IS BASELINE STRAIN INDEX A PROGNOSTIC FACTOR FOR SMALL UNILATERAL SUPRASPINATUS TENDON TEARS? A PROSPECTIVE STUDY

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ABSTRACT

Purpose: From prospectively report the 2-year follow-up clinical and real-time sonoelastography (RTSE) outcomes of a group of patients affected by small unilateral supraspinatus tendon tears. Our hypothesis was that patients with lower baseline strain indexes would have worst outcomes at follow-up. **Methods:** We recruited patients suffering from a single rotator cuff tear. All patients have prospectively scrutinized. Patients were initially managed nonoperatively, after at least three months of failed conservative treatment patients went under surgery. Our clinical evaluation and follow-up were done by complete physical examination; VAS for pain; Quick DASH; Constant–Murley score; Simple Shoulder Test; ASES score and UCLA score. Conventional ultrasounds and RTSE evaluated the mechanical properties of tissues, and they were estimated using the Strain Index. **Results:** Forty-three patients were available for evaluation at two years. Fifteen had undergone surgery (operative group), while 28 recovered from pain and dysfunction with conservative management and had not required surgery (non-operative group). Patients in both groups significantly improved at follow-up and no differences were found in all considered clinical outcomes. The biomechanical properties of repaired tendons were maintained, while non-operatively treated tendons softened over time. Baseline and follow-up strain indexes were linearly correlated with clinical outcomes at two years. **Conclusions:** Baselinestrain index could be associated with postoperative functional outcomes at 2-year follow-up. The biomechanical properties of surgically repaired tendons were maintained, while non-operatively treated tendons softened over time. At least in this cohort of patients, baseline strain index did not suggest who could be managed conservatively and who will need surgery.

KEYWORDS: Elastography, Rotator Cuff, Strain Index, Sovraspinatus Tear; Shoulder

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Introduction

Today there is increased interest in the determination of prognostic factors in patients suffering by rotator cuff tears. In particular, the muscular's quality and tendon tissues have been reported to be one of the most important issues for successful clinical and structural outcomes [1-2].

Real-time sonoelastography (RTSE) is a noninvasive and reproducible device; it is also safe and cheap that uses ultrasounds (US) to display and evaluate real-time the stiffness and elasticity (mechanical properties) of tissues [3,4], indirectly reflecting their quality. For these reasons, RTSE has been used in clinical practice, and its application in orthopedics and sports medicine is rapidly increasing [5-7]; but to the best of our knowledge, few papers have been published about the application of RTSE in the shoulder [2-6].

The aim of this prospective study was to evaluate whether baseline RSTE can predict clinical outcomes at follow-up. Our hypothesis was that patients with lower baseline strain indexes would have worst outcomes at follow-up.

Materials and methods

Our study reports the data of 2-years follow-up of two groups prospectively evaluated for a small unilateral supraspinatus tendon tear, whose baseline data have been previously published [8]. We enrolled 43 patients in our study according to the inclusion and exclusion criteria. The inclusion criteria were: unilateral supraspinatus tendon tear, partial and full-thickness small non-retracted tears, degenerative tears. The exclusion criteria were: previous or concurrent diagnosis of frozen shoulder, previous infection of the shoulder, glenohumeral osteoarthritis, connective tissue diseases, metabolic diseases, endocrine diseases and steroid or estrogen medication. We excluded all tears greater of Snyder C2 [9] because it was not possible to view them over the acromion with the US scanner on both axial and longitudinal sections. A disease of the long head of the biceps was not considered an exclusion criterion.

We clinically suspected every tendon tear, and we had confirmed through MRI that is the gold standard exam for rotator cuff tears diagnosis.

