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2013 Neer Award: predictors of failure of nonoperative treatment of chronic, symptomatic, full-thickness rotator cuff tears

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Background: The purpose of this study is to help define the indications for rotator cuff repair by identifying predictors of failure of nonoperative treatment.

Methods: A prospective, multicenter, cohort study design was used. All patients with full-thickness rotator cuff tears on magnetic resonance imaging were offered participation. Baseline data from this cohort were used to examine risk factors for failing a standard rehabilitation protocol. Patients who underwent surgery were defined as failing nonoperative treatment. A Cox proportional hazards model was fit to determine

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the baseline factors that predicted failure. The dependent variable was time to surgery. The independent variables were tear severity and baseline patient factors: age, activity level, body mass index, sex, Single Assessment Numeric Evaluation score, visual analog scale score for pain, education, handedness, comorbidities, duration of symptoms, strength, employment, smoking status, and patient expectations.
Results: Of the 433 subjects in this study, 87 underwent surgery with 93% follow-up at 1 year and 88% follow-up at 2 years. The median age was 62 years, and 49% were female patients. Multivariate modeling, adjusted for the covariates listed previously, identified patient expectations regarding physical therapy ($P < .0001$) as the strongest predictor of surgery. Higher activity level ($P = .011$) and not smoking ($P = .023$) were also significant predictors of surgery.
Conclusion: A patient's decision to undergo surgery is influenced more by low expectations regarding the effectiveness of physical therapy than by patient symptoms or anatomic features of the rotator cuff tear. As such, patient symptoms and anatomic features of the chronic rotator cuff tear may not be the best features to use when deciding on surgical intervention.
Level of evidence: Level I; Prospective Cohort Study; Prognosis Study

Keywords: Atraumatic rotator cuff tear; nonoperative treatment; patient expectations; activity level; prospective cohort; rehabilitation; outcomes; prognosis study

Currently, consensus on indications for surgical treatment of rotator cuff tears is lacking. Oh et al conducted a systematic review to identify factors that affect the treatment outcome and indications for surgery.[30] Although the findings were based primarily on multiple case series, the authors suggested that weakness or functional disability may be the best indications for surgical intervention, and older age did not predict a poorer outcome. Wolf et al[38] offered a treatment algorithm for rotator cuff tears, based on expert opinion supported by their sampling of the literature. Because there are no high-level comparative investigations to which one can turn to assist with clinical decision making, it is not surprising that surveys of physicians yield little agreement on the approach to patients[9] and substantial geographic variation exists in surgical repair rates.[36]

Nonoperative treatment of rotator cuff tears is effective for many patients.[1,18,26] This is not surprising because rotator cuff tears are prevalent, affecting 10% of persons over age 60 years in the United States.[31] On the basis of 2010 US census data, this would mean that close to 6 million US citizens have rotator cuff tears.[37] Industry estimates suggest 75,000 to 250,000 repairs occur in the United States annually,[18] which would mean fewer than 5% of subjects with cuff tears in the United States undergo surgery each year.

Interestingly, in patients who do undergo cuff repair, failure rates range from 25% to 90%[2,10-12,16,25,35,42]; however, in several studies, subjects with failed repairs had patient-reported outcomes similar to subjects with healed repairs.[10,32,33] Given that subjects in these studies likely participated in physical therapy after surgery, it is possible that the postoperative rehabilitation could explain why these 2 groups (healed vs failure to heal) have similar outcomes.

The intention of this study is to identify predictors of surgery using a multicenter, prospective, cohort study design. We hypothesized that age and activity level would predict failure of nonsurgical treatment and these criteria could be used as indications for surgery.

Materials and methods

The Multicenter Orthopaedic Outcomes Network (MOON) Shoulder consortium has been described in detail previously, as have the inclusion and exclusion criteria, data collection details, outcome measures, institutional review board approval, and standardized physical therapy protocol used in this cohort study.[18]

Patient expectations of the results of treatment (rehabilitation) were measured using 6 items from the Musculoskeletal Outcomes Data Evaluation System (MODEMS) survey. Each item is scored from 1 (lowest level of expectations) to 5 (highest level of expectations), and a mean score for the 6 items is calculated. Patient expectations were measured at baseline, 6 weeks, and 12 weeks.

We really do not know which atraumatic rotator cuff tears need to be fixed.[9,30,38] Identifying factors that differentiate those undergoing surgery from those that do not could lead to a better understanding of the indications for surgery and perhaps assist with surgical decision making. This article describes the baseline factors associated with failure of nonoperative treatment, with the primary endpoint being time to surgery, after enrollment of 433 subjects.

Statistical methods

A Cox proportional hazards model was fit to identify baseline features that predicted failure of the physical therapy program leading to surgical intervention. The dependent variable was time to surgery; the independent variables were tear severity and baseline patient factors (age, activity level, body mass index, sex, visual analog scale score for pain, education, handedness, comorbidities, symptom duration, forward elevation strength, occupation, smoking status, and patient expectations). Statistical analyses were completed using open-source R software.

Results

Enrollment

Details regarding enrollment and differences between subjects enrolled and those declining to enroll have been previously published.[18] There were a total of 452 subjects enrolled, and 30 subjects elected to subsequently withdraw. Baseline and 6-week follow-up was obtained on 11 of these 30 subjects.

Follow-up

Follow-up at the 2- and 5-year time points is ongoing; however, all 433 subjects have reached their 1-year time point, for which we have 94% follow-up.

Demographic data

The median age of the cohort was 62 years, and 51% were male patients. The dominant side was involved in 68%. Regarding smoking status, 90% reported "no." Other demographic features stratified by failure are listed in Table I. Baseline factors associated with tear severity stratified by failure are listed in Table II.

Failure of nonoperative treatment: predictors of surgery

Overall, 87 of 433 patients (20%) decided to undergo surgery. Subjects who went on to undergo surgery did so relatively early during the follow-up period (median, 120 days; interquartile range, 72 to 176 days) versus subjects who improved with the physical therapy program, who had a median follow-up of 731 days (interquartile range, 366 to 739 days). Multivariate modeling, adjusted for tear severity, age, activity level, body mass index, sex, visual analog scale score for pain, Single Assessment Numeric Evaluation score, education, handedness, comorbidities, symptom duration, forward elevation strength, occupation, smoking status, and patient expectations, found patient expectations about the effectiveness of rehabilitation ($P < .0001$) to be the most significant predictor of failure of rehabilitation and ultimate

Table I Baseline demographic data stratified by failure

	n	No (n = 346)	Yes (n = 87)	Combined (N = 433)
Sex	433			
Female		51% (176/346)	43% (37/87)	49% (213/433)
Male		49% (170/346)	57% (50/87)	51% (220/433)
Age, y	433	62 (57, 79)	58 (55, 65)	62 (57, 69)
Baseline BMI	428	28 (24, 32)	28 (24, 32)	28 (24, 32)
Dominant side	431			
No		30% (105/345)	33% (28/86)	31% (133/431)
Yes		70% (240/345)	67% (58/86)	69% (298/431)
Race	429			
Other		7% (23/342)	1% (1/87)	6% (24/429)
Black		9% (31/342)	6% (5/87)	8% (36/429)
White		84% (288/342)	93% (81/87)	86% (369/429)
Education	433			
High school or less		30% (103/346)	37% (32/87)	31% (135/433)
Some college		27% (95/346)	23% (20/87)	27% (115/433)
Bachelor's degree		19% (67/346)	21% (18/87)	20% (85/433)
Graduate degree		23% (81/346)	20% (17/87)	23% (98/433)
Employment	433			
Full time		45% (155/346)	51% (44/87)	46% (199/433)
Part time		9% (32/346)	9% (8/87)	9% (40/433)
Retired		35% (121/346)	30% (26/87)	34% (147/433)
Homemaker		4% (15/346)	2% (2/87)	4% (17/433)
Not working		7% (23/346)	8% (7/87)	7% (30/433)
Smoker	430			
No		89% (305/344)	94% (81/86)	90% (356/430)
Yes		11% (39/344)	6% (5/86)	10% (44/430)
Comorbidity	433	3 (2, 6)	3 (1, 6)	3 (2, 6)
Marx score	425	10 (6, 13)	12 (9, 14)	10 (7, 13)
Patient expectations	426	4.2 (3.8, 4.8)	4.0 (3.0, 4.7)	4.2 (3.7, 4.8)
ASES 3	428	4.2 (2.4, 6.4)	4.6 (3.0, 6.4)	4.4 (2.6, 6.4)

For continuous variables, data are presented as median (lower quartile, upper quartile).
ASES, American Shoulder and Elbow Surgeons; *BMI*, body mass index; *n or N*, number of patients with non-missing variables.

