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ORIGINAL ARTICLE

Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis

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Background: Rotator cuff disease is the most common pathology of the shoulder, responsible for approximately 70% of clinic visits for shoulder pain. However, no consensus exists on the optimal treatment. The aim of this study was to analyze level I and II research comparing operative versus nonoperative management of full-thickness rotator cuff tears.

Methods: A literature search was performed, in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, to identify level I and II studies comparing operative versus nonoperative treatment of rotator cuff tears. Two independent researchers reviewed a total of 1013 articles. Three studies qualified for inclusion. These included 269 patients with 1-year follow-up. The mean age ranged from 59 to 65 years. Clinical outcome measures included the Constant score and visual analog scale (VAS) score for pain. Meta-analysis, using both fixed- and random-effects models, was performed on pooled results to determine overall significance.

Results: Statistically significant differences favoring surgery were found in both Constant and VAS scores after 1 year, with mean differences of 5.64 (95% confidence interval, 2.06 to 9.21; $P = .002$) and −1.08 (95% confidence interval, −1.56 to −0.59; $P < .0001$), respectively.

Conclusion: There was a statistically significant improvement in outcomes for patients managed operatively compared with those managed nonoperatively. The differences in both Constant and VAS scores were small and did not meet the minimal difference considered clinically significant. Larger studies with longer follow-up are required to determine whether clinical differences between these treatments become evident over time.

Level of evidence: Level II; Meta-Analysis

Keywords: Rotator cuff tear; atraumatic tears; rotator cuff disease; operative treatment; nonoperative treatment; conservative management; rotator cuff repair; arthroscopy

Rotator cuff disease is the most common etiology of shoulder pain, responsible for up to 70% of all shoulder-related visits to physicians.[18,21] Rotator cuff tearing is present in 20% to 54% of persons aged between 60 and 80 years.[1,15]

This study was exempt from institutional review board review.

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Despite this wide prevalence, controversy exists over the optimal treatment. Physical therapy is widely used for atraumatic tears, and several studies have demonstrated its reliable and durable success.[6,11,25] Treatment with physical therapy does not result in healing of the torn rotator cuff, however, and natural history studies have raised concerns about tear progression and irreversible fatty infiltration worsening over time.[7,22,24]

Operative treatment is also a successful treatment option. The widespread use of arthroscopy has corresponded to a significant increase in rotator cuff repair procedures in recent decades.[4] Operatively treated patients return to work sooner and incur less cost burden when compared with patients treated nonoperatively.[17] Successful outcomes following rotator cuff repair do not diminish with midterm and long-term follow-up.[8]

Several randomized controlled trials have compared operative and nonoperative treatment of full-thickness rotator cuff tears; the results have been mixed. The aim of this study was to analyze level I and II comparisons of operative versus nonoperative management of atraumatic rotator cuff tears through meta-analysis.

Materials and methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[19] One independent reviewer systematically searched MEDLINE (via Ovid), PubMed (National Library of Medicine), Scopus (Elsevier, Amsterdam, Netherlands), and the Cochrane Controlled Trials Register (John Wiley & Sons, Hoboken, NJ, USA) from inception to October 2016. The database search was limited to level I and II studies, English-language studies, and human studies. The search strategy applied a combination of MeSH (Medical Subject Headings) and keyword searches using the following search terms: "rotator cuff injury"; "rotator cuff"; "rotator cuff tear"; "non traumatic tears"; "rotator cuff rupture"; "rotator cuff disease" and "surgical procedures, operative"; "general surgery"; "surgery"; "operative treatment"; "non operative treatment"; "conservative management"; "rotator cuff repair"; "orthopedic procedures"; "surgical procedures, operative"; "operative surgical procedures"; "impingement syndrome"; and "arthroscopy." The references of selected articles were also reviewed, when applicable, to identify additional studies.

Two independent reviewers (C.C.P. and A.J.H.) screened all articles eligible for inclusion. The inclusion criteria were as follows: randomized controlled trial, full-thickness rotator cuff tear, and age 18 years or old. The exclusion criteria included any history of rotator cuff surgery and a follow-up period of less than 1 year.

Meta-analyses were performed comparing outcomes after operative versus nonoperative treatment of rotator cuff tears. Differences in Constant scores and pain scores (as rated by a visual analog scale [VAS]) before and after intervention (surgery or physical therapy) were selected outcomes measured because they were included in all studies. Pooled mean differences were calculated using fixed- and random-effects models.[5] We tested the significance of heterogeneity between studies using the Q test and I^2 statistic.[3,13] Fixed-effects models were chosen if the Q test was not significant and I^2 was low (<20%). Otherwise, random-effects models were applied. Forest plots were used for presentation of the mean differences in outcomes and confidence intervals from individual studies along with the pooled mean difference and test for homogeneity.

