Clinical effectiveness and cost-effectiveness of open and arthroscopic rotator cuff repair [the UK Rotator Cuff Surgery (UKUFF) randomised trial]

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Scientific summary

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Background

Painful shoulders are a significant socioeconomic burden; disability of the shoulder can result in time off work and impair the ability to work or perform household tasks. Shoulder problems account for 2.4% of all general practitioner (GP) consultations in the UK and 4.5 million visits to physicians annually in the USA. More than 300,000 surgical repairs for rotator cuff pathologies are performed annually in the USA, where the annual financial burden of shoulder pain management has been estimated to be US$3B. The most frequent indications for surgery are persistent and severe pain combined with functional restrictions that are resistant to conservative treatment. Open surgery involves the rotator cuff being repaired under direct vision through an incision in the skin. Arthroscopic surgery involves the repair being performed through smaller arthroscopic portals with a camera used to visualise the operative site on a monitor. There is conflicting evidence regarding the effectiveness of open and arthroscopic repair. It has been suggested that arthroscopic rotator cuff surgery may have advantages over standard open techniques by causing less trauma to the deltoid muscle and overlying soft tissue. Arguably, this causes less postoperative patient discomfort and allows an earlier return of movement. However, the success of the repair depends partly on the ability of the surgeon to achieve a secure attachment of tendon to bone. This may be more easily and reliably achieved by open surgery. Other potential disadvantages of the arthroscopic approach include longer time in the operating room and greater use of costly equipment.

Objective

To determine the effectiveness and cost-effectiveness of open compared with arthroscopic rotator cuff repair.

Methods

Eligible patients were those for whom care had been provided by a participating surgeon, who were deemed suitable for rotator cuff repair surgery and for whom the surgeon was uncertain which surgical procedure was better. In addition, patients had to be aged $\geq$ 50 years, have symptoms from a degenerative full-thickness rotator cuff tear and be able to give informed consent. Surgery was either arthroscopic (fixation of tendon to bone using only arthroscopic techniques) or open (fixation to bone under direct vision through a surgically created opening in the deltoid muscle). The precise technique and method of fixation were not prescribed and surgeons used their preferred and usual technique. The primary outcome measure was the Oxford Shoulder Score (OSS), completed at 24 months after randomisation. The primary measure of cost-effectiveness was the incremental cost per quality-adjusted life-year (QALY). The secondary outcome measures were used to assess functional outcome and patient health-related quality of life. These assessed a range of symptoms often experienced with rotator cuff tears, for example pain, weakness and a loss of function. The measures used included the Shoulder Pain and Disability Index (SPADI), the Mental Health Inventory 5 (MHI-5), the European Quality of Life-5 Dimensions (EQ-5D), participants' ratings of how pleased they were with shoulder symptoms at 12 and 24 months after randomisation, patients' views of the overall state of their shoulder at 8, 12 and 24 months after randomisation and intraoperative and postoperative surgical complications at 2 and 8 weeks post surgery and 12 and 24 months after randomisation. All patients who underwent a rotator cuff repair were assessed with magnetic resonance imaging (MRI) or high-definition ultrasound imaging at 12 months after surgery by an experienced clinician blinded to the treatment group. The sample size was designed to detect a difference in OSS score of 0.38 of a standard deviation (SD) for the comparison of arthroscopic surgery with open surgery. Initially, a conservative comparator (rest then exercise) was included, but because of high rates of crossover to surgery

(77%) this arm was closed down and the trial was reconfigured to a randomised comparison of open and arthroscopic repair. An additional 173 patients from 28 further centres formed surgeon preference groups (91 arthroscopic repair and 82 open repair) and were followed up in the same way.

Results

Nineteen centres throughout the UK recruited to the randomised open surgery and randomised arthroscopic surgery comparison and a further 28 centres recruited to the preference groups where surgeons performed either only open repair or only arthroscopic repair. Recruitment to the trial began on 9 November 2007 and finished on 28 February 2012, although not all centres enrolled over the total period because of the staggered introduction of centres (range 6–39 months from the first to the last participant randomised). Tears were small or medium in size (< 3 cm) in about 75% of participants. The average age of the participants was 63 years, 40% were female and 90% were right-handed. The mean time that the participants had had the shoulder problem before surgery was approximately 2.5 years. There were no substantive differences within or between the groups for any of the sociodemographic factors. The mean OSS was 25.7 across the groups. The EQ-5D, MHI-5 and SPADI measures were not significantly different across and within the groups.

Only around 9% of the participants had received no previous treatment to their shoulder. Previous treatments primarily included physiotherapy and/or cortisone injections. The high frequency of previous conservative treatment probably explains the difficulty in achieving a comparison of a further programme of conservative care, the rest-then-exercise programme, in the context of a pragmatic trial in 47 centres during routine NHS care.

Of the 137 participants randomised to receive open surgical management, 85 (62.0%) underwent an open repair of a tear and five (3.6%) an arthroscopic repair. Of the 136 patients randomised to receive arthroscopic surgical management, 100 (73.5%) received arthroscopic surgery but only 63 (46.3%) received an arthroscopic repair; nine (6.6%) began as an arthroscopic procedure and converted to open surgery. The size of tear and surgical completeness were similar between the randomised groups. The ease of repair, although broadly similar, was reported to be easier in the open procedure (18% of arthroscopic repairs were determined by the surgeon to be easy to perform vs. 36% of the open repairs). Only 162 of 273 (59%) patients randomised to surgery underwent cuff repair. In total, 59 of 273 (22%) withdrew while on the waiting list, with the most common reasons for this being improvement in symptoms and the development of other medical conditions, and 52 of 273 (19%) underwent subacromial decompression and no cuff repair, with the most common reasons for this being that no tear was found or that the tear was impossible to repair.

The mean operation time in minutes was statistically significantly lower in the open procedure group [–12.2, 95% confidence interval (CI) –21.4 to –3.0; $p = 0.010$], as was mean total time in theatre in munites (–12.7, 95% CI –23.5 to –1.9; $p = 0.021$). The number of intraoperative adverse events was generally low. There were 11 (8.1%) participants with any intraoperative complication in the randomised arthroscopic group compared with nine (6.6%) in the open group. The difference was not statistically significant (difference 3.1%, 95% CI –4.8% to 11.0%; $p = 0.190$). Post operation, three participants in the arthroscopic group and three in the open group required inpatient hospitalisation as a result of taking part in the trial. The inpatient admissions were as a result of two participants in each group requiring revision surgery and a single participant in each group having a postoperative complication. One complication was a deep infection requiring formal debridement and vacuum pump application. The patient had this surgery after 3 weeks of treatment by his GP with antibiotics. The other complication involved a participant requiring a longer stay in hospital for a continuous interscalene block in the shoulder for postoperative pain relief and some bleeding during surgery. All complications and revision surgeries were managed within 17 months of randomisation. There were no deaths related to the surgery.

At 2 weeks post surgery very few participants reported being pain free and approximately two-thirds were taking painkillers. Of those participants who were employed, about 80% were still off sick. At 8 weeks the results were similar, with the exception that those who reported no or mild pain increased from 35% to 50%, with an apparent concomitant effect of reducing painkiller use from 66% to 55% and increasing the number of participants returning to usual work (none or a little interference) from 28% to 55%. There were no clinically important differences between or within the groups at either 2 or 8 weeks.

Outcomes at 8, 12 and 24 months were primarily obtained from questionnaire returns. The return rates were similar across groups and ranged from 90% at 8 and 12 months to 86% at 24 months. The OSS increased markedly from baseline (mean 25.7) to 8 months (mean 36.5) and continued to increase thereafter (at a much slower rate) to 24 months (mean 41.5). The groups followed a similar pattern with regard to the EQ-5D, SPADI and MHI-5. At 8 months, 77% of participants reported that shoulder problems were much or slightly better, and this increased to 85% at 24 months. When asked how pleased the participants were with their shoulder symptoms, 77% on average were very or fairly pleased at 8 months, and this increased to 83% by 24 months. Again, the groups responded in a similar manner.

The mean OSS improved from 26.3 (SD 8.2) at baseline to 41.7 (SD 7.9) at 24 months for arthroscopic surgery and from 25.0 (SD 8.0) at baseline to 41.5 (SD 7.9) at 24 months for open surgery for the intention-to-treat (ITT) analysis. There was no statistically significant difference between the groups. When effect sizes are shown for the intervention, a negative sign indicates that an open procedure is favoured. For the ITT analysis there was no statistical difference between the groups, the difference in OSS score at 24 months was –0.76 (95% CI –2.75 to 1.22; $p = 0.452$) and the CI excluded the predetermined clinically important difference in the OSS of 3 points. There was also no statistically significant difference when the groups were compared per protocol (difference in OSS score –0.46, 95% CI –5.30 to 4.39; $p = 0.854$). The rate of re-tear was 46.4% in the arthroscopy group and 38.6% in the open group ($p = 0.256$). In the non-randomised groups the rates were 36.6% for arthroscopic repair and 35.0% for open repair. These differences were not significant. A healed repair (a participant having no tear on the MRI assessment at 12 months) resulted in the greatest improvement in the OSS. In the randomised group the OSS improved from 26.3 (SD 8.2) at baseline to 44.5 (SD 4.1) for the arthroscopic group and from 25.0 (SD 8.0) to 43.6 (SD 5.8) for the open group. The next best results for OSS were for the repaired tears that re-tore, which improved to 41.8 (SD 8.8) in the arthroscopic group and 40.8 (SD 7.6) in the open group. The worst OSS results were seen for the tears that were impossible to repair, which improved to 37.3 (SD 6.1) in the arthroscopic group and 33.8 (SD 9.5) in the open group. The results were similar for the non-randomised groups.

