Giovanni Merolla, Paolo Paladini, Marco Saporito, Giuseppe Porcellini

Shoulder and Elbow Surgery D. Cervesi Hospital, Cattolica - Italy

Corresponding author:

Giovanni Merolla Shoulder and Elbow Surgery D. Cervesi Hospital, Cattolica - Italy e mail: gmerolla@shouldertech.it

Summary

Rotator cuff tears are a common cause of pain and shoulder dysfunction. The prevalence of the rotator cuff tears increases with the age reaching the 80% in patients aged more than 80 year. Symptomatic shoulders usually are initially treated conservatively and then, in case of poor outcomes, with surgery. Different parameters are still used to decide between the conservative or surgical treatment in patients with rotator cuff tears. Aim of the current study is to characterize the various features used in decision making and to validate a "Prediction Score" that let us know which patients could have a good and stable outcome with non operative treatment. We enrolled 60 patients (mean age 52 years) with symptomatic rotator cuff tears who were assigned to conservative treatment and were evaluated at 6.9 and 12 months follow-up. We developed a score based on 18 clinical and radiographic parameters. 27 patients ("non conservative") (45%) with a mean prediction score of 16.1 ± 1.7 interrupted the conservative treatment, while 33 patients ("conservative") (55%) with an average prediction score of 11.3 ± 1.8 remained conservatively treated at last follow-up. The conservative patients were 14 years older than non conservative patients. According to the results of this study we identified a value of 13 points as a "cut-off" score to predict good results by conservative management of rotator cuff tear. These outcomes support the assumption that a predictive prognostic score may guarantee a rational approach in the management of subjects with RC tears, especially in elderly who continue to have the higher rate of recurrence and therefore could be well treated with standard conservative therapies.

Key Words: shoulder, rotator cuff, conservative treatment, prediction score.

Introduction

Degenerative tear of the rotator cuff (RC) is a very common cause of pain and deficit of the shoulder. A high rate of patients after fifty years of age are affected by a RC tear and the most of them are asymptomatic (1-7). The prevalence of the RC tear increases with the age reaching the 80% in patients aged more than 80 years (8). Symptomatic shoulders in patients affected by RC tears usually are initially treated conservatively and then, in case of poor outcomes, with surgery (9-12). Often a symptomatic rotator cuff tear is associated with an asymptomatic cuff tear in the contralateral shoulder (13). The clinical outcome of the surgical treatment is still controversial due to the high percentage of recurrence tears (14-17). The factors determining the rerupture of the cuff have been described (18-20). On the contrary, the rate of successful conservative treatment varies from less than 50% to greater than 90%, in short or long term follow-up, with a wide variety of methods, duration of treatment and evaluation tools (10,11,21-23). Different parameters are still used to chooce the conservative or surgical treatment in patients with rotator cuff tears. Aim of the study is to characterize the various features used in decision making and to validate a prognostic score to predict which patients could have a good and stable outcomes with non operative treatment.

Patients and methods

Because all participating subjects followed a standard of care this study did not undergo institutional review board approval. All patients consented to voluntarily take part in this research. In January 2006, 60 consecutive patients with rotator cuff tears were prospectively enrolled. All the patients had a symptomatic rotator cuff tear. RC tears were detected with MRI (24). We excluded patients with the following associated lesions: glenohumeral osteoarthritis, A/C joint arthritis or dislocations, nerve palsy, previous shoulder surgery, calcifying tendonitis, gleno-humeral instability, SLAP lesions, rheumatoid arthritis, fractures, wheelchair users. We also excluded subjects with cognitive limitations. Demographic data of the patients are reported in Table 1.

All cases were evaluated at baseline (enrolling time), and at 6, 9 and 12 months by three independent clinicians with expertise in shoulder surgery. The Constant-Murley score (CS) (26) was used to evaluate the outcomes in the clinical examinations. Subjective satisfaction was graded on a nominal scale (0-100) as: excellent (80-100), good (60-

Table 1 - Demographic data of the population enrolled in the study.

Variable	Data
Patients (N°)	60
Mean age, (years + SD)	52 + 6.3
Gender (M/F) (%)	24(40)/36(60)
Dominant arm (right/left) (%) 50(83)/10(17)
Clinical tools	Constant-Murley score
	VAS score
Conservative therapies	Rehabilitation, Laser, NSAIDs
Follow-ups (months)	6 months
,	9 months
	12 months

sual analogic scale (VAS), asking the patients "How severe is your pain" using a 10 mm line with 0 (no pain) on the left and 10 (worse pain) on the right. All the patients were followed in our unit by a therapist team who set a 6 months schedule divided in 4 phases similiar to other standard protocols of rehabilitation (10, 26):

- Phase 1: pain control and self assisted excercises
- Phase 2: passive soft tissue streching, active mobilization in water pool
- Phase 3: strengthening exercises for humeral positioners and anterior deltoid
- Phase 4: maintenance program with active and passive mobilization including home exercises.

The program included 2 weeks (3 sessions/week) of assisted mobilization in the scapular plane, external and internal rotation; from the 3rd week began active mobilization in water-pool (3 sessions/week for 1 mounth) including assisted exercises for humeral depressors, and external/internal rotators. After completing the cycle of hydrotherapy, continued supervised strengthening exercises with elastic band for anterior deltoid, humeral positioners and internal/external rotators (2 sessions/week); in this phase the patients were instructed to begin home rehabilitation including active self-assisted mobilization, streching and strengthening exercises. In subjects with positive drop-sign, exercises for external rotation were not included in the schedule. Starting from the 4th mounths, all the patients followed a program of home exercises to reinforce the humeral depressor/deltoid anterior, external/internal rotators and scapular pivot.

All patients received 10 applications of Laser therapy at the end of every section of physiotherapy in the 1st mounth; antiflogistic non steroid drugs (NSAIDs) were assumpted in case of acute pain. None had steroid injections. We developed a score based on the following 18 parameters (Table 2): age, working activity, working compensation (WC), overhead sports, trauma, shoulder pain, previous rehabilitation, rotator cuff (RC) tear, drop sign, LHB tear or instability, acromion-humeral distance, scapular dyskinesis, muscle atrophy, fatty infiltration, stiffness, active range of motion (ROM), bilateral tear. The drop-sign (27) was assessed placing the the shoulder at 0° of abduction and 45° of external rotation (Fig. 1A), then the examiner ask the patient to maintain it in this position when he left the arm. The test is positive when the forearm drops back to 0° of external rotation (Fig. 1B). Scapular dyskinesis (28) was evaluated on the patients standing with the shoulder flexed at 90° (Fig. 2). Passive stiffness was assessed in supine using a standard goniometer, active motion was measured

Table 2 - Clinical and radiographic prognostic features of the rotator cuff prediction score.

Prognostic features	points	Prognostic features	points
Age		Drop sign	
> 60 years	0	Yes	0
< 60 years	1	No	1
Working activity		LHB	
light	0	Nomal	0
heavy	1	Rupture	0
Working compensation		Instability	1
Yes	0	AH interval	
No	1	> 7 mm	1
Overhead sport		< 7 mm	0
Yes	1	Scapular dyskinesis	
No	0	Yes	0
Shoulder trauma		No	1
< 6 months	1	RC muscle atrophy	
> 6 months	0	Grade I	3
Previous rehabilitation		Grade II	2
Yes	1	Grade III	1
No	0	Grade IV	0
RC tear		RC fatty infiltration	
complete	1	Grade 0 or I	2
partial	0	Grade II	1
Subscapularis tear		Grade III	0
Yes	1	Passive stiffness	
No	0	None or mild	2
Bilateral tear		Moderate	1
Yes	0	Severe	Ó
No	1	Active ROM	
		> 90%	0
		< 90%	1



Figure 1 A-B - Clinical assessment of "drop sign". When the examiner place the shoulder at 45° of external rotation (A) and it drop back to 0° (B) the test is positive.



Figure 2 - Patient's position to evaluate scapular dyskinesis.

in standing position. The questionnarie was administered to every patients at the baseline in order to obtain a mean of the scores attributed by the three surgeons.

No further scores were taken at follow-up examinations to avoid changing of the patients' treatment management. All the patients followed the previous reported rehabilitation program without variations based on the results of the score.

Statistical analysis

To ensure reliability of the final outcome scores, the preand post-rehabilitation program CS attributed by the three examiners were analyzed using Pearson's intraclass correlation coefficient (ICC) to determine the realibility of repeated values collected between testers. Data were averaged out among the different results (p<0.001). Student's t-test was used to highlight significant differences between pre- and post-rehabilitation program scores.

Results

The mean age of the patients enrolled was 52 years, with 20 patients younger than 60 years (min: 40, max: 59) and 40 patients older than 60 years (min: 60, max: 80). The average CS increased significantly at all 3 follow-ups (p < 0.01) (Fig. 3); the analysis of active ROM showed a significant improvement of forward elevation and abduction (p < 0.01), the internal and external rotation remain unchanged (p > 0.05) (Table 3).

The conservative treatment was interrupted by 27 patients (45%) who underwent to surgical procedure. We considered failed the conservative treatment when the patients complained for persistent pain at rest and were unable to perform daily living activity. At 6 months 40 subjects (67%) were very satisfied with a mean CS of 72±6.9 (P=0.00863) and 20 cases (33%) had worse score with an average 52.1±4.5 (P=0.0692); 16 of these underwent surgical ther-

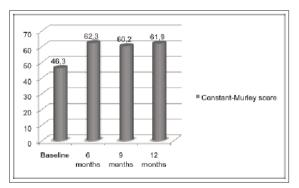


Figure 3 - Constant-Murley score of the study population at all three follow-ups.

Follow-up									
Active ROM	Baseline	6 months	P value	9 months	P value	12 months	P value		
FE (°)	108 + 3.2	160 + 4.9	0.00895	150 + 6.2	0.00987	145 + 5.8	0.00992		
Abduction (°)	92 + 2.8	150 + 4.3	0.00793	145 + 7.1	0.00679	140 + 6.1	0.00785		
ER(°)	45 + 5.2	42 + 4.9	0.0673	47 + 3.6	0.0753	46 + 5.6	0.0691		
IR(°)	50 + 6.4	52 + 3.7	0.0642	48 + 4.7	0.0629	54 + 3.5	0.0747		

Table 3 - Values of active ROM at all three follow-ups versus baseline.

apy. At 9 months 36 patients (60%) referred good subjective satisfaction with an average CS of 69.8 ± 5.1 (P =0.00895) while poor outcomes were found in 8 cases (13%) with a mean CS of 50.2+4.7 (P=0.0626); 6 subjects were surgically managed. Higher values of the CS (68.5 ± 3.9) (P =0.00961) were registered in 33 patients (55%) at 12 months, lower scores (50.9 ± 3.6) (P =0.0649) were recorded in 5 cases (8%) who underwent to surgical treatment. The course of VAS score is described in Figure 4. The analysis of the prediction score in the study population showed a mean value of 13.5 ± 2.7 (min: 8, max: 19). Among the 33 patients who remained conservatively treated at last follow-up the average prediction score was 11.3 ± 1.8 while the values registered in the 27 patients surgically managed were 16.1 ± 1.7 .

Among the 33 patients who reported good outcome after 12 months of conservative treatment, the mean age was 68 years and only 3 of them were under 60 years. The remaining 27 patients who did not continue the conservative therapy, had a mean age of 54 years with only 10 of these were older than 60 years. The values of Pearson's ICC recorded at each follow-up were closed to 1 (0.987; 0.978; 0.983) indicating a good interobserver correlation.

Discussion

RC injuries are a widespread problem that affect shoulder function and related patients' guality of life (1, 29, 30). Furhermore, the effects of shoulder pain due to RC tear are emphasized by aging and the following increased functional demands in elderly (31). Therefore, chronic RC pathology has become an issue of social interest for the considerable disability, poor quality of life and the expensive utilization of health care resources (32, 33). The decision to undertake a conservative (34) rather than surgical (35) treatment is controversial (36), especially for symptomatic degenerative RC ruptures (30, 37). Another aspect concerns the asymptomatic rotator cuff tears (38) that pass from subclinic condition in 10% in the fourth decade to 50% in the sixth decade and about 80% in the eight decade of life (39). Patients fifty years and older with a subclinical or asymptomatic RC tears develop a painful and weak shoulder within 5 years (1). Whereas the objective of non-surgical treatment is aimed to obtain pain relief and improving in shoulder function, there is no clear evidence about which treatments are most suitable and what they entail (10, 22, 34). Common conservative treatment include oral analgesics and NSAIDs, steroid injections, massage and exercises

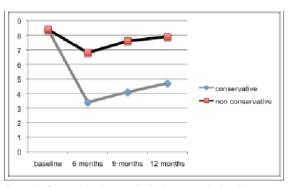


Figure 4 - Course of pain score in the "conservative" and "non conservative" subjects from baseline to 12 months

therapy, instrumental interventions (Laser, TENS, Ultrasounds), but there are few studies to support this kind of non surgical therapies (37,40-42). Arthroscopic and open repair of the RC showed satisfactory outcomes for pain and shoulder function, as recently reported by Millett et al. (43), who registered, after arthroscopic rotator cuff repair, a survivorship (defined as a shoulder requiring additional surgery) of 94% at 5 years and 83% at 10 years with a statistical significant improvement in mean ASES score; however, most of the results of arthroscopy included mid-term follow-up studies (12, 44, 45) and therefore the outcomes are not as well established as for long-term open procedure (46, 47). It should be also noted that, despite the good clinical results for pain relief and abilty to perform daily living activity, ultrasound (45, 47) and MRI (48, 49) findings demonstrated an high rate of recurrent defects. The factors affecting tendon healing included the patient's age at the time of the operation, the size and extent of the tear, and the presence of fatty degeneration in the rotator cuff muscle (47, 48). The decision to start a surgical procedure remains a choice of the surgeon in accordance with the patient and at the same time, there are no guidelines that can direct the cases to be submitted to conservative treatment. Although several older (11, 50-55) and recent (29, 36, 56-60) research articles reported the outcomes of conservative therapy in patients with symptomathyc fullthickness rotator cuff tears, few of these studies (52, 55, 59) have indicated the criteria for non surgical treatment. As results, we still have little understanding about which factors are related to good outcomes after conservative interventions. Since it is not possible to establish uniform criteria, the common treatment strategy is tailored to the individual case. According to the aforementioned considerations, we have identified the prognostic factors implicated in the selection of subjects could have satisfactory results by conservative treatment and on the basis of them we built a prediction score. With regard to the various parameters examined in the prediction score, we need to make some observations that emerge from tha current literature. The age is the most commonly used parameter in the decision making for the surgery of degenerative (9, 10, 23, 48, 61) and traumatic (62, 63) rupture of the rotator cuff. Poor results are found in patients aged 63 years and older (61, 64). Heavy work, especially if associated with repetitive movements of the arm above the equatorial plane, are often responsible for cuff injuries. Patients with work related injuries should be surgically treated but they have worse outocome compared to those of standard population and the difference are even greater when manual labour are involved (65, 66). Similarly, overhead sports can induce rotator cuff weakness or injuries and LHB pathology due to overuse syndrome (67, 68). Another important feature influencing the decision making of subjects with rotator cuff tears is made up by working compensation patients who have been recognized as having inferior surgical outcomes respect to the non-WC patients (69). About the timing for rotator cuff repair, recent research findings have demonstred that traumatic tears with a delayed surgerv within 3 months (62, 63) achieve better satisfatctory outcomes than chronic tears70, similarly the long duration of the symptoms represent an adverse prognostic factor for surgical approach (11). A previous history of non operative treatment is associated with unsatisfactory results in case of new conservative treatment (71). Although the surgical approach of partial RC tears is controversial, the rehabilitation seems to give better outcomes compared with full-thickness tendon tears and the prognosis become worse when a complete subscapularis lesion is associated (27, 72). Massive RC tears, including the whole external rotators, have been showed to not achieve good outcomes with non surgical measures and therefore a latissimus dorsi tendon transfer is recommended (73). Various pathologies affecting the LHB, including tendinitis, instability and incomplete tears, have been indicated as source of pain at rest and during the daily living activities; the inflammation of the LHB is attributed to surrounding RC pathologies and characterized as secondary process (74). LHB tendinitis and instability don't respond to common conservative therapies and should be treated with surgical intervention (75). An alteration of scapulohumeral rhythm, due to the fatigue of scapular stabilizers, can induce shoulder dysfunction with an associated decrease in rotator cuff strength (28, 76). In case of type II scapular dyskinesis associated with a cuff tear, surgical results may be negatively affected (77). Preoperative imaging, including X-ray, MRI and CT scans, can provide essential prognostic informations, in fact, it has been demonstred that a superior migration of the humeral head due to a complete lesion of the postero-superior RC associated with muscle atrophy and the fatty infiltration, complicate the surgical treatment with an high rate of recurrent tears, persistent pain and disability (19, 78-82). When the cuff lesion is associated with a controlateral tear and the range of motion is passively and actively limited, a conservative treatment should be preferred (83, 84).

