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Effectiveness of physical therapy in treating atraumatic full-thickness rotator cuff tears: a multicenter prospective cohort study

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Purpose: To assess the effectiveness of a specific nonoperative physical therapy program in treating atraumatic full-thickness rotator cuff tears using a multicenter prospective cohort study design.

Materials and methods: Patients with atraumatic full-thickness rotator cuff tears who consented to enroll provided data via questionnaire on demographics, symptom characteristics, comorbidities, willingness to undergo surgery, and patient-related outcome assessments (Short Form 12 score, American Shoulder and Elbow Surgeons score, Western Ontario Rotator Cuff score, Single Assessment Numeric Evaluation score, and Shoulder Activity Scale). Physicians recorded physical examination and imaging data. Patients began a physical therapy program developed from a systematic review of the literature and returned for evaluation at 6 and 12 weeks. At those visits, patients could choose 1 of 3 courses: (1) cured (no formal follow-up scheduled), (2) improved (continue therapy with scheduled reassessment in 6 weeks), or (3) no better (surgery offered). Patients were contacted by telephone at 1 and 2 years to determine whether they had undergone surgery since their last visit. A Wilcoxon signed rank test with continuity correction was used to compare initial, 6-week, and 12-week outcome scores.

Results: The cohort consists of 452 patients. Patient-reported outcomes improved significantly at 6 and 12 weeks. Patients elected to undergo surgery less than 25% of the time. Patients who decided to have surgery generally did so between 6 and 12 weeks, and few had surgery between 3 and 24 months.

Conclusion: Nonoperative treatment using this physical therapy protocol is effective for treating atraumatic full-thickness rotator cuff tears in approximately 75% of patients followed up for 2 years.

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Rotator cuff tears are extremely common, affecting at least 10% of persons aged older than 60 years in the United States.[28] By use of 2010 US census data, this equates to over 5.7 million persons.[37] Industry estimates suggest that rotator cuff surgeries are performed on between 75,000 and 250,000 patients per year in the United States.[21,34] These data show that fewer than 5% of patients with rotator cuff tears in the United States are treated surgically.

Interestingly, in patients who do have surgical repair of rotator cuff tears, the failure rate is between 25% and 90%,[4,9,10,11,12-,16,24,32,42] yet patients whose repairs fail report satisfaction levels and outcome scores that are nearly indistinguishable from those whose repairs are intact.[30] Because most patients in these studies undergo postoperative physical therapy, it is conceivable that the postoperative physical therapy may be responsible for the improvements in outcome. Finally, a number of retrospective case series[1] and 1 randomized controlled trial[25] have suggested that nonoperative treatment of full-thickness rotator cuff tears may be successful in some patients.

These data led to the hypothesis that physical therapy may be effective in treating patients with symptomatic atraumatic full-thickness rotator cuff tears. In 2009, we published a systematic review on the effectiveness of exercise on treating rotator cuff impingement syndrome and offered a synthesized physical therapy protocol.[18] The specific objectives of this multicenter prospective cohort study are (1) to determine the effectiveness of this rehabilitation protocol in treating patients with atraumatic rotator cuff tears, with failure defined as patients electing to have surgery, and (2) to determine the effect of this nonoperative physical therapy protocol on patient-reported measures of outcome.

Materials and methods

The MOON (Multicenter Orthopaedic Outcomes Network) Shoulder Group is a team of 16 fellowship-trained orthopaedic surgeons and research personnel from 9 geographically dispersed sites within the United States, representing both academic and private practice patient environments. This group was formed to conduct large multicenter studies on conditions of the shoulder.

From May 2004 through October 2006, the MOON Shoulder Group met regularly to formulate research questions of interest; develop and standardize radiographic and magnetic resonance imaging (MRI) protocols; assemble validated behavioral and patient-oriented outcome assessment forms for data collection; and conduct validation studies on MRI classification of rotator cuff tears,[31] rotator cuff tear classification based on arthroscopic videos,[19] and radiographic findings associated with rotator cuff disease.[2]

In addition, the group performed systematic reviews of the literature to evaluate postoperative rotator cuff repair rehabilitation,[3] summarize the literature regarding indications for surgical treatment of rotator cuff tears,[27,39] and determine the effectiveness of physical therapy in treating rotator cuff disease and develop a standard physical therapy protocol based on the evidence.[18]

With regard to atraumatic rotator cuff tears, the indications for surgery are not clear,[7,27,39] and our research group could not develop standard indications for surgery by consensus. Therefore, the group decided to conduct a prospective cohort study on the nonoperative treatment of atraumatic full-thickness rotator cuff tears using the physical therapy protocol derived from the systematic review.[18] We expected that some patients would be successfully treated and decline surgical intervention whereas nonoperative treatment would fail in others and they would undergo rotator cuff repair. By identifying features that distinguish these groups, we expect to have insight into appropriate indications for surgery. This article documents the demographic data of this cohort and reports on the success of nonoperative treatment in the first 422 patients enrolled in this study who have follow-up of at least 12 weeks.

Inclusion and exclusion criteria

All patients aged 18 to 100 years with shoulder symptoms and MRI-documented, atraumatic, full-thickness rotator cuff tears were invited to participate. Any patient with a history of an injury leading to his or her presenting symptoms was excluded. Other exclusion criteria included pain related to the cervical spine, scapular pain, previous shoulder surgery, glenohumeral arthritis, inflammatory arthritis, adhesive capsulitis, previous proximal humeral fracture, bilateral rotator cuff tears, and dementia.

Protocol

All patients who met inclusion criteria were offered an opportunity to enroll in the study. At the initial visit, patients completed a questionnaire that detailed demographic data and included validated patient-reported outcome measures (Short Form 12 [SF-12] score,[36] American Shoulder and Elbow Surgeons [ASES] score,[29] Western Ontario Rotator Cuff [WORC] index score,[15] Single Assessment Numeric Evaluation [SANE] score,[38] and Shoulder Activity Scale[5]). Physicians performed a standard physical examination and reviewed radiographs and MRI images for each patient and then recorded information on standard Teleform data collection forms (Cardiff, Vista, CA, USA).

Physical therapy program

Patients were given 2 instructive rehabilitation books (Appendix 1, available on the journal's website at www.jshoulderelbow.org)

—one for physical therapists and another for home-based physical therapy written at the eighth-grade level with an accompanying DVD. This physical therapy program was derived from a systematic review of the literature that showed that exercise was effective in treating impingement syndrome.[18] The specific exercises included daily range of motion (postural exercises, active-assisted motion, active training of scapular muscles, active range of motion); daily flexibility (anterior and posterior shoulder stretching); and strengthening 3 times per week (rotator cuff and scapula exercises). Therapists were instructed to provide manual mobilization exercises as needed, because there is evidence to support their use in impingement,[18] and to progress the patient to a home therapy program when ready. Heat and cold were recommended as modalities, but ultrasound was not. Patients completed a compliance diary regarding their physical therapy visits and the frequency of home therapy events.

Patients returned after performing the therapy program for 6 weeks. At that point, patients were given 3 options: (1) If they considered themselves "cured," no additional treatment or formal follow-up was prescribed. (2) If they were "improved," patients continued the physical therapy program for another 6 weeks. (3) If they were "no better," they could elect to have surgery. Patients could choose to have surgery at any time in the course of treatment.

Outcome measures

Patient demographic information including age, gender, race, employment status, workers' compensation or automobile claims, tobacco history, and comorbidities was collected at entry into the study. Data on whether the patients had undergone surgery for their rotator cuff tear were collected at each follow-up time point. The following patient-related measures of outcome were collected at study entry, 6 weeks, 12 weeks, 1 year, and 2 years: SF-12 score,[36] ASES score,[29] WORC index score,[15] SANE score,[38] and Shoulder Activity Scale.[5]

At the initial visit, physicians completed a data collection form that included findings from the physical examination, as well as interpretation of radiographs and MRI grading of the rotator cuff tear.[31] Physical examination data were also collected at the 6- and 12-week visits.

Statistical methods

Most epidemiologic data are presented as descriptive data in table form. Comparisons of patient-related outcome scores were analyzed with a Wilcoxon signed rank test with continuity correction. Failure of nonoperative treatment data is presented as descriptive data and was analyzed with a Kaplan-Meier survivorship curve. Statistical analysis was performed with free open-source R statistical software (R Foundation for Statistical Computing, Vienna, Austria).

Results

Enrollment

The group saw 2233 rotator cuff tear patients during the enrollment period. Of these patients, 1280 were excluded for the following reasons: acute tears (38%), previous surgery (11%), bilateral disease (8%), neck disorders (6%), frozen shoulder (2%), dislocation (3%), rheumatoid disease (1%), and fracture (1%). Of the remaining 953 patients eligible to enroll in the study, 452 (47%) elected to do so. These 452 patients are followed up as a prospective cohort with rolling entry into the study. Of this group, 30 patients withdrew from the study. This report is based on 422 patients for whom we have follow-up data at a minimum of 3 months and with up to 2 years' follow-up for 90% of the cohort (n = 381).

Table I Race characteristics of study population

Race	No. (%)
White	345 (86)
Black	32 (8)
Asian	12 (3)
American Indian	6 (1.5)
Hawaiian	1 (<1)
No answer	8 (2)

The mean age of patients who enrolled was 62 years, whereas the mean age of those who did not was 58 years ($P < .001$). Equal numbers of men and women enrolled, whereas of those who did not enroll, men predominated (63%). This difference was statistically significant ($P < .001$).

Demographic data for study population

The mean age of the study population was 62.6 years (range, 31-90 years), with 206 men (51%) and 194 women (49%). The dominant arm was affected in 68% of subjects. The right arm was affected in 70% of subjects. With regard to tobacco use, 89.5% were nonsmokers. Other demographic features, including race, ethnicity, education level, and employment status, are listed in Tables I through IV. Many patients had comorbidities, with hypertension, back pain, and osteoarthritis most common (Table V). Geographically, the patient mix was fairly well distributed (Table VI). Interestingly, only 18% of patients reported a family history of rotator cuff problems, whereas 60% did not. With regard to treatment before enrolling in the study, 23% of patients had already tried some physical therapy, 40% had received injections, and 80% had tried nonsteroidal anti-inflammatory drugs.

MRI features of rotator cuff tears

Superior humeral head migration was recognized on MRI in 15% of patients. Tears involving only the supraspinatus were seen in 70% of patients (Table VII). Tear size was minimal in 48% of patients and was retracted to the mid humeral head in 33.5% of patients (Table VIII).

Compliance with physical therapy program

Overall, 77.7% of patients submitted their physical therapy compliance diaries. In the first 6 weeks of treatment, most

Table II Ethnicity of study population

Ethnicity	No. (%)
Hispanic	11 (2.5)
Not Hispanic	319 (80)
No answer	70 (17.5)

Table III Education level of study population

Education level	No. (%)
No high school	14 (3.5)
Some high school	15 (4)
High school graduate/GED	96 (24)
Some college	85 (21)
Associate degree	20 (5)
Bachelor's degree	77 (19)
Graduate degree	92 (23)
No answer	1 (<1)

Table IV Employment status of study population

Employment status	No. (%)
Full time	187 (47)
Part time	38 (9.5)
Retired	130 (32.5)
Homemaker	17 (4)
Unemployed	6 (1.5)
Disabled	21 (5)
No answer	1 (<1)

Table V Comorbidities of study population

Comorbidities	No. (%)
Hypertension	197 (49)
Back pain	146 (36.5)
Osteoarthritis/degenerative arthritis	133 (33)
Other medical problems	102 (25.5)
Depression	69 (17)
Heart disease	62 (15.5)
Diabetes	54 (13.5)
Rheumatoid arthritis	32 (8)
Cancer	30 (7.5)
Ulcer/stomach disease	27 (7)
Lung disease	24 (6)
Anemia/other blood disease	20 (5)
Kidney disease	13 (3)
Liver disease	7 (2)

patients performed both supervised and home physical therapy. Patients averaged only 8 supervised physical therapy visits over the first 6 weeks. During the second 6 weeks of physical therapy, a higher proportion of patients did only home therapy, with a mean of 7 visits of supervised therapy over the 6-week period (Table IX).

Table VI Geographic distribution of study population

Site	No. (%)
Vanderbilt University, Nashville, TN, USA	92 (23)
The Ohio State University, Columbus, OH, USA	84 (21)
Washington University in St Louis, St Louis, MO, USA	40 (10)
Knoxville Orthopaedic Clinic, Knoxville, TN, USA	40 (10)
Orthopaedic Institute, Sioux Falls, SD, USA	36 (9)
University of California, San Francisco, CA, USA	36 (9)
Hospital for Special Surgery, New York, NY, USA	30 (8)
University of Colorado, Denver, CO, USA	27 (7)
University of Iowa, Iowa City, IA, USA	15 (4)

Table VII MRI size of tear based on number of tendons involved

Tendon involvement	No. (%)
Supraspinatus only	281 (70)
Supraspinatus and infraspinatus	83 (21)
Supraspinatus, infraspinatus, and teres minor	3 (<1)
Subscapularis	2 (<1)
Supraspinatus and subscapularis	20 (5)
Supraspinatus, infraspinatus, and subscapularis	7 (2)
Unknown	4 (1)

Table VIII Degree of rotator cuff retraction in coronal plane on MRI

Degree of retraction	No. (%)
Minimal	191 (48)
Mid humeral	134 (33.5)
Glenohumeral	52 (13)
Medial to glenoid	19 (5)
Unknown	4 (1)

Improvements in range of motion

Average active range of motion progressively improved over the 12-week period of treatment, notably for forward elevation and abduction (Table X).

Improvements in patient-reported measures of outcome

Statistically and clinically significant improvements were noted over the 12-week period of treatment for the ASES, WORC, and SANE scores (Table XI). No clinically important change was noted for the SF-12 domains or the Shoulder Activity Scale.

Failure of nonoperative treatment: surgery rates

The cohort of patients was collected over a 3-year period, and this report is a cross-sectional study of the cohort when

Table IX Compliance with physical therapy program

	No. who returned	No therapy	Supervised and home	Supervised only	Home only	Mean No. of supervised visits
1-6 wk	230/291 (79%)	4	180	5	41	8
7-12 wk	143/206 (69%)	2	66	1	67	7

Table X Improvement in active range of motion during treatment

Active motion	Baseline (N = 452)	6 wk (n = 402)	12 wk (n = 399)
Forward elevation (°)	149.8	163.3	162.9
Abduction (°)	136.8	154.9	154.7
External rotation at side (°)	52.9	55.6	55.8
Internal rotation at side (°)	56.7	56.9	58.3
External rotation at 90° of abduction (°)	74.8	80.3	80.9
Internal rotation at 90° of abduction (°)	45.3	46.4	52.3

all members of the cohort had reached 1-year follow-up and 75% of the cohort had reached 2-year follow-up. The data presented are a cross-sectional evaluation of patients in the cohort based on different time points as of March 2012.

All patients in the cohort have reached the 6-week time point (n = 422). Of this group, we have data on 402 patients (95%) at 6 weeks. Of this group, 35 patients (9%) had elected to have surgery within 6 weeks of starting the physical therapy program (Fig. 1).

All of the patients in the cohort have reached the 12-week follow-up point, and we have complete data on 399 (95%). An additional 24 patients elected to have surgery between 6 and 12 weeks after starting the physical therapy program; as such, the total number of patients who had decided to have surgery at 12 weeks was 59 (15%) (Fig. 2).

All patients in the cohort have reached the 1-year follow-up point. We have data on 396 (94%). At 1-year follow-up, 82 patients (21%) had elected to undergo surgery (Fig. 3).

As of March 2012, 381 of the 422 patients in the cohort (90%) had reached the 2-year follow-up point. Of this group, 319 patients had data available (84% follow-up). Of this group, 82 patients had decided to have surgery (26%) (Fig. 4).

Kaplan-Meier survivorship analysis shows that patients who elect to undergo surgery do so within 12 weeks. If a patient avoids surgery in the first 12 weeks, he or she is unlikely to undergo surgery at a later time point, up to 2 years (Fig. 5).

Discussion

The key findings of this study are that physical therapy is effective in the nonoperative treatment of atraumatic full-thickness rotator cuff tears as shown by the surprisingly low rate of surgery, as well as the significant improvements in validated patient-related scores of outcome. It is interesting to note that in most patients in whom nonoperative treatment failed, this failure occurred within the first 12 weeks. It is also of interest that only approximately 1 supervised physical therapy visit per week was required during the typical 12-week course of treatment.

Limitations of this study include the potential for selection bias (eg, patients who are less interested in surgery may be more inclined to participate, or the decision to have surgery may be influenced by the type of insurance a patient may have) or performance bias (some patients may have received medications, acupuncture, or other pain-relieving treatments that we did not examine). Moreover, generalizability may be limited because patients who presented with a history of trauma were excluded from the study. In addition, this report is a cross-sectional study of the data as they stand today. The data could potentially change as the cohort continues to move through time.

Despite these potential limitations, our study included patients from multiple practices across the United States, has 400 subjects, and was performed as a prospective cohort study. As such, for atraumatic rotator cuff tears, the results of this study may be generalized to the US population.

Substantial variation has been noted geographically in the frequency of rotator cuff surgery,[35] as well as in orthopaedic surgeons' approaches to individual case scenarios.[8] As a result, the indications for rotator cuff repair are not clearly defined or accepted.[27,39] Patients who present with shoulder pain without a history of an injury and an MRI-documented rotator cuff tear present a dilemma to physicians because there are few data to help make decisions regarding appropriate treatment.

Clearly, larger tears were once small, and progression has been documented in some patients.[20,22,23,41,43] It is known that asymptomatic tears may become symptomatic[41] and that in patients with bilateral rotator cuff tears where one is symptomatic and the other is not, the symptomatic tears is typically larger.[40] This information would lead some surgeons to recommend surgery for all patients with rotator cuff tears. However, it is also known that progression can occur without the development of symptoms.[41] Unfortunately, the literature does not identify the risks for progression of rotator cuff tear size or for predicting in which patients symptoms will develop.

One randomized controlled trial compared rotator cuff repair with nonoperative treatment in patients with rotator

Table XI Patient-reported measures of outcome

Assessment tool	Baseline (N = 452)	6 wk (n = 402)	*P* value	12 wk (n = 399)	*P* value
SF-12 MCS	40.3	40.6	.36	40.8	.895
SF-12 PCS	35.3	35.6	<.0001	36.1	<.0001
ASES score	54.5	78.0	<.0001	83.7	<.0001
WORC score	47.2	62.5	<.0001	69.7	<.0001
SANE score	46.6	62.7	<.0001	70.3	<.0001
Marks Activity Scale	9.9	10.2	.096	10.0	.47

MCS, mental component score; *PCS*, physical component score.
Patient-reported measures of outcome are compared with baseline scores with *P* values.

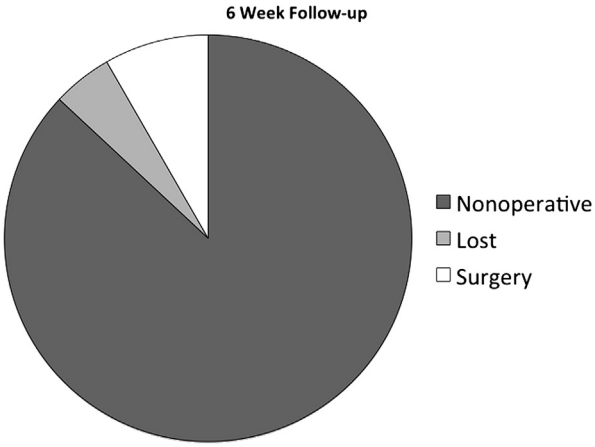

Figure 1 Six-week data. The entire cohort of 422 patients has reached the 6-week follow-up point. Of this group, 20 patients (5%) were lost to follow-up. Of the 402 patients remaining, 35 had surgery (9%).

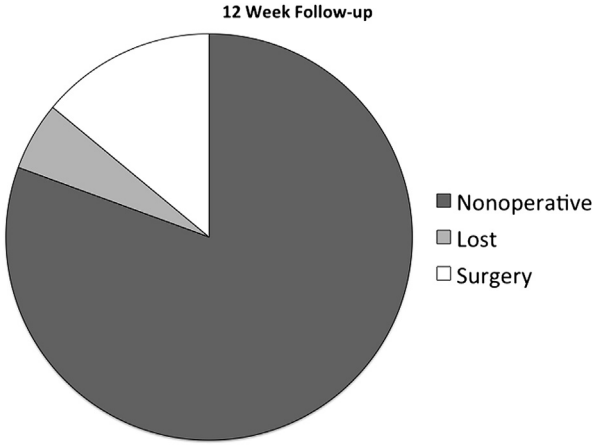

Figure 2 Twelve-week data. The entire cohort of 422 patients has reached the 12-week follow-up point. Of this group, 23 (5%) were lost to follow-up. Of the 399 patients remaining, 59 had surgery (15%).

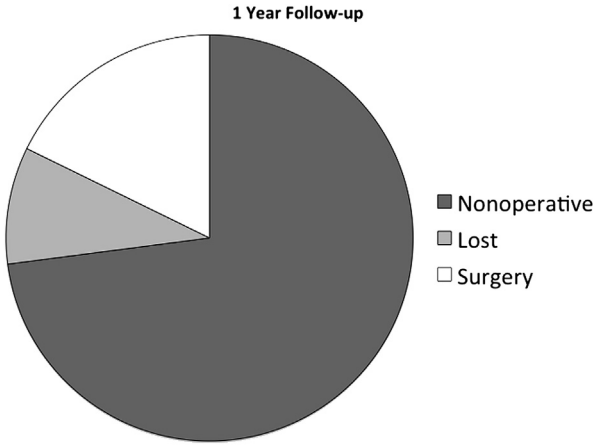

Figure 3 One-year data. The entire cohort of 422 patients has reached the 1-year follow-up point. Of this group, 26 (6%) were lost to follow-up. Of the 396 patients remaining, 82 had surgery (20%).

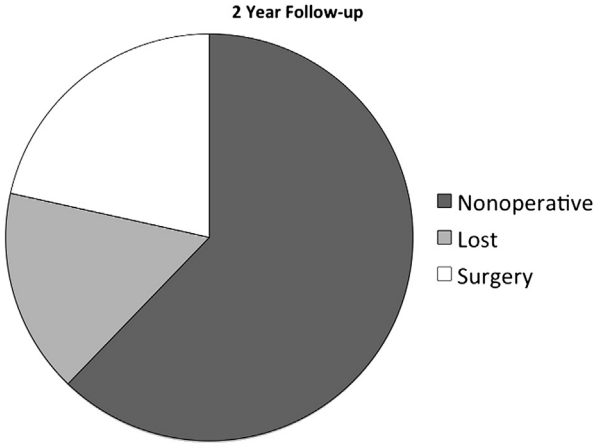

Figure 4 Two-year data. As of March 2012, 381 patients have been enrolled in the study for at least 2 years. Of this group, 62 (16%) were lost to follow-up. Of the 319 patients remaining, 82 had surgery (26%).

cuff tears less than 3 cm in size.[25] In this study, the Constant scores at 12 months were significantly better in the surgery group (76.8 vs 66.8); however, of the 51 patients randomized to their therapy group, only 9 patients (17%) had failure and elected to have surgery. These data parallel the findings in our study and suggest that surgical treatment may not be necessary for many individuals.

