

Executive Summary

Comparative effectiveness research of conservative treatment and rotator cuff repair for the patient with rotator cuff tears

Jae-Young Lim^{1,2,3}, Ji Eun Choi¹, Min Jee Kim¹, Seihee Kim¹, Yunjung Kim¹, Hyun Kyung Do³, Seongwoo Seo¹, Shi-Uk Lee^{2,4}, Woo Hyung Lee³, Joong Hoon Lee³, Soong-nang Jang⁶, Sun Gun Chung^{2,5}, Seul gy choi¹, Jinseub Hwang¹

1. National Evidence-Based Healthcare Collaborating Agency, Seoul
2. Dept of Rehabilitation Medicine, Seoul National University College of Medicine
3. Seoul National University Bundang Hospital, Seongnam
4. Seoul National University Hospital, Seoul, Seoul
5. SMG-SNU Boramae Medical Center, Seoul
6. Red Cross College of Nursing, Chung-Ang University, Seoul

□ Introduction

Due to population aging, emphasis on prolonged and healthy lives, and advancement in radiologic diagnostics, the interest in the most effective treatment and management of rotator cuff tears has been growing in recent years, leading to the development of various novel or improved treatment methods, including surgeries. However, the clinical evidence for the proper therapeutic indications of rotator cuff tears in middle-aged and elderly patients is inadequate, and objective evidences are still lacking.

Therefore, the main objective of the present study was to compare the effects of conservative versus surgical treatment in patients with rotator cuff tears by: 1) identifying the status of and trends in treatments for patients with rotator cuff tears in Korea; 2) comparing the effects of surgical

treatment versus conservative treatment through a systematic review of the literature on the treatment of rotator cuff tears; 3) comparing the effects of arthroscopic rotator cuff repair versus conservative treatment by establishing a retrospective cohort of patients with small and medium complete tears, as well as high-grade partial tears, for which the decision on the treatment method is difficult in the actual clinical setting; and 4) identifying the expert perspectives on the treatment of rotator cuff tears.

□ Current state of treatments for rotator cuff tears

To identify the current state of treatments for rotator cuff lesion pathology, claims data from the National Health Insurance Service, covering 10 years between 2004 and 2013, were used. For the selection of the study subjects, claims statements of those 50 years or older who had shoulder lesions (code: M75), damages to the rotator cuff muscles or tendons (S460), acromioplasty (N0935), acromioplasty and rotator cuff tear repair (primary suture) (N0936), and/or acromioplasty and rotator cuff tear repair (accompanying myoplasty and tenoplasty) (N0937) were analyzed. The current state of non-surgical therapy was analyzed using the codes for injection therapy, physical therapy, exercise therapy, acupuncture, bead therapy, cupping therapy, and hot-and-cold meridian therapy in patients who met the above conditions.

The analysis results revealed that the number of claims paid for shoulder lesions and damages to the muscles and tendons of the shoulder rotator cuff increased by 10.0~15.0% annually, while the numbers of acromioplasty (N0935) and acromioplasty and rotator cuff tear repair (N0936, N0937) also showed increasing trends every year. Similarly, the state of non-surgical therapies, including injection therapy, also showed an annual increase of 10.0~15.0%, and the number of claims for acupuncture, dialectical royalty fee, bead therapy, cupping therapy, and hot-and-cold meridian therapy, which were covered starting from 2010, showed increasing trends as well.

As of 2013, the number of patients who underwent undergoing acromioplasty or acromioplasty and rotator cuff tear repair was 55,854,

while the number of patients treated by non-surgical therapies, such as injection therapy, was 2,082,658, exceeding 2 million for the first time. Among these patients, the number of patients who received Western, or conventional, treatment was 1,473,117, while patients who received Chinese, or alternative, medicine treatment was 855,980. Based on the claim data, which contained both the disease and surgery codes, the mean duration of hospital stay was 6.5 days for top-tier general hospitals, 14.6 days for general hospitals, 10.5 days for clinics, and 10 days for Oriental medical centers, with the duration of stay ranging from 8.1 to 18.3 days, depending on the type and location of the care facility.

