Acupuncture in patients with valvular heart disease and prosthetic valves - an apology

This article described a study in which a group of patients who were theoretically at risk of endocarditis and had received acupuncture treatment within the previous ten years, were given a physical examination and some diagnostic tests in order to determine whether they had incurred endocarditis. Since the publication of the article, it has come to our attention that the study should have had prior approval from the local ethics committee, and that patients should have been given more explicit information that they were being asked to participate in a research project. We apologise unreservedly for what technically amounts to misconduct in both research and publication. A further minor inaccuracy in the report that has been pointed out is that the project was described as prospective when it was not.

There is often confusion on the borderline between audit and research. The most useful distinction between them is that research involves the active participation of the subjects. Clearly, this was the case here. The issue may have appeared clouded in this case, because the researcher’s plans were initially inspired by good, caring practice. While this may have been the original motive, the idea clearly developed well beyond this into a formal research project. It seems probable that the gradual evolution of the project in this way meant that the project crossed the line into ‘research’ without that being recognised.

The submitted article was fully reviewed by peers and by the editor in the usual way for any scientific journal, but the ethical problems were not identified. Reviewers and editors may be invaluable but are not infallible. There is evidence for that: ‘Several studies show that reviewers are poor at detecting major errors that are apparent in the text’. The editors have taken this mistake seriously, have tightened up the published advice to authors and the processes of publication, and will continue to review the procedures regularly.

In conversations with the editor, and in his letter below, the author confirmed that there was no intention to deceive patients or readers, and this is accepted. This event is very far removed from fraud, and therefore there is no question of retracting the paper or the evidence it offers. The study itself was innovative and valuable, addressing an important and under-researched topic. It is extremely unlikely that the patients in the study would have refused to participate if they had been told that they were being invited to join a research project about the possible risks of acupuncture. It is also unlikely that they were harmed in any significant way: they gave their time, underwent some invasive procedures, and may have experienced some anxiety while awaiting test results, and deserve an apology. The editors have obtained independent external opinion on the case from a lawyer, who confirmed the misconduct but did not recommend retraction, and further independent advice is being sought.

The lessons of this for researchers are clear: all research projects should be peer reviewed during their design stage, should be conducted by a collaboration of at least two people, and should be guided by a formal protocol which should be based on an accepted template that can act as a checklist. The lessons for editors are that neither they nor the journal’s peer reviewers are infallible, and that there is no substitute for check-lists for essential items.

On a final point, the problems with this paper were brought to our attention by a reader who sent an anonymous letter to the editor – stating that it was anonymous because the writer was ‘sure you
will not publish’ the complaint. Since we cannot reply to the writer directly, we hope he or she has read this article and is satisfied that the journal takes the ethical aspects of research and publishing extremely seriously. We urge correspondents to sign their letters, even if they want them published ‘name and address withheld’.

Reference List

Comment from the author

*Editor* – I am writing with regard to the anonymous letter sent to *Acupuncture in Medicine*, in which the writer criticises a study of acupuncture in patients with valvular heart disease, claiming the study was unethical.

There are two points I would like raise:

First, the letter was sent anonymously. The editor of the journal, in answering the letter, may have set a precedent to receive such anonymous letters. Is the future position to be that these will also be investigated and published? Are letters sent anonymously because of the hidden agenda of the author, ie vindictiveness or professional jealousy, to be published in future? My understanding of the protocol for the scientific process is that a letter submitted to be published has the right of reply from the author to answer and if necessary an editor’s reply, if so decided, followed by an open scientific debate. This is not possible with this letter.

Secondly, with regard to the study, this was a simple observational study in a busy general practice, such that for scientific purposes had to be concluded for completion in a subsequent publication. In order to ensure that patients did not have an ongoing infection at the completion of the study, a blood test was taken and the reason for this explained to each patient. This single blood test has been deemed unethical because written consent was not obtained for the test nor the Ethics Committee informed of the study. It is interesting to note that under the terms of the GMS II Contract for General Practice, patients will be asked to provide numerous blood samples without written consent, which will result in the practice receiving financial reimbursements for points achieved under the Quality and Outcomes Framework. Some of these blood tests will be unnecessary and therefore should be deemed unethical. Will the patients in this situation be fully informed as to why the sample is to be taken?

All of my patients in the study had the reason for the sample explained; all patients consented by allowing me to take the sample. No patient was coerced into providing a sample. From the explanation I gave they were aware that we were trying to establish the safety of acupuncture in patients with these cardiac conditions.

As far as carrying out echocardiograms, these would have been performed as part of the ongoing monitoring of the disease process just as those arranged by a cardiologist would in an outpatients setting. Do I really need to submit a 20 page document to the Ethics Committee for approval for a single blood test?

Do I believe that I have acted unethically towards my patients? No, I do not.

Have my patients suffered as a result of this study? No.

Would the patients involved take part again? I have asked this question and the answer has been a resounding ‘Yes’. This is mainly because of the established openness, trust and rapport which have developed over the years I have cared for them. Indeed four consecutive patient questionnaires over the past ten years have consistently demonstrated 99 – 100% patient satisfaction ranging over a wide number of questions including the doctor/patient relationship. Coupled with this, the practice has had no complaints over the past five years. Surely, our intention is to encourage innovative approaches in general practice where the majority of acupuncture is performed.

Let us have an open debate, whereby the anonymous author has the courage of his or her convictions.

The question I would like to pose is: is the author of this letter any less unethical in his or her anonymity?
Comment from the author

Antony Stellon

doi: 10.1136/aim.22.2.99

Updated information and services can be found at:
[http://aim.bmj.com/content/22/2/99.citation](http://aim.bmj.com/content/22/2/99.citation)

**Email alerting service**

*These include:*

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:

To order reprints go to:
[http://journals.bmj.com/content/subscribers](http://journals.bmj.com/content/subscribers)

To subscribe to BMJ go to:
[http://group.bmj.com/subscribe/](http://group.bmj.com/subscribe/)