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

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.

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.

4. Please account for variations in labral tear size, location, and type of repair (as this should be somewhat standardized). Again, recommend against inclusion of posterior labral tears.

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.

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).

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

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.