



Review Article

Outcome assessment in the treatment of rotator cuff tear: what is utilized in Brazil?☆



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ARTICLE INFO

Article history:

Received 16 June 2016

Accepted 26 July 2016

Available online 1 September 2017

Keywords:

Shoulder

Evaluation of results of therapeutic interventions

Rotator cuff

ABSTRACT

This review evaluated the outcomes used in clinical studies involving rotator cuff tear published in the last decade in the two leading Brazilian orthopedic journals. A literature review was performed using the journals Revista Brasileira de Ortopedia and Acta Ortopédica Brasileira. It included all original clinical articles describing at least one outcome measured before or after any clinical or surgical intervention related to rotator cuff tear, published between 2006 and 2015. The authors evaluated range of motion, muscle strength, patient satisfaction, and tendon integrity and functional outcomes scores. There were 25 clinical studies published about rotator cuff in the two principal Brazilian orthopedic journals in the last decade, 20 case series (80%), one case-control (4%), and four cohorts (16%). Objective measures such as muscle strength, patient satisfaction, and evaluation of tendon integrity were little used. Range of motion measurements were performed in 52% of the articles. Evaluations of muscle strength and patient satisfaction were reported by 28% and 16% of the studies, respectively. Only 28% of the articles evaluated tendon integrity after surgery. Of these, 16% did so by magnetic resonance imaging and 12% by ultrasonography. The most used scale was the UCLA, present in 92% of the articles, while the Constant-Murley appeared in 20%. Scales deemed reliable, with high internal consistency and good responsiveness, were rarely used.

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<http://dx.doi.org/10.1016/j.rboe.2017.08.013>

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Avaliação dos desfechos no tratamento da rotura do manguito rotador: o que usamos no Brasil?

RESUMO

Palavras-chave:

Ombro

Avaliação de resultado de intervenções terapêuticas

Manguito rotador

Avaliamos os desfechos usados nos estudos clínicos que envolvem rotura do manguito rotador publicados na última década nos dois principais periódicos ortopédicos brasileiros. Foi feita uma revisão da literatura nos periódicos *Revista Brasileira de Ortopedia* e *Acta Ortopédica Brasileira*. Foram incluídos todos os artigos clínicos originais que descreviam ao menos uma medida de desfecho antes ou após alguma intervenção clínica ou cirúrgica referente ao manguito rotador publicados entre 2006 e 2015. Os desfechos avaliados foram arco de movimento, força muscular, satisfação, integridade tendínea e escalas clínicas. Foram publicados 25 estudos clínicos sobre manguito rotador nos dois principais periódicos ortopédicos brasileiros na última década, 20 séries de casos (80%), um estudo tipo caso-controle (4%) e quatro coortes (16%). Medidas objetivas como força muscular, satisfação do paciente e avaliação da integridade tendínea foram pouco empregadas. As medidas do arco de movimento foram descritas em 52% dos artigos. A avaliação da força muscular e a satisfação do paciente foram descritas em 28% e 16% dos estudos, respectivamente. Apenas 28% dos artigos avaliaram a integridade tendínea após a cirurgia. Desses, 16% o fizeram com a ressonância magnética e 12% com a ultrassonografia. A escala mais usada foi a da UCLA, presente em 92% dos artigos, enquanto a de Constant-Murley foi usada em 20%. Escalas consideradas confiáveis, com grande consistência interna e boa responsividade, raramente foram usadas.

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Introduction

Shoulder pain has a high prevalence in the population, ranging from 7 to 26%.¹ Rotator cuff conditions, the main cause of pain in the shoulder girdle, affect 20% of the general population and up to 50% of patients over 80 years.²

Standardized clinical assessment is essential to determine the efficacy of a treatment and also to compare the results of different studies; it is crucial in clinical research.^{3,4} Methods for evaluating the results of orthopedic treatment have been modified in recent years.^{5,6} Previously, measurements were based on physical examination, by examining joint mobility and muscle strength. However, questionnaires or clinical scales have been developed that have improved the evaluation of results.^{7,8} However, there is a wide variation in the measurement tools.⁹ More than 40 scales are described to assess shoulder pain and function.¹⁰ In addition, the measurement of the range of motion and strength, and the description of the imaging findings also do not have a consensus.⁹

Makhni et al.⁹ recently published a review involving the six leading international orthopedic journals, and described the tools used to assess outcome in rotator cuff disorders. We do not have a survey showing the main types of clinical evaluation in Brazil. Most instruments have been developed and evaluated in the English language.¹⁰ For these instruments to be used in Brazil, translation, cultural adaptation, as well as tests that evaluate measurement properties of these instruments, such as internal consistency, reproducibility, validity and responsiveness are recommended.⁵

The objective of this study was to evaluate the outcome used in clinical studies involving the rotator cuff published

in the last decade in the two main Brazilian orthopedic journals.

Methods

Design

A literature review was performed in the two main Brazilian orthopedic journals, *Revista Brasileira de Ortopedia* (RBO) and *Acta Ortopédica Brasileira*. The period covered was one decade (January 2006 to December 2015). This study was approved by the local Ethics Committee with number 1197.

Search strategy

The search strategy initially included the reading of all titles of the articles by one of the authors (JHA), using the journals' table of contents. In cases of doubt with the reading of the title, the abstract was evaluated. This way, all articles that did not involve the shoulder joint were excluded. Then the abstracts were read by three authors (JHA, EAM and VRD) and, if necessary, the full text, to determine if the article fit the selection criteria. In case of disagreement in the selection of a particular article among the three authors, whether including it or not was defined by consensus.

Selection criteria

All original clinical articles (randomized controlled trial, cohort, case-control and case series) that included at least

one outcome measure before or after a certain clinical or surgical intervention for the rotator cuff were included. Case reports, description of surgical technique, articles on diagnostic methods accuracy, anatomical studies, articles involving animals or cadavers, basic science or reviews were excluded.

Outcomes

Data regarding the study title, year and volume of the publication, casuistry, minimum follow-up, regular follow-up and level of evidence were tabulated. In addition, the following outcomes were assessed:

Range of motion

The evaluation of the range of motion was investigated: frontal flexion, elevation, abduction, lateral rotation (with the arm at the side of the body or abduction) and medial rotation (with the hand toward the back or with the arm in abduction). The measure in any of the aforementioned positions was listed. Data were only considered if quantitatively described in the results section. The position of the patient (supine, sitting or in a orthostatic position) and the use of a goniometer were also evaluated.

Muscle strength

The position in which strength was evaluated was studied: frontal flexion, elevation, abduction, lateral rotation (with the arm at the side of the body or abduction) and medial rotation (with the hand toward the back or with the arm in abduction). The measure in any of the positions was listed. Data were only considered if quantitatively described in the results section. The position of the patient (supine, sitting or in a orthostatic position) and the use of dynamometer were also evaluated. Manual evaluation data (graduation from 0 to 5) were computed. Data on a subdomain of a clinical scale were also reported.

Tendon integrity

The imaging method used (magnetic resonance with or without contrast, computed tomography with or without contrast or ultrasonography) was evaluated. Radiographs were not analyzed. The periodicity and timing in which the test was performed were reported. The use of some integrity assessment scales, or categorical evaluation in ruptured and intact tendons has been described. We also describe the presence or absence of data related to the acquisition and analysis of imaging tests: device used, evaluators, images obtained.

Satisfaction

Any data regarding patient satisfaction was studied. This included questions regarding treatment satisfaction or whether the patient would recommend the procedure to a third party or if they would have surgery again. Data on a subdomain of a clinical scale were also reported.

Evaluation scales and questionnaires

The functional scales and the evaluation questionnaires used by the authors were evaluated. We also reported studies that used visual analogue scale (VAS) for pain or function.

Statistical analysis

Data were exposed in a descriptive way, by means of absolute numbers and percentage.

