Author's response to reviews

Title: Does surgery followed by physiotherapy improve short and long term outcome for patients with atraumatic shoulder instability compared with physiotherapy alone? Protocol for a randomized controlled clinical trial

Authors:

Anju Jaggi (Anju.Jaggi@rnoh.nhs.uk)
Susan Alexander (Susan.Alexander@rnoh.nhs.uk)
Robert Herbert (r.herbert@neura.edu.au)
Lennard Funk (lenfunk@shoulderdoc.co.uk)
Karen A Ginn (karen.ginn@sydney.edu.au)

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Author's response to reviews: see over
Dear Mr Aldea,

We have further revised our manuscript “Does surgery followed by physiotherapy improve short and long term outcome for patients with atraumatic shoulder instability compared with physiotherapy alone? Protocol for a randomized controlled clinical trial” in response to Dr Wiater’s comments/requests.

We have addressed all comments in blue below and have made changes to the revised manuscript in “Track Changes”.

Yours sincerely,
A/Prof Karen Ginn
(on behalf of Ms Anju Jaggi, Dr Susan Alexander, Professor Len Funk & Prof Rob Herbert)

Title: Does surgery followed by physiotherapy improve short and long term outcome for patients with atraumatic shoulder instability compared with physiotherapy alone? Protocol for a randomized controlled clinical trial

Version: 6

Date: 22 October 2014
Reviewer: J. Michael Wiater, MD

Reviewer’s report:
The authors present a revised protocol for a multi-center prospective, randomized controlled trial evaluating the effectiveness of capsulolabral repair inpatients with atraumatic shoulder instability. The protocol has been revised in response to previous review. Some previous issues have been clarified in the protocol, however, a few concerns still remain.

Major Compulsory Revisions
1. The previous review requested inclusion of “history of shoulder dislocation” as exclusion criteria. The current manuscript version indicates “high collision shoulder injury” without specifically stating “history of shoulder dislocation”. Please clarify this.

A history of shoulder dislocation is not an exclusion criterion for this study. Patients with a history of shoulder dislocation are eligible to participate as long as their episodes of shoulder dislocation are not associated with a high collision shoulder injury. Indeed, any patient with a history of a high collision injury that has resulted in apprehension symptoms at the shoulder, even if they have not suffered a frank dislocation, will be excluded.

2. In the adverse events section “participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder
instability” is not further defined as previously requested. The risks of this study greater than use of MRI for evaluation should be stated.

In our previous response we argued, with supporting evidence, that the gold standard for diagnosis of capsulolabral lesions at the shoulder joint is arthroscopy and therefore, that best practice management of patients suffering from shoulder instability would include arthroscopic investigation. At the two clinical sites involved in this study standard care for patients with atraumatic shoulder instability includes arthroscopic investigation. As MRI evaluation is not best practice to investigate capsulolabral lesions in patients with atraumatic shoulder instability and not standard care for these patients at the sites conducting this clinical trial we do not think it is appropriate to discuss the comparative risks of arthroscopic and MRI investigation in this manuscript. We have added the following underlined text to the manuscript to clarify these points:

“Arthroscopic examination
All potentially eligible patients will undergo arthroscopic examination of the shoulder under general anaesthetic. Arthroscopy is the gold standard for diagnosing subtle capsulolabral lesions at the shoulder [21, 22].”

“Adverse Events
Participants in this clinical trial will be subjected to the risks associated with orthopaedic surgery under general anaesthesia. However, participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder instability at the clinical sites involved in the study.”

3. Postoperative clinical assessment is not well defined. Please define in further detail how this assessment will be done and how complications will be monitored

The following underlined text has been added to the manuscript to clarify the postoperative clinical care.

“Stabilization surgery
.... All participants will receive the same post-operative clinical care from the surgical team to monitor progress and deal with any complications that may arise. Standard care includes review at 1, 3 and 6 months post surgical examination/intervention.

Discretionary Revisions
1. Please mention that you will record data on pathology variations by location, tear size, and type of repair (number of anchors, all-arthroscopic, types of suture fixation).

Full reports of the findings of the arthroscopic procedure & the details of the surgical intervention will be available in the clinical file for each participant kept as part of their normal clinical record. Details of the pathology confirmed at arthroscopy and the surgical intervention performed in the final cohort will be summarized in manuscript/s reporting the findings of this clinical trial.

Level of interest:
An article of importance in its field

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