Medium- to long-term results of a randomized controlled trial to assess the efficacy of arthroscopic-subacromial decompression versus mini-open repair for the treatment of medium-sized rotator cuff tears

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Abstract

Background: We report on the medium- to long-term results of a randomized controlled trial (RCT) aiming to determine whether rotator cuff repair confers any advantage over arthroscopic sub-acromial decompression (ASAD) alone in the management of medium-sized rotator cuff tears.

Methods: Ethical approval was sought to follow-up patients previously enrolled in a completed and previously published RCT comparing the outcome of ASAD with mini-open cuff repair for the treatment of rotator cuff tear. Forty-two patients were enrolled in the original study, with a mean of 64 years (range 54 years to 77 years).

Results: Fifteen of the original 17 patients randomized to ASAD alone and 18 of the original 25 patients randomized to cuff repair were available for follow-up. Each patient underwent American Shoulder and Elbow Surgeons (ASES), Disabilities of the Arm, Shoulder and Hand (DASH) and Constant scoring, and clinical and ultrasound examination. Mean duration of follow-up was 7 years (range 5 years to 11 years). There was no statistically significant difference in terms of ASES, DASH and Constant scores at follow-up between the two groups. Some 33% of patients in the cuff-repair group had a proven re-rupture on ultrasound. This patient subgroup had significantly worse Constant scores compared to patients where the repair remained intact. None of the patients from either group developed cuff-tear arthropathy requiring arthroplasty surgery.

Conclusions: In this medium- to longer-term study, there is no demonstrable significant benefit of cuff repair over decompression alone for the treatment of medium-sized rotator cuff tears, in terms of ASES, DASH and Constant scores for pain, function and strength modules. The presence of cuff tear does not necessitate surgical repair. This conclusion should drive surgical strategies and shared decision-making between patients and surgeons.

Keywords

cuff repair, cuff tear, shoulder arthroscopy

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Introduction

Rotator cuff tears are a common cause of shoulder pain and loss of function. Cuff tears of the shoulder are increasing in prevalence in the context of the improved patient life expectancy and an ageing population with

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increased functional demands.^{1,2} The aetiology of non-traumatic tears has been described as extrinsic, caused by direct impingement of the supraspinatus tendon underneath the acromion, or intrinsic, as a result of tendon degeneration itself.

Surgery, in the form of direct tendon repair, with the aim of regaining strength and improving function has often been advocated, even in an older population and open and arthroscopic repair for rotator cuff tears have shown to have good to excellent long-term functional outcomes in several studies.³⁻⁵ However poor tendon quality leads to a high re-rupture rate, reportedly as high as 40% for isolated supraspinatus tears and 94% for massive rotator cuff tears.

As an alternative to formal supraspinatus tendon repair, arthroscopic-subacromial decompression (ASAD) alone has also led to favourable results in numerous studies.⁶⁻⁹ It has been postulated that improvement is based on reducing the progression of the size of the tear.

Randomized controlled trials (RCTs) comparing ASAD with surgical repair for cuff tears are limited^{2,10} and the evidence is mainly limited to small-scale retrospective cohort studies.

The present study aimed to report the medium- to long-term results of patients previously enrolled¹ in a RCT within our unit, comparing ASAD with mini-open repair for the treatment of medium-sized rotator cuff tears. The null hypothesis is that there will be no difference in improvement in terms of patient symptoms and function between patients undergoing cuff repair and those undergoing ASAD alone.

Materials and Methods

Ethical approval (NRES REC Reference 10/01/0189) was sought to review patients previously enrolled in a RCT run in our unit, with the minimum 2-year follow up having been published.¹ Patients were contacted after obtaining up-to-date contact details by using the NHS Spine portal.

In the original study, patients were recruited from 2002 to 2008 having been assessed by the senior authors. All patients had medium-sized cuff tears confirmed on magnetic resonance imaging or an ultrasound scan. Patients who had successful diagnostic injections of local anaesthetic and corticosteroid, together with a physiotherapy programme, where symptoms had recurred, were included. Patients with a diagnosis of traumatic cuff tears were excluded.

Patients initially underwent arthroscopy. The presence of a full-thickness cuff tear was then confirmed and the size classified as either small (<1 cm), medium (1 cm to 3 cm), large (3 cm to 5 cm) or massive (>5 cm). Patients were excluded from the study if they were

found to have a large or massive cuff tear on arthroscopy or features of cuff-tear arthropathy, or if the tear was not repairable. On confirmation of a repairable tear, patients were randomized (block randomization in pre-sealed envelope) to either ASAD alone or ASAD with a mini-open single-row cuff repair through a deltoid split.