Results

The initial database search yielded 1472 abstracts. After removal of duplicates, 1013 articles remained for review, of which 5 met the criteria for inclusion in the study. Of these 5 articles, 2 were excluded because they were follow-up studies on articles already chosen for review; these patient populations could not be considered separately from their original studies for statistical review purposes and were excluded (Fig. 1). Thus, 3 studies with a total of 269 patients with 1-year follow-up were included.[12,15,20] Patient demographic data and study characteristics are displayed in Table I. All studies had similar follow-up intervals and a minimum of 12 months' follow-up.

One study included 3 subgroups of patients for analysis, 1 of which underwent physical therapy and subacromial decompression without rotator cuff repair.[15] This cohort of patients (57 patients) was excluded. This same study used a subscale of the Constant score (scale of 0-15) to measure pain instead of a VAS (scale of 0-10). These pain scores were plotted on a graph from which no numerical data could accurately be extracted. This study was not included in the analysis of VAS scores. The Q test was not significant, and

Table I Study characteristics

	Kukkonen et al[15]	Moosmayer et al[20]	Heerspink et al[12]
Total patients	110*	103	56
Sex, n			
Men	50	73	35
Women	60	30	21
Treatment, n			
Nonoperative	55	51	31
Operative	55	52	25
Average age, yr	65	60	60
Follow-up, mo	3, 6, and 12	6 and 12	12

* One-third of patients (n = 57) received physical therapy and subacromial decompression without rotator cuff repair and were excluded from this study.

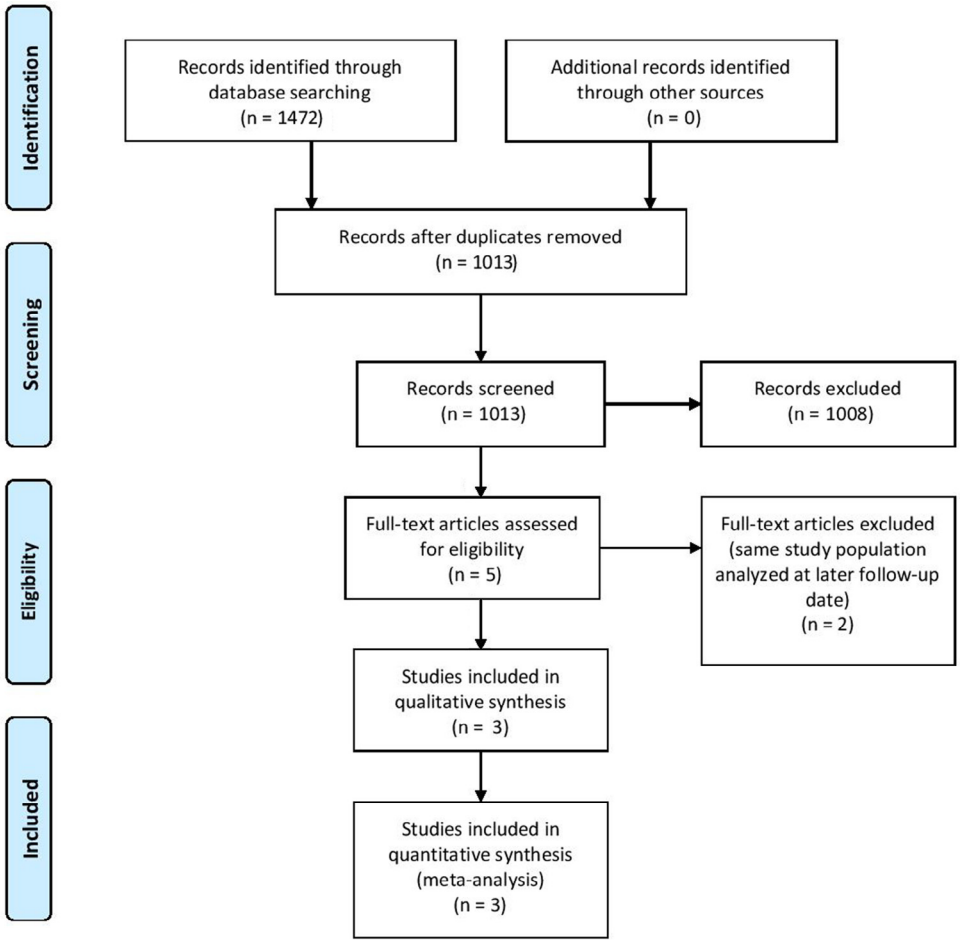

Figure 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram. Modified from Moher D, Liberati A, Tetzlaff J, Altman DG, Prisma Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6:e1000097. http://dx.doi.org/10.1371/journal.pmed.1000097.[19]

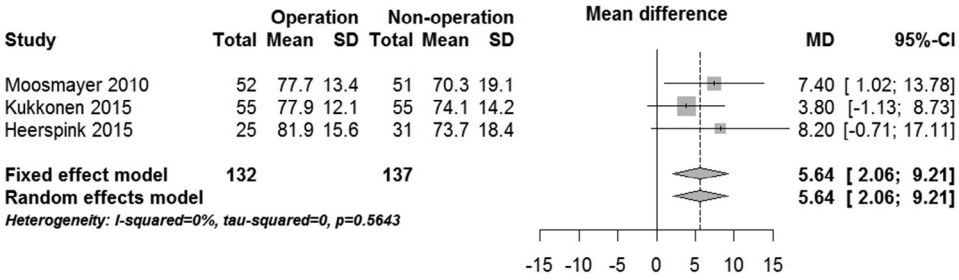

Figure 2 Forest plot for Constant scores. *SD*, standard deviation; *MD*, mean difference; *CI*, confidence interval.

I^2 equaled 0 for both outcomes, implying low between-study heterogeneity. Therefore, our results were derived from mean differences calculated using fixed-effects models (Figs. 2 and 3).

A greater improvement in Constant score was found in operative patients relative to patients treated nonoperatively, and this was statistically significant. The mean difference between operatively treated patients and nonoperatively treated patients was 5.64 (95% confidence interval, 2.06-9.21; $P = .002$). Patients treated operatively had significantly decreased pain scores at 1-year follow-up as compared with the nonoperative cohort, with a mean difference in VAS score of −1.08 (95% confidence interval, −1.56 to −0.59; $P < .0001$).

Discussion

The combined analysis of the 3 randomized controlled trials showed a statistically significant benefit in both Constant and VAS scores for the operative cohort compared with the

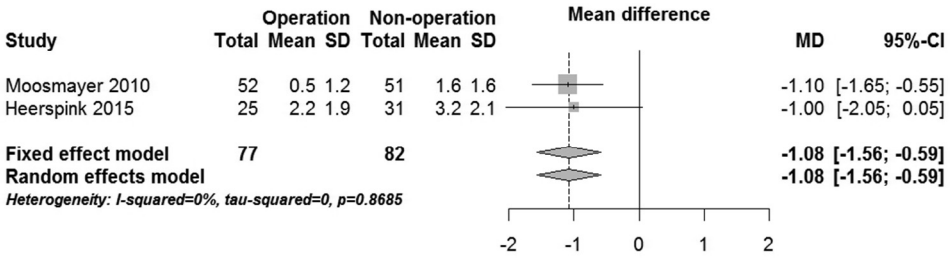

Figure 3 Forest plot for visual analog scale (*VAS*) scores. *SD*, standard deviation; *MD*, mean difference; *CI*, confidence interval.

nonoperative cohort. However, both values were below the minimal clinically important differences of 10.4 and 1.4 for the Constant and VAS scores, respectively.[16,23] The clinical significance of this statistical advantage is therefore limited. Many studies have evaluated the success of surgical and nonsurgical management of small- and medium-sized rotator cuff tears, but high-level direct comparisons are few. In the short term, there is not a significant clinical advantage to operative treatment. Whether longer-term follow-up will demonstrate clinical superiority of either treatment cannot be determined from the current data. Two-year follow-up of the patients studied by Kukkonen et al[15] showed clinical equivalence persisted between all treatment groups. Five-year follow-up reported by Moosmayer et al[20] showed 37% of patients treated without surgery had tear progression on ultrasound imaging, and this correlated with worsening clinical outcome scores. Of 52 patients, 12 opted to undergo later surgical repair, but clinically significant differences between the 2 treatment groups were not present at later time points.

