
Design: Randomized clinical trial

Population/sample size/setting:

- 103 patients (73 men, 30 women, mean age 60) treated for rotator cuff tears in an orthopedics department in Norway
- Eligible if they had lateral shoulder pain either with rest or exercise, positive impingement signs, and a passive ROM of at least 140° for abduction and flexion, with a full-thickness tear not longer than 3 cm by sonogram and MRI
- Exclusion criteria were muscle atrophy greater than stage 2, age under 18, tears with an absolute indication for surgery such as involvement of the subscapularis tendon, previous tendon surgery on the relevant shoulder, and diseases affecting shoulder function
  - The “stage 2” atrophy is the one defined by Thomazeau et al 1996, and defines atrophy of the supraspinatus by the proportion of the supraspinatus fossa which the muscle occupies in MRI
    - Stage 1 is normal; the muscle occupies 60 to 100% of the fossa
    - Stage 2 is moderately atrophied with the muscle belly occupying 40 to 60% of the fossa
    - Stage 3 is severely atrophied, with the muscle occupying less than 40% of the fossa; these were excluded from the study

Main outcome measures

- Randomized to either surgery (n=52) or physical therapy (n=51)
  - Surgery was either mini-open (n=9) or open repair (n=42), followed postoperatively by a sling and passive ROM exercises, with active movements after 6 weeks, supplemented by strengthening exercises after 12 weeks
    - Anteroinferior acromioplasty was done in all patients
    - Tendon repair was carried out with a combination of tendon-to-tendon and tendon-to-bone techniques; the deltoid was repaired to the acromion through drill holes, and in 18 patients with inflammation or a partial tear of the long head of the biceps, a biceps tenotomy was done
  - PT was not standardized, but attention was directed toward scapulothoracic stability and glenohumeral muscle control, including exercises to center the
humeral head in the glenoid fossa, gradual increasing of loads and joint positions, and additional specific exercises for sports and work activities

- Outcomes were assessed by a blinded observer at baseline and at 6 and 12 weeks after intervention
  - Constant score on a 100 point scale was primary outcome, and American Shoulder and Elbow Surgeons (ASES) on a 100 point scale was a secondary outcome, along with the SF-36 scores
  - At 12 months, patient satisfaction was measured, and surgical patients had a repeat MRI to assess tendon healing
  - There were 9 PT patients who failed to improve after at least 15 sessions of PT; these were later treated surgically, but their outcomes were analyzed as their final score before this secondary surgery was done

- By 12 months, both groups had improved their Constant scores from baseline (surgical group mean improvement was 41.4; PT improvement was 28.4, mean between-group difference was 13 points in favor of surgery)
- Similarly, at 12 months, the ASES improvement was 47.1 for surgery and 31.0 points for PT; the between-group difference was 16.1 points in favor of surgery
- SF-36 scores did not differ significantly between groups
- Patient satisfaction was greater for the surgery group (mean of 9 on a 10 point scale) than for PT (mean of 7.2 points) at 12 months
- The 12-month MRI for the operated group showed intact rotator cuff in 76%, partial-thickness tear in 12%, and full-thickness tear in 8%
- One patient in the surgery group sustained a proximal humeral fracture 3 months postop; this was treated with a sling and the 12-month MRI showed an intact tendon repair

Authors’ conclusions:

- For small and medium-sized tears of the rotator cuff, the between-group difference in the primary outcome was clinically relevant
- Tendon repair should be done prior to the onset of muscle atrophy and tendon retraction; a failed period of PT may delay surgery and affect the outcome
- A limitation of the study was a follow-up period of only one year; further follow-up is necessary and is being done for these patients
- Either PT of surgery may be beneficial, but better results can be expected from primary repair

Comments:

- If the authors are correct, previous studies of the effectiveness of surgery and PT have been retrospective, with a lack of head-to-head comparative studies
If this were the case, this study would be the only randomized “indication” trial of rotator cuff surgery (as opposed to “technical” studies comparing different techniques of repair).

However, other randomized comparative studies have been done between surgery and active PT in a systematic review (Gebremariam et al 2011), which found three studies (of uncertain quality) in which surgery and physiotherapy were not different.

- The authors followed acceptable design, analysis, and reporting practices for randomized trials, including care to include all patients in an intention-to-treat analysis, with complete follow-up of participants; examiner blinding by a T-shirt covering the shoulder helps to control another source of bias.
  - Intention-to-treat analysis preserves the initial randomization; 9 of the PT patients crossed over to surgery because of a lack of improvement with PT, but only one patient randomized to surgery did not have surgery.

- The staging method of Thomazeau et al differs from that of Goutallier et al 1996, which emphasizes fatty infiltration on CT rather than supraspinatus volume on MRI.

- The Constant score combines patient-reported pain (15 points) and function (20 points) plus examiner-assessed movement (40 points) and strength (25 points); pain scores are a minor component of the score, and baseline pain scores are not reported by themselves.
  - The Constant score normal values for age 61-70 are 83 points for men and 70 points for women (Constant et al 2008); the final mean constant score for all patients was 69.8, but scores were not reported separately for men and women and the authors’ interpretation of the scores with respect to age and sex is not discussed.

- At 6 months, both groups appear to have improved equally; the group differences appear to have emerged at the 12 month follow-up.
  - Whether this is due to the fact that shoulder surgery requires a lengthy recovery period is possible but not certain.

- PT was not standardized; this is not necessarily a weakness of the study, since good clinical practice of PT tailors the details of treatment to the individual patient; the same consideration holds true for the fact that not all surgical patients had the same procedure technique.

- Constant score improvements were reported for the patients who had delayed surgery, and appeared to be less favorable than for patients randomized to surgery, but it does not follow that they had less favorable results because of the delay in surgery.
  - These patients, who had failed to improve with PT, probably represented a group with less favorable prognosis at baseline.
  - The methods section states that the primary outcome was ascertained “12 months after invention,” but it is not clear which intervention is referred to: if
the secondary surgery group had its 12 month assessment 12 months after the PT intervention, it would still be on the path to recovery from the operation at its 12 month assessment, with some expectation of additional improvement 12 months after the secondary intervention of surgery

- The surgery had several components, not all of which may have been relevant to the outcome in the surgical group
  - Acromioplasty is under review as an effective operation for rotator cuff pathology
  - The tendon repairs of the rotator cuff and the tenotomy of the long head of the biceps may have been the effective components of the surgical intervention

Assessment: High quality RCT supporting good evidence that symptomatic full thickness rotator cuff tears less than 3 cm in size, in the absence of severe supraspinatus atrophy, receive more benefit from arthroscopic tendon repair than from physical therapy at 12 months

References:


