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A Prospective Multipractice Investigation of Patients with Full-Thickness Rotator Cuff Tears: The Importance of Comorbidities, Practice, and Other Covariables on Self-Assessed Shoulder Function and Health Status

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Supplementary material

Commentary and Perspective, data tables, additional images, video clips and/or translated abstracts are available for this article. This information can be accessed at <http://www.ejbs.org/cgi/content/full/85/4/690/DC1>

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A PROSPECTIVE MULTIPRACTICE INVESTIGATION OF PATIENTS WITH FULL-THICKNESS ROTATOR CUFF TEARS

THE IMPORTANCE OF COMORBIDITIES, PRACTICE, AND OTHER COVARIABLES ON SELF-ASSESSED SHOULDER FUNCTION AND HEALTH STATUS

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Background: Rotator cuff tears are among the most common conditions of the shoulder. One of the major difficulties in studying patients with rotator cuff tears is that the clinical expression of these tears varies widely and different practices may have substantially different patient populations. The goals of the present prospective multipractice study were to use patient self-assessment questionnaires (1) to identify some of the characteristics of patients with rotator cuff tears, other than the size of the cuff tear, that are correlated with shoulder function, and (2) to determine whether there are significant differences in these characteristics among patients from the practices of different surgeons.

Methods: Ten surgeons enrolled a total of 333 patients with a full-thickness tear of the supraspinatus tendon into this prospective study. Each patient completed self-assessment questionnaires that included items regarding demographic characteristics, prior treatment, medical and social comorbidities, general health status, and shoulder function.

Results: As expected, patients who had an infraspinatus tendon tear as well as a supraspinatus tendon tear had significantly worse ability to use the arm overhead compared with those who had a supraspinatus tear alone ($p < 0.005$). However, shoulder function and health status were correlated with patient characteristics other than the size of the rotator cuff tear. The number of shoulder functions that were performable was correlated with the subscales of the Short Form-36 and was inversely associated with medical and social comorbidities. The patients from the ten different surgeon practices showed significant differences in almost every parameter, including age, gender, method of tear documentation, tear size, prior treatment, medical and social comorbidities, general health status, and shoulder function.

Conclusions: Clinical studies on the natural history of rotator cuff tears and the effectiveness of treatment must control for a wide range of variables, many of which do not pertain directly to the shoulder. Patients from the practices of different surgeons cannot be assumed to be similar with respect to these variables. Patient self-assessment questionnaires appear to offer a practical method of uniform assessment across different practices.

Level of Evidence: Prognostic study, Level I-1 (prospective study). See Instructions to Authors for a complete description of levels of evidence.

Rotator cuff tears are among the most common clinical problems of the shoulder¹⁻³. While the efficacy of treatment of cuff tears in the context of specialized practices is well documented⁴⁻¹², the effectiveness and appropriateness of rotator cuff tear treatment across multiple practices is essentially unknown. The assessment tools applicable to multipractice studies are, of necessity, different from those that are used in a single practice. Clinical research on the efficacy of treatment of rotator cuff tears across the orthopaedic community is further complicated by the many factors that may affect the preoperative and postoperative function of the shoulder, such as tear size^{11,13-19}, chronicity¹⁷, and degree of functional loss¹⁷. Consider-

ing the number of observers and the different imaging methods that are used to evaluate these tears, one can understand how characterizing these variables in a consistent manner across multiple practices would be challenging.

Duckworth et al.²⁰ and others^{16,17,21-26} have documented substantial variation in the clinical manifestation of rotator cuff tears and have pointed out that many of the influential factors are external to the shoulder. Viola et al.²⁷ and others^{10,11,28} have demonstrated that patients whose shoulder conditions were covered by Workers' Compensation had lower self-assessed shoulder function and health status than patients in whom the same shoulder conditions were not related to on-

the-job injuries. Smith et al.²⁹, in a series of 191 patients with rotator cuff tears, found that female gender, involvement of the infraspinatus, and Workers' Compensation claims were correlated with lower shoulder function. Rozencwaig et al.³⁰, in a study of eighty-five consecutive patients with severe glenohumeral degenerative joint disease, found that shoulder function had a negative correlation with the number of comorbidities.

Because most health care is delivered outside major centers, studies of the effectiveness and appropriateness of different treatment strategies that are based on a broad-based population sample from multiple practices are desirable but challenging. To further our understanding of the patients in different practices, we undertook a prospective study of patients with rotator cuff tears from multiple orthopaedic practices with use of patient self-assessment tools. Our first hypothesis was that certain factors external to the shoulder (such as comorbidities, age, and gender) would be correlated with the shoulder function of individuals with rotator cuff tears. Our second hypothesis was that the characteristics of patients with rotator cuff tears would differ among the practices of different orthopaedic surgeons.

Materials and Methods

One hundred and twenty shoulder surgeons (all of whom were members or candidate members of the American Shoulder and Elbow Surgeons) were invited to participate in the present prospective study. While it was recognized that these surgeons are not representative of all orthopaedic surgeons, they were selected as being most likely to enroll patients in the investigation and the group was considered sufficient to test the hypotheses of the study. None of the authors of the present report were invited to enroll patients in the study. Participating surgeons were invited to enroll patients with documented rotator cuff tears after obtaining their informed consent with use of a form approved by our Human Subjects Review Committee. For each enrolled patient, the physician completed a questionnaire regarding the diagnosis and the method with which it had been documented.

Forty-two surgeons enrolled at least one patient; of these, only ten enrolled ten patients or more. The analysis in this paper was restricted to the 369 patients enrolled by the ten surgeons who enrolled ten patients or more. Surgeons who enrolled fewer than ten patients were not included because of concern that these samples would not be representative of their practice. For the purposes of this study, the tear of a rotator cuff tendon was considered to have been documented if the surgeon confirmed that the tear had been observed with arthrography, magnetic resonance imaging, sonography, arthroscopy, surgery, or some combination of these methods. The data from the different practices did not permit us to accurately determine the size of the tear beyond the documentation of which tendons were torn. Specifically, we did not have confidence in the reliability of information regarding the degree of retraction, the dimensions of the tear, or the quality of

the remaining tissue. The thirty-six patients who did not have conclusive documentation of a full-thickness supraspinatus tendon tear were eliminated from further consideration in our analysis. Thus, the final study group consisted of 333 patients with a full-thickness supraspinatus tear (with or without additional cuff defects) from ten different surgeon practices that had enrolled at least ten patients each.

Once the patient had been enrolled in the study, we obtained all subsequent data directly from the patient without any involvement of the physician's office. The patient completed a questionnaire regarding possible medical comorbidities, including back pain, hypertension, degenerative joint disease, heart disease, diabetes, peptic ulcer disease, depression, pulmonary disease, cancer, rheumatoid arthritis, kidney problems, liver problems, and problems with the blood. The questionnaire asked the patient to indicate (1) whether the condition was present, (2) whether the condition was being treated, and (3) whether the condition limited the patient's function. For the purpose of this analysis, 1 "comorbidity point" was assigned for each positive response. Nonmedical, or "social," comorbidities included Social Security, disability, and Workers' Compensation benefits. Nonmedical comorbidities were scored in a manner similar to the medical comorbidities, with the patient indicating whether he or she was receiving benefits, applying for benefits, or planning to apply for benefits. It is recognized that this assignment of points creates only a qualitative indication of the severity of the comorbidity and not a parametric quantification. It is also recognized that the point assignment for the medical and nonmedical comorbidity categories are not parallel: the latter are exclusive, and the former are not. We made no attempt to verify the patients' assessment of these comorbidities.

All patients completed the Short Form-36 (SF-36) health survey^{31,32}. The SF-36 has been widely used for the self-assessment of individuals with shoulder disorders, even though it is not a joint-specific tool^{20,21,33-37}. The SF-36 scores were normalized by dividing by the values for age-matched and gender-matched controls³⁸.

Finally, all patients completed a standardized questionnaire of twelve shoulder functions (the Simple Shoulder Test [SST])^{20,21,33-36,39}. This instrument has been widely used for the self-assessment of shoulder function^{4,5,21,30,33-35,39-48}. In certain analyses, the responses to question 5 ("Can you place a coin on a shelf at the level of your shoulder without bending your elbow?"), question 6 ("Can you lift one pound [a full pint container] to the level of your shoulder without bending your elbow?"), and question 7 ("Can you lift eight pounds [a full gallon container] to the level of your shoulder without bending your elbow?") of the SST were studied separately because of their particular relevance to the ability to elevate the arm, an activity that is recognized as involving the rotator cuff.

Statistical analyses included t tests and analyses of variance and covariance. Statistical tests were performed with use of StatView software (Abacus Concepts, Berkeley, California). Corrections for multiple comparisons were not performed.

Results

Data Relevant to the Entire Population

Three hundred and thirty-three patients were distributed over the ten practices. One hundred and ninety-six (59%) of these patients were male, and the average age (and standard deviation) of the patients was 58 ± 12 years. The medical comorbidities and the number of patients responding positively to each question are shown in Table I. The most prevalent medical comorbidities were back pain, hypertension, and degenerative joint disease.

The social comorbidities are shown in Table II. More than one-third of the patients were receiving Social Security income, and approximately one in five were currently receiving or were seeking Workers' Compensation coverage.

The patients could perform an average of 4.4 (range, zero to twelve) of the twelve functions of the SST (Fig. 1). The self-assessed shoulder function for this group of patients was less than half of that for a group of forty-nine patients who were sixty to seventy years old and had no clinical or sonographic evidence of a rotator cuff tear, who were able to perform all twelve of the SST functions³³ (Appendix). In comparison with the normal controls, the greatest functional deficits among the patients with full-thickness tears were in the ability to throw overhand, the ability to lift 8 lb (3.6 kg) to shoulder level, and the ability to sleep comfortably. Two hundred and sixty-six (80%) of the patients in our study were unable to perform these functions.

Seventy-four (22%) of the 333 patients, including forty-

five (23%) of the male patients and twenty-nine (21%) of the female patients, had an infraspinatus tear in addition to the supraspinatus tear. Patients with a tear involving the infraspinatus as well as the supraspinatus were significantly older than those with a tear confined to the supraspinatus (63.7 ± 9.8 years compared with 56.4 ± 11.8 years; $p < 0.0001$, unpaired t test). Infraspinatus integrity had a significant effect on the four SST functions that required lifting the arm (questions 5, 6, and 7) (Appendix).

Analysis of variance demonstrated a strong positive correlation between male gender and the overall SST score, but it did not demonstrate a significant correlation between infraspinatus integrity and the overall SST score. The relationship between infraspinatus integrity and function was significant when the analysis was confined to the three SST questions concerning the ability to lift different weights to shoulder level (questions 5, 6, and 7) (Appendix).

Shoulder function was negatively correlated with medical comorbidity ($r = -0.167$, $p < 0.005$) and with social comorbidity ($r = -0.181$, $p < 0.001$). Shoulder function was positively correlated with age-corrected and gender-corrected SF-36 scores, especially the comfort and physical function scores. Social comorbidity was negatively correlated with the emotional role function score, the social function score, and the other SF-36 scores. Medical comorbidity was negatively correlated with the general health score, the physical function score, and the other SF-36 scores (Appendix).

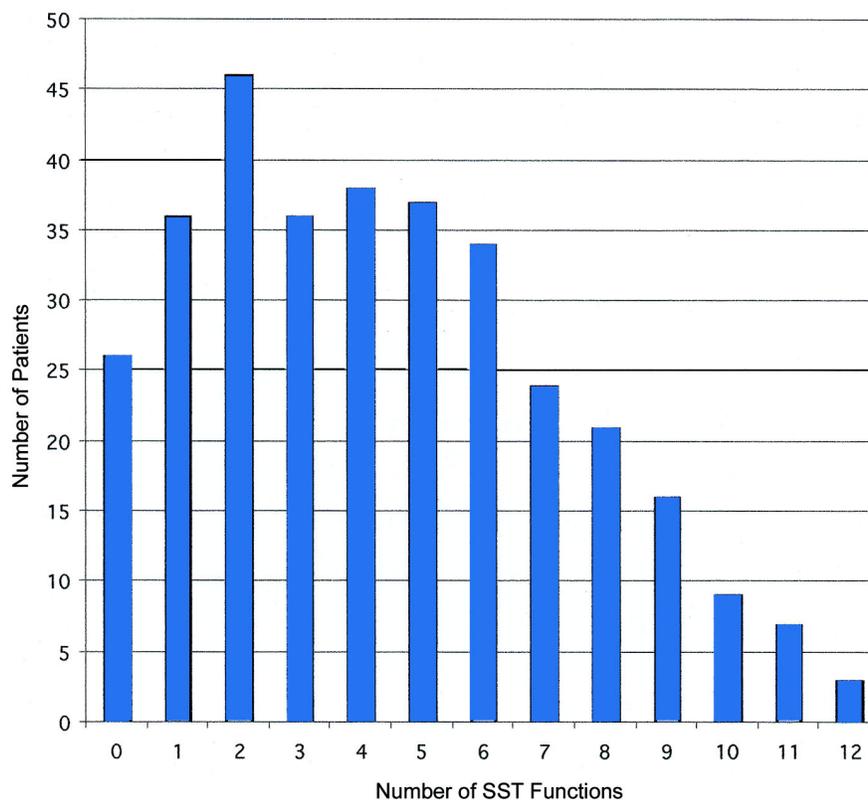


Fig. 1

The frequency distribution of the total number of the twelve Simple Shoulder Test (SST) functions that were performable by the 333 patients.

TABLE I Results of Questionnaire Regarding Thirteen Medical Conditions*

Condition	Question		
	Have You Been Diagnosed with This Condition?	Are You Receiving Treatment for This Condition?	Does This Condition Limit Your Function?
Back pain	90 (27%)	30 (9%)	47 (14%)
Hypertension	80 (24%)	70 (21%)	7 (2%)
Degenerative joint disease	60 (18%)	30 (9%)	30 (9%)
Heart disease	33 (10%)	20 (6%)	7 (2%)
Diabetes	23 (7%)	20 (6%)	3 (1%)
Peptic ulcer disease	23 (7%)	10 (3%)	3 (1%)
Depression	20 (6%)	17 (5%)	0
Pulmonary disease	10 (3%)	7 (2%)	10 (3%)
Cancer	13 (4%)	10 (3%)	3 (1%)
Rheumatoid arthritis	10 (3%)	7 (2%)	3 (1%)
Kidney problems	0	0	0
Liver problems	0	0	0
Blood problems	0	0	0

*The data are given as the number of patients (total, 333) who responded positively to each question, with the percentage in parentheses.

Data Relevant to the Populations of the Different Practices

Analysis of variance indicated that the patients from the ten practices differed significantly with regard to many important variables, including age, gender, method of tear documentation, tendon involvement, prior treatment, medical and social comorbidities, general health status, and shoulder function (Appendix).

Discussion

Most of the current publications regarding rotator cuff tears and their treatment are based on the individual practices of a few specialists using evaluations conducted by the treating physicians and their staff. These reports have described a wide variety of treatment methods, including non-operative management^{5,9}, surgery without repair¹², surgery with repair⁸, repair with acromioplasty^{6,11,16}, repair without acromioplasty⁴, repair with use of tendon transfers⁴⁹⁻⁵¹, repair

with use of grafts^{52,53}, and repair with use of metal reinforcement of the tuberosity⁷. The standardized assessment of patients from multiple practices requires specialized research methodology. Conventional metrics, such as measurements of range of motion and strength, are difficult to standardize across different practices without prohibitive expense in terms of personnel training and time. The advent of validated self-assessment instruments for the documentation of shoulder function and health status makes standardized assessment possible across multiple practices. The aims of the present multipractice study were to use patient self-assessment questionnaires (1) to identify variables other than cuff tear size that are correlated with the shoulder function of patients with rotator cuff tears and (2) to test the hypothesis that patients from different practices differ with respect to these variables.

When viewed as a whole, the study population of patients with supraspinatus tears was similar to that in previously reported series of rotator cuff tears with respect to age

TABLE II Results of Questionnaire Regarding Social Comorbidities*

Comorbidity	Question		
	Are You Currently Receiving Benefits?	Are You Applying for Benefits?	Are You Planning to Apply for Benefits?
Social Security	123 (37%)	7 (2%)	10 (3%)
Workers' Compensation	50 (15%)	13 (4%)	7 (2%)
Disability	17 (5%)	7 (2%)	7 (2%)

*The data are given as the number of patients (total, 333) who responded positively to each question, with the percentage in parentheses.

(average, fifty-eight years), gender (59% male), and prevalence of infraspinatus involvement (23%). Patients with infraspinatus and supraspinatus tears were, on the average, more than seven years older than those with a supraspinatus tear alone.

The typical patient in this series was able to perform only four of the twelve shoulder functions of the SST, whereas normal patients in the same age-group can typically perform all twelve of these functions³³. However, the range of shoulder function among these patients was broad in that some of the patients could perform none of the functions whereas others could perform all twelve. Tears of the infraspinatus were associated with a significantly impaired ability to lift the arm forward ($p < 0.005$). Men had significantly higher self-assessed shoulder function than women did, even when the data were controlled for infraspinatus involvement ($p < 0.005$). The analysis of the effect of medical and social comorbidities indicates that patients with rotator cuff tears often have general health-related issues as well as socioeconomic issues that correlate with their shoulder comfort and function. The significant inverse relationship between comorbidity and shoulder function that was observed in the present study of patients with rotator cuff tears was similar to that reported by Rozenzweig et al.³⁰ in their study of patients with degenerative glenohumeral joint disease.