Table II Baseline cuff tear characteristics stratified by failure

	n	No (n = 346)	Yes (n = 87)	Combined (N = 433)
Duration of symptoms	430			
≤1 mo		8% (28/345)	7% (6/85)	8% (34/430)
1-3 mo		23% (78/345)	19% (16/85)	22% (94/430)
4-6 mo		20% (68/345)	19% (16/85)	20% (84/430)
7-12 mo		14% (48/345)	14% (12/85)	14% (60/430)
>12 mo		36% (123/345)	41% (35/85)	37% (158/430)
Retraction	428			
Minimal		47% (161/342)	53% (46/86)	48% (207/428)
Midhumeral		33% (113/342)	37% (32/86)	34% (145/428)
Glenohumeral		15% (50/342)	7% (6/86)	13% (56/428)
Glenoid		5% (18/342)	2% (2/86)	5% (20/428)
Superior humeral head migration	419			
No		83% (279/335)	90% (76/84)	85% (355/419)
Yes		17% (56/335)	10% (8/84)	15% (64/419)
Involved tendons	422			
SSp		70% (237/338)	82% (69/84)	73% (306/422)
SSp/ISp/Tm		23% (78/338)	13% (11/84)	21% (89/422)
Subscapularis		7% (23/338)	5% (4/84)	6% (27/422)
Strength in forward elevation	433			
3		9% (31/346)	6% (5/87)	8% (36/433)
4		45% (157/346)	41% (36/87)	45% (193/433)
5		46% (158/346)	53% (46/87)	47% (204/433)
Acromiohumeral interval, mm	370	10 (8, 11)	10 (8, 11)	10 (8, 11)

For continuous variables, data are presented as median (lower quartile, upper quartile).
n or N, number of patients with non-missing variables; *SSp*, supraspinatus; *SSp/ISp/Tm*, supraspinatus/infraspinatus/teres minor.

surgical intervention. Patients with a higher activity level ($P = .011$) and nonsmoking patients ($P = .023$) were also more likely to undergo surgery. Structural factors (tear size, retraction), pain scale score, and weakness were not predictors of choosing surgical intervention.

Kaplan-Meier estimates of cumulative event-free probabilities showed that subjects who fail rehabilitation and go on to surgery declare themselves within 12 weeks. If subjects avoid surgery for the first 12 weeks, they likely not need it over longer-term follow-up of up to 2 years (Fig. 1). Survival plots showing surgery-free probability stratified by level of patient expectations, activity level, and smoking status are shown in Figures 2, 3, and 4, respectively.

Figure 5 is a nomogram derived from the fitted Cox multivariate model in this study that can be used to predict the probability that a patient will fail the nonoperative rehabilitation protocol and elect to undergo surgery. Although statistically significant features included the patient's expectations, activity level, and smoking status, other features, which did not achieve statistical significance, can be used in a nomogram. Features with a wider line on the x-axis have a larger effect on the outcome (surgery) than features with a smaller line.

Discussion

Results of this study show that structural factors (tear size, retraction), pain, and weakness were not predictors of failure of nonoperative treatment. The strongest predictor was low patient expectations about physical therapy. Other predictors of surgery were activity level and smoking status. It is worth mentioning that subjects who failed rehabilitation identified themselves early, within 12 weeks, emphasizing the strength of the effect of the expectations for treatment.

Other authors have reported that patient expectations are associated with outcomes after rotator cuff repair. Henn et al[13] used multivariate analysis to determine that greater preoperative expectations are a significant independent predictor of outcome measurements after repair of chronic cuff tears. Several other studies have also concluded that patient expectations are associated with outcomes after cuff repair,[13,29] but to our knowledge, the relationship between expectations and the outcome of rehabilitation for rotator cuff tears has not been investigated.

Study limitations include potential selection bias (eg, patients who do not want to undergo surgery may be more eager to enroll) and performance bias (some patients may have received other treatments such as medications or other pain-relieving modalities that were not measured); moreover, external validity may be limited because acute cuff tears were not enrolled in this study. Strengths of this study include its prospective design, as well as recruitment and retention of 433 patients from different surgical practices (private and academic) across the United States. Hence, these results might be generalizable to a US population of atraumatic cuff tear patients. Follow-up bias is likely not a factor in this study

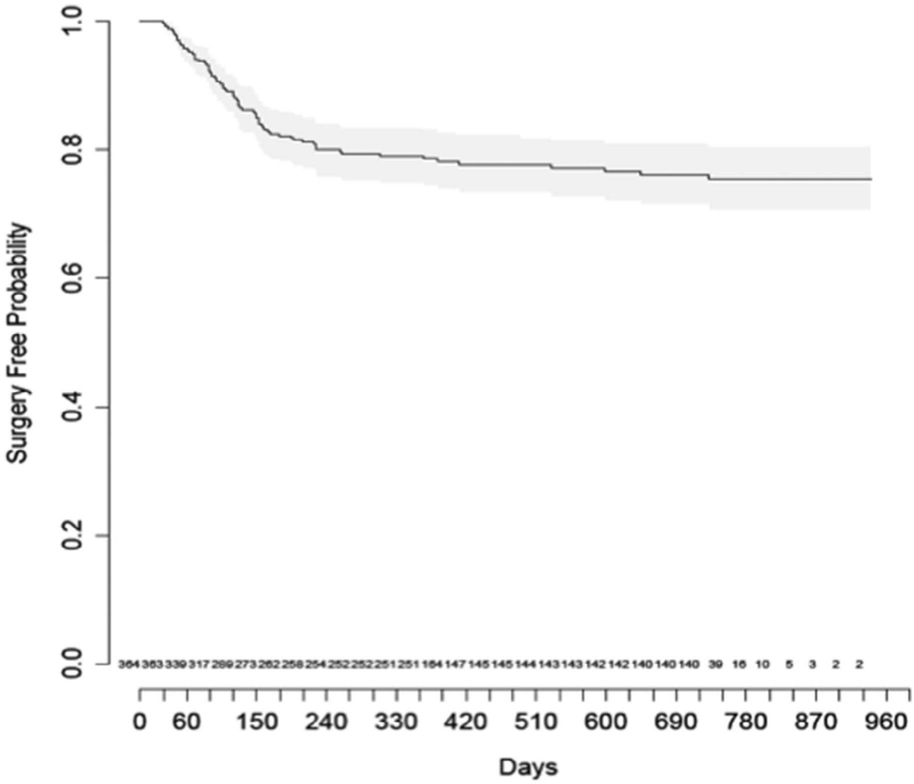

Figure 1 Kaplan-Meier estimates of cumulative event-free probabilities: estimates of lack of failure of physical therapy as a treatment for atraumatic rotator cuff tears. One should note that most patients fail the physical therapy program and elect to undergo surgery between 6 weeks (42 days) and 12 weeks (84 days) after initiating the therapy program.

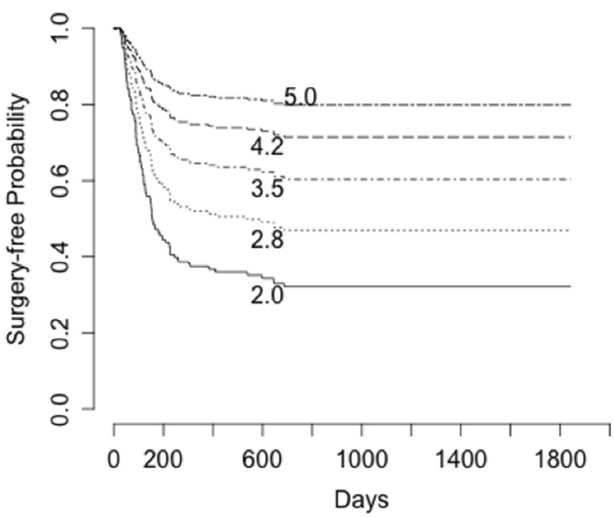

Figure 2 Survival plot of surgery-free probability stratified by patient expectations regarding physical therapy, with a score of 5 indicating high expectations that physical therapy will lead to improvement and lower scores indicating lower expectations.

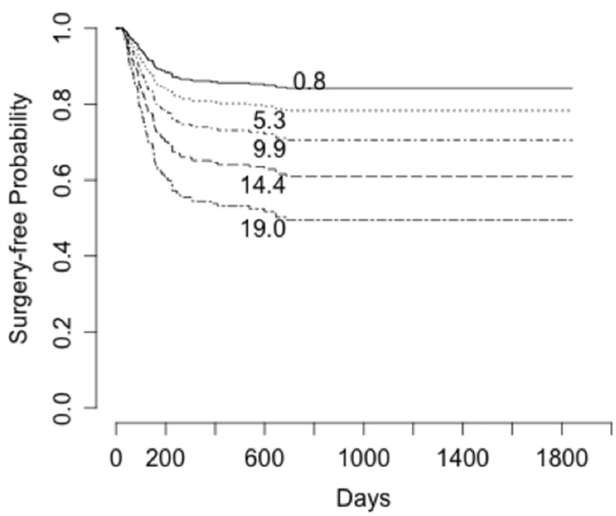

Figure 3 Survival plot of surgery-free probability stratified by activity level, with a score of 0.8 indicating low activity levels and higher scores indicating higher activity levels.

because nearly all subjects undergoing surgery did so early, and we have 94% follow-up at the 1-year time point. As mentioned earlier, 2- and 5-year follow-up is ongoing; to date, we have 84% and 68% follow-up at 2 and 5 years, respectively (some subjects have not reached these time points yet).

Considerable geographic variation in the frequency of rotator cuff surgery exists,[36] and there is also lack of

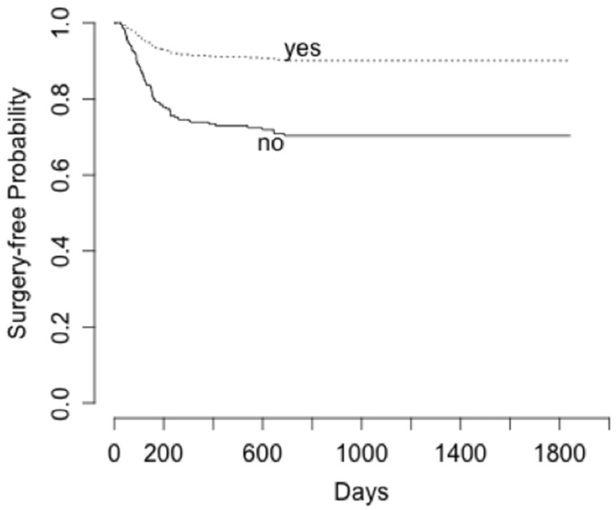

Figure 4 Survival plot of surgery-free probability stratified by smoking status (yes or no).

clinical agreement regarding orthopedic surgeons' approaches to individual case scenarios.[9] To that end, the indications for rotator cuff repair have not been clearly established.[38] Patients with atraumatic shoulder pain with a rotator cuff tear can be a clinical quandary given the lack of evidence to assist with medical decision making.

In some subjects a large tear was likely a small tear at some point, and tear size progression has been documented.[22-24,41] Asymptomatic tears can evolve into symptomatic tears,[40] and in patients with bilateral rotator cuff tears in whom only 1 side is symptomatic, the symptomatic tears are typically larger.[39] This information could be used to justify recommending surgery to all cuff tear patients. However, we also believe that tear size progression can occur in the absence of symptoms.[41] Regrettably, the existing evidence has not identified risk factors for tear size progression nor has it identified factors that predict which patients may become symptomatic in the future.

A randomized controlled trial compared cuff repair with nonoperative management in subjects with rotator cuff tears less than 3 cm in size.[26] The ASES and Constant scores at 1 year were significantly improved in both groups, although the surgical arm showed more improvement. Of the 51 subjects in the rehabilitation arm, 9 (17%) failed and ultimately underwent surgical repair. Recently, 5-year follow-up of this study has been reported, and the authors found both groups maintained the improved American Shoulder and Elbow Surgeons and Constant scores seen at 1 year; in addition, although the surgery group had more improvement than the rehabilitation group, these between-group differences were likely not of the magnitude of clinically important differences.[27] Of note, treatment failure was similar between groups: 24% of patients randomized to therapy had gone on to surgery at 5 years, whereas 25% of the surgery group showed either partial or complete failure of healing. These data are consistent with our finding that only 20% of patients decided to undergo surgery, suggesting that rotator cuff repair may not be required for certain patients. Another trial comparing 3 groups—physical therapy, acromioplasty and therapy, and cuff repair—found no significant differences in Constant scores at 1 year in patients with atraumatic rotator cuff tears.[19]

Prevalence data support the contention that many individuals with atraumatic cuff tears may not require surgery. Data from multiple cadaveric and imaging studies have suggested that 10% of Americans over age 60 years have full-thickness rotator cuff tears,[31] which corresponds to almost 6 million Americans with full-thickness cuff tears. By use of the highest number from the range of repairs that take place annually, that is, 250,000, fewer than 5% of full-thickness cuff tears are repaired annually.

Several case series have reported successful outcomes after nonoperative management, with rates ranging from 59% to 85%; however, much of this research has been retrospective, often plagued with bias, and in many instances has been limited to massive tears that are potentially not repairable. A prospective study of 103 rotator cuff tears treated nonoperatively showed continued pain relief at 13 years' follow-up, and 72% of patients reported no problems with activities of daily living; however, subjects reporting pain or functional deficits were younger at the time of presentation.[15]

This study confirms other research concluding that atraumatic rotator cuff tears can be successfully managed with rehabilitation. Given the prevalence data we have discussed, it is likely that a majority, and most certainly at least a significant minority, of subjects with rotator cuff tears are either asymptomatic or are minimally symptomatic and that the rehabilitation protocol used in the study can achieve a relatively asymptomatic state in patients with atraumatic cuff tears.

This study raises some unanswered questions: First, what are the risk factors predictive of tear size progression and of the onset of symptoms in an asymptomatic tear? Also, what factors predict failure of a repaired tear to heal? This information is critical to the shared decision-making process between surgeons and patients.

The cause of the patient's symptoms and the patient's expectations of management options are important to consider when one is making decisions about treatment options for rotator cuff tears. Most patients present with a chief complaint of pain. Cross-sectional analysis of baseline data from this cohort has shown that structural measures of tear severity have no correlation with reported pain,[8] symptom duration,[34] or the patient's activity level.[3] Of note, subjects with failed cuff repairs have outcome scores that are not significantly different from subjects whose repairs have healed,[6,14,16,17,28] except when the outcome is heavily based on strength assessment (eg, the Constant score), in which case healed repairs have better outcomes.[4,5,7,20,21]

The physical therapy program in this study was highly effective in alleviating patient symptoms despite the fact that patients continued to have tears of the rotator cuff. This leads

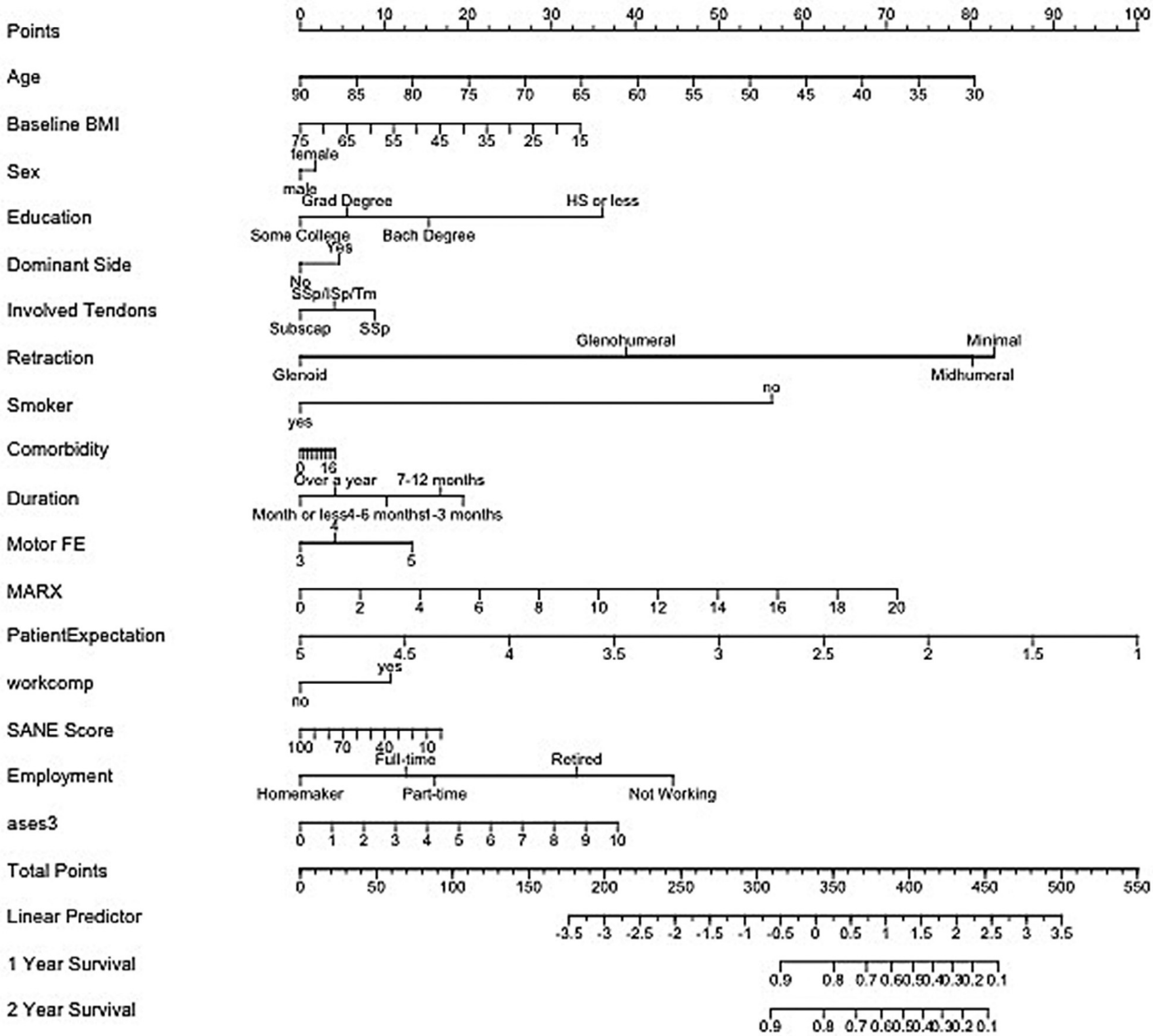

Figure 5 Nomogram for predicting success using a physical therapy program in patients with atraumatic full-thickness rotator cuff tears. To use the nomogram, one should identify where an individual patient falls on the spectrum for each feature, draw a perpendicular line from the position on that feature spectrum to the "Points" line, summarize all of the points for an individual patient and identify the position on the "Total Points" line, and finally, draw a perpendicular line to the 1-year survival line. This gives the probability that the patient will require surgery. *ASES*, American Shoulder and Elbow Surgeons; *Bach*, bachelor's; *BMI*, body mass index; *FE*, forward elevation; *Grad*, graduate; *HS*, high school; *MARX*, Marx score; *SANE*, Single Assessment Numeric Evaluation; *SSp*, supraspinatus; *SSp/ISp/Tm*, supraspinatus/infraspinatus/teres minor; *Subscap*, subscapularis; *workcomp*, worker's compensation.

one to believe that pain may not be the best indication for rotator cuff repair. Baseline pain level was included in our multivariate model and was not a predictor of surgery, nor was forward elevation weakness or severity of the tear on magnetic resonance imaging.

Higher activity level, as expected, was associated with failure of nonoperative treatment and could be considered a reasonable indication for surgical intervention of rotator cuff tears. However, it is not clear how patient expectations of treatment, the strongest predictor of failure of rehabilitation, could be helpful in determining the indications for surgical intervention. Patients who smoke were less likely to undergo rotator cuff repair, but more research is needed to better understand the reason (or reasons) for this effect and how it can best guide treatment. There may be bias by the surgeon, patient, or both against fixing rotator cuff tears in smokers, particularly in light of evidence that smoking impedes healing after rotator cuff repair.[32] This does not necessarily mean, however, that not smoking is an indication for repair in this population.

Conclusions

This large, prospective study shows that physical therapy can be effective in the treatment of atraumatic full-thickness rotator cuff tears.[18] Patient expectations regarding the role of rehabilitation were the strongest predictor of surgery. Other factors associated with surgery were higher activity level and not smoking. On the basis of our data, indications for surgery might be better based on higher activity level rather than severity of the tear. Anatomic features of the rotator cuff tear and the severity of patient's reported pain did not predict failure of nonoperative treatment. Patients who have low expectations regarding the effectiveness of physical therapy are more likely to fail nonoperative treatment. This concept clearly deserves further study.

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