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

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Version: 6 Date: 7 October 2014

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

Please find below our responses (in blue) to the reports from Reviewers regarding our revised 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.”

We look forward to hearing from you,
Karen Ginn
(On behalf of Ms Jaggi, Dr Alexander, Prof Herbert & Prof Funk)

Reviewer's report
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: 4
Date: 11 July 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 in patients with atraumatic shoulder instability. The protocol has been revised in response to previous review. Many previous issues have been clarified in the protocol. However, a few concerns still remain. Overall the protocol is focused toward the study of its intended purpose. The discussion and referencing of supporting literature is appropriate.

Please provide explanation for the following issues:

Major Compulsory Revisions
1. The definition of included patients with atraumatic instability: Background section defines shoulder dislocation as traumatic (even when not associated with high-energy trauma). Please include history of shoulder dislocation as an exclusion criteria in Participants section of protocol.

We are not sure what the reviewer is referring to here. In the Background section of the manuscript we defined shoulder instability “as symptomatic, abnormal motion at the shoulder (glenohumeral) joint” which “can result in a spectrum of symptoms including pain, a feeling of insecurity, and dislocation.” This applied to all shoulder instability whether it was associated with a traumatic episode or not. All patients suffering from shoulder instability, who do not report a history of a high collision shoulder injury precipitating their symptoms, will be eligible to
participate in this study whether they have a history of shoulder dislocation or not. Therefore, history of shoulder dislocation is NOT an exclusion criterion for this study.

Also, one of the secondary outcomes is number of shoulder dislocations. Please clarify this as postoperative dislocation. I suspect this would be rare in those with no previous dislocation, and in patients with no prior dislocation this is possibly iatrogenic.

This has been clarified on page 9 as follows:
“number of episodes of post-operative shoulder dislocation.”

2. The definition of what qualifies as capsulolabral injury is never defined. Please be more specific about labral tears, or capsular tears/avulsions. Does this include SLAP tears?

Additional information to clarify what constitutes capsulolabral damage has been added to the Participants section on page 7:

“Damage to the capsulolabral complex includes any splits, fraying or detachment of any region of the glenoid labrum including the superior labrum.”

This would eliminate patients with “redundant” capsule from receiving any stabilization procedures, as this does not reliably constitute damage.

Yes this is correct.

There should be a defineable lesion to determine patient assignment to randomization.

Yes this is correct

3. Again, stating that “participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder instability” is not accurate. There are other modalities than arthroscopy to evaluate these patients for capsulolabral damage. While you added “risks associated with orthopaedic surgery under general anesthesia,” the risks were not defined.

Also, this does constitute additional risk to patients that could be assessed otherwise with MRI. The standard care options for patients with atraumatic shoulder instability do not include diagnostic arthroscopy. In fact, this is the exception rather than the standard, performed when other care options as physiotherapy or MRI have failed to improve the symptoms or determine a
diagnosis.
The alternative to your protocol, to be sham-controlled, is to determine patients with capsulolabral damage on MRI, ultrasound, or arthrography. If they are determined to have some damaged structure, inclusion criteria would be met and arthroscopy could then be performed. The true sham procedure would be arthroscopy without repair, versus the alternative stabilization procedures. This eliminates added risk to patients with atraumatic instability and no capsulolabral damage.

We respectfully disagree with the reviewer with regard to the role of diagnostic arthroscopy in the management of patients with atraumatic instability. Numerous studies indicate that the accuracy, sensitivity and specificity of MRI and MR Arthrogram for injuries of the labrum and capsule are less than arthroscopic evaluation (Kalson et al 2011; Steinbach 2008). This is particularly true for the subtle injuries that are associated with the cohort of patients under investigation in this study i.e. splits and fraying of the labrum, but no actual frank detachment. We would therefore, submit that the gold standard for diagnosis of capsulolabral lesions is arthroscopy and that arthroscopic investigation should be part of best practice management for patients with atraumatic instability. We would also submit that our statement that “participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder instability” is indeed accurate. This view was supported by the ethics committees which approved this study. The trial is now substantially underway and it is not possible to change this aspect of the trial protocol.

- Kalson et al. Magnetic resonance arthrogram and arthroscopy of the shoulder: a comparative retrospective study with emphasis on posterior labral lesions and radiologist locality. Shoulder Elbow 2011; 3:210-214

4. There is no mention of postoperative clinical assessment, other than those done by blinded research assistants. When will these patients be assessed clinically for reasonable monitoring for postoperative complications such as infection, neurologic injury, stiffness, etc. There are safety concerns in these patients, though complications will likely be rare.

The following has been added to the Methods section on page 8 to clarify that all participants will be receiving post-operative assessment:

“All participants will receive the same, standard post-operative clinical care from the surgical team.”

Minor Essential Revisions
1. Please make clear if you are including patients of all age groups and activity levels.
The manuscript currently states that “Patients over 18 years of age of all activity levels will be eligible to participate if they report insecurity (apprehension) at the shoulder joint, have physical signs of shoulder instability ….”

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.

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

Reviewer's report
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: 4 Date: 3 July 2014
Reviewer: Rita M Kiss

Reviewer's report:
The authors corrected the paper taken into account my comments.

Level of interest: An article of importance in its field
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen