Author’s response to reviews

Title: Image-guided versus blind corticosteroid injections in adults with shoulder pain: A systematic review

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Version: 7 Date: 10 June 2011

Author’s response to reviews: see over
Dear Dr Lee Herrington,

Thank you for giving us the opportunity to revise our manuscript.

Following on from this note is a summary of our responses to the peer reviewers. I have also attached separately the revised manuscript with highlighted tracked changes. These changes also include formatting alterations as requested by Elaine Patricia Cruz; Table 1 has been removed from the main manuscript and uploaded separately as an additional file (following the Instructions for Authors guidelines for large datasets).

We would like to make a specific mention on reviewer comments and statements of a statistical nature. Two of our co-authors are PhD statisticians and we have tried to address the reviewers’ statistical queries. With all due respect, if there are persistent concerns of a statistical nature, we would suggest a review by a journal-appointed statistician.

Yours sincerely,

Edmund Soh
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Summary of responses to peer reviewers’ comments

REVIEWER 1 EVALUATION

Reviewer’s report

Title: Image-guided versus blind corticosteroid injections in adults with shoulder pain: A systematic review

Version: 4 Date: 13 May 2011

Reviewer: Eric Hegedus

Reviewer’s report:
Major revisions:
1. none

Minor revisions:
1. There are some minor grammatical errors

RESPONSE: Minor grammar mistakes were corrected with Microsoft Office Word 2007 built-in checker.

Discretionary revisions:
1. The only question is a philosophical one: Why limit the review to RCT's when the result is only 2 papers. This focus limits the readership for this article

RESPONSE: The intention of this study was to assess the best-available evidence in keeping with Cochrane systematic reviews. As such, we only considered RCTs. The final number of suitable studies available was not pre-planned.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

Declaration of competing interests: I declare I have no competing interests
Reviewer’s report

Title: Image-guided versus blind corticosteroid injections in adults with shoulder pain: A systematic review

Version: 4 Date: 3 May 2011

Reviewer: Ian Horsley

Reviewer’s report: Major Compulsory reviews: All seem to have been addressed in accordance with the reviewers

Minor Revisions: All seem in order following revisions

Discretionary Revisions; nil The authors have acted on the reviewers suggestions and produced a much improved piece of work, which will add to the paucity of data around this subject.

RESPONSE: Thank you for your comments.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests: I declare that I have no competing interests
REVIEWER 3 EVALUATION

Reviewer's report

Title: Image-guided versus blind corticosteroid injections in adults with shoulder pain: A systematic review

Version: 4 Date: 10 May 2011

Reviewer: Christer Rolf

Reviewer's report:
The article has been improved by the review. There are two major points to raise;

1. There is an obvious bias in that a manufacturer of US machines is co author of this article which now has been declared openly and considered by the Editor.

RESPONSE: The competing interest had been openly declared from the original submitted manuscript. A minor revision was made for the revised manuscript as the abovementioned co-author had a change in employment details; this had already been stated in the appropriate cover letter to the Editor. The authors had every intention of declaring all competing interests so that readers can judge the manuscript appropriately.

2. The response states that Cochrane principles for Metaanalysis is used to collect and analyse the data. I can not find corresponding pooled calculations and statistical analysis of the pooled data from the (only 2) articles referred to. The authors should provide the power analysis and state whether the used data reached this power before claiming their conclusion.

RESPONSE: We reported the pooled effects in the 'Data synthesis' section of the Abstract and also in the Results section of the main text. In particular we reported in the Abstract: “A meta-analysis demonstrated greater improvement with USG injection at 6 weeks after injection in both pain (mean difference=2.23 [95% CI: 1.27, 3.18]), as assessed with a 0-10 VAS, and shoulder function (standardized mean difference=1.09 [95% CI: 0.61, 1.57]) as assessed with shoulder function scores”. Although more adverse events (all mild) were reported with LMG injections, the difference was not statistically significant (risk ratio=0.20 [95% CI: 0.04, 1.13]). These findings were restated in the last paragraph of the Results section of the main text on p.8.

Was it possible for us to plan how many studies to include in order to detect main effects as statistically significant assuming these existed? The answer is 'No'. Power analysis for a main effect requires plausible values for the effect size and precision. In a random effects meta-analysis, the specification of a value for precision further requires assumptions about the size of the within-study error and the between-study variance. We did not have enough data to rationalize our choice of the effect size and even much less support for sensible sizes of the within-study...
error and the between-study variance. Our approach was to simply state the observed effect size with its 95% confidence interval which we thought sufficiently addressed our review objectives.

In fact, the PRISMA checklist (http://prisma-statement.org/2.1.2%20-%20PRISMA%202009%20Checklist.pdf) and the Cochrane Handbook for Systematic Review of Interventions (http://www.cochrane-handbook.org/) do not currently elaborate on power analyses for meta-analyses except in the case of prospective meta-analyses (Cochrane Handbook Chapter 19).

The authors still claim differences between adverse events and then go on to say that this is not significant. As commented last time either there is a significant difference or not based on the statistical analysis used. If it is not significant there is no difference simple as that.

This goes for the differences claimed between the two treatment groups as well. Either the authors have done a power analysis for their Metaanalysis or not. Why in such case do they state that the power “may be low?” If this analysis is done, please present those data and base your conclusion clearly on your findings. If not done, please do one and reconsider the conclusion based on facts. Now again it is diffusely mentioned that “there is a difference between the two treatment groups” but why then refer to limited sample size. Again either the sample size is sufficient or not based on your power analysis. Please provide such confirmed data.

RESPONSE: In our synthesis of adverse events, we see no contradiction in reporting that “Although more adverse events (all mild) were reported with LMG injections, the difference was not statistically significant (risk ratio=0.20 [95% CI: 0.04, 1.13]).” The first phrase is a statement of the observed treatment effect (more adverse events with LMG than USG) and the latter is a statement of the statistical compatibility of this observation with the hypothesis of no treatment effect (the difference was not statistically significant). The reported 95% confidence interval makes clear the range of plausible true treatment effects (0.04 < risk ratio <1.13) that is compatible with the observed risk ratio of 0.20.

We respectfully disagree with the comment that “If it is not significant there is no difference simple as that”. A statistical test of significance can prove the falsity of the null hypothesis but cannot be used to establish its truth. The non-statistically significant finding for adverse events does not prove that there is no difference in safety between LMG and USG. It could be due to low power (in a random effects model, this means an insufficient number of primary studies and insufficient sample size at the level of primary studies). We had only two primary studies and although these primary studies did not talk about sample size calculations, we know for a fact that primary studies are rarely, if at all, powered to detect differences in safety.

The statement about ‘low power’ in our article referred to the test of heterogeneity (Results, p. 7, first paragraph). The null hypothesis in question is that the between-study variance equals zero. Since the review only contained two studies, a non-
significant chi-square test could be attributed to low power (to detect heterogeneity) rather than to the absence of heterogeneity.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**
I have no competing interests