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: 3
Date: 25 June 2014

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

Thank you for the opportunity to revise 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”.

We have addressed all comments made by the Reviewers in red below and have made all 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)

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: 2
Date: 2 April 2014
Reviewer: J. Michael Wiater, MD

Reviewer’s report:
The authors present a protocol for a multi-center prospective, randomized controlled trial evaluating the effectiveness of capsulolabral repair in patients with atraumatic shoulder instability. The protocol appears very well-organized and well-written. There are several questions that arise, which are detailed below. Overall the protocol is simple and focused toward the study of its intended purpose. The discussion and referencing of supporting literature is appropriate as well.

Please provide explanation for the following issues:
1. The definition of included patients with atraumatic instability is somewhat unclear. Those patients with symptoms and clinical findings of apprehension are clearly eligible. Can these patients have a history of shoulder dislocation requiring reduction? If so, it may not be advised to include all patients in a large category. Included patients should be more specific.

Perhaps you should only evaluate patients with anterior instability, as those with posterior instability are not always comparable in etiology and risk of recurrence. Those with multidirectional instability often have different presentation and outcomes, and patients with history of multiple dislocations may also be significantly different

2. Also, are you including SLAP tear patients as a capsulolabral injury? Though these patients often complain of feelings of instability, they rarely have any true dislocation risk and should be excluded.

We have chosen to include:
1. patients who have had a history of dislocation requiring reduction
2. all types of atraumatic shoulder instability
3. SLAP tear patients
because:
• the surgical procedure & physiotherapy program to be used in this study are equally relevant to all types of atraumatic shoulder instability
• evidence for the efficacy of treatment for atraumatic instability is weak i.e. there are no data to indicate that the effect of the surgery plus physiotherapy rehabilitation would be qualitatively different in those with a history of dislocation and those without or between those with anterior, posterior or multidirectional atraumatic instability
• a SLAP tear would be considered capsulolabral damage & patients would be included as long as there was no evidence of bony injury around the glenoid labrum
• variation in history of dislocation, type of instability and presence of SLAP tear are dealt with by randomization which ensures approximate exchangeability of groups

As the study has started recruiting we would be very reluctant to change the inclusion criteria at this stage.

Please make clear if you are including patients of all age groups and activity levels.

The following underlined section has been added to the description of eligible participants:
“Patients over 18 years of age of all activity levels will be eligible to participate if they report insecurity (apprehension) at the shoulder joint ……”

Also identify if patients have or have not undergone prior treatment with physiotherapy (more likely to fail with therapy alone if they have already failed therapy treatment, prior surgery patients already excluded).

The following underlined section has been added to the description of eligible participants:
“Prior physiotherapy treatment will not exclude eligible patients from participating in this clinical trial.”

3. Many patients with atraumatic shoulder instability do not have capsulolabral damage. Please be more specific how these patients will be managed, as they will be consented for the study, but will be excluded based on findings at the time of surgery.

Expert opinion suggests that surgery can be detrimental for patients with atraumatic instability that is not associated with any bony or capsulolabral damage. Therefore, patients who do not have capsulolabral damage will be excluded from the trial & will treated in the normal way ie specialist physiotherapy treatment, in the participating hospitals.

4. Please account for variations in labral tear size, location, and type of repair (as
Inevitably there will be variation in capsulolabral damage in the patients with atraumatic shoulder instability in this trial, including labral tear size and location, and in the exact procedure of the surgical repair undertaken. This variation is dealt with by randomization which ensures approximate exchangeability of groups. It is our intention to record and provide a summary report of capsulolabral pathology by location & size, type of instability and type of repair in our description of the volunteer cohort at the end of the trial.

5. It seems more logical to assess these patients with MRI rather than arthroscopy. Arthroscopy on all patients is certainly beneficial to diminish the placebo effect of surgery on your results. However, 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 entirely accurate. If it is standard in your practice to perform arthroscopy on every patient who presents with atraumatic shoulder instability, rather than treat first with a course of nonoperative management and physiotherapy, then this protocol does not deviate from this treatment. Surgical arthroscopy exposes patients to the risks of surgery, including patients without structural damage to shoulder capsule or ligaments. If this has been approved by respective Ethics and IRB committees, however, then it may still be acceptable to keep this protocol. While generally regarded as a safe procedure, arthroscopy does pose minimal additional risk to these patients.