Results

In the period evaluated, 712 original articles were published in the Brazilian Journal of Orthopedics and 588 in Acta Ortopédica Brasileira, or 1300 publications. Among these, 84 (6.7% of the total) were clinical articles on shoulder diseases; 25 publications (1.9% of the total)¹¹⁻³⁵ evaluated the clinical results of treatment of rotator cuff tears (Table 1); twenty studies (80%) were case series (level of evidence IV), one (4%) case-control study (level of evidence III) and four (16%) cohorts (level of evidence II). No randomized study was published in the period. We studied 1651 shoulders, 66.1 ± 50.3 shoulders per study. Eight articles (32%) had follow-up time of patients greater than two years and only two (8%) followed up with standardized assessment time. The mean of the evaluated outcome was 2.2 ± 1.1 (Fig. 1).

Range of motion

Among the studies evaluated, 12 (48%) did not report the measurement of the range of motion in any position in the postoperative period. Nine articles (36%) presented medial rotation, 11 (44%) evaluated the lateral rotation, same number found of publications that evaluated the patients' elevation. Three publications (12%) evaluated only one position of the range of motion, one (4%) evaluated two positions and nine (36%) presented the measurements of the range of motion in three positions (Fig. 2). The methodology applied in the measurement of the range of motion was reported in seven (28%) articles, the others did not report the use of goniometer, the measurement technique or the patient position.

Muscle strength

Muscle strength after rotator cuff repair was reported in seven studies (28%). In three studies (12%) it was presented as a subdomain of a functional scale, and in two articles (8%) it was reported categorically with the use of the contralateral side as a reference. Two studies (8%) used quantitative measurement of muscle strength using a dynamometer and reported the patient's position (orthostatic). Six studies (24%) evaluated only one position movement (elevation or abduction), one study¹⁵ evaluated the elevation and lateral rotation.

Tendon integrity

In 18 studies (72%), no postoperative imaging was performed to assess the integrity of the rotator cuff repair. Four

Table 1 – Publications on treatment of rotator cuff tears between 2006 and 2015.

Author(s)	Title	Journal	Year	Volume (number)	Pages
Pecora et al.	Prognostic factors for the clinical outcome following rotator cuff repair	Acta Ortopédica Brasileira	2015	23 (3)	146-149
Porto et al.	Evaluation of patients undergoing rotator cuff suture with the modified Mason-Allen technique	Acta Ortopédica Brasileira	2013	21 (3)	167-169
Ramos et al.	Results of arthroscopic treatment of rotator cuff tears	Acta Ortopédica Brasileira	2010	18 (1)	15-18
Checchia et al.	Isolated tear of the subscapular tendon	Acta Ortopédica Brasileira	2009	17 (1)	26-30
Veadó et al.	Rotator cuff tear in patients over 65 years: evaluation of function, integrity and strength	Revista Brasileira de Ortopedia	2015	50 (3)	318-323
Miyazaki et al.	Evaluation of results of arthroscopic surgical treatment of rotator cuff tears in patients ≥65 years	Revista Brasileira de Ortopedia	2015	50 (3)	305-311
Godinho et al.	Long-term functional evaluation of videoarthroscopic treatment of partial tears of the rotator cuff	Revista Brasileira de Ortopedia	2015	50 (2)	200-205
Godinho et al.	Result of arthroscopic surgical treatment of retears of the shoulder rotator cuff	Revista Brasileira de Ortopedia	2015	50 (1)	89-93
Almeida et al.	Comparative analysis of arthroscopic suture of large and extensive tears of the rotator cuff related to the level of osteopenia	Revista Brasileira de Ortopedia	2015	50 (1)	83-88
Miyazaki et al.	Functional evaluation of arthroscopic repair of the rotator cuff tears in pseudoparalysis patients	Revista Brasileira de Ortopedia	2014	49 (2)	178-182
Ikemoto et al.	Evaluation of the clinical-functional results of the repair of extensive rotator cuff tear with inclusion of the tendon of the long head of the biceps	Revista Brasileira de Ortopedia	2013	48 (2)	165-169
Malavolta et al.	Platelet-rich plasma in the arthroscopic repair of complete tears of the rotator cuff	Revista Brasileira de Ortopedia	2012	47 (6)	741-747
Ikemoto et al.	Arthroscopic repair of small and medium tears of the supraspinal muscle tendon: evaluation of clinical-functional results after two years of follow-up	Revista Brasileira de Ortopedia	2012	47 (4)	436-440
Godinho et al.	Results of the arthroscopic repair of isolated tears of the subscapular muscle tendon	Revista Brasileira de Ortopedia	2012	47 (3)	330-336
Veadó et al.	Prospective and comparative study of the functional results after the open and arthroscopic repair of rotator cuff tears	Revista Brasileira de Ortopedia	2011	46 (5)	546-552
Miyazaki et al.	Evaluation of results of the arthroscopic repair of rotator cuff tears in patients up to 50 years of age	Revista Brasileira de Ortopedia	2011	46 (3)	276-280
Almeida et al.	Comparative analysis of the result of arthroscopic suture of the rotator cuff in smoking and non-smoking patients	Revista Brasileira de Ortopedia	2011	46 (2)	172-175
Miyazaki et al.	Evaluation of results of reoperations of patients with rotator cuff tears	Revista Brasileira de Ortopedia	2011	46 (1)	45-50
Veadó et al.	Functional evaluation of patients undergoing arthroscopic debridement for the treatment of extensive and irreparable tears of the rotator cuff	Revista Brasileira de Ortopedia	2010	45 (5)	426-431
Godinho et al.	Evaluation of the anatomical integrity through ultrasound and functional integrity through Constant & Murley index of the rotator cuff after arthroscopic repair	Revista Brasileira de Ortopedia	2010	45 (2)	174-180
Miyazaki et al.	Extensive tears of the rotator cuff: evaluation of results of the arthroscopic repair	Revista Brasileira de Ortopedia	2009	44 (2)	148-152
Veadó et al.	Functional evaluation of the arthroscopic repair of complete tears of the rotator cuff associated with acromioplasty	Revista Brasileira de Ortopedia	2008	43 (11/12)	505-512
Balsini et al.	Arthroscopic repair of complete isolated tears of the subscapular	Revista Brasileira de Ortopedia	2008	43 (11/12)	497-504
Veadó et al.	Functional and structural analysis of rotator cuff extensive tears repair	Revista Brasileira de Ortopedia	2006	41 (8)	294-301
Veadó et al.	Efficacy of arthroscopic debridement in partial rotator cuff tears	Revista Brasileira de Ortopedia	2006	41 (1/2)	22-28

publications (16%) used non-enhanced magnetic resonance imaging to check for tendon integrity, and in three (12%) an ultrasound exam was used. All studies used only a categorical evaluation, complete or ruptured repair. Only three studies (12%) mention the number of evaluators and in two (8%) the specifications of the device used are reported. No study mentions image acquisition protocols. The tests were done once

in all studies, and only one study performed the exam on a regular basis (12 months).²²

Satisfaction

Only four studies (16%) reported patient satisfaction in their results; two studies (8%) assessed whether the patient would

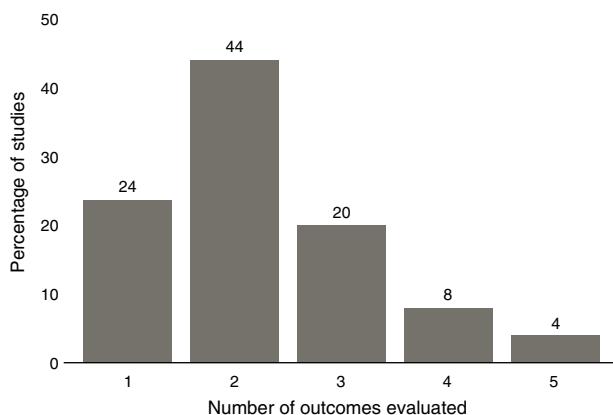


Fig. 1 – Percentage distribution of number of outcomes analyzed per study.

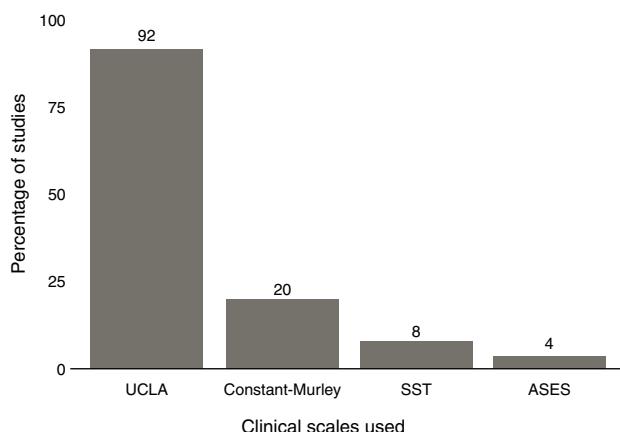


Fig. 3 – Percentage of studies using clinical scales.

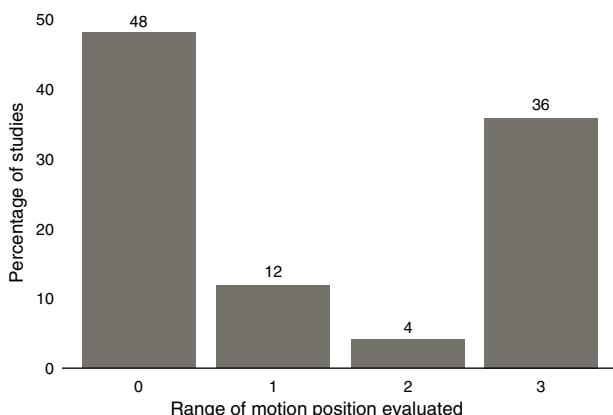


Fig. 2 – Percentage distribution of number of range of motion positions evaluated per study.

agree to undergo treatment again, and two (8%) assessed satisfaction through a simple question with two categories (satisfied/dissatisfied).

Evaluation scales and questionnaires

Of the 25 studies included, 23 (92%) used the University of California, Los Angeles Shoulder Rating Scale (UCLA),³⁶ five papers (20%) used the Constant–Murley evaluation questionnaire,³⁷ two (8%) evaluated the results through the Simple Shoulder Test (SST)³⁸ and one (4%) through the questionnaire American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form (ASES)³⁹ (Fig. 3); 20 publications (80%) used only one scale, four (16%) made the evaluation through two scales and one study (4%) through three questionnaires. In four articles (16%) VAS was used to quantify pain before and after treatment.

Discussion

Rotator cuff tear is the main cause of shoulder pain² and the repair of the rotator cuff is the most commonly performed surgery of this joint.⁴⁰ However, in the period evaluated, only

25 publications were found that evaluated the clinical results of the treatment of rotator cuff tears in the two main Brazilian journals of orthopedics and traumatology. The national average was 2.5 articles per year. Between 2010 and 2014, an average of 4.8 and 8.8 articles per year were published in the two major comprehensive orthopedic journals, Journal of Bone & Joint Surgery and The American Journal of Sports Medicine, respectively.

The Brazilian studies evaluated the results with a mean of 2.2 outcomes per article, a number that was similar to that observed in international studies.⁹ However, only 32% of the studies had patients' follow-up of more than two years, and 8% had a follow-up with standardized evaluation time. We also found that national publications on this topic have a low level of evidence, 80% were case series, and we did not find an article with level I evidence, unlike the main foreign journals, which report 13% of studies with level I, 17% with level II, 26% with level III, and only 43% with level IV.⁹ The predominance of case series is a characteristic of Brazilian orthopedic publications.⁴¹

The most used evaluation questionnaire for Brazilian studies was the UCLA scale, used in 92% of the publications. This number is far superior to that of Makhni et al.,⁹ who found that it had been used only in 35% of articles, the third in prevalence. This scale was initially developed for patients undergoing total shoulder arthroplasty.⁴² Ellman et al.⁴³ were the first authors to apply this tool to evaluate the results of the treatment of rotator cuff tears; since then, it has been used in several publications. However, there are no studies to validate its development and the application of this instrument in these patients. It is considered a scale with low reliability and validity, and has several limitations in the collection of information.⁴⁴ A recent systematic review comparing the assessment scales for shoulder diseases found that the best are the ASES, SST and Oxford Shoulder Score scales. They are considered reliable, with great internal consistency, good responsiveness, and were previously validated.⁴⁵ In our study, only one publication (4%)¹⁸ used the ASES scale, and two studies (8%)^{15,32} used SST for evaluation. On their turn, Makhni et al.⁹ observed that the publications of the six major international orthopedic journals between 2010 and 2014 used scales

considered more reliable; ASES questionnaire was used in 59%, and the SST in 28%.

