
Design: Randomized clinical trial

Study question: In patients with small to medium-sized full thickness rotator cuff tears and no acromial spurs, does acromioplasty at the time of rotator cuff repair improve the outcome of surgery?

Population/sample size/setting:

- 120 patients (67 men, 53 women, mean age 57) treated for full thickness rotator cuff tears in a department of orthopedic surgery at Seoul National University
  - 150 patients were enrolled originally, but 30 were lost to followup or withdrew, and their demographics are not described
- Eligibility criteria were the presence of a small to medium sized tear
  - Small tears were less than 1 cm in the longest direction
  - Medium sized tears were 1 to 3 cm in the longest direction
- Exclusion criteria included large to massive tears, partial-thickness tears, subscapularis tears requiring operation, acromial osteophytes/spurs, concomitant pathology such as SLAP or Bankart lesions, and revision surgery

Main outcome measures:

- All patients had rotator cuff repair with single or double row technique, and were randomized to acromioplasty (Group I, n=75) or non-acromioplasty (Group II, n=75)
  - Group I had subacromial decompression with bursectomy, release of the coracoacromial ligament, and standard acromioplasty in which the acromion was made flat from the medial to the lateral aspect
  - Group II had the repair without acromioplasty, and the coracoacromial ligament was debrided but not released
  - In both groups, the surgical approach to the long head of the biceps (debridement, tenodesis, tenotomy) was dictated by what was found intraoperatively and by the age of the patient
- The same postoperative rehabilitation program was applied to all patients, with four weeks of immobilization with a brace, pendulum and gentle range-of-motion exercises 3 days after surgery, and active exercises beginning after weaning from the brace
- The planned followup time was at least 24 months, but 15 patients in each group were not followed for that long, which is when the principal outcomes were assessed
- The main outcomes were scores on the pain VAS, ASES, UCLA, and Constant scales; ROM for forward flexion, internal rotation, and external rotation were also measured
- The patients who completed at least 2 years of followup had some variation in the timing of the last followup (mean 35 months, range 24 to 54 months)
- At the last followup, both groups had substantial reductions in pain VAS from the baseline value of 5.5 (1.1 in Group I and 1.3 in Group II); there was no difference between the groups
  - Similarly, the functional scores improved substantially for both groups, but no differences between the groups were observed
  - Patient satisfaction (8.4 in group I and 8.3 in group II) was also equal
- Some radiological indices of rotator cuff healing were also done, but by different methods (MRI, CT arthrogram) depending on the economic circumstances of the patient; the rates of failure of radiographic healing were about equal (17% in Group I and 20% in Group II)
- Postoperative shoulder stiffness was reported in 3 patients in Group I and in 1 patient in Group II, with no statistically significant differences between groups

Authors’ conclusions;

- Arthroscopic repair of small to medium-sized full thickness rotator cuff repairs was successful in both groups
- Acromioplasty did not lead to better outcomes in the patients who underwent the procedure
- The followup period was fairly short to evaluate the clinical outcomes of cuff healing
- Acromioplasty may not be necessary in patients with small to medium-sized full thickness tears when acromial spurs are not present

Comments:

- Aside from the musculoskeletal radiologist who was not involved in the study, the assessment of outcomes does not appear to have been blinded
  - The equal co-interventions and the equal attrition rates compensate to some degree for lack of blinding
- Some of the radiological evaluation prior to surgery is incompletely described; it is stated that all patients had MRI, and it is stated that preoperative fatty degeneration of the cuff muscle was classified by the Goutallier system, but the Goutallier system is defined by fatty degeneration on CT scan; it follows that all patients must also have had CT prior to surgery, even though this is not clearly stated
- The statistical analysis in the methods section says that the Mann-Whitney U test was done for “dichotomous” variables; since this nonparametric test is for the comparison of two groups with continuous or ordinal variables, it is likely to refer to the
comparison of two groups, with the language barrier accounting for the inexact phrasing

- Some other parts of the methodology are incompletely described, such as the method of randomization
  
  o The randomization appears to have been done after patient consent and enrollment had occurred, which is likely to prevent the selection bias that can arise from lack of allocation concealment; allocation into the study groups would not have been determined by patient characteristics

- The “last followup” outcomes varied in length from surgery, from 24 to 54 months; this is not likely to bias the results in a particular direction, but it would be informative to have more information about whether the groups differed in length of followup

Assessment: adequate for some evidence that in the setting of full thickness rotator cuff tears smaller than 3 cm in the longest direction and in the absence of acromial spurs, acromioplasty with cuff repair does not improve the 2 year pain and functional outcomes compared to cuff repair alone