In order to the specific features of the prediction score, some findings need to be emphasized from our study. About half

of the population enrolled ("conservative") continued the conservative therapy at last follow-up referring a good satisfaction, pain improvement and an acceptable quality of life. This subgroup conservatively treated, had a complete RC tear that was bilateral in 1 case and involved the upper portion of the subscapularis in 2 cases. Spontaneous rupture of the LHB was observed in 10 cases while only 2 patients were heavy workers and other 2 cases had a work-related injury; in 9 subjects with a positive drop-sign, we found a posterior superior cuff lesion with A/H interval lower than 7 mm. The MRI showed a grade III of muscle atrophy and relative fatty infiltration in 18 cases. In 30 out of 33 subjects, the active shoulder motion was higher than 90% with an an associated type II scapular dyskinesis. It was interesting to note that the 33 conservative patients were older than the remaining 27 subjects ("non conservative") who preferred to stop the protocol due to persistent pain and disability. The prediction score in the conservative patients ranged from 10.6 to 12.8, resulting lower compared with non conservative subgroup in which the average values were recorded 5 point higher (range: 15.2 - 17.3). Since the patients who benefit from conservative treatment had a score lower than 13 points, we identified this values as a "cut-off" score to predict a good results by conservative management of RC tear. Patients with an intermediate score ranging from 14 to 15 points, referred good satisfaction at an early follow-up but the outcomes have deteriorated over time so that only 5 out of 12 followed the conservative treatment after 12 months.

Some weak point are noteworthy in this study: 1) since this is a prognostic study the sample size of the study population could be too small to give definitive conclusions, 2) the clinical tool (Constant-Murley score) used to assess the patients is not adjusted and there is no comparison with other clinical scores to get supplemental data to analyze and discuss, 3) conservative treatment included rehabilitation, Laser therapy and NSAIDs, excluding steroid injections that are commonly used in the treatment of painful RC tears, 4) the sensitivity, specificity and accuracy of the prediction score "cut-off" was not calculated.

Although these limitations, the outcomes of our study support the assumption that a predictive prognostic score may guarantee a rational approach in the management of subjects with RC tears, expecially in elderly who continue to have the higher rate of recurrence and therefore could be well treated with standard conservative therapies. Specifically for the point 4, we think that further realibility studies are required to validate the prediction score as common clinical tool to use in the clinical practice.

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