few points used over the chest cavity, we would not expect to see any pneumothorax. If on the other hand there were many applications on the chest cavity without any occurrence of AEs then this
more serious adverse event is demonstrably absent when the risk might be considered higher giving good information.

The Abstract implies that there was an assessment of practitioner experience as it relates to incidence of AEs. This is a plausible hypothesis but the data from the text and tables does not show this to be analyzed within these trials. The same point applies to patient compliance, and to some degree the anatomic location of application although this is given subjective consideration.

There are numerous instances whereby the choice of English words are awkward or misleading. Having a native English speaker with experience in medical writing review and edit this paper once all substantive changes are made is necessary before resubmission.

Minor Essential Revisions

Were the adverse events defined a priori before reviewing the data or were they defined along the way as the AEs were noted? It would be good to note this in the manuscript and briefly describe the process for defining AEs and characterizing them. From the manuscript it seems that AEs were carefully documented in each clinical trial, however this needs to be more explicit and clearly described.

Characterizing not only the number of patients in the trial but also the number of actual individual acupuncture applications would give greater depth to the data.

Sentence of the first section of the ‘Methods - Subjects’ section needs completion.

The Audit described on page 6, stating that “…10 CRFs and data from database were randomly selected and checked again...” seems a bit odd given the dataset of nearly 2000 patients. Could this be “…10 percent of CRFs...”

In the discussion on page 11, the paragraph starting with “Fourthly, acupuncture...” somehow relates to patient’s compliance. I did not understand how this association was made as it does not come out of the data and additionally there are no citations to show the association. In the same paragraph, the use of ‘taboo’ is confusing, I think this is likely ‘contraindication’.

The conclusion which states that “These AEs could be entirely avoided such as...” is not justified. Perhaps the risks could be reduced and mitigated but ‘entirely avoided’ is too strong of a statement to make.

Discretionary Revisions

In addition to patient and practitioner characteristics it could be useful to include the morbid condition and/or general location of acupuncture application in the regression analysis. It is discussed, for example, that in certain parts of the body (i.e. face, scalp) there is greater likelihood for bleeding. By including location (i.e. thorax, face, scalp, extremities, etc...) this could perhaps be quantitatively assessed.
**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests.