Reviewer's report

Title: "Hydrodilatation, corticosteroids and adhesive capsulitis: A randomized controlled trial

Version: 3 Date: 30 October 2007

Reviewer: Rachelle Buchbinder

Reviewer's report:

General

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

This paper reports the results of a single blind randomized controlled trial of 3 glenohumeral injections given at 2 weekly intervals (under fluoroscopic guidance) of either hydrodilatation including corticosteroid versus corticosteroid alone for adhesive capsulitis. The important aim is to determine whether hydrodilatation adds any additional benefit over steroid injection alone. The paper is generally clearly written but some points need further explanation and/or clarification and then it will be a useful contribution to the literature on this topic.

1. Why were 3 injections rather than a single injection given? It may be that the high amount of steroid injected over time may have diluted any true effect of the hydrodilatation per se. It is not clear whether the authors expected a cumulative effect?

2. As the authors point out, one possible explanation for the lack of difference between groups may have been the similar amount of fluid injected in both groups. As they point out the ‘control’ volume of 10ml is the same volume as some investigators have used for distension in the past (e.g. Jacobs, as noted in this paper). What was the mean (SD) volume injected in each group? At each time point and overall? It is not clear from the paper how many patients needed more than the 20ml in the hydrodilatation group to achieve the desired endpoint. Also 4 patients in the steroid injection group had rupture which suggests that some/many of the participants in the steroid inj group may also have received a hydrodilatation.

3. Randomisation was achieved using the minimisation method with ‘loaded’ dice. Most readers would not be familiar with this approach and it would be desirable to provide further details explaining this approach. Was minimisation only performed based upon SPADI score? It is not clear what happened if the SPADI score was 50 (as only mentions greater or less than 50). If minimisation performed based upon other factors as well, these need to be listed. If only stratified for a single variable (SPADI) then I am not clear what advantage this method would have over simple randomisation stratified by SPADI score? This
needs to be explained. Similarly the ‘loaded’ dice needs further explanation – what was the loading?

4. It is stated that randomisation and allocation of patients was conducted by an independent person but it is not clear who this person was and their expertise in the minimisation approach. Was this person also involved in the outcome assessment?

5. Participants were not blinded, which is a problem and could have introduced bias, particularly since the primary outcome (SPADI) is a self-reported form. How might this have biased the results? What were patients told? What did they know about the two treatments? What were their expectations, as patient expectation/beliefs may influence outcome.

6. There was a delay of about 2 months between treatment allocation and receipt of treatment. It is not indicated whether this was similar for both groups. Please provide mean time for each group.

7. It is also not clear whether baseline assessment was performed at time of randomisation or at time of initial treatment. Authors should specify exactly when the baseline measurements were taken. If performed at time of randomisation, then if time to treatment was different in the two groups then this could have affected the outcome. If baseline measurements had been made at inclusion, there could have been considerable spontaneous improvement in this time leaving a smaller margin for improvement as a result of treatment. The discussion does not clarify this issue.

8. Participants were allowed to continue other treatments such as physiotherapy and manipulation programs. It is unclear if this was balanced between groups as not reported. Were new treatments started (as the primary physician was responsible for this) and were these balanced between treatment groups?

9. What is the intra-rater reliability of the single assessor who performed active and passive shoulder movements? Was this assessed or has it been assessed for this method? Isn’t it unusual that active movements are so much better than passive movements – isn’t it usually the other way around? Was end-range defined a priori? Was it to the onset of pain or what?

10. Adverse effects are only reported as a total, not by intervention group or divided by different effects. This should be clarified.

11. Authors report that because they “did not suspect any problems with randomisation, no baseline tests of imbalance performed.” However, they say in the results section that differences between the DIL and INJ groups at follow-up for ‘daily analgesic use’ and ‘on sick leave’ could be due to observed differences at baseline. No formal test results are provided for this statement that could be supported if baseline comparisons were made.

It is not clear that one can not do the tests then say some of the results could be explained by baseline differences.

12. The discussion mentions possible baseline differences between the groups leading to misinterpretation. I don’t understand why they didn’t just do the comparisons and resolve the issue. It is true that the regression analysis
comparing SPADI improvement in the two groups would address this for the SPADI outcome but the ROM outcomes were not treated similarly. Follow-up scores for ROM seem to be based on differences between the groups at follow-up rather than mean change scores for the groups. Thus baseline differences are explicitly ignored. Reporting of results: Please provide mean change (SD of change) scores for SPADI and ROM outcomes as well as the mean baseline and follow up scores for each treatment group.

13. Multiple regression results are given for the model with all predictors included. What are the results when only significant predictors are included in the model? Why include the non-significant predictors?

14. In the background it is stated that recent studies of frozen shoulder have not reported distinct intra-articular adhesions – this requires references as MRI studies including our own (Connell D et al. Eur Radiol 2002) have demonstrated the presence of adhesions.

15. How many patients were excluded due to baseline range of motion measures being too painful? These patients (e.g. worse at baseline) could respond differently to treatments.

16. Some reasons are given for dropouts, but not whether this is evenly distributed between groups.

17. States that baseline score was adopted as follow-up score for one patient who moved to another part of the country and was lost to follow up. What about the other 4 participants who couldn't come to all three appointments? Results are reported for all 76 participants, so presumably a similar approach was taken? Text should be clarified.

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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)

I don't think that Figures 2 and 3 contribute much to the paper and could be removed. Why only a figure for SPADI but not the movements?

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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 whose findings are important to those with closely related research interests

Quality of written English: Acceptable
**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests. I am first author on two of the trials referred to in the manuscript and I am first author of a Cochrane review that has been accepted for publication in the next issue of the Cochrane Database of Systematic Reviews (Issue 1, 2008) entitled "Arthrographic distension for adhesive capsulitis (frozen shoulder)".