□ Comparison of the effects of surgical treatment versus conservative treatment through a systematic literature review

To compare the effects of the various treatment methods for rotator cuff tears, we conducted a thorough systematic review (until September 2014), using a total of 10 databases, including Ovid-Medline, Ovid-Embase, Cochrane central, AMED, CINAHL, and PubMed from overseas, and KoreaMed, Korean Medical database, academic journal database, and Korea Education and Research Information Service from Korea, with emphasis on randomly-assigned comparative clinical trials on conservative and surgical treatments of rotator cuff tears. Two independent reviewers extracted the data using a predetermined literature exclusion strategy and extraction format. Furthermore, the quality of the literature was assessed independently by using the Cochrane Risk of Bias tool. Considering the variability in rotator cuff tear treatment methods, an indirect comparative analysis was used to compare the treatments when randomly-assigned comparative clinical trials that directly compared the treatments were unavailable.

A total of 8 studies were finally selected, and since intention-to-treat (ITT) analysis and per-protocol (PP) groups were intermixed in some studies, analyses on both of these analysis groups were conducted in the present study.

Seven studies reported on the levels of functional improvement. In the ITT analysis groups, patients who received physiotherapy after open rotator cuff repairs showed clinically significant functional improvements compared to patients who received physiotherapy after mini-open rotator cuff repair and those who only received physiotherapy (mean differences, 11.9 and 11.0 points, respectively). There was no significant difference in the functional improvement between the other treatments. In the PP analysis groups, studies that included open rotator cuff repair were excluded, and no significant differences in the functional improvements were observed between all treatments, including for stand-alone physiotherapy.

In terms of the range of motion (ROM), two studies on forward flexion and external rotation were analyzed, and since both studies presented only the values analyzed by ITT, PP analysis was not performed. The analysis results revealed that the group that received early passive motion physiotherapy after arthroscopic rotator cuff repair showed a significantly higher ROM of approximately 9-10° in forward flexion and external rotation one year after the treatment compared to the group that received initial physiotherapy after mini open repair of the rotator cuff. However, the differences were not clinically significant.

For the level of change in terms of the pain, 4 studies were analyzed. In the ITT analysis group, arthroscopic rotator cuff repair, combination of arthroscopic rotator cuff repair and platelet-rich plasma therapy, acromioplasty, and open rotator cuff repair showed decreases in pain one year after treatment compared to e physiotherapy alone. In the PP analysis group, after excluding studies on physiotherapy that reported only the results of ITT analyses, arthroscopic rotator cuff repair using platelet-rich plasma were found to be associated with a statistically significant improvement in pain compared to mini open repair of the rotator cuff (mean difference, 0.4 points); however, the difference was not considered clinically significant.

□ Outcomes analysis using retrospective cohort data

To compare the outcomes of arthroscopic rotator cuff repair, which is the most commonly used treatment for rotator cuff tears, and conservative treatment, a patient registration database was established by retrospectively investigating the medical records of subjects 50 years or older who received treatments for rotator cuff tears between 2008 and 2013 from 3 university hospitals located in Seoul and Gyeonggi-do and who met all the following selection criteria :patients who had high-grade partial (fiber disruption >50%) or small-to-medium-sized full thickness tears (≤ 3 cm) were included in this study. Patients were excluded if they had 1) severe adhesive capsulitis ($< 120^\circ$ in forward flexion or $< 40^\circ$ in external rotation), 2) neuropathy affecting the shoulder girdle muscles, or 3) pre-existing low-grade partial-thickness (fiber disruption $< 50\%$) or large-to-massive-sized full-thickness tears (≥ 3 cm). The outcome variables included the pain and ROM at 3, 6, and 12 months after treatment, and propensity score matching was performed using basic characteristic variables, from which differences in the changes between different treatments were identified using a generalized estimation system model with the matched subjects as the basis.

A total of 337 study subjects were included in the analysis, including 157 who received conservative treatment and 180 who received surgical treatment. The result of applying the generalized estimating equation for the changes in pain demonstrated that both groups showed a tendency of decreased pain over time; at 3 and 6 months, the surgical treatment group showed a statistically significant decrease in pain compared to the conservative treatment group, whereas no significant difference in pain was observed at 12 months.

