The Rotator Cuff Quality-of-Life Index Predicts the Outcome of Nonoperative Treatment of Patients with a Chronic Rotator Cuff Tear

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**Background:** Chronic rotator cuff tears are prevalent and can be disabling. The existing literature is unclear regarding the effectiveness of nonoperative treatment. The purposes of this study were to determine whether the outcome of nonoperative treatment can be predicted on the basis of the presenting clinical characteristics and whether the outcome achieved at three months after treatment can be maintained at two years.

**Methods:** The prospective cohort included ninety-three patients with a documented chronic full-thickness rotator cuff tear. Patients underwent a three-month supervised program of nonoperative treatment and were then evaluated by an orthopaedic surgeon. The treatment outcome was defined as a success if surgical treatment was no longer deemed appropriate by both patient and surgeon because the patient had improved considerably and was predominantly asymptomatic. The outcome was defined as a failure if the patient elected to have surgery after failing to improve and remaining symptomatic. The presenting clinical characteristics that were analyzed included age, sex, smoking status, hand dominance, duration of symptoms, onset (traumatic etiology or insidious onset), shoulder motion, external rotation strength, tear size as documented by ultrasonography or magnetic resonance imaging, and the Rotator Cuff Quality-of-Life Index (RC-QOL).

**Results:** Seventy (75%) of the patients were successfully treated. Logistic regression analysis showed that the baseline RC-QOL score was a significant predictor of outcome \( (p = 0.017) \). Eighty-nine percent of patients maintained their three-month outcome at two years of follow-up.

**Conclusions:** The RC-QOL was predictive of the outcome of nonoperative treatment of patients with a chronic full-thickness rotator cuff tear. Patients in whom the nonoperative treatment was deemed successful at the conclusion of three months of treatment had a very high chance of ongoing success at two years after the initiation of treatment.

**Level of Evidence:** Prognostic Level II. See Instructions for Authors for a complete description of levels of evidence.

**Disclosure:**

One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, one or more of the authors has had another relationship, or has engaged in another activity, that could be perceived to influence or have the potential to influence what is written in this work. The complete Disclosures of Potential Conflicts of Interest submitted by authors are always provided with the online version of the article.
TABLE I Inclusion and Exclusion Criteria

Inclusion criteria
Age 40-85 yr
Full-thickness rotator cuff tear confirmed by ultrasonography or MRI
Symptomatic for a minimum of 3 mo

Exclusion criteria
Already exhausted nonoperative treatment (i.e., had already undertaken a 3-mo program of stretching and strengthening exercises, with use of analgesics, anti-inflammatory medications, and/or other modalities, plus or minus injections)
Concomitant symptomatic pathology of the affected shoulder (i.e., instability, high-riding humeral head indicating cuff tear arthropathy, osteoarthritis, or full-thickness tear of subscapularis or teres minor demonstrated on imaging)
Injury/onset of symptoms <3 mo prior
Elite athlete
Substantial cervical spine pathology and/or radiculopathy
Substantial medical issues precluding surgery
Secondary gain issues (i.e., workers’ compensation or litigation)
Unable or unwilling to complete study outcome instruments
Unable or unwilling to provide informed consent

There are many treatment options for patients with a chronic full-thickness rotator cuff tear, ranging from nonoperative to operative. In 1963, Rowe stated, “…the more experienced the surgeon, the more emphasis he will place on the conservative management of rotator cuff lesions, and the slower he is to approach this problem surgically.”

Many surgeons agree that a patient should have exhausted a course of adequate nonoperative or conservative management lasting a minimum of three months before surgery is considered. However, no standard definition of “adequate” exists, nor can one assume that what is adequate for one patient is adequate for another. As there is no consensus regarding adequate nonoperative treatment, it is often overlooked as an effective, noninvasive, and economical treatment option for patients with a chronic, symptomatic, full-thickness rotator cuff tear.

The existing literature reports conflicting results regarding the outcomes of nonoperative treatment for a chronic full-thickness rotator cuff tear, with reported success rates varying between 33% and 92%.

The primary purpose of the present study was to determine whether the outcome of nonoperative treatment of a chronic full-thickness rotator cuff tear could be predicted on the basis of the presenting baseline clinical characteristics. The secondary purpose was to determine whether a successful outcome achieved after three months of treatment of a symptomatic full-thickness rotator cuff tear is maintained at two years.

Materials and Methods

This prospective cohort study was approved by the local medical bioethics board. The study was conducted in a university-based, sports medicine-specialized, tertiary referral center and had a follow-up duration of two years. Participants were identified from a consecutive series of new referrals from general practitioner physicians to two subspecialized shoulder orthopaedic surgeons. The inclusion and exclusion criteria for the study are presented in Table I.

The dependent variable was the outcome of nonoperative treatment, classified as either success or failure at the three-month appointment. Patients were deemed to have a successful outcome if surgery was no longer deemed an appropriate treatment option by both patient and surgeon because the patient had improved considerably and was predominantly asymptomatic. The nonoperative management was deemed to have failed if the patient elected to schedule surgery because he or she had not improved and remained symptomatic.

Ten baseline clinical characteristics (see Appendix) were examined for their predictive ability. An a priori calculation (based on the accepted practice of using at least ten patients per independent variable examined in a logistic regression model) indicated that a sample size of 100 patients was an appropriate target.

Of the 116 consecutive patients who were screened prospectively, 104 met the inclusion and exclusion criteria and provided informed consent for participation. Each participant then underwent a series of five visits, including two to a sports medicine physician, two to a study physiotherapist, and one to an orthopaedic surgeon. The sports medicine physician and physiotherapist instituted a rehabilitation program. The research coordinator initially educated the patients regarding their condition and the goals of the rehabilitation program, then oversaw the supervision of the patients during the rehabilitation program via a weekly contact with each patient. The rehabilitation program included stretching exercises and strengthening exercises for the shoulder as well as optional use of anti-inflammatory medications (see Appendix). Strengthening exercises were not introduced until pain and shoulder motion had improved. Each patient was evaluated individually and was treated on the basis of the level of symptoms. Few patients continued with physical therapy past the three-month time point. At three months, the patient was scheduled to meet the surgeon to whom he or she had originally been referred. At this appointment, the surgeon assessed the patient as he or she would assess any new patient presenting to the clinic with a chronic full-thickness rotator cuff tear. The surgeon discussed the shoulder history with the patient, performed a physical examination of the shoulder, and discussed the risks and benefits of surgery as well as alternatives to surgery. At the end of the consultation, the surgeon classified the outcome of the rehabilitation as either a success or a failure. The Rotator Cuff Quality-of-Life Index (RC-QOL) instrument was administered on the patient’s arrival at the initial visit to the sports medicine physician, on arrival at the three-month surgical consultation, and twenty-four months after the initial visit or baseline assessment. Both the sport medicine physician and the surgeon were blinded to the RC-QOL results of the patient.

Injury/onset of symptoms <3 mo prior
Elite athlete
Substantial cervical spine pathology and/or radiculopathy
Substantial medical issues precluding surgery
Secondary gain issues (i.e., workers’ Compensation or litigation)
Unable or unwilling to complete study outcome instruments
Unable or unwilling to provide informed consent
Patients were grouped on the basis of the outcome of the nonoperative treatment (success or failure), and the ability to correctly predict this dichotomous outcome on the basis of the baseline characteristics was analyzed with use of logistic regression. Each of the ten characteristics that had been selected on an a priori basis was first examined for association with the dependent variable (outcome of nonoperative treatment) in univariate logistic regression analysis with use of the “Enter” method. The likelihood that the relationship was due to chance was assessed with use of the p value. If the relationship was not likely to be explained by chance (p < 0.05), it was concluded that the baseline characteristic accounted for a significant proportion of the variability in the outcome.

Tear size was not reported on the ultrasonographic or magnetic resonance imaging (MRI) reports in thirty-three of the cases. Because of the large amount of missing data, regression models were examined both with and without this variable to determine whether imaging findings were an important predictor of outcome. The β values showed minimal change when this variable was excluded; therefore, we performed the final analysis without the use of the tear size variable, allowing us to retain all ninety-three cases in the analysis.

### Source of Funding
This study was supported by grants from the Calgary Orthopaedic Research and Education Fund and the Workers’ Compensation Board of Alberta. The funds were used to pay for supplies and the salary of the research coordinator.

### Results
Eleven of the 104 patients who were eligible and were enrolled were subsequently excluded from the analysis: two applied for Workers’ Compensation following their enrollment, and nine were lost to follow-up and had insufficient data for analysis. Thus, ninety-three patients were analyzed; the baseline demographic characteristics of these patients are summarized in Table II.

Seventy (75%) of the analyzed patients were classified as having a successful outcome at the three-month surgical consultation visit, as surgery was no longer considered necessary by both patient and surgeon; the remaining twenty-three patients (25%) were classified as having failed nonoperative treatment and elected to undergo rotator cuff repair surgery. The baseline demographic characteristics of the patients in each group are summarized in Table III.


**Discussion**

The principal finding of this study was that the RC-QOL was necessarily addressed by other components of the physical examination or history. For example, hand dominance could be reflected in a patient’s quality-of-life score; if the injury involved the shoulder of the dominant arm, the ability of the patient to perform activities of daily living as well as recreational and sport activities would be impacted, resulting in a lower overall quality-of-life score. Shoulder motion and strength may likewise be represented on the RC-QOL, as those patients with limited shoulder motion or strength would struggle with activities of daily living and report a lower overall RC-QOL score.

On the basis of the findings of this study, we believe that the RC-QOL can be used to determine whether a patient is likely to have a successful or failed nonoperative course of treatment for a chronic full-thickness rotator cuff tear. The RC-QOL is easily administered in the clinic, either on paper or online, and it only takes a few minutes for the patient to complete. It is easy and quick for a clinical assistant to score (requiring a ruler and a calculator), or it can be scored automatically if completed online.

The RC-QOL is also useful for tracking patient progress over time. In the present study, we administered the RC-QOL at three time points: the patient’s initial visit and three months and two years after that visit. The mean RC-QOL score in the successfully treated group rose 33 (out of 100) points from baseline to three months, and it only dropped two points from three months to two years. The score in the group with treatment failure only rose five points from baseline to three months. Patients in the successfully treated group typically remained relatively asymptomatic, and their RC-QOL scores at two years were similar to those of patients who had received surgical intervention for a full-thickness rotator cuff tear in previous studies.

Seventy-five percent of the patients were deemed to have been successfully treated with our comprehensive, nonoperative program at the three-month time point. This success rate falls within the wide range of reported success rates in the existing literature.

The success rate in the present study was higher than we had anticipated. We believe that this may be due to the close contact that the research coordinator maintained with the study participants throughout the course of the study. The research coordinator set up all appointments for the patients and made weekly phone calls to the patients to both monitor and encourage compliance. Adherence to the program was very high, and the success experienced in this study may not be generalizable to general practice unless this level of patient compliance is maintained.

Eighty-three (89%) of the ninety-three patients maintained their three-month outcome (success or failure) at two years. Of particular note, only six (9%) of the seventy patients in the successfully treated group worsened over the remainder of the twenty-four month follow-up. These results suggest that a successful result at three months is most often durable over time. Although longer-term follow-up would be interesting, it was not part of our present study.

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**TABLE IV Significance of the Independent Variables**