Unfortunately, MRIs were performed at different facilities (depending on patients' convenience) with various scanners, and were assessed by different radiologists before patients had an orthopedic examination, and were enrolled in the study. MRIs were not acquired again at the authors' institution for costs reasons and were not re-assessed by the radiologist involved in the study. Nevertheless, we considered unnecessary to execute a 2-years follow-up MRI because we needed a semi-quantitative value of the tendon stiffness (that we cannot obtain with MRI); so we used MRI only to get a certain diagnosis tendon tear. For these reasons, MRI could not be used as a gold standard to be compared to RTSE. Furthermore, a free additional RTSE was performed to the patients.

During the same day, patients were evaluated clinically and radiologically by a single surgeon and a single radiologist from the baseline to 2-year follow-up. Clinical evaluation was performed first in all patients. During follow-up evaluation, the clinician performing a physical examination and the radiologist were both blinded to baseline data. Furthermore, the radiologist was also blinded to clinical follow-up findings. The clinical evaluation included: complete physical examination, measurement of the range of motion(ROM) of the index and contralateral shoulders in elevation, abduction and external rotation with a manual goniometer, VAS for pain [10], Quick DASH [11], Constant Score [12], Simple shoulder test [13], ASES score [14] and UCLA score [15].Patients were asked about their hand dominance, working activities, retirement status, physical and sports activities and co-morbidities. A radiologist performed all US scan and RTSE with five years of experience in musculoskeletal RTSE imaging using a modified scanner (Philips UI22, Philips Medical Electronics Systems, Eindhoven, The Netherlands) with a 7.5 MHz probe. The patient's position was sitting position with forearm behind the back and elbow flexed to 90° with the palm facing in the posterior direction, US guidance positioned under, a Region of Interest (ROI) including the lesion on the supraspinatus tendon in longitudinal and axial planes on the affected and contralateral shoulders. The probe was carefully taken perpendicular to the tendon to avoid anisotropy during the US and to prevent tissue shifting during FTSE. The relative stiffness of the tissues ranged from red (soft) to blue (stiff) while intermediate values were with green and yellow [16]. The electrograms were influenced by the dimension of this window, in fact, the more surrounding soft tissue is included a larger window and a tendon harder structured made by it (more blue color) compared with a smaller window, where less soft surrounding tissue is included [17]. For these reasons, window size was standardized accordingly; we used a standardized window size to avoid radiologist's bias ant to obtain an objective value about tendon stiffness.

The hardness of the supraspinatus tendon was semi-quantitatively estimated by the strain index and by comparing the strain rate of tendon to bone. Three cycles of compression were performed both in the axial and coronal planes, and we averaged the values. The entire examination was approximately long 10 minutes for each patient. The color-coded images were analyzed on a personal computer using the QLAB (Philips Medical Electronics Systems, Eindhoven, The Netherlands) and the colored image from all pixel data were transformed into a histogram and RTSE-Mean elasticity (RTSE-Me) values were calculated. RTSE-Me was described in arbitrary units [a.u.].

Ninety-two patients were scrutinized, from 93 only 50 enrolled patients after the exclusion criteria in the study, and 43 (86%) available for follow-up evaluation at two years. Reasons for missed follow-up were: 3 patients had a proper function of the shoulder and did not want a further evaluation, two could not be located, one patient died, one patient reported a reduced function of the shoulder and had already consulted another surgeon. In both groups, there were 22 males and 21 females with a mean age of 60 ±10 years and the dominant arm was involved in 31 cases (72%).

Physical therapy has already been proven to treating atraumatic full-thickness rotator cuff tears. For this reason, all the patients were initially managed non-operatively using the protocol described by Kuhn et al. [8], and surgery was considered after at three months of not good outcomes by conservative treatment. During the 2-year follow-up, 15 out of 43 patients (35%) failed initial conservative treatment and underwent arthroscopic rotator cuff repair due to pain and shoulder dysfunction (operative group). Furthermore, biceps tenotomy was also performed in 7 of these cases due to biceps tendonitis and/or instability. The same surgeon (CT) performed all procedures with a single-row technique using 1 or 2 (depending on tear size) No two double-loaded suture anchors (Arthrex, Naples, Florida) placed in the greater tuberosity. Sutures were passed through the cuff

Table 1 Comparison in both groups between baseline and follow-up data.