The Constant–Murley scale³⁷ was the second most used, observed in five articles (20%). This scale is the most used in internationally published studies (61% of publications). This tool has as main limitation the difficulty and variability for the evaluation of the abduction strength, which represents 25% of its total score. Several authors report its inconsistency,⁴⁶ depending on the dynamometer used,⁴⁷ on the degree of shoulder abduction and rotation,⁴⁸ and on strength relative to age and gender.⁴⁹ Only recently has this scale been translated and culturally adapted to the Portuguese language.³⁷ Indexes of normality are available for some countries but have not been validated in Brazil.⁴⁹ We believe that the use of the Constant–Murley Individual Relative Scale, when compared to the contralateral shoulder when it is asymptomatic, the use of digital dynamometers, and scale training reduced bias in the use of this instrument.⁵⁰⁻⁵²

In the Brazilian journals, only 28% of studies evaluate tendinous integrity after surgery. Of these, 16% do so with MRI, and 12% with ultrasound. These values are lower than those reported in international journals, in which 65% of the studies use imaging in the postoperative period, MRI is cited in 38%, ultrasound in 31%, and arthrotomography in 8%.⁹ In addition, none of the articles evaluating integrity through MRI use a scale of evaluation, only the stratification into intact and ruptured. Except for the determination of the simple absence or presence of a tear, the classification proposed by Sugaya et al.⁵³ is the most used and reliable, cited in 33 studies in a recent meta-analysis.⁵⁴

Our results show that the description of measures of the range of motion is made in 52% of the articles, a figure slightly lower than the 63% reported in foreign journals.⁹ The same occurs regarding evaluation of strength, described in 28% of national studies, and 38% of international ones.⁹ Satisfaction, in its turn, is evaluated in only 16% of the studies, considerably less than the 54% found in international studies.⁹ However, few articles have reported the methodology used to evaluate these measures clearly and reproducibly. It should be noted that none of the national studies used tools to measure quality of life, unlike international journals, which cite these outcomes in more than 15% of cases.⁹

Our study has some limitations. It included all types of clinical studies, thus having level IV of evidence. However, the greater possibility of bias in articles of lower level of evidence did not influence our results, since we evaluated the tools used, not the outcomes themselves. In addition, we have reviewed the articles of only one decade and two national journals. The aim of this approach was to plot the national picture in a relatively recent period. Finally, our search strategy may have included articles by foreign authors published in national journals, and did not include articles by Brazilian authors published in international journals.

We believe that the members of the Brazilian Society of Shoulder and Elbow Surgery should initiate a discussion to standardize the evaluation tools. Attitudes such as these, already taken by US⁵⁵ and Japan⁵⁶ societies, facilitate data comparison among the studies, allow for more consistent exposure of results, and increase the possibilities of citing national articles. ASES and SST scale, already validated for the

Portuguese language, and with good reliability,^{38,57} should be prioritized, along with the Constant–Murley scale adjusted for gender and age; normality indices should be obtained for the Brazilian population. In addition, quality of life assessment should be encouraged. Likewise, the assessment of strength and amplitude could be in line with that used in international studies. The assessment of tendinous integrity after surgery should be encouraged and when MRI is used, it should be made through the classification by Sugaya et al.⁵³

Final considerations

Twenty-five clinical studies on rotator cuff were published in the two main Brazilian orthopedic journals in the last decade. The most used scale was UCLA, present in 92% of the articles. Scales considered reliable, with great internal consistency and good responsiveness, were rarely used. Objective measures such as muscle strength, patient satisfaction and evaluation of tendon integrity were poorly used.

Conflicts of interest

The authors declare no conflicts of interest.

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