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BACKGROUND

Rotator Cuff Repair Overview

Rotator cuff tears are classified as full-thickness and partial-thickness tears, and partial-thickness tears can be further classified as articular-sided, bursal-sided, and intratendinous.

Surgical options include single-row, double-row, and transosseous techniques.¹

Health Technology Assessment

Health technology assessment bodies are increasingly reviewing the clinical and economic evidence on various surgical procedures.

Such reviews typically use a hierarchy of evidence:

- Level I or Level II: randomized controlled trials (RCTs)
- Level III: case-control studies
- Level IV: case-series studies

RCTs in surgical patients are expensive and difficult to design and implement, and the requirements of randomization and blinding are problematic.^{2,3}

OBJECTIVE

To explore the available evidence to determine the value of a well-established surgical procedure, rotator cuff repair.

METHODS

A structured search of PubMed was conducted from 1/1/2002 to 4/17/2012, using Medical Subject Heading search terms.

- Seventeen systematic literature/evidence-based medicine reviews were found for shoulder surgical interventions.
- Articles also were obtained that specifically discussed evidence-based medicine, comparative effectiveness research, and clinical guidelines.

Internet searches identified additional evidence-based guidelines for rotator cuff repair.

RESULTS

Two RCTs concluded that arthroscopic repair of rotator cuff tears was superior to the alternatives studied (Table 1).

Numerous studies considered surgical repair to be efficacious and examined modifications to improve surgical techniques.

Ten systematic reviews evaluated these studies (Table 2).

- Most studies were conducted outside the United States, and sample sizes were small (< 50 patients per arm).
- All reported study limitations, but some drew conclusions on the best surgical technique leading to better clinical outcomes.
- All reviews showed that most studies used Level IV evidence; fewer than 5 Level I-III studies were identified in each review.
- The systematic reviews covered two main research topics: outcomes of arthroscopic versus open surgery (n = 4) and outcomes for different surgical techniques (n = 6).
- The results for open versus arthroscopic repair were inconclusive in most systematic reviews, and the benefit of using double-row versus single-row anchors was not well demonstrated.

- In 2010, the American Academy of Orthopaedic Surgeons (AAOS) published a guideline on the best available evidence with the goal of improving treatment.¹⁵
- The guideline summarized multiple systematic reviews of the literature (1966-10/1/2008) on the treatment of rotator cuff problems.
 - RCTs identified were considered first. In the absence of two or more RCTs, prospective controlled trials, prospective comparative studies, retrospective comparative studies, and case-series studies were sought.
 - Only studies of the highest level of available evidence were included, assuming that there were two or more studies of that higher level; 74 studies were included in the current guidelines.
- The AAOS authors acknowledged that many of the excluded articles were both important and clinically relevant but fell below the quality criteria for inclusion in their evidence-based clinical guidelines.
- Of the 25 guidelines, 15 were characterized as inconclusive owing to the levels of evidence.

Table 2. Rotator Cuff/Shoulder Comparative Systematic Literature Reviews (2002-2012)

Author and Year	Procedure Comparison	Review Objective	Level of Studies Found	Conclusion
Barfield and Kuhn, 2007 ⁶	Arthroscopic vs. open acromioplasty	Determine whether an arthroscopic approach to acromioplasty produced different outcomes (e.g., pain relief) than traditional open procedures	5 studies: • 4 Level I RCTs • 1 Level II RCT	• No appreciable differences found between the 2 techniques • Studies with the highest evidence level have a variety of important sources of bias
Duquin et al., 2010 ⁷	Different repair methods: • TO • SA • DA • SB • O approach • MO approach • A approach	Determine whether different repair methods and surgical approaches resulted in different rates of recurrent tearing	23 studies: • 1 Level I • 1 Level III • 21 Level IV Retear rates were available for 1,252 repairs (data were combined) 90% of patients had O:TO, A:SA, or A:DA repairs	• Double-row repair methods lead to significantly lower retear rates than single-row methods for tears > 1 cm • Surgical approach had no effect on retear rate
Freedman et al., 2004 ⁸	Open Bankart repair vs. arthroscopic repair with bioabsorbable tacks or transglenoid sutures	Compare open vs. arthroscopic stabilization for recurrent, traumatic, anterior or shoulder instability by meta-analysis	6 studies: • 2 RCTs • 3 prospective cohort • 1 retrospective cohort	• Arthroscopic Bankart repair using transglenoid sutures or bioabsorbable tacks results in a higher rate of recurrence of instability compared with open techniques • Open Bankart repair led to a lower rate of recurrent dislocation and total recurrence and a higher percentage of patients with a good or excellent postoperative Rowe score (all $P < 0.0001$)
Kakar et al., 2007 ⁹	Open vs. arthroscopic surgery of posterior shoulder instability	Compare clinical outcomes of open vs. arthroscopic soft-tissue reconstruction procedures in the treatment of posterior shoulder instability	16 studies: • No RCTs • ~ Half could not be clearly classified • Most were retrospective	• No statistical difference in clinical outcomes was shown between open and arthroscopic surgery for posterior shoulder instability
Papalia et al., 2011 ¹	Different repair options	Report the best viable surgical action for management of partial-thickness rotator cuff tears	23 studies: • 3 prospective nonrandomized trials • 20 retrospective	• The heterogeneity of the treatment options and of the outcome assessment methods makes it difficult to compare the results of the different studies (thus, no conclusion could be reached)
Papalia et al., 2012 ¹⁰	Single-row vs. double-row repair	Compare the biomechanical, clinical, and biological features of single- and double-row repair	17 studies: • 8 biomedical studies (using human specimens) • 9 clinical studies Evidence level was not described, but all compared the 2 procedures	• Biomechanically, the double-row repair had greater performance in terms of higher fixation strength, greater footprint coverage, improved contact area and pressure, decreased gap formation, and higher load to failure • Results of clinical studies demonstrated no significantly better outcomes for double-row repair than single-row repair, but better results are achieved by double-row repair for larger lesions (tear size, 2.5cm-3.5 cm) • Considering the lack of statistically significant differences between the 2 techniques, and that the double-row technique is a high-cost and high surgical-skill-dependent technique, the authors suggest using the double-row technique only in strictly selected patients
Prasathaporn et al., 2011 ¹¹	Single-row vs. double-row repair	Compare double-row with single-row repair in patients with full-thickness rotator cuff tears using meta-analysis	5 studies: • 3 Level I RCTs • 2 Level II cohort designs	• Double-row repair showed a significantly higher rate of tendon healing and greater external rotation than single-row repair; no significant improvement in shoulder function, muscle strength, forward flexion, internal rotation, patient satisfaction, or return to work • Double-row repair had a significantly increased operative time and decreased recurrence rate
Pulavarti et al., 2009 ¹²	Open vs. arthroscopic surgery	Compare the effectiveness of various surgical interventions for recurrent anterior instability of the shoulder	3 RCTs (Level I)	• Pooled results showed no statistically significant difference between groups, but the evidence was considered insufficient to draw a conclusion
Saridakis and Jones, 2010 ¹³	Single-row vs. double-row repair	Compare single-row and double-row fixation in terms of clinical outcomes and radiographic healing	6 studies: • 3 Level I • 2 Level II • 1 Level III	• There appears to be a benefit of structural healing when an arthroscopic rotator cuff repair is performed with double-row fixation as opposed to single row • However, there was no significant difference between the groups in terms of postoperative clinical outcomes, except possibly for patients with large or massive tears (≥ 3 cm) • A risk/reward analysis of patient's age, functional demands, and other quality of life issues should be considered before deciding which method to use
Strauss et al., 2011 ¹⁴	Different surgical techniques: • Debridement alone • Debridement with subacromial decompression • Takedown and repair • Transtendon repair • Transosseous repair	Evaluate the effectiveness of various surgical techniques for partial-thickness rotator cuff tears	16 Level IV studies	• Tears that involve less than 50% of the tendon can be treated with debridement with or without acromioplasty; when the tear is greater than 50%, surgical intervention should be considered • Both tear completion and transtendon repair were successful; there was not a differential outcome

A = arthroscopic approach; DA = double-row suture anchor; MO = mini-open approach; O = open approach; SA = single-row suture anchor; SB = suture bridge; TO = transosseous.

Table 1. Two RCTs Evaluating the Efficacy of Arthroscopic Repair of Rotator Cuff Tears

Author and Year	Procedure Comparison	Review Objective	Level of Study	Conclusion
Moosmayer et al., 2010 ⁴	Operative repair vs. physiotherapy	To compare operative repair with physiotherapy in the treatment of small and medium-sized full-thickness rotator cuff tears	Single-center RCT (N = 103) Level II	• Improved results for the surgery group on the Constant Shoulder Score ($P = 0.002$), the ASES Score ($P < 0.0005$), and a visual analogue pain scale ($P < 0.0005$) • 9 (18%) of the physiotherapy patients subsequently underwent surgery
Dezaly et al., 2011 ⁵	Arthroscopic rotator cuff repair vs. acromioplasty-tendonotomy	To compare clinical results between arthroscopic rotator cuff repair and acromioplasty-tendonotomy in patients aged ≥ 60 years	Single-center RCT (N = 142) Level II	• Rotator cuff repair in patients ≥ 60 years yielded better short-term functional results than isolated acromioplasty-tendonotomy performed when the tear was repairable • Whatever the size of the tear, the mean weighted constant score was significantly better in patients with tendon healing than patients without

ASES = American Shoulder and Elbow Surgeons.

DISCUSSION

- Ideally, surgical clinical societies, such as the AAOS, would be able to develop clinical practice guidelines based on evidence-based medicine for different types of common surgeries.
- Unfortunately, the current systematic literature reviews for rotator cuff surgery have concluded that because relatively low levels of evidence exist for most clinical research questions, higher levels of evidence need to be generated (Level I and II) to answer outstanding clinical questions regarding surgical procedures.
 - In other words, the authors have stated that considerably more high-quality RCTs must be conducted in the surgical setting.
- That conclusion seems laudable, but conducting RCTs in the surgical setting is challenging and in some cases could be considered unethical.
 - RCTs in surgery are well known to be difficult to design and often suffer from recruitment problems; adding a placebo component (or sham surgery) to the design increases this complexity.^{2,3}
 - Operational and practical issues cannot be underestimated in the design and implementation of RCTs in surgery.^{2,3}

CONCLUSIONS

- The pharmaceutical framework for evidence hierarchy often may not be appropriate for surgical procedures and devices.
- There are challenges to running clinical trials in a surgical setting, making them impractical and unaffordable.
- Especially with well-established procedures, evidence review will require a balanced approach using the best available evidence and clinical expertise.

REFERENCES

Please see handout.

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