	Operative group			Non-operative group		
	Baseline	Follow-up	P	Baseline	Follow-up	P
VAS for pain	4.8±2.2	2.5±2.3	0.01	5.2±2.7	3.5±2.7	0.02
Quick DASH	41.2±17.3	17.1±16.9	0.001	41.6±21.9	23.6±17.9	0.002
Constant Score	59.5±8.4	73.0±14.4	0.006	56.3±18.5	69.1±19.8	0.02
Simple Shoulder test	7.2±1.5	9.7±2.8	0.007	6.6±2.5	9.5±2.7	0.0001
ASES score	50.1±14.9	78.9±18.1	0.0001	50.2±20.4	70.4±19.3	0.0004
UCLA score	17.5±3.2	26.8±8.0	0.0008	18.1±6.7	23.5±8.5	0.01
Strain Index affected shoulder	0.71±0.12	0.69±0.17	0.78	0.73±0.11	0.59±0.16	0.0004

with a suture passer (Arthrex, Naples, Florida, USA) and tied with a simple knot and a mattress knot for each anchor. The same postoperative protocol was prescribed to all the patients [58]. Twenty-eight patients were satisfied with the results of their shoulder with conservative treatment, reporting proper functioning and relief from pain so, in agreement with them, it was decided not to proceed with surgery and to continue non-operative treatment (home-based exercises) and follow-up visits (non-operative group).

Statistical analysis

Descriptive statistics were used to summarize the characteristics of the study group and subgroups, including means and standard deviations of all continuous variables. The t-test was used to compare continuous outcomes. The Chi-square test or Fisher(in subgroups smaller than ten patients) exact test was used to compare Categorical variables. The statistical significance was defined as p<0.05.

We used Pearson correlation coefficient (r) was used to compare the predictive score of outcomes and quality of life. Statistical analyses were performed with SPSS v.15.0 (SPSS Inc., an IBM Company, Chicago, IL, USA). Mean ages (and their standard deviations) of the patients were rounded at the closest year. The predictive score of outcomes and quality of life and their standard deviations were approximated at the first decimal while at the second decimal was approximated Pearson correlation coefficient (r).

Results

Clinical and functional outcomes of patients in both groups at two years follow-up were better than baseline time (Table 1); in fact, every patient took advantage from surgery and nonoperative treatment. Comparing the two groups at baseline, there were no statistical differences regarding age; comorbidities; education; and socio-economical status. Female gender was more in the operative group(11/15 vs. 10/28, respectively; p=0.02). On the other hand, there were no differences between operative and non-operative groups regarding return to sport (6/6 vs. 7/11, respectively; p>0.05), and return to work (7/9 vs. 17/17, respectively; p>0.05). The injured shoulders range of motion(ROM) of at follow-up was comparable in both groups, with the exception that patients in the operative group achieved, with the arm at 90° of abduction (p=0.01), a greater active external rotation, and a trend towards more significant forward elevation without reaching statistical significance. During the follow-up, analyzing VAS for pain and functional scales, no differences were found between the two groups in all considered outcomes (Table 2).

At baseline RTSE evaluation of the mean strain index, there was not significantly different between the two groups. Therefore, at least in this cohort of patients, baseline RTSE did not suggest who would fail conservative treatment and may need surgery. During the follow-up of the operative group, the mean strain index was not significantly different from its baseline value; on the other hand, in the non-operative group, the mean strain index was significantly lower. Therefore the supraspinatus tendons were deemed to have softened over time in this group of patients (Table 1). At follow-up, the mean strain index in the affected there was a statistical difference for the operative group (0.69±0.17 and 0.59±0.16, respectively; p=0.04).

During the follow-up, we found a linear correlation between strain index measured and clinical outcomes in both groups. During the follow Interestingly, the baseline strain index was also linearly correlated with clinical outcomes (Table 3). Again, at least in this cohort of patients, baseline RTSE did not suggest which patients should have surgical treatment and which should have physical therapy.