Tear progression remains a concern with nonoperative treatment because spontaneous healing of a torn rotator cuff tendon is not thought to occur.[14] Tear size may increase in most patients over a period of 2 or more years.[20,24] Whether the progression of rotator cuff tearing is a sufficient risk to warrant prophylactic tendon repair remains unknown. Although rotator cuff repair may halt further tear progression, fatty infiltration, and muscle atrophy, even the most successful repair cannot reverse pre-existing degenerative changes within the rotator cuff.[10] Dunn et al[6] showed that patient expectations are the most significant factor influencing the success of nonoperative treatment, and patients who choose to undergo surgery after initial nonoperative treatment typically do so in the first 12 weeks. This would suggest that tear progression and its clinical sequela, which are unlikely to change during such a short time, do not affect a patient's decision for surgery. Structural factors such as tear size and retraction were, in fact, not predictors for choosing surgery in this cohort.

The limitations of this meta-analysis are directly related to the inherent characteristics of the 3 studies included. Although these were well-designed trials, there were differences among them that made their grouping imperfect. There was variation in the types of rotator cuff tears included. Kukkonen et al[15] limited their inclusion criteria to isolated supraspinatus tears, whereas Heerspink et al[12] included both infraspinatus and subscapularis tears in addition to tears of the supraspinatus. Whereas both Moosmayer et al[20] and Kukkonen et al[15] were clear in their exclusion of massive cuff tears, maximum tear size was not explicitly limited by Heerspink et al. Tear size has consistently been shown to be inversely proportional to treatment success of tendon repair.[10] Although appropriate randomization should ensure that this variable is equally distributed between treatment groups within a single trial, the effect on the intertrial comparison is unknown. A subset of traumatic rotator cuff tears was also included in the study by Moosmayer et al. These patients were not subdivided from the atraumatic cuff tear group in the analysis and may have influenced the findings that more strongly favored surgery than the other trials.

Lack of uniformity in treatment modalities among the 3 studies was another limitation. Heerspink et al[12] used a standardized physical therapy protocol, but the other studies did not. Heerspink et al also offered a maximum of 3 corticosteroid injections to the control group in addition to formal physical therapy sessions. The duration of physical therapy was not controlled and was left to the patient's discretion. Surgical technique also lacked uniformity between studies. Two of the three studies performed cuff repair via an open or mini-open approach, whereas the other study used arthroscopy. These techniques have been shown to be equivalent for most tear sizes and are unlikely to substantially alter outcomes.[2] Supplemental procedures such as acromioplasty and biceps procedures were left to the discretion of the surgeon, and their effect on clinical outcomes remains a matter of controversy.[9]

Conclusion

On the basis of the results of this meta-analysis, there is a statistically significant advantage in both objective and subjective outcomes for patients treated with surgery for a full-thickness rotator cuff tear. However, this statistical advantage is not a clinically significant one. The most remarkable finding of this study is the paucity of high-level evidence available to guide treatment of full-thickness rotator cuff tears. Both operative managementand nonoperative management reliably improve func-

tional outcome and pain scores and are reasonable initial treatment choices. Longer-term follow-up and larger studies are needed to determine whether the risk of tear progression and irreversible degeneration of the rotator cuff are sufficiently high to warrant early tendon repair.

