Reviewer's report

Title: Chinese herbal recipe versus diclofenac in symptomatic treatment of osteoarthritis of the knee: a randomized controlled trial.

Version: 1 Date: 31 August 2004

Reviewer: Flavia Cicuttini

Reviewer's report:

General
The aim of this study was to determine whether a Chinese herb recipe is effective in the treatment of symptoms in knee OA where the comparison treatment is diclofenac.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Main points.
1. The investigators have performed an RCT. In the methods they discuss placebo treatment. However there does not appear to be a placebo component to this study (see Figure 1). This needs to be corrected.

2. The scientific quality of the data on post intervention treatment outcomes is very poor. This should be mentioned in the result section, however only with caution. It should not form a major component of the study or results. To this end, the table relating to this data should be removed and no major conclusions discussed, as they are flawed.

3. It is important to note that the 2 treatments are not blinded since the diclofenac group was taking one tablet 3 times a day and the Chinese herb group 6 tablets 3 times a day. In addition, as the authors describe, the herbal treatment had distinctive characteristics.

4. The authors have concluded that there were no significant side effect. However 30% of study subjects in each group had significant side effects. This is very important since it is acknowledged that diclofenac has significant numbers of side effects and is generally prescribed by a medical practitioner. However, the side-effect profile with the Chinese herb recipe is similarly bad. This needs to be discussed and the cautious use of treatment considered.

5. The authors need to give greater perspective as to how they see the results of this study being used. They need to carefully review the evidence for treatment of knee OA. The current recommendations are for paracetamol to be used for symptoms and NSAID to be used for acute episodes that do not respond to treatment. There has been no recommendation for continuous use of any medication. Paracetamol has a generally safe and well-established and tested side effect profile which is better compared to NSAID. This is important given the high rate of side effects in the Chinese herb recipe group. This must be considered by the authors in more detail.

6. There is no evidence for any of the above therapies effecting structural change. Consequently regular use over long periods of time is not justified, particularly as the authors have shown that both the NSAID and the Chinese herb recipe group have little in the way of symptoms after one month. In fact, there is also the issue of the tendency for symptoms in knee OA to fluctuate and it may be that
after a week or 2 no further treatment is needed.

7. The authors need to show care in concluding that the herbal medicine took longer to be active. Could it be simply that diclofenac worked quickly, but that patients got better anyway by 2-3 weeks so neither treatment was still needed?

8. Given that subjects are likely to have known what treatment they are on (given the characteristic features of the Chinese herbal treatment), this may have biased the long-term use of these treatments.

Specific points:
1. Did one physician do all the outcomes?
2. In the abstract, methods. The number of responders is not an outcome.
3. In the analyses: Comparing an individual to their baseline measure is interesting, but the main outcomes of interest are the differences between the diclofenac and NSAID groups.
4. The discussion needs to be re-structured. The first paragraph is a sample size that should go in the methods section
5. There is a lot of unnecessary information in the discussion section. In general the authors should describe what they found, how what they found compares to other literature, potential limitations of their study, what the results mean and a conclusion. The discussion as currently written does not cover those points. It is too long and does not follow logically.
6. The authors need to discuss the possibility that even if the subjects had been on placebo, the tendency in knee OA over 2-4 weeks is for symptoms to improve. This is a possible explanation for the late effect of the Chinese herbal medicine and not that it worked slowly. This is important since the herbal medicine had significant side-effects.
7. I would strongly suggest that the investigators must be more guarded about their conclusions: They showed no statistically significant difference between the diclofenac and chines herb group. Both groups showed significant improvement from baseline. The side effect profile was quite high, but similar, in the 2 groups. The possibility remains that there is no effect of the herbal treatment but that we are seeing the natural history of knee OA symptoms to improve. There is no evidence for long-term use of either diclofenac or the Chinese herbal treatment.

I think making more of the results is not justified. However I think these results are interesting.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
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Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No
Declaration of competing interests:
None