Discussion

The most important data found in our study are:

- Baseline RTSE could be associated with postoperative functional outcomes at 2-year follow-up.
- The biomechanical properties of surgically repaired tendons were maintained over time.
- Nonoperatively treated tendons softened over time.
- At least in this cohort of patients, baseline RTSE did not suggest who could be managed conservatively and who will need surgery.

In everyday clinical practice, this information may help your doctor for more accurate counseling of patients suffering from rotator cuff injuries.

The patients enrolled in the two groups by us; they obtained comparable clinical results at follow-up. This is in agreement with a recent randomized controlled trial that, similarly to our study, included only non-traumatic tears [27]. On the other hand,

Table 2 Comparison in ROM between both the groups during the follow-up.

Operative group (N=15)		Non-operative group (N=28)	
Forward elevation			
Active	166±19	147±36	0.06
Passive	171±21	153±31	0.05
External rotation with the arm confortable at side			
Active	52±13	46±16	0.21
Passive	55±11	50±18	0.33
External rotation with the arm at 90° of abduction			
Active	85±16	74±12	0.01
Passive	88±12	79±17	0.07

Table 3 Pearson's correlation coefficient(r) between clinical variables and strain index at baseline and follow-up.

Operative group			Non-operative group	
	Baseline	Follow-up	Baseline	Follow-up
VAS for pain	-0.70	-0.76	-0.77	-0.73
Quick DASH	-0.69	-0.92	-0.52	-0.83
Constant Score	0.69	0.93	0.62	0.96
Simple Shoulder test	0.59	0.87	0.49	0.80
ASES score	0.63	0.88	0.67	0.64
UCLA score	0.76	0.95	0.59	0.92

operative treatment was associated with better results than conservative treatment in another study [19], but it has to be acknowledged that most of those tears (57%) were trauma-related. Several factors have been related to the failure of non-operative treatment, such as impingement sign, active external rotation angle, the integrity of the supraspinatus's intramuscular tendon of on MRI and presence of its atrophy on MRI. In our experience, also if the same standardized physical therapy programs were prescribed to all patients, the results of conservative treatment were highly influenced by therapist's skills and expertise. In agreement with Tanaka et al. [28], we think that degenerated quality of the tendons could be responsible for the failure of non-operative treatment. We are still working on histologic investigations to confirm this hypothesis [28].

In the present study, while the biomechanical properties of surgically repaired tendons were maintained, non-operatively treated tendons softened over time. This is in agreement with previous studies reporting that muscle atrophy and fatty infiltration are progressive if left untreated [28]. The protective effect of surgery on tissue quality is still controversial, in fact, muscle atrophy and fatty infiltration have been reported to improve, halt or deteriorate [29]. The present study favors the hypothesis that surgery may stop or slow down the progression of tendon degeneration.

Even if strain index at follow-up was lower in the non-operative group, patients obtained comparable outcomes in both groups. Observing the data reported in Table 3, a trend toward stronger correlation coefficients was found in the operative group comparing outcomes at follow-up and baseline strain index. Should patients with a certain value of strain index at baseline be indicated surgery immediately? Is there a threshold in strain index value that is associated with good results after operative/non-operative treatment? Can surgical repair influence the natural history of tendon degeneration in atraumatic rotator cuff tears? These questions are still unanswered, and more studies are needed in the future to improve our counseling to the patients.

The main limitation of our study is to determine an appropriate sampling and evaluation of inter and intra. observer variability. Although the same standardized physical therapy programs were prescribed to all patients, different therapists with different skills and expertise were involved, and this could have biased the results of the study

Conclusion

A correlation between baseline strain index and postoperative functional outcomes at 2-year follow-up could exist. Surgery seems to have a protective role in the injured tendons' quality over time. Nonoperatively treated tendons softened over time.

At least in this cohort of patients, baseline RTSE did not suggest who could be managed conservatively and who will need surgery.

Authors' Statements

Competing Interests

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

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