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References

1. Bartolozzi A, Andreychik D, Ahmad S. Determinants of outcome in the treatment of rotator cuff disease. Clin Orthop Relat Res 1994;(308):90-7.
2. Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. J Shoulder Elbow Surg 2006;15:290-9. http://dx.doi.org/10.1016/j.jse.2005.09.017
3. Cochran WG. The combination of estimates from different experiments. Biometrics 1954;10:101-29.
4. Colvin AC, Egorova N, Harrison AK, Moskowitz A, Flatow EL. National trends in rotator cuff repair. J Bone Joint Surg Am 2012;94:227-33. http://dx.doi.org/10.2106/JBJS.J.00739
5. DerSimonian R, Laird N. Meta-analysis in clinical trials. Control Clin Trials 1986;7:177-88.
6. Dunn WR, Kuhn JE, Sanders R, An Q, Baumgarten KM, Bishop JY, et al. 2013 Neer Award: predictors of failure of nonoperative treatment of chronic, symptomatic, full-thickness rotator cuff tears. J Shoulder Elbow Surg 2016;25:1303-11. http://dx.doi.org/10.1016/j.jse.2016.04.030
7. Fucentese SF, Andreas L, Pfirrmann CW, Gerber C, Jost B. Evolution of nonoperatively treated symptomatic isolated full-thickness supraspinatus tears. J Bone Joint Surg Am 2012;94:801-8. http://dx.doi.org/10.2106/JBJS.I.01286
8. Galatz LM, Griggs S, Cameron BD, Iannotti JP. Prospective longitudinal analysis of postoperative shoulder function. J Bone Joint Surg Am 2001;83:1052-6.
9. Gartsman GM, O'Connor DP. Arthroscopic rotator cuff repair with and without arthroscopic subacromial decompression: a prospective, randomized study of one-year outcomes. J Shoulder Elbow Surg 2004;13:424-6. http://dx.doi.org/10.1016/j.jse.2004.02.006
10. Gladstone JN, Bishop JY, Lo IK, Flatow EL. Fatty infiltration and atrophy of the rotator cuff do not improve after rotator cuff repair and correlate with poor functional outcome. Am J Sports Med 2007;35:719-28. https://doi.org/10.1177/0363546506297539
11. Goldberg BA, Nowinski RJ, Matsen FA III. Outcome of nonoperative management of full-thickness rotator cuff tears. Clin Orthop Relat Res 2001;(382):99-107.
12. Heerspink FO, van Raay JJ, Koorevaar RC, van Eerden PJ, Westerbeek RE, van't Riet E, et al. Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial. J Shoulder Elbow Surg 2015;24:1274-81. http://dx.doi.org/10.1016/j.jse.2015.05.040
13. Higgins J, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses [journal article as teaching resource, deposited by John Flynn]. BMJ 2003;327:557-60. http://dx.doi.org/10.1136/bmj.327.7414.557
14. Keener JD, Galatz LM, Teefey SA, Middleton WD, Steger-May K, Stobbs-Cucchi G, et al. A prospective evaluation of survivorship of asymptomatic degenerative rotator cuff tears. J Bone Joint Surg Am 2015;97:89-98. http://dx.doi.org/10.2106/JBJS.N.00099
15. Kukkonen J, Joukainen A, Lehtinen J, Mattila KT, Tuominen EK, Kauko T, et al. Treatment of nontraumatic rotator cuff tears. A randomized controlled trial with two years of clinical and imaging follow-up. J Bone Joint Surg Am 2015;97:1729-37. http://dx.doi.org/10.2106/JBJS.N.01051
16. Kukkonen J, Kauko T, Vahlberg T, Joukainen A, Äärimaa V. Investigating minimal clinically important difference for Constant score in patients undergoing rotator cuff surgery. J Shoulder Elbow Surg 2013;22:1650-5. http://dx.doi.org/10.1016/j.jse.2013.05.002
17. Mather RC, Koenig L, Acevedo D, Dall TM, Gallo P, Romeo A, et al. The societal and economic value of rotator cuff repair. J Bone Joint Surg Am 2013;95:1993-2000. http://dx.doi.org/10.2106/JBJS.L.01495
18. Mitchell C, Adebajo A, Hay E, Carr A. Shoulder pain: diagnosis and management in primary care. BMJ 2005;331:1124-8. http://dx.doi.org/10.1136/bmj.331.7525.1124
19. Moher D, Liberati A, Tetzlaff J, Altman DG, Prisma Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med 2009;6:e1000097. http://dx.doi.org/10.1371/journal.pmed.1000097
20. Moosmayer S, Lund G, Seljom U, Svege I, Hennig T, Tariq R, et al. Comparison between surgery and physiotherapy in the treatment of small and medium-sized tears of the rotator cuff: a randomised controlled study of 103 patients with one-year follow-up. Bone Joint J 2010;92:83-91. http://dx.doi.org/10.1302/0301-620X.92B1.22609
21. Rees JL. The pathogenesis and surgical treatment of tears of the rotator cuff. Bone Joint J 2008;90:827-32. http://dx.doi.org/10.1302/0301-620X.90B7.19874
22. Safran O, Schroeder J, Bloom R, Weil Y, Milgrom C. Natural history of nonoperatively treated symptomatic rotator cuff tears in patients 60 years old or younger. Am J Sports Med 2011;39:710-4. http://dx.doi.org/10.1177/0363546510393944
23. Tashjian RZ, Deloach J, Porucznik CA, Powell AP. Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease. J Shoulder Elbow Surg 2009;18:927-32. http://dx.doi.org/10.1016/j.jse.2009.03.021
24. Yamaguchi K, Tetro AM, Blam O, Evanoff BA, Teefey SA, Middleton WD. Natural history of asymptomatic rotator cuff tears: a longitudinal analysis of asymptomatic tears detected sonographically. J Shoulder Elbow Surg 2001;10:199-203.
25. Zingg PO, Jost B, Sukthankar A, Buhler M, Pfirrmann CW, Gerber C. Clinical and structural outcomes of nonoperative management of massive rotator cuff tears. J Bone Joint Surg Am 2007;89:1928-34. http://dx.doi.org/10.2106/JBJS.F.01073