This study has gained ethical approval through the NHS Trusts in the UK participating in the study. A sentence detailing this has been added to the Methods/Design section of the manuscript. Expert opinion suggests that surgery can be detrimental for patients with atraumatic instability that is not associated with any bony or capsulolabral damage. Diagnostic arthroscopy examination is the gold standard procedure to determine if patients have sustained bony or capsuloligamentous damage as a result of their atraumatic instability. A diagnostic arthroscopic examination is standard practice to determine the care plan for patients diagnosed with atraumatic shoulder instability in the participating hospitals to ensure implementation of current best practice treatment for these patients. Therefore, the statement that “participation in this clinical trial will not entail additional risks beyond those associated with standard care options for atraumatic shoulder instability” is accurate.

6. If eligibility to the study requires capsulolabral damage found at arthroscopy, it seems inappropriate to be treating these patients with capsular plication alone. If the labrum is torn, labral repair is warranted. Again, please clarify stabilization treatment, including categorization of pathology by location, size, and type of repair (number of anchors, all-arthroscopic, types of suture fixation).

The following additional details describing the surgical procedure (underlined below) have been added to the manuscript:

“Participants allocated to the stabilization surgery group will undergo capsular plication and labrum repair surgery as appropriate. Capsular plication surgery
will involve the placement of suture anchors into the bony glenoid with sutures passed through the shoulder joint capsule to secure the redundant capsule to the glenoid fossa, effectively ‘tightening’ the joint. Labrum repair will be performed using standard suture anchors incorporating the plication where appropriate.”

7. Postoperative protocol: Do all patients have a period of immobilization after surgery whether or not they underwent stabilization?

Yes – as stated page 8 under Physiotherapy heading:
“All participants will receive the same post-operative physiotherapy protocol aimed at improving shoulder muscle function based on a pre-prepared treatment algorithm. ..... Thus restrictions on post-operative treatment to protect the surgical procedure will apply to all participants.”

8. Assuming a worst-case 10% loss to follow-up is hopeful with a two-year follow-up period. Suggest increasing this number, but certainly not necessary.

We believe that the assumption of a worst-case loss to follow-up of 10% is not unrealistic. Even if it was excessively optimistic, power drops off only slowly with loss to follow up. Moreover, we have a buffer of statistical power because our sample size calculations conservatively ignore the (probably considerable) extra power conferred by the longitudinal analysis.

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: 2
Date: 13 May 2014
Reviewer: Rita M Kiss
Reviewer's report:
Major comments:
1. Introduction: Please shorten the Introduction, but please extend it by the result of research by motion analysis.

The Introduction has been slightly shortened – see Track Changes in revised manuscript. We don’t understand what is meant by “the result of research by motion analysis”.

2. Study Objectives: Please provide your hypothesis here.

The following hypothesis has been added to the revised manuscript:
“We hypothesized that the patients receiving stabilization surgery followed by post-operative physiotherapy rehabilitation would have significantly greater short and long term improvement in pain and function.”

3. Method: Do you have ethical permission under the Helsinki Agreement? If yes,
please write it in the article.

Yes this study has Ethics approval under the Helsinki Agreement. The following underlined section has been added to Methods/Design section of the manuscript: “Ethics approval to conduct this study has been granted by the NRES Committee London-Stanmore and NRES Committee Wighton, Wigan and Leigh.”

4. Method - Physiotherapy: Please provide more details (with references) about the rehabilitation, specially about the physiotherapy.

The following additional details describing the post-operative physiotherapy rehabilitation (underlined below) have been added to the manuscript: “All participants will receive the same post-operative physiotherapy protocol aimed at improving shoulder muscle function based on a pre-prepared treatment algorithm. All participants will be immobilised in a sling for four weeks following the surgical procedure but will be allowed to perform controlled scapular and glenohumeral joint movements within ranges which would not compromise a capsulolabral repair. Thus restrictions on post-operative treatment to protect the surgical procedure will apply to all participants. Thereafter, the aim of physiotherapy treatment will be to improve the function of the rotator cuff muscles by an active home-based exercise program. The treatment algorithm allows the physiotherapist to choose specific exercises directed to the rotator cuff or to improve their function by incorporating exercises which involve the entire kinetic chain. To ensure accurate exercise performance multimodal feedback (visual, biofeedback, taping) can be utilized. The type, load and frequency of exercises will be individually tailored to the needs of each participant by the physiotherapist who will monitor and upgrade the exercises as rotator cuff muscle function improves. A maximum of 12 treatment sessions with the physiotherapist over a maximum period of six months after surgery will be conducted.”

1. Will the study design adequately test the hypothesis?
The author did not summarize the hypothesis of their research. However, the study design is adequate for testing the goal of research.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
The research cannot be replicated because the step and exercises of physiotherapy are unknown.

3. Is the planned statistical analysis appropriate?
Yes

4. Is the writing acceptable?
The language of the study protocol is acceptable. If the author extended the study protocol, specially with more details about the physiotherapy, the writing could be acceptable.
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