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Assessment of rotator cuff repair integrity using ultrasound and magnetic resonance imaging in a multicenter study

Michael J. Codsi, MD^a,*, Scott A. Rodeo, MD^b, Jason J. Scalise, MD^c, Tara McDonnell Moorehead, BA^d, C. Benjamin Ma, MD^e

^aThe Everett Clinic, Everett, WA, USA ^bHospital for Special Surgery, New York, NY, USA ^cThe CORE Institute, Phoenix, AZ, USA ^dinVentiv Health Clinical, contracted to Pfizer Inc, Cambridge, MA, USA ^eUniversity of California San Francisco, Orthopedic Surgery, San Francisco, CA, USA

Background: This study compared ultrasound and magnetic resonance imaging (MRI) evaluation of the repaired rotator cuff to determine concordance between these imaging studies.

Methods: We performed a concordance study using the data from a prospective nonrandomized multicenter study at 13 centers. A suture bridge technique was used to repair 113 rotator cuff tears that were between 1 and 4 cm wide. Repairs were evaluated with MRI and ultrasound at multiple time points after surgery. The MRI scans were read by a central radiologist and the surgeon, and the ultrasounds were read by a local radiologist or the surgeon who performed the ultrasound.

Results: The concordance between the central radiologist's MRI reading and the investigator's MRI readings at all time points was 89%, with a κ coefficient of 0.60. The concordance between the central radiologist's MRI and ultrasound readings at all time points was 85%, with a κ coefficient of 0.40. The concordance between the investigator's MRI and ultrasound readings was 92%, with a κ coefficient of 0.70. **Conclusions:** In the community setting, ultrasound may be used to evaluate the integrity of a repaired rotator cuff tendon and constitutes a comparable alternative to MRI when evaluating the integrity of a rotator cuff repair. Clinical investigators should compare their postoperative ultrasound results with their postoperative MRI results for a certain time period to establish the accuracy of ultrasound before relying solely on ultrasound imaging to evaluate the integrity of their rotator cuff repairs.

Level of evidence: Level III, Diagnostic Study.

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Keywords: Rotator cuff repair; MRI; ultrasound; surