
Design: Randomized clinical trial

Research question: In the setting of rotator cuff tears in patients over 60, does rotator cuff repair provide better results than isolated acromioplasty/tenotomy?

Population/sample size/setting:
- 127 patients (69 women, 58 men, mean age 68) treated for symptomatic rotator cuff tears at a surgical center in France
- Inclusion criteria were age over 60 with a reparable rotator cuff tear involving the supraspinatus with greater or lesser extension to the infraspinatus, resistant to medical management, with “flexible shoulder”—probably means not having frozen shoulder
  o “Reparable” meant that fatty infiltration was less than or equal to Goutallier grade 2 (less than 50% fatty muscle atrophy)
- Exclusion criteria were a history of surgery to the affected shoulder, osteoarthritis of the shoulder, tear extension to the subscapularis or long head of the biceps (LHB) found clinically or on imaging

Main outcome measures:
- All patients had arthroscopic surgery in which the lesion was explored and its extent determined
  o 12 patients from the original enrollment cohort were excluded because arthroscopy disclosed non-reducible retracted cuff tears or tears of the LHB
- All patients had acromioplasty and LHB tenotomy
- Randomization was to one of two groups: cuff repair (CR, n=68) or acromioplasty/tenotomy without cuff repair (AT, n=59)
  o In the repair group, metal suture anchors were used (single-row in 24 cases and double-row in 44 cases)
- Postoperative care was identical in the two groups, with early self-rehabilitation and partial immobilization in a sling for 4 weeks
- Main outcome was the Constant score at the 12 month followup
  o Both groups improved their average Constant scores; the entire cohort had a mean baseline Constant score of 43.6% and a mean score of 72.6% at 1 year
The mean Constant score for the CR group (75.8%) was higher than the mean score for the AT group (68.8%)

- The Constant score items for pain, activity, and strength were higher for the CR than for the AT group; the motion item did not differ between groups

An additional analysis was done by subgroup by the type of tear: the CR group had significantly higher Constant scores for intermediate tears, but for distal cuff tears and for retracted tears, the treatment groups did not differ

The CR group had an ultrasound examination by a single physician at 1 year; the tendon healing rate was judged to be 67.6% overall

- Patients over 70 had lower rates of healing (52.4%) than patients under 70 (74.4%)
- Tendon healing influenced Constant scores at 1 year: for healed tears, the mean Constant score was 80%; for non-healed tears, the mean score was 66.9%

No patient required revision surgery, but 3 patients had transient neurapraxia of the brachial plexus, and 3 developed adhesive capsulitis with continuing limitation of motion at the one-year followup

Authors’ conclusions:

- Rotator cuff repair with acromioplasty/tenotomy gave better one-year functional results than acromioplasty/tenotomy without repair in patients over 60
- Tendon healing assessed by ultrasound is a predictor of functional outcome assessed by Constant scores
- One year is a fairly short followup time; a three year followup is in progress and will be needed to assess lasting benefit

Comments:

- Although the randomization sequence is not described in full, the allocation was disclosed to patients the day before surgery, after they had been enrolled in the study; this indicates that allocation concealment was satisfactory
- While the patients were not blinded, the outcome assessment was blinded
- The comparison of one-year Constant scores is likely to have acceptable control of bias, but the mean weighted scores (75.8% in the CR group and 68.8% in the AT group) differ by less than the 10 point expected difference which was the basis of the power calculation
- The subgroup analysis by distal/intermediate/retracted tear appears to have been done post hoc; they do not appear to have formed part of the study hypothesis
- The healing rate was assessed by ultrasound only in the CR group, and no comparison can be made with the condition of the tendons in the AT group
- The term “iterative tear” refers to the rate of re-tear, and was 32.4% (100% - 67.6% with tendon healing assessed by ultrasound at one year)
  o While patients were included in the study with Goutallier grades 0, 1, and 2 fatty degeneration, the relation between re-tear and Goutallier grade is not reported; it might be useful to determine whether the extent of fatty degeneration affected the rate of re-tear at one year

Assessment: adequate for some evidence that in patients over 60 with symptomatic rotator cuff tears, repair of the tear at the time of acromioplasty/tenotomy leads to better function at one year than acromioplasty/tenotomy alone