Medical and social comorbidity scores were negatively correlated with all eight subscales of the SF-36. In their study of patients with degenerative glenohumeral joint disease, Rozenzweig et al.³⁰ also found that the SF-36 subscales had a significant negative correlation with the number of comorbidities and concluded that the SF-36 may provide a practical way to integrate the effects of all potential comorbidities on individual patients. This is particularly important in that any list of potential comorbidities is necessarily incomplete; many such lists fail to include, for example, blindness, spinal cord injury, amputation, crutch use, and domestic considerations.

The ten different practices included in this study varied markedly. Some had predominantly male patients, and others had predominantly female patients. One group of patients was, on the average, more than a decade older than the other groups. Some of the most striking differences concerned the manner in which the cuff tears had been documented. Some of the surgeons had relied heavily on magnetic resonance imaging and arthrography, whereas others had relied on arthroscopy and surgical findings. In some practices only tears of the supraspinatus had been documented, whereas in others infraspinatus tears had been documented in more than half of the patients. The patients from different practices reported substantial variation in the duration of their symptoms, the relationship to injury, and the treatment that they had received prior to entering the study. Four of the twelve patients from one practice had had difficulties with healing following previous surgical procedures, whereas patients from other practices reported no such difficulties. The patients from the practice that had documented no infraspinatus tears reported the best shoulder function, whereas the patients from the

practice that had documented eight infraspinatus tears in twelve shoulders had the worst shoulder function.

We were unable to find any previous reports on variation among physician practices in our review of the orthopaedic literature. However, such variation has been investigated in other disciplines. Miskulin et al.⁵⁴ found significant interpractice variation in a multicenter hemodialysis trial. Those authors suggested that the variability across clinical centers was probably due to differences in the case mix of the patients (that is, differences in mean age, proportion of patients with diabetes, SF-36 scores, and so on) and that comorbidity assessment and standardization are necessary to avoid confounding imbalances across clinical centers in terms of outcome measurements. Flaherty et al.⁵⁵, in a study comparing overall survival and cancer response rates between a single-institution trial and a cooperative group trial, found that the patients in the group trial were older, had worse performance, had more visceral involvement, and were more likely to have two or more metastatic sites. Sagar et al.⁵⁶, in a study examining the morbidity and mortality rates among patients who had been managed by five general surgeons, concluded that direct comparison of surgeon performance can be misleading and that risk-adjusted analysis is more meaningful because of the differences in the case mix and physiologic status of the different patient groups. Taken together with our results, those studies indicate that prospective investigations across multiple practices can be carried out but that great care must be taken to identify and control for critical variables, such as age, gender, health status, and comorbidities; it cannot be assumed that all practices will consist of patients who are similar.

The present study must be interpreted in view of certain limitations. We did not verify that all patients with rotator cuff tears seen by each of the participating surgeons had been submitted to the investigators. We did not verify the documentation of the tears but rather accepted the decision of the individual surgeon in this matter. No characterizations of the size of the tear, the degree of retraction, the quality of the tendon, atrophy, or fatty degeneration were attempted because of concern about interobserver variation in the interpretation of these factors. We did not verify the individual patients' assessments of their health status, comorbidities, treatment history, or shoulder function. The surgeons who participated in this study did not represent the diversity of practices in the United States but rather represented surgeons who were most likely to participate in such a study. Only a fraction of the surgeons who had been invited to participate did so, and only a fraction of the participating physicians enrolled ten patients or more. Many rotator cuff tears are treated by individuals other than orthopaedic surgeons. Finally, the list of covariables considered in this analysis is incomplete, and many other factors may have been correlated with the shoulder function of these patients.

In conclusion, the present investigation demonstrates that self-assessment of shoulder function and health status provides a practical means with which patients from multiple practices can be assessed in a standardized manner. This observation greatly increases the number of cases that could

potentially be included in clinical research regarding rotator cuff tears. In addition, this study demonstrates that multiple factors, in addition to the number of tendons that are torn, are associated with the function of patients with rotator cuff tears. Finally, this investigation shows that patients with rotator cuff tears from different practices cannot be assumed to be samples of the same population. We conclude that multipractice studies are challenging to conduct properly and must involve a conscientious effort to control multiple variables, including the practice from which the patients were obtained.

Appendix

eA Tables showing the results of the SST, the association of gender and infraspinatus integrity with performance on the SST, the relation of shoulder function to medical comorbidities, and the specific characteristics of each of the ten practices studied are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on "Supplementary Material") and on our quarterly CD-

ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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