Surgical procedures were performed under general anaesthesia with an interscalene block in all patients. Arthroscopy was performed either in beach chair position or lateral decubitus position, according to the preference of the surgeon. In all cases, an ASAD was performed using standard arthroscopic portals, the undersurface of the acromion was flattened and the coraco-acromial ligament was released using soft-tissue resectors and a burr. In patients who underwent cuff repair, the operative field was re-prepped and draped. The surgical approach was performed using a 'mini-open' deltoid split. The footprint was prepared and cuff was brought to greater tuberosity using two or three 5.5-mm TwinFix anchors (Smith and Nephew, London UK) in a medial row configuration. A drain was inserted and removed at 24 hours.

Patients undergoing cuff repair were immobilised in a sling for 3 weeks to 4 weeks, with passive range of motion activities alone. This was followed by gentle isometric and graduated active glenohumeral exercises over the next 2 weeks to 3 weeks. The shoulder sling was weaned off at this time. The last phase of rehabilitation consisted of full range of motion active exercises along with cuff strengthening, closed chain and proprioceptive exercises. Patients in the 'ASAD alone' group were also discharged with a shoulder sling; however, it was removed within 2 days to 3 days. This was followed by active-assisted shoulder movements in all planes. Once the pain settled, patients were commenced on isometric cuff strengthening exercises.

As part of the study protocol, patients were invited to attend specifically created follow-up clinics led by an assessor who was blinded to the original surgical procedure. Patients underwent American Shoulder and Elbow Surgeons (ASES), Disabilities of the Arm, Shoulder and Hand (DASH) and Constant scoring. Patients were also invited for ultrasound examination by an experienced musculoskeletal radiologist. A third assessor reviewed the clinical notes to confirm the incidence of postoperative complications and the requirement for further surgical intervention.

Statistical analysis was performed in conjunction with a medical statistician. No power calculation was performed as part of the original study. Prior to this study, a power calculation was performed with an improvement of 15 points on DASH score to be clinically important. This required each group to have 32 patients, or 40 if a 20% loss to follow-up was to

be accounted for. Nonparametric statistical procedures were used for the outcome measures because they are ordinal, not ratio/interval. Change scores (pre- and postoperative) were used to compare groups to correct for baseline group differences. The Mann–Whitney *U*-test and Fisher's exact test, as a result of low expected cell frequencies, were used for between-group comparisons of continuous variables and categorical variables respectively. All comparisons were considered to be statistically significant at an alpha-level of 0.05; no corrections were made for multiple comparisons. All statistical analyses were undertaken using Stata, version 13 (StataCorp., College Station, TX, USA).

Results

Fifteen of the 17 patients originally recruited into the ASAD were available for follow-up, whereas 18 from the original 25 patients were available from the cuff-repair group. Three patients from the original series had died. Two patients were not contactable and a further four patients were unable to participate as a result of being too infirm to travel for assessment.

The minimum follow-up was 5 years and the maximum was 11 years, with a mean of 7 years. The patient demographics for each group are illustrated in Table 1. The mean tear size was 1.8 cm, with a range of 1.5 cm to 2.5 cm.

The outcome in terms of mean Constant scores is illustrated in Fig. 1. Although cuff repair has a higher improvement in Constant score, this difference does not reach statistical significance ($p = 0.24$). In terms of the strength module, mean strength decreased by 2 lbs (mean pre-operative 5 lbs/postoperative 3 lbs) in the ASAD groups and by 4 lbs (mean pre-operative 12 lbs/postoperative 8 lbs) in the cuff-repair group; however, there was also no difference between the two groups ($p = 0.7832$).

Similarly as demonstrated in Figs 2 and 3, in terms of mean ASES (pain and function) and DASH score,

Table 1. Patient demographics for each group.

Intervention	ASAD	Cuff repair
Number of patients	15	18
Age range (years)	54 to 72	55 to 77
Mean age (years)	71	65
Sex M : F	11 : 4	15 : 3

Mean (range) follow-up was 7 years (5 years to 11 years).

ASAD, arthroscopic sub-acromial decompression; M, male; F, female.

there is improvement in the cuff-repair group over the ASAD group, although this does not achieve statistical significance.

Of the patients recalled for clinical assessment, 30 patients were able to attend for ultrasound scanning. From the cuff-repair group, 33% of patients had repair failure and had progressed to full-thickness tears. Overall, these patients have a significantly lower Constant score ($p < 0.05$) than those patients where the cuff repair was intact. Similarly, there was also a trend towards lower ASES scores ($p = 0.07$) in the repair failure group.