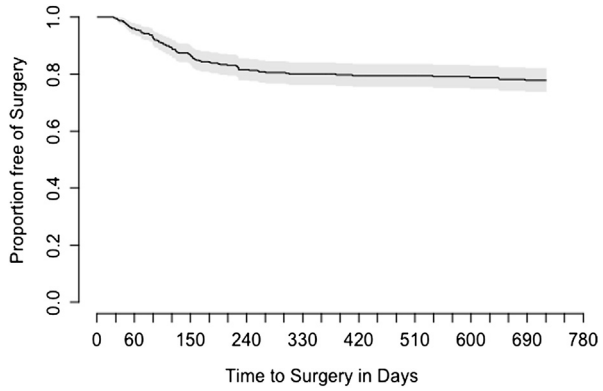

Figure 5 Kaplan-Meier survival analysis curve: failure of physical therapy as a treatment for atraumatic rotator cuff tears. It should be noted that the physical therapy program fails in most patients and they elect to have surgery between 6 weeks (42 days) and 12 weeks (84 days) after initiating the therapy program.

Prevalence data support this contention. On the basis of multiple cadaveric and MRI studies, a conservative estimate would suggest that 10% of Americans aged over 60 years have full-thickness rotator cuff tears.[28] This would mean that nearly 6 million Americans have full-thickness rotator cuff tears. A generous estimate of the number of rotator cuff repairs performed each year in the United States is 250,000,[21] which would mean that fewer than 5% of all of the full-thickness rotator cuff tears that exist in the US population are treated surgically.

Multiple case series report success rates with nonoperative treatment to range between 59% and 85%; however, these studies are subject to selection bias and are retrospective in design, and many of these studies include only those patients with massive tears in whom surgery cannot be performed.[1] One prospective cohort study of 103 shoulders with rotator cuff tears treated without surgery showed lasting pain relief 13 years after diagnosis, and 72% of patients had no disturbance in activities of daily living[14]; however, those who had pain or functional loss tended to be younger at the time of diagnosis.

Our prospectively collected data enrolling all patients with atraumatic rotator cuff tears suggest that physical therapy is highly effective at improving symptoms. On the basis of the prevalence data described earlier, the majority of patients with rotator cuff tears either are asymptomatic or have minimal symptoms, and it seems that the physical therapy program used in this protocol may bring patients to a relatively asymptomatic state.

This research has raised many questions. First, it would be important to know exactly what the risk factors are that would predict progression of known rotator tears or development of symptoms. Equally important would be information that allows us to predict which repaired tears are likely to fail. This information would certainly help surgeons and patients make informed decisions regarding surgery.

The nature of the patient's symptoms and the patient's expectations of treatment are important to appreciate when one is making decisions regarding surgery for rotator cuff tears. Most patients will present to the physician with pain as a chief complaint. Preliminary analysis of data from this study have shown that the severity of the rotator cuff tear has no correlation with the severity of pain[7] or the duration of symptoms.[33] Interestingly, patients with failed rotator cuff repairs report outcome scores that are not significantly different from scores in patients whose repairs have healed,[6,13,16,17,26,30] unless the outcome score includes a large component for strength (eg, Constant score), in which case healed repairs have better scores.[25,30]

The physical therapy program in this study was highly effective in alleviating patient symptoms despite the fact that patients continued to have tears in the rotator cuff. This leads one to believe that pain may not be the best indication for rotator cuff repair. Weakness or loss of function may be a better indication for surgery than pain. Further analysis of this cohort will be undertaken to identify those features that distinguish patients who decided to have surgery from those who did not. These data should provide some insight into the features that predict failure of nonoperative treatment and should help clarify indications for surgery.

Conclusions

This large, multicenter prospective cohort study has shown that a specific physical therapy protocol can be very effective in treating symptoms in patients with atraumatic full-thickness rotator cuff tears. If failure is defined as patients electing to have surgery, then this program is successful in approximately 75% of patients at 2-year follow-up. Interestingly, much of the physical therapy was done at home, with patients averaging slightly more than 1 physical therapy visit per week. Physical therapy is not ideal for all patients, and some will elect to undergo surgery early. Others may be at risk for symptom or rotator cuff tear progression. Decisions regarding surgery should be made individually with each patient but should include information that the physical therapy program used in this study is highly effective in alleviating symptoms.

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Supplementary data

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