In terms of the ROM, the surgical treatment group had a significantly smaller mean ROM compared to the conservative treatment group at 3 months, while no significant difference was noted at 12 months.

A total of 5.7% and 5.0% of patients switched from surgical to conservative treatment and vice versa in the conservative and surgical treatment groups,

respectively, while the re-tear rate at 12 months was reported to be 8.3% in the surgical treatment group.

□ Survey of expert perceptions on the treatment and management of rotator cuff lesions

An online survey was conducted between November 4th and December 7th 2014 on 226 specialists from the fields of orthopedics, rehabilitative medicine, rheumatology, anesthesiology, and family medicine who treat patients with rotator cuff tears, to examine the multi-disciplinary expert perceptions on the appropriate management of rotator cuff tears, with the aim to establish effective treatment and management programs. In terms of the natural progression of rotator cuff tears, the most common perceptions were that the size of the tear would increase (n=146, 64.6%) and that the activities of daily living would worsen without treatment (n=143, 63.3%). In terms of the pain of these patients, most experts (n=84, 37.2%) responded that it would increase. Regarding conservative treatment, the most common perceptions were that the size of the tear would remain the same (n=81, 35.8%), that the pain would decrease (n=188, 83.2%), and that the activities of daily living would be improved (n=170, 75.2%). Finally, in terms of surgical treatment, the most common perceptions were that the pain would decrease (n=164, 72.6%) and that the activities of daily living would be improved after surgery (n=174, 77%).

Regarding clinicians choosing not perform therapeutic management of rotator cuff tears, the consensus between the doctors who do perform treatments was that general monitoring of progression was viewed as 'controversial' (n=112, 49.6%) or 'highly controversial' (n=18, 8%), suggesting that there is discrepancy between the experts.

With respect to factors with clinical significance for the decision-making of applying surgical treatment, as assessed on a 5-point Likert scale, the patient age had the highest score, with 4.45 points, followed by the type of tear based on the radiologic evaluation (4.37 points), level of patient

activities of daily living (4.26 points), agreement between the symptoms and physical examination of the rotator cuff tear (4.22 points), weakness (4.19 points), pain severity (4.14 points), occupation (4.13 points), and size of the tear based on the radiologic evaluation (4.09 points).

Next, the patient characteristics were classified into 13 types according to the presence of injury, presence of symptoms, full-thickness tear, and the size of the tear, and a survey was conducted on whether representative sets of patient characteristics indicated surgical or conservative treatment. The indications for which more than 70% of the respondents agreed on the treatment totaled 7, including: conservative treatment for symptomatic non-traumatic full-thickness rotator cuff tear with tear size smaller than 1 cm (n=166, 73.5%); surgical treatment for symptomatic non-traumatic full-thickness rotator cuff tear with tear size bigger than 5 cm (n=166, 73.5%); conservative treatment for symptomatic non-traumatic full-thickness rotator cuff tear with mild impairment (n=213, 94.2%); conservative treatment for traumatic full-thickness rotator cuff tear with tear size smaller than 1 cm (n=164, 72.6%); surgical treatment for traumatic full-thickness rotator cuff tear with tear size smaller than 3~5 cm (n=167, 73.9%); surgical treatment for traumatic full-thickness rotator cuff tear with tear size bigger than 5 cm (n=191, 84.5%); and conservative treatment for traumatic partial rotator cuff tear with mild impairment (n=201, 88.9%).

□ Conclusion and policy recommendations

The medical costs associated with surgical and conservative treatments of rotator cuff tears are constantly increasing in Korea. Although both surgical and conservative treatments for rotator cuff tears have been shown to significantly improve the functional state, pain, and ROM compared to before the treatment, strong evidence for determining which of the two treatment methods is more effective is still lacking. Furthermore, there are still disagreements between specialists who diagnose and treat rotator cuff tears in terms of the most appropriate treatment and the surgical

indications, causing clinical confusion.

Therefore, based on the findings of the present study, further clinical trials and feasibility studies on the factors that influence the indications for the appropriate treatment of rotator cuff tears are needed to help select the appropriate treatment and to ensure effective utilization of medical expenditure.

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Key words

rotator cuff tear, surgical treatment, conservative treatment, functional state, pain, range of motion