Three patients from the cuff-repair group underwent further surgery: revision cuff repair in one for early failure and acromioclavicular joint (ACJ) excision in two patients. From the ASAD group, one patient failed to improve after 12 months and underwent cuff repair. One further patient underwent ACJ excision. No patients from either group progressed to a cuff-tear arthropathy requiring shoulder replacement.

Figure 1. Demonstrating better improvement in mean Constant score for cuff-repair group over arthroscopic sub-acromial decompression (ASAD), which did not reach statistical significance ($p = 0.24$).

Figure 2. Demonstrating better improvement in Disabilities of the Arm, Shoulder and Hand (DASH) score for cuff-repair group over arthroscopic sub-acromial decompression (ASAD), which did not reach statistical significance ($p = 0.67$).

Figure 3. Demonstrating better improvement in mean American Shoulder and Elbow Surgeons (ASES) for pain ($p = 0.10$), function ($p = 0.50$) modules and overall ($p = 0.49$) score for cuff-repair group over arthroscopic sub-acromial decompression (ASAD), which did not reach statistical significance.

Discussion

The present study aimed to report on the medium- to longer-term benefits of rotator cuff repair over ASAD in the management of a symptomatic cuff tear, which has failed to respond to non-operative treatment. The null hypothesis is that there would be no difference in outcome between the cuff repair and ASAD alone groups. In the present study, we have been able unable to refute the null hypothesis.

In terms of the medical literature, Ogilvie-Harris et al.¹⁰ found, in a RCT with follow-up at 2 years, superior strength and function in patients who had undergone cuff repair as opposed to ASAD alone. They found that pain relief and the range of movement was similar in both patient groups; however, those patients in the cuff-repair group took much longer to achieve improvements in strength and range of movement than those patients who had undergone ASAD alone. Smaller cohort studies have shown significant improvement in terms of pain and function for the management of cuff tears with both sub-acromial decompression and cuff repair.^{3,4,6-9} It has been postulated that ASAD prevents mechanical impingement on the rotator cuff and therefore halts progression of cuff tear.⁷ In keeping with the published literature, the present study has confirmed the medium- to long-term benefit with both ASAD and cuff repair, although with no superiority of one treatment over the other. However, in contrast to the literature,^{4,9} we have demonstrated that a failed cuff repair (rate of failure 33%) in the longer-term fairs worse in terms of pain and function than a repair that remains intact.

The results of the present study can be applied directly into clinical practice. Knowing that failed repairs

perform poorly in the medium- to longer-term should influence surgical strategies. Individual surgeons may wish to consider their level of surgical proficiency in cuff repair knowing that ASAD alone would also provide benefit to a patient. Alternatively, surgeons may pursue strategies to create a more stable repair; for example, using a double-row technique. Additionally, if an unexpected tear is found intra-operatively, the results of the present study would not support proceeding to cuff repair where a patient has not consented appropriately beforehand. From the patient's point of view, an ASAD may appear to comprise a reasonable option to treat a cuff tear, which would lead to improvement in pain and function without the commitment of a cuff-repair rehabilitation programme. Recovery from cuff repair can be lengthy in comparison to ASAD alone and has been reported to take over 6 months in up to 30% of patients.⁵ In addition, patients who opt for ASAD in the first instance could undergo a delayed cuff repair at a later date, if they struggle to improve with an ASAD alone.

The strengths of the present study include that it reports a long-term follow-up of a RCT with over 80% patients followed-up clinically and 70% radiologically. Comprehensive outcome measures have been used to compare outcomes as reported in other studies in the literature.

We also acknowledge the limitations of the present study. No radiographs were taken because of the implications of exposure to ionizing radiation on asymptomatic patients. There was no power calculation in the original study and the calculation performed at the commencement of the present study identified that the original study was underpowered. Therefore, the present study highlights the need for further appropriately designed trials with larger numbers and a long-term follow up that also reflects the shift towards arthroscopic techniques for rotator cuff repair.

In the present study, we have been unable to demonstrate a statistical difference in benefit between cuff repair and ASAD alone in the management of medium-sized rotator cuff tears in the medium- to long-term. We do, however, acknowledge that the numbers are small and there is a definite trend for a better outcome with cuff repair. We note that failed cuff repair performed poorly in comparison to when the repair was intact. It is also of note that approximately one-third of our repairs had failed. These findings lead to the conclusion that the presence of a cuff tear does not necessary mean that it needs to be repaired and that patients postoperative requirements should be balanced against a prolonged cuff-repair rehabilitation programme with associated potential problems and cost.

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Ethical Review and Patient Consent

Ethical approval (NRES REC Reference 10/01/0189) was sought to review patients previously enrolled RCT run in our unit, with the minimum 2-year follow up having being published.

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