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>P Value</th>
<th>Exp(β)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.420</td>
<td>1.030</td>
<td>0.958-1.107</td>
</tr>
<tr>
<td>Sex</td>
<td>0.877</td>
<td>1.111</td>
<td>0.292-4.221</td>
</tr>
<tr>
<td>Duration</td>
<td>0.681</td>
<td>0.996</td>
<td>0.977-1.015</td>
</tr>
<tr>
<td>Onset</td>
<td>0.693</td>
<td>0.772</td>
<td>0.214-2.786</td>
</tr>
<tr>
<td>Dominant side</td>
<td>0.675</td>
<td>0.744</td>
<td>0.187-2.961</td>
</tr>
<tr>
<td>Full ER strength</td>
<td>0.966</td>
<td>0.971</td>
<td>0.255-3.694</td>
</tr>
<tr>
<td>FE range of motion</td>
<td>0.618</td>
<td>0.992</td>
<td>0.961-1.024</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.452</td>
<td>1.889</td>
<td>0.360-9.900</td>
</tr>
<tr>
<td>Baseline RC-QOL</td>
<td>0.017</td>
<td>1.047</td>
<td>1.008-1.087</td>
</tr>
<tr>
<td>Intercept</td>
<td>0.706</td>
<td>0.240</td>
<td></td>
</tr>
</tbody>
</table>

*FE = forward elevation, and ER = external rotation.*

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**Univariate Logistic Regression Analyses**

The only baseline characteristic that was significant in predicting success or failure in the univariate analyses was the RC-QOL (p = 0.017, 95% CI [confidence interval] for exp(β) = 1.008 to 1.087). The p values of the remaining characteristics ranged from 0.42 to 0.97 (Table IV).

**Two-Year Follow-up**

During the two years of follow-up, ten patients crossed over to the opposite treatment. Four patients who had originally been classified as having had a treatment failure experienced subsequent improvement and canceled their scheduled surgery. Six patients originally classified as having had a successful treatment experienced increased symptoms in the affected shoulder and underwent surgery. Four of the latter six patients fell and re-injured the shoulder, one injured the shoulder lifting a suitcase into the trunk of a car, and the sixth patient attributed her need for surgery to the daily struggle of dressing with compression stockings.

The mean RC-QOL score (and standard deviation) in the successfully treated group improved from 49 ± 21 (range, 0 to 84) out of 100 at baseline to 82 ± 12 (range, 43 to 100) at three months, whereas the group with treatment failure improved only from 33 ± 15 (range, 6 to 66) at baseline to 38 ± 21 (range, 3 to 83) at three months. At twenty-four months, the mean RC-QOL of those patients who did not undergo surgery was 80 ± 18 (range, 22 to 100).

**Discussion**

The principal finding of this study was that the RC-QOL was the only investigated factor that was predictive of the outcome (p = 0.017). The RC-QOL is a comprehensive patient-derived questionnaire that encompasses not only physical symptoms but also work, recreational, lifestyle, social, and emotional domains. It is likely that the comprehensive nature of the questionnaire takes into account factors that are important to a patient but may not necessarily be addressed by other components of the physical examination or history. For example, hand dominance could be reflected in a patient’s quality-of-life score; if the injury involved the shoulder of the dominant arm, the ability of the patient to perform activities of daily living as well as recreational and sport activities would be impacted, resulting in a lower overall quality-of-life score. Shoulder motion and strength may likewise be represented on the RC-QOL, as those patients with limited shoulder motion or strength would struggle with activities of daily living and report a lower overall RC-QOL score.

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The study has several key strengths: all participants were from a consecutive series of patients, patients were followed prospectively for two years, and the percentage of patients who completed the treatment program and follow-up was high (91%). Study weaknesses include the nonstandardized nature of the nonoperative program, the limited duration of follow-up, patient bias with regard to self-assessment, the subjective nature of the dependent variable, and the inability to study additional variables (e.g., patient expectations and medical comorbidities) shown in previous studies to impact outcome.

In conclusion, the baseline RC-QOL score was identified as a significant predictor of which patients are likely to be successfully treated with our comprehensive, nonoperative treatment program and which are likely to experience treatment failure and require rotator cuff repair surgery. This study provides evidence that this validated, patient-derived, standardized outcome measure, the type of measure that is frequently used to evaluate the success of an intervention, can also be used as a predictive tool. The results indicate that the RC-QOL can be used in optimizing clinical decision-making when consulting with patients with a chronic full-thickness rotator cuff tear.

Appendix

A table summarizing the independent variables that were investigated as well as an appendix outlining the non-operative rotator cuff home rehabilitation program are available with the online version of this article as a data supplement at jbjs.org.

References


