Reviewer's report

**Title:** Subacromial corticosteroid injections for shoulder pain, the effectiveness in the first days

**Version:** 1  
**Date:** 8 August 2014

**Reviewer:** Edward Roddy

**Reviewer's report:**

This manuscript describes secondary analysis of data from an RCT examining the speed of response to corticosteroid, hyaluronic acid and normal saline injections into the subacromial space in patients with subacromial impingement. Whilst the findings are of interest and have a degree of novel value, the manuscript would benefit from more detailed description of the study methods and provision of more detailed analysis/results. I have a number of suggestions to improve the manuscript:

**Major compulsory revisions**

1) **The title of the manuscript should state the study design**

2) **Background, para 1:** reference is made only to drug treatments for subacromial impingement. Other treatments are commonly used, for example, exercises and physiotherapy, which should at least be mentioned. It is also not clear why hyaluronic acid was chosen as an intervention. As the authors state, corticosteroid injection are very widely used to treat shoulder pain. What was the rationale for using hyaluronic acid?

3) **Background, para 1:** it is stated that a few studies have investigated the effect of corticosteroids in the first days after injection citing two studies (Coombes et al, Lewis et al). The authors should clarify in the text how much of this evidence pertains to shoulder pain/subacromial impingement and how much to pain at other sites. The systematic review of Coombes et al includes studies of different tendinopathies and the study by Lewis et al is a study of injections for tennis elbow. Furthermore, no mention is made of the trial published by Crawshaw et al (BMJ 2010) which compared subacromial injection plus physiotherapy versus physiotherapy alone in patients with shoulder pain, demonstrating additional benefit of corticosteroid injection at one week.

4) **Background, paras 5 & 6:** these paragraphs describe detail of and the rationale for use of pain diaries and would be better placed in the methods rather than the background.

5) **Background, paras 4 & 7:** the objectives of the study could be expressed more clearly. In particular, it is not clear what is meant by “a booster effect”

6) **Methods, Settings and participants:** it is stated that a large majority of participants could be included after direct referral by general practitioners. How many participants were recruited after referral by this route? Does this mean that
GPs could refer directly for assessment for study entry? The inclusion and exclusion criteria are not stated.

7) Methods, Interventions: the intervention in group C (lidocaine plus NaCl) is described as a placebo which is not accurate as lidocaine is a pharmacologically active substance with analgesic properties. Injections were repeated, if necessary, after 3 and 6 weeks. How was it decided whether a repeat injection was necessary?

8) Methods, Outcome assessment: more detail is needed of how adverse events were assessed in the pain diary. Did the participant select from a pre-specified list of adverse events or was this a free-text response? If a pre-specified list was used, what adverse events were listed?

9) Methods, Statistical analysis: missing data were accounted for using a combination of last-observation-carried-forward and mean trend substitution. Both of those are slightly outdated now and are inferior to multiple imputation.

10) Results, para 2: it is stated that there were no significant differences between the groups at baseline but no numerical data are presented.

11) Results, para 3, non-return of diaries: this section refers to the first, second and third time-periods. These periods are not mentioned or defined in the methods so it is not clear to what they refer. I assume from the results section and figures that the effect of each injection was observed for 21 days and then a new period of observation commenced if a second or third injection was given but this is not clear from the methods.

12) Results, effect of interventions on pain VAS: it is stated in the statistical analysis section of the methods that analysis of variance was used to establish effects of both interventions but the results of statistical tests comparing the effects of the interventions are not presented. I would like to see between group differences presented.

13) Results, adverse events: more detail is needed of the rates of adverse events in each of the three groups. For use of escape analgesia, it is simply stated that the hyaluronic acid group needed significantly more medication after the second injection with p-values but the actual numbers of people requiring escape medication in each of the groups after each of the three injections is not provided. Similarly, it is stated that flushes, headache, nausea, redness at injection site and tingling sensations were reported in the pain diaries but no indication is given of how commonly these occurred and how they differed between the three groups.

14) Figure 2,3,4: these figures use different scales on their y-axes which is confusing. The same axis should be used on each.

15) Discussion: some discussion of the strengths and limitations of the study is needed.

Minor essential revisions

1) NaCl needs to be spelt out in full when first used in the abstract and main text. I assume this is sodium chloride?
2) Abstract, results: typo line 46, hyaluronic acid an NaCl. “an” should be “and”
3) Background, para 2: I think the sentence about weakening of rat rotator cuff would benefit from a more clear statement that these are animal studies eg starting the sentence with “Some animal studies…..”
4) Typo: “lidocain” should be “lidocaine”. It would also be helpful to add the strength throughout the manuscript eg 1% lidocaine
5) Methods, Settings and participants: “holding 75 men and 84 women” would read better as “including 75 men and 84 women”. Please clarify what the numbers in parentheses (20 to 87) are – presumably range? It is stated that a large
6) Methods, Settings and participants: “current episode of shoulder complaints” would be better as “current episode of shoulder pain”
7) Group B is referred to as corticosteroid throughout the results and discussion and as kenacort in the figures. It would be more accurate to refer to as triamcinolone acetonide throughout.

Discretionary revisions
Nil

**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:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests' below.