

Further Research Is Needed to Define the Benefits of Non-operative Rotator Cuff Treatment

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Abstract Kukkonen et al.'s "Treatment of Nontraumatic Rotator Cuff Tears: A Randomized Controlled Trial with Two Years of Clinical and Imaging Follow-up" compared the efficacy of physical therapy, acromioplasty, and rotator cuff repair for the treatment of degenerative supraspinatus tendon tears in patients aged over 55. This review examines the authors' findings and their implications on clinical practice. Kukkonen et al. reported no significant difference in clinical outcome among patients treated operatively versus non-operatively for degenerative rotator cuff tears. The authors concluded that non-operative treatment is an appropriate option for patients aged 55 or older. Rotator cuff treatment outcomes are closely linked to patient age, and while this level I study found no evidence of a benefit of surgical treatment, the age range in the studied demographic was perhaps too wide to draw generalizable conclusions. Furthermore, 2-year follow-up may be inadequate to fully demonstrate the differences in outcomes between these treatment options.

Keywords rotator cuff tear · nontraumatic · non-operative treatment

Introduction

Degenerative rotator cuff tears are a common condition estimated to affect up to 51% of older patients [21, 23].

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Although sometimes asymptomatic, these tears can frequently lead to pain, difficulty with daily activities, and poorer general health status [9, 17].

While atraumatic, full-thickness rotator cuff tears are often surgically repaired [16], it is clear that many patients respond well to non-surgical treatment in the short term. There is no clear consensus on the indications for rotator cuff repair, and there is a lack of data comparing surgical and non-surgical treatment.

Rotator cuff repair surgery has good to excellent outcomes [2, 6], but it is a costly operation with potential for complications [5, 24]. Therefore, it is critically important to identify patients that would most benefit from surgery.

The subject of this review is Kukkonen et al.'s [13] randomized controlled trial, which compared the efficacy of physical therapy, acromioplasty, and surgical repair of degenerative supraspinatus tears in patients over age 55. The authors found no significant difference in outcomes between the groups and thus concluded that non-operative treatment is appropriate in this age group. The aims of the present review are (1) to critically evaluate the methodology, results, and conclusions reported in this study and (2) to discuss the implications of these findings on clinical practice.

The Article

Treatment of Nontraumatic Rotator Cuff Tears: A Randomized Controlled Trial with Two Years of Clinical and Imaging Follow-Up. Kukkonen J, Joukainen A, Lehtinen J, Mattila KT, Touminen EKJ, Kauko T, Aarimaa V. *J Bone Joint Surg Am.* 2015;97:1729–37.

These authors examined the effectiveness of physical therapy, acromioplasty, and surgical repair in the treatment of nontraumatic rotator cuff tears. One hundred sixty patients (167 shoulders) with symptomatic, isolated, full-

thickness supraspinatus tears were followed up for at least 2 years. The age of the study population ranged from 55 to 81 years old. The authors noted that 28 patients with massive rotator cuff tears were excluded, but their specific definition of massive tear was not stated. Only patients with isolated supraspinatus tears were included, thus excluding patients with tears present in multiple tendons. Other exclusion criteria were arthritis, defined by osteophytes visible on radiographs, stiffness of the shoulder joint, defined as passive external rotations less than 30° and/or elevation greater than 120°, and a history of prior shoulder surgery.

The authors noted that 73% of patients in group 1, 55% of patients in group 2, and 57% of patients in group 3 had undergone prior corticosteroid injections. The time of the injections was not noted, and it was not documented if any of the patients underwent corticosteroid injections during the study period.

Patients were randomized to one of the three groups. Patients in group 1 received physical therapy alone. Group 2 included patients who underwent acromioplasty and physical therapy. Patients in group 3 underwent rotator cuff repair, acromioplasty, and physical therapy. The Constant score [8], which assesses range of motion, strength, pain, and activity level, was the primary outcome measure. Secondary outcomes included visual analog scale (VAS) for pain, patient satisfaction, rotator cuff integrity on follow-up MRI, and treatment costs.

The authors found no significant difference in overall Constant scores between the three groups. The Constant subscale scores for pain ($P=0.01$) and activities of daily living ($P<0.01$) were significantly worse in group 1 compared to groups 2 and 3. These data were reported graphically with no raw numbers provided in the manuscript. At 2-year follow-up, the size of the rotator cuff tear on MRI was significantly smaller in group 3 compared to groups 1 and 2. There was no difference in patient satisfaction between the three groups. A total of six patients from groups 1 and 2 crossed over to group 3. The data was analyzed using intention-to-treat analysis.

Commentary

In the treatment of atraumatic, isolated supraspinatus tears in patients older than 55, Kukkonen et al. [13] concluded that there was no significant difference in clinical outcome between operative and non-operative treatment. With an incidence of up to 51%, degenerative rotator cuff tears represent a significant cause of morbidity in older patients [21, 23]. While operative repair has been the standard of care for this condition, it is well known that conservative treatment is effective in many patients.

Few prior studies have examined operative versus non-operative treatment for rotator cuff tears. In their randomized controlled trial, Moosmayer et al. found that operative treatment yielded significantly higher Constant scores, higher American Shoulder and Elbow Surgeons scores, and

improved pain compared to treatment with physical therapy alone at 1- and 5-year follow-up [18, 19]. At 5 years, Moosmayer et al. concluded that these noted improvements were small and may be below clinical importance [19]. More recently, Lambers Heerspink et al. conducted a similarly designed randomized controlled trial of 56 patients with a degenerative full-thickness rotator cuff tear [15]. Analogous to the Kukkonen study, Lambers Heerspink et al. found no significant difference in overall Constant scores at 1-year follow-up. Lambers Heerspink and colleagues did not consider Constant subscales in their analysis. However, significant differences in pain and disability, measured on a VAS scale, were noted in favor of operative treatment. Kukkonen et al.'s study has several strengths. The authors used a standardized physical therapy protocol, and the surgeries were performed by a small number of experienced surgeons. Second, approximately 94% of eligible patients agreed to participate in the study, contributing to a low risk of selection bias and, ultimately, only 7% of patients dropped out. Furthermore, the Constant score, which was used as the primary outcome measure, has been validated in the literature [7] and includes both objective and subjective outcome components. Finally, the authors included MRI findings to further strengthen their analysis.

The study also had several weaknesses. First, it was unblinded to both the patients and the clinicians, which may have introduced bias in both patient-reported and functional outcome data. Second, the authors reported only an intention-to-treat analysis. There was a 9% crossover rate from non-operative to surgical treatment. Although the authors included a table showing the outcome scores of the patients who crossed over, there was no as-treated analysis reported, and it is therefore difficult to determine how these crossover patients may have skewed the outcomes.

The authors chose to restrict the study to patients aged 55 and older, a notable distinction compared to earlier studies. The age range, though, was perhaps too wide to make the results generalizable to all “older” patients. The study included patients ranging in age from 55 to 81, with a mean age of 65. Tashjian et al. [22] and Boileau et al. [4] both demonstrated previously that age is one of the most important factors in predicting rotator cuff healing after surgery. As noted by Yamaguchi [18], the mean age of a patient that heals after rotator cuff repair is between 53 and 55, while the mean age of a patient that does not heal after rotator cuff surgery is between 63 and 65. Relatively younger patients, therefore, have greater healing potential, a potential that may be lost if surgery is delayed. Given their decreased healing potential and decreased demands, a delay to surgery in older patients may be less harmful. Defining the specific age at which non-operative treatment becomes equally or more effective than operative treatment would require further investigation.

The article noted that >50% of patients in each group had undergone prior corticosteroid injections, but there is no comment on corticosteroid injections performed during the

study period [13]. Although the efficacy of corticosteroid injections for treatment of rotator cuff pathology has been questioned [11], some studies have shown that injections can be beneficial for both pain [1] and range of motion [1, 3, 20] in patients with rotator cuff disease. Given the lack of explanation in the Kukkonen et al. study, it is unclear how injections of corticosteroids may have biased the overall results.

Kukkonen and colleagues initially published the results of this trial with 1-year outcome data [12] and found no significant difference in overall Constant scores and no significant difference in any of the Constant subscales between the three groups. In the present study at 2-year follow-up, a statistically significant difference between operative and non-operative treatment in two of the Constant subscales had emerged [13]. It is possible, however, that the 2-year follow-up period presented in this study may not be long enough to fully elucidate all of the differences in outcomes between operative and non-operative treatment. At 2-year follow-up, the mean tear size was significantly smaller in the repair group. This finding is consistent with the documented natural history of rotator cuff tears [7]. The progression in tear size is often associated with worsening symptoms [10]. It is conceivable, then, that tear progression at greater than 2 years could lead to clinically significant differences in pain and function.

Finally, the authors noted that the subjective subscales of the Constant score (pain and activities of daily living) were significantly worse for patients who had undergone non-operative treatment. These differences in scores were noted to be small and perhaps clinically irrelevant. Prior research has defined the minimal clinically important difference (MCID) for the overall Constant score as 10.4 points [14]. No studies have been done to evaluate the MCID for the constant subscale scores. In the Kukkonen et al. article [13], the data on Constant subscales was only reported graphically, without raw numbers reported, which precludes further analysis. At this point, it is difficult to determine the clinical relevance of these subscale differences, and further longer-term investigation would be needed to evaluate the significance.

Interpreted in the context of the current literature, the results of this study suggest that older patients (>65 years old) are less likely to benefit from surgery. It is reasonable, then, to consider initial non-operative care in older patients. It remains unclear, however, how to best counsel younger patients (<60–65) with a full-thickness rotator cuff tear. There is a role for surveillance of tear progression in these patients, the goal of which is to avoid tear progression and worsening symptoms before the biology of the tear and the patient's age adversely affect healing potential. Longer-term follow-up is required to better define the age after which patients are unlikely to benefit from rotator cuff repair and to better understand the consequences of non-operative treatment.

Compliance with Ethical Standards

Conflict of Interest: Cynthia A. Kahlenberg, MD, and David M. Dare, MD, have declared that they have no conflict of interest. Joshua S. Dines, MD reports other from American Journal of Orthopedics, American Shoulder and Elbow Surgeons, and Journal of Shoulder and Elbow Surgery and received personal fees from Arthrex, Biomet, CONMED Linvatec, Ossur, and Wolters Kluwer Health, outside the work.

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