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REVIEW ARTICLE

Outcomes assessment in rotator cuff pathology: what are we measuring?

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Background: Assessments used to measure outcomes associated with rotator cuff pathology and after repair are varied. This lack of standardization leads to difficulty drawing comparisons across studies. We hypothesize that this variability in patient-reported outcome measures and objective metrics used in rotator cuff studies persists even in high-impact, peer reviewed journals.

Methods: All studies assessing rotator cuff tear and repair outcomes in 6 orthopedic journals with a high impact factor from January 2010 to December 2014 were reviewed. Cadaveric and animal studies and those without outcomes were excluded. Outcome measures included range of motion (forward elevation, abduction, external rotation, and internal rotation), strength (in the same 4 planes), tendon integrity imaging, patient satisfaction, and functional assessment scores.

Results: Of the 156 included studies, 63% documented range of motion measurements, with 18% reporting range of motion in all 4 planes. Only 38% of studies reported quantitative strength measurements. In 65% of studies, tendon integrity was documented with imaging (38% magnetic resonance imaging/magnetic resonance anrhrogram, 31% ultrasound, and 8% computed tomography arthrogram). Finally, functional score reporting varied significantly, with the 5 most frequently reported scores ranging from 16% to 61% in studies, and 15 of the least reported outcomes were each reported in $\leq$6% of studies.

Conclusions: Significant variability exists in outcomes reporting after rotator cuff tear and repair, making comparisons between clinical studies difficult. Creating a uniformly accepted, validated outcomes tool that assesses pain, function, patient satisfaction, and anatomic integrity would enable consistent outcomes assessment after operative and nonoperative management and allow comparisons across the literature.

Level of Evidence: Level IV, Systematic Review.

Keywords: Rotator cuff tear; outcomes; rotator cuff repair; patient-reported outcomes

During the past several years, patient-reported outcomes (PRO) have become increasingly important in orthopedic management and literature, such that multiple different outcomes are routinely reported in patient encounters and clinical studies. This increased use, however, causes challenges due to

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the variable nature of administration[26] and reporting of these outcomes tools. In addition, there is a lack of consensus when considering the collection and reporting of conventional metrics such as range of motion, strength, and imaging findings. This lack of standardization creates challenges when attempting to compare results across multiple studies.

The goal of this study was to quantify the variability in outcomes reporting of a common orthopedic condition—rotator cuff tear—across articles published in high-impact orthopedic journals. We hypothesize that there will be significant variability across the types of metric reported (ie, range of motion, strength, imaging, functional scores, and satisfaction) as well as across individual metrics (ie, among the available validated outcomes scores). Understanding this variability is crucial in taking the first steps toward standardizing reporting of outcomes for patients with any given disease.

Materials and methods

A comprehensive literature review was performed across 6 orthopedic journals with high impact factors during a 5-year period (January 2010 through December 2014) to identify all literature pertaining to clinical trials of rotator cuff pathology and repair. These journals were intentionally chosen to extract the highest quality studies from publications that include literature on shoulder surgery.[1,3,4,6,16,17] The journals selected were *Journal of Shoulder and Elbow Surgery, The Journal of Bone & Joint Surgery* (*American volume*), *The Journal of Bone & Joint Surgery* (*British volume*)/*The Bone & Joint Journal*, *Clinical Orthopaedics and Related Research*, *The American Journal of Sports Medicine*, and *Arthroscopy.* All articles with keywords of ''rotator cuff,'' ''rotator cuff tear,'' and ''rotator cuff repair'' were selected for review. This methodology has been used previously[12,21] in similar studies.

Inclusionary criteria consisted of any study reporting clinical outcomes for patients with any type of rotator cuff pathology at baseline or after an nonoperative or operative intervention. Exclusionary criteria included any study that predominately focused on screening or diagnostic outcomes, such as studies documenting imaging findings without any clinical correlations, cadaveric, animal, or basic science studies, and review articles/meta-analyses, case reports, and registry studies.

For each study that met final inclusionary criteria, several metrics were collected. These included country of origin (corresponding to the origin of the senior author), level of evidence, number of patients, mean patient age, predominate size of the tear (partial, small, or medium vs large or massive vs not specified or all inclusive), and outcomes assessed. Outcomes were grouped into 5 categories: range of motion, quantitative strength testing, imaging assessing tendon integrity or healing, patient satisfaction, and PRO scores. When appropriate (eg, comparison of number of PRO used across journal types), analysis of variance testing was used to analyze continuous data.

Range of motion

Range of motion outcomes for each study were reported in any of the following planes: forward elevation/flexion, abduction, external rotation (at the side or in abduction), and internal rotation (at the side or in abduction). Range of motion noted in any of these planes was recorded (ie, a study did not need to report motion in all of these planes), and was only documented as being reported in a given study if it was clearly included or referenced in the results section. This includes reporting of actual values for given range of motion parameters or conclusions based on relative values (eg, with regards to change in value preoperatively and postoperatively). Reporting of patient position (eg, supine, standing) and the measuring tool (eg, goniometer) was varied, and only quantitative values of range of motion were considered valid for reporting.

Strength

Strength was documented as being reported in a given study if a quantitative measurement of strength was performed and reported. The following planes of strength measurement were considered: forward elevation/flexion, abduction, external rotation, and internal rotation. Strength noted in any of these planes was recorded (ie, a study did not need to report strength in all of these planes). Any reporting of ''supraspinatus'' strength was defined as being measured in abduction. For this study, only quantitative strength measurements, such as those obtained with the use of a dynamometer, were considered. Testing through manual muscle testing, which usually was on a 0 to 5 rating system, was not included because it was not a quantitative outcome measurement. Strength that was reported as a subset of a functional score (eg, Constant score) was included for the appropriate plane of motion, provided it was a quantitative measurement.

Imaging for tendon integrity

Imaging for the purpose of assessing tendon integrity was noted for each study. This included any use of imaging to assess the status of tendon repair or incidence of repeat tear after an intervention. Baseline radiography was not considered. Moreover, only methodologic use of follow-up imaging was considered, as opposed to its use in only a subset of study patients such as those with complications. These modalities included ultrasound, computed tomography with contrast, or magnetic resonance imaging (MRI)/magnetic resonance arthrogram (MRA) (with or without contrast).

Patient satisfaction

Any reporting of patient satisfaction was noted. This included questions related to satisfaction of treatment, willingness to recommend a surgery or treatment to another person, or whether the patient would undergo the treatment if offered it again. Any study that specifically documented patient satisfaction in any of these parameters was noted. Satisfaction that was reported as a subset of a validated patient-reported outcome measure, such as the University of California, Los Angeles (UCLA) Shoulder Rating Scale, was not included in this calculation because these measures are reported elsewhere.

Clinician and Patient Derived Outcomes

All validated outcomes—both clinician-derived and patient-derived—were documented (complete listing in Table I). With regards to validated functional outcomes, any reporting of the