Recognising that caution must be used when interpreting the per-protocol group, we nevertheless note that the lack of important differences between the arthroscopic and the open ITT groups was also observed in the per-protocol data.

Economic evaluation

For the base-case ITT analysis (without adjustment for covariates) there were no significant differences in mean costs between the arthroscopic repair group and the open repair group for any of the component resource-use categories, nor for the total follow-up costs at 12 months or 24 months. The total cost of surgery alone (excluding nights in hospital) was significantly different between the two groups, at £463 (95% CI £260 to £660) more costly for arthroscopic repair. Total QALYs accrued at 2 years averaged 1.34 (SD 0.04) in the arthroscopic repair group and 1.35 (SD 0.04) in the open repair group. The overall treatment cost at 2 years was £2567 (SD £176) for arthroscopic surgery and £2699 (SD £149) for open surgery by ITT analysis. Neither the difference in costs nor the difference in quality-of-life outcomes were statistically significant between the arthroscopic repair group and the open repair group.

Overall, arthroscopic repair was less costly but less effective than open repair in the base-case analysis, resulting in a point estimate for the incremental cost-effectiveness ratio of £30,001 per QALY gained. The probability of arthroscopic repair being less costly than open repair was 75%, and the probability of it being more effective than open repair was 45%.

Comparison with similar randomised trials

The trial was considered in relation to the only other randomised clinical trial of open compared with arthroscopic rotator cuff repair published in 2013. This was a single-centre study of 100 patients with small and medium tears with unblinded follow-up to 1 year using the Disabilities of the Arm, Shoulder and Hand score. This trial also reported no difference in outcome between the groups. It did not include a health economic analysis.

Conclusions

In patients aged ≥ 50 years with a degenerative rotator cuff tear there was no difference in effectiveness or cost-effectiveness between open and arthroscopic repair at 2 years for the primary outcome (OSS) and all other prespecified secondary outcomes. Rotator cuff surgery resulted in marked improvement in symptoms (OSS 25.7/48 at baseline to 41.5/48 at 2 years). A healed repair gave the best outcome, followed by a repair that subsequently re-tore. The worst outcome was in patients whose tear was unrepairable at surgery. Re-tears were found in 93 of 233 (40%) patients who underwent repair surgery, with no difference between the open group and the arthroscopic group. Re-tears occurred after repairs to all tear sizes and the risk of re-tear was not influenced by age.

Implications for health care

Rotator cuff surgery results in a significant improvement in symptoms in patients who have completed a programme of conservative care with symptom duration of > 12 months and there is no difference in clinical effectiveness or cost-effectiveness between open and arthroscopic rotator cuff repair. There is no evidence of an effect of age or tear size on clinical outcome. The overall re-tear rate was 40%, with no difference between the groups. The statistically significant treatment effect seen in all patients, including those in whom a repair was not possible or in whom there was a postoperative re-tear, suggests that there are other treatment effects. Per protocol the costs of arthroscopic surgery were significantly greater than those of open surgery. This is largely because of the longer operating time.

Recommendations for research

This unique study cohort provides the opportunity to determine the longer-term consequences of rotator cuff tear and repair. There is a case for continuing the follow-up of the patients who underwent surgery and who had a repair that healed, re-tore or was impossible to repair. There is early evidence at 2 years' follow-up that these groups have different outcomes. It is important to know whether these differences remain in the longer term and whether or not particular groups are prone to further deterioration.

There is a need to evaluate cost-effectiveness over a longer period than 24 months, using further follow-up data from this study and elsewhere on the longer-term consequences of rotator cuff tear and repair.

It would be of value to explore the basis of the treatment effect seen with a randomised controlled trial of rotator cuff repair compared with placebo surgery.

Trial registration

This trial is registered as ISRCTN97804283.

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