Effective Health Care Program

Comparative Effectiveness of Nonoperative and Operative Treatments for Rotator Cuff Tears

Executive Summary

Introduction

The rotator cuff (RC) is comprised of four muscle-tendon units, which stabilize the humeral head within the shoulder joint and aid in powering the movement of the upper extremity. RC tears refer to a partial or full discontinuation of one or more of the muscles or tendons and may occur as a result of traumatic injury or degeneration over a period of years. The incidence of RC tears is related to increasing age; 54 percent of patients over the age of 60 years have a partial or complete RC tear compared with only 4 percent of adults under 40 years of age. Although not a life-threatening condition, RC tears may cause significant pain, weakness, and limitation of motion.

Both nonoperative and operative treatments are used in an attempt to relieve pain and restore movement and function of the shoulder. The majority of patients first undergo 6 weeks to 3 months of nonoperative treatment, which may consist of any combination of pain management (medications and injections), rest from activity, passive and active exercise, and treatments with heat, cold or ultrasound. Failing nonoperative treatment, the cuff may be surgically repaired using an open, mini-open, or all-arthroscopic approach.

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The Effective Health Care Program was initiated in 2005 to provide valid evidence about the comparative effectiveness of different medical interventions. The object is to help consumers, health care providers, and others in making informed choices among treatment alternatives. Through its Comparative Effectiveness Reviews, the program supports systematic appraisals of existing scientific evidence regarding treatments for high-priority health conditions. It also promotes and generates new scientific evidence by identifying gaps in existing scientific evidence and supporting new research. The program puts special emphasis on translating findings into a variety of useful formats for different stakeholders, including consumers.

The full report and this summary are available at **www.effectivehealthcare.ahrq.gov/reports/final.cfm.**

A variety of postoperative rehabilitation programs are used to restore range of motion, muscle strength, and function following operative treatment.

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Earlier operative treatment has been proposed to improve patient outcomes, and result in an earlier return to work, and decreased costs; therefore, patients and clinicians face the difficult decision of when to forgo attempts at nonoperative treatment in favor of operative treatment. Moreover, the comparative effectiveness of the various nonoperative and operative treatment options for patients with RC tears remains uncertain.

Key Questions

The following key questions (KQ) were investigated for a population of adult patients with partial- and full-thickness RC tears:

1. Does early surgical repair compared to late surgical repair (i.e., nonoperative intervention followed by surgery) lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
2. What is the comparative effectiveness of operative approaches (e.g., open surgery, mini-open surgery, and arthroscopy) and postoperative rehabilitation on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
    i. Which operative approach should be used for different types of tears (e.g., partial-thickness or full-thickness; small, medium, large, or massive; with or without fatty infiltration of muscle tissue)?
3. What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength? Nonoperative interventions include, but are not limited to, exercise, manual therapy, cortisone injections, acupuncture, and treatments and modalities typically delivered by physical therapists, osteopaths, and chiropractors.
    i. Which nonoperative treatment approach should be used for different types of tears (e.g., partial-thickness, full-thickness; small, medium, large, or massive; with or without fatty infiltration of muscle tissue)?
4. Does operative repair compared with nonoperative treatment lead to improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?
5. What are the associated risks, adverse effects, and potential harms of nonoperative and operative therapies?
6. Which demographic (e.g., age, gender, ethnicity, comorbidities, workers' compensation claims) and clinical (e.g., size/severity of tear, duration of injury, fatty infiltration of muscle) prognostic factors predict better outcomes following nonoperative and operative treatment?
    i. Which (if any) demographic and clinical factors account for potential differences in surgical outcomes between patients who undergo early versus delayed surgical treatment?

Methods

Literature Search

The following bibliographic databases were searched systematically for studies published between 1990 and 2009: Medline®, Embase, Evidence-Based Medicine Reviews – The Cochrane Library, AMED, Cumulative Index to Nursing and Allied Health Literature (CINAHL), SPORTDiscus with Full Text, Academic Search Elite, Health Source, Science Citation Index Expanded (via Web of Science®), Scopus®, BIOSIS Previews®, and PubMed. Additional searches of the Grey Literature were conducted in Conference Papers Index, Computer Retrieval of Information on Scientific Projects (CRISP), Scopus®, as well as government Web sites by the U.S. Food and Drug Administration and Health Canada. Databases that yielded included studies (Medline®, Embase, Central, and CINAHL®) were searched again in September 2009 to identify recently published studies. Hand searches were conducted to

identify literature from symposia proceedings from the following scientific meetings: Arthroscopy Association of North America (2007-2009), American Academy of Orthopaedic Surgeons (2007-2009), American Physical Therapy Association (2006-2008), American Shoulder and Elbow Surgeons (2005-2008), American Society of Shoulder and Elbow Therapists (2004-2008), European Congress of Physical and Rehabilitation Medicine 2008, Congress of the European Society for Surgery of the Shoulder and the Elbow (2009), and the Mid-America Orthopaedic Association (2006-2008). Ongoing studies were identified by searching clinical trials registers and by contacting experts in the field. Reference lists of relevant reviews were searched to identify additional studies. No language restrictions were applied.

Study Selection

Two reviewers independently screened titles and abstracts using general inclusion criteria. The full text publication of all articles identified as "include" or "unclear" were retrieved for formal review. Each full-text article was assessed independently by two reviewers using detailed a priori inclusion criteria and a standardized form. Disagreements were resolved by consensus or by third-party adjudication.

Controlled and prospective uncontrolled studies were included in the review if they were published in 1990 or later, included a minimum of 11 participants, focused on adults with a partial or full-thickness tear that was confirmed by imaging or intraoperative findings, and examined any operative or nonoperative intervention or postoperative rehabilitation. In addition, studies were required to report on at least one outcome of interest (quality of life, function, time to return to work, cuff integrity, pain, range of motion, and/or strength) and have a minimum followup duration of 12 months for operative studies. For the review update, only controlled studies were included.

Quality Assessment and Rating of the Body of Evidence

Two reviewers independently assessed the methodological quality of included studies. The Cochrane Collaboration's "risk of bias" tool was used to assess randomized controlled trials and controlled clinical trials. Observational analytic studies were assessed using modified cohort and case-control Newcastle-Ottawa Quality Assessment Scales. The methodological quality of uncontrolled studies was assessed using a quality checklist developed by the University of Alberta Evidence-based Practice Center; the checklist consisted of three items: consecutive enrollment, incomplete outcome data, and standardized/independent approach to outcome assessment. In addition, the source of funding was recorded for all studies.

The body of evidence was rated by one reviewer using the EPC GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach. The strength of evidence was assessed for four key outcomes considered by the clinical investigators to be most clinically relevant: health-related quality of life, functional outcomes, time to return to work, and cuff integrity. The following four major domains were assessed: risk of bias (low, medium, high), consistency (no inconsistency, inconsistency present, unknown, or not applicable), directness (direct, indirect), and precision (precise, imprecise).

Data Extraction

Data were extracted by one reviewer using a standardized form and verified for accuracy and completeness by a second reviewer. Extracted data included study characteristics, inclusion/exclusion criteria, participant characteristics, interventions, and outcomes. Reviewers resolved discrepancies by consensus or in consultation with a third party.

Data Analysis

Evidence tables and qualitative descriptions of results were presented for all included studies. Comparative studies were considered appropriate to combine in a meta-analysis if the study design, study population, interventions being compared, and outcomes were deemed sufficiently similar. Results were combined using random effects models. Statistical heterogeneity was quantified using the I-squared (I^2) statistic. Graphs were created to display the preoperative and postoperative scores of uncontrolled studies, cohort studies, and trials over the duration of the study followup period.

Results

Description of Included Studies

The search strategy identified 5,677 citations; 137 unique studies met the eligibility criteria and were included in the review. The studies included 27 trials, 39 cohort studies, and 71 uncontrolled studies. The number of participants in the studies ranged from 12 to 224 (median=55 [IQR: 33 to 93]). The mean age of study participants ranged from 41.2 to 80 years.

Methodological Quality of Included Studies

All the randomized controlled trials and controlled clinical trials were considered to have a high risk of bias. The most common sources of potential bias were inadequate blinding, inadequate allocation concealment, and incomplete outcome data. The methodological quality of the cohort studies was moderate, with a median score of 5 stars on a possible score of 8 stars (IQR: 4 to 6). Common weaknesses in the design of the studies included lack of independent blind outcome assessment and failure to control adequately for potential confounding factors. Uncontrolled studies generally had moderate quality, with consecutive enrollment, adequate followup, and standardized outcome assessment being reported in 63 percent, 77 percent, and 44 percent of studies, respectively. Across all studies, a source of funding was rarely reported (n=49, 36 percent).

Results of Included Studies

The results of the included studies are presented by the key question(s) they address. A table with the summary of findings for nonoperative and operative interventions is presented below.

Key Question 1: Early versus late surgical repair. One study compared early surgical repair versus late surgical repair after failed nonoperative treatment. Patients receiving early surgery had superior function compared with the delayed surgical group; however, the level of significance was not reported.

Key Question 2: Comparative effectiveness of operative interventions and postoperative rehabilitation. A total of 113 studies examined the effectiveness of operative interventions, while 11 studies evaluated postoperative rehabilitation protocols following surgery. A median of 55 patients (IQR: 34 to 95) with a median age of 58.6 years (IQR: 55.5 to 61.7) were included in the operative studies. Males comprised an average of 64.6 percent of study participants. For postoperative rehabilitation, studies included a median of 61 participants (IQR: 36 to 79.5) with a median age of 58.0 years (IQR: 56.3 to 60.8). Males comprised an average of 58.9 percent of study participants.

Studies assessing operative treatments were categorized as focusing on an operative approach (e.g., open, mini-open, arthroscopic, and debridement), technique (i.e., suture or anchor type or configuration) or augmentation for RC repair. The majority of surgical studies (32 comparative studies and 58 uncontrolled studies) evaluated operative approaches. The comparative studies provided moderate evidence indicating no statistical or clinically important differences in function between open and mini-open repairs; however, there was some evidence suggesting an earlier return to work by approximately 1 month for mini-open repairs. Similarly, there was moderate evidence demonstrating no difference in function between mini-open and arthroscopic repair and arthroscopic repair with and without acromioplasty. There was moderate evidence for greater improvement in function for open repairs compared with arthroscopic debridement. The strength of evidence was low for the remaining comparisons and outcomes examined in the studies, precluding any conclusions regarding their comparative effectiveness. The uncontrolled studies consistently reported functional improvement from preoperative to postoperative scores, regardless of the type of approach used (open, mini-open, or arthroscopic), the study design, the sample size of the study, or the type of outcome measure used.

Operative techniques were examined in 15 comparative studies. Six studies compared single-row versus double-row fixation of repairs, providing moderate evidence of no clinically significant difference in function and no difference in cuff integrity. There was moderate evidence for no difference in cuff integrity between mattress locking and simple stitch. The evidence was too limited to make conclusions about the other techniques.

Eight studies, including three comparative and five uncontrolled studies, assessed augmentations for operative repair. The three comparative studies were relatively small and no overall conclusions were possible. Although the five uncontrolled studies evaluated different types of augmentation, they all indicated improvement in functional score from baseline to final followup.

Of the 11 postoperative rehabilitation studies (10 comparative, 1 uncontrolled), 3 compared continuous passive motion with physical therapy versus physical therapy alone. These three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with continuous passive motion. Each of the remaining studies examined different rehabilitation protocols; therefore, the evidence was too limited to make any conclusions regarding their comparative effectiveness.

Key Question 3: Comparative effectiveness of nonoperative interventions. Nonoperative interventions were examined in three comparative and seven uncontrolled studies. The studies included a median of 42 patients (IQR: 25.3 to 73.3), with a median age of 61 years (IQR: 60.4 to 61.5). Males comprised an average of 50 percent of participants. Each of the comparative studies assessed different interventions, including: sodium hyaluraonate versus dexamethasone; rehabilitation versus no rehabilitation (not otherwise specified); and physical therapy, oral medications, and steroid injection versus physical therapy, oral medications, and no steroid injection. The limited evidence precludes conclusions of comparative effectiveness. The degree of improvement in functional outcome scores varied considerably across the uncontrolled studies.

Key Question 4: Comparative effectiveness of nonoperative versus operative interventions. Five studies compared nonoperative to operative treatments, with a median sample size of 103 (IQR: 40 to 108). The mean ages in the studies ranged from 46.8 to 64.8 years. Males represented 55 percent of study participants. The interventions varied across studies, but generally the nonoperative arms included components such as steroid injection, stretching, and strengthening and were compared with open repair or debridement. The evidence was too limited to make conclusions regarding the comparative effectiveness of the interventions.

Key Question 5: Complications. A total of 85 studies provided data on 34 different complications of nonoperative, operative, and postoperative rehabilitation interventions. Complications were poorly reported, with studies providing limited information on how complications were defined and assessed. In 21 studies, it was reported that no complications occurred during the course of the study. In general, the rates of complication were low and the majority of complications were not deemed to be clinically important or were reported in few studies.

Key Question 6: Prognostic factors. Overall, 72 of the 137 studies examined the impact of prognostic factors on patient outcomes. General conclusions are limited, due to the varied methodologies across studies, particularly the different outcomes for which prognostic factors were evaluated. There is some evidence that tear size, age, and extent of preoperative symptoms may modify outcomes; while, workers' compensation board (WCB) status, sex, and duration of symptoms generally showed no significant impact.

The following table summarizes the findings of the studies and indicates the overall strength of the evidence on each topic examined.

Summary of strength of evidence for nonoperative and operative interventions for RC tears

Comparison (number of studies)	Strength of evidence	Summary
Early vs. late repair		
Early RCR vs. late RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Operative approaches		
Open RCR vs. mini-open RCR (n=3)	Moderate	No statistically significant or clinically important difference for function. Some evidence for earlier return to work or sports (by approximately 1 month) with mini-open repairs.
	Low	The evidence was too limited to make a conclusion for health-related quality of life.
Mini-open RCR vs. arthroscopic RCR (n=10)	Moderate	No difference in function or cuff integrity.
Open RCR vs. arthroscopic RCR (n=3)	Low	The evidence was too limited to make a conclusion.
Open or mini-open RCR vs. arthroscopic RCR (n=2)	Moderate	No difference in function.
	Low	The evidence was too limited to make a conclusion for cuff integrity.
Open RCR vs. open or arthroscopic debridement (n=4)	Moderate	Some evidence for greater improvement in function for open RCR.
Arthroscopic RCR with acromioplasty vs. without acromioplasty (n=3)	Moderate	No difference in function.
Arthroscopic RCR vs. acromioplasty alone	Low	The evidence was too limited to make a conclusion.
Biceps tenotomy vs. tenodesis (n=1)	Low	The evidence was too limited to make a conclusion.
RCR vs. palliative treatment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic RCR with SLAP repair vs. arthroscopic RCR with biceps tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Mini-open RCR plus tenodesis with detachment vs. without detachment (n=1)	Low	The evidence was too limited to make a conclusion.
Arthroscopic debridement with biceps tenotomy vs. without tenotomy (n=1)	Low	The evidence was too limited to make a conclusion.
Complete open RCR vs. partial open RCR vs. debridement (n=1)	Low	The evidence was too limited to make a conclusion.
Open RCR with classic open acromioplasty vs. open RCR with modified open acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.
Operative techniques		
Single-row vs. double-row suture anchor fixation (n=6)	Moderate	No clinically important difference for function and no difference for cuff integrity.
Bioabsorbable tacs vs. suture tying (n=1)	Low	The evidence was too limited to make a conclusion.
Side-to-side vs. tendon-to-bone fixation (n=1)	Low	The evidence was too limited to make a conclusion.
Nonabsorbable vs. absorbable sutures (n=1)	Low	The evidence was too limited to make a conclusion.
Bioabsorbable corkscrews vs. metal suture anchor (n=1)	Low	The evidence was too limited to make a conclusion.

The following table summarizes the findings of the studies and indicates the overall strength of the evidence on each topic examined.

Summary of strength of evidence for nonoperative and operative interventions for RC tears

Comparison (number of studies)	Strength of evidence	Summary
Operative techniques (continued)		
Mattress locking vs. simple stitch (n=2)	Moderate	No difference in cuff integrity.
	Low	The evidence was too limited to make a conclusion for function.
Mattress vs. transosseous suture (n=1)	Low	The evidence was too limited to make a conclusion.
Ultrasonic welding vs. hand-tied knots (n=1)	Low	The evidence was too limited to make a conclusion.
Staple fixation vs. side-to-side suture (n=1)	Low	The evidence was too limited to make a conclusion.
Operative augmentation		
Porcine small intestine submucosa vs. no augmentation (n=2)	Low	The evidence was too limited to make a conclusion.
Patch graft vs. no augmentation (n=1)	Low	The evidence was too limited to make a conclusion.
Postoperative rehabilitation		
Continuous passive motion with PT treatment vs. PT treatment (n=3)	Moderate	No clinical or statistical difference in function. Some evidence for earlier return to work with continuous passive motion.
Aquatic therapy with land-based therapy vs. land-based therapy (n=1)	Low	The evidence was too limited to make a conclusion.
Inpatient vs. day patient rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Individualized PT program with home exercise vs. home exercise (n=1)	Low	The evidence was too limited to make a conclusion.
Progressive vs. traditional loading (n=1)	Low	The evidence was too limited to make a conclusion.
Inpatient rehabilitation vs. outpatient CGE (n=1)	Low	The evidence was too limited to make a conclusion.
Standardized vs. non-standardized PT program (n=1)	Low	The evidence was too limited to make a conclusion.
Videotape vs. PT home exercise instruction (n=1)	Low	The evidence was too limited to make a conclusion.
Nonoperative interventions		
Sodium hyaluraonate vs. dexamethasone (n=1)	Low	The evidence was too limited to make a conclusion.
Rehabilitation vs. no rehabilitation (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy, oral medications and steroid injection vs. physical therapy, oral medications and no steroid injection (n=1)	Low	The evidence was too limited to make a conclusion.
Nonoperative vs. operative treatment		
Shock-wave therapy vs. mini-open RCR (n=1)	Low	The evidence was too limited to make a conclusion.
Steroid injection, physical therapy, and activity modification vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.
Physical therapy vs. open or mini-open RCR	Low	The evidence was too limited to make a conclusion.
Physical therapy treatment, oral medication, and steroid injection vs. arthroscopic debridement vs. open repair (n=1)	Low	The evidence was too limited to make a conclusion.

The following table summarizes the findings of the studies and indicates the overall strength of the evidence on each topic examined.

Summary of strength of evidence for nonoperative and operative interventions for RC tears

Comparison (number of studies)	Strength of evidence	Summary
Nonoperative vs. operative treatment (continued)		
Passive stretching, strengthening, and corticosteroid injection vs. open repair with acromioplasty (n=1)	Low	The evidence was too limited to make a conclusion.

CGE = Concept Global d'Epaule; RCR = rotator cuff repair; SLAP = superior labral from anterior to posterior

Future Research

Recommendations for further research:

- Primary evidence is needed, comparing the effectiveness of early versus delayed surgery, nonoperative versus operative interventions, and among the nonoperative treatment options. Future research examining the comparative effectiveness of open, mini-open, or arthroscopic approaches is also a priority, as arthroscopic procedures are more costly and technically difficult.
- All future studies should employ a comparison or control group and should ensure comparability of treatment groups, optimally through the use of randomization.
- Future research should seek to minimize bias by blinding outcome assessors, using validated and standardized outcome assessment instruments, and ensuring adequate allocation concealment (where applicable) and the appropriate handling and reporting of missing data.
- Studies examining the long-term effectiveness of treatments over the course of several years are needed; at the very least, studies should follow patients for a minimum of 12 months.
- To avoid numerous studies on disparate interventions, the interventions and comparisons chosen for study should be guided by consensus regarding the most promising and/or controversial interventions.
- To ensure consistency and comparability across future studies, consensus is needed on outcomes that are important to both clinicians and patients. Moreover, consensus on minimal clinically important differences is needed to guide study design and interpretation of results.
- To permit the appropriate interpretation of results, future research needs to be reported in a consistent and comprehensive manner.

Conclusions

For the majority of interventions, only sparse data are available, precluding firm conclusions for any single approach or for the optimal overall management of this condition. The paucity of evidence related to early versus delayed surgery is of particular concern, as patients and providers must decide whether to attempt initial nonoperative management or proceed immediately with surgical repair. The majority of the data is derived from studies of low methodological quality or from study designs associated with higher risk of bias (e.g., observational and before-and-after studies). Overall, the evidence shows that all interventions result in substantial improvements; however, few differences of clinical importance are evident when comparisons between interventions are available. Complication rates were generally low and the majority of complications were not deemed to be clinically important; therefore, the benefit of receiving treatment for rotator cuff tears appears to outweigh the risk of associated harms. Future research is needed to determine the relative effectiveness of rotator cuff treatment options.

AHRQ Pub. No. 10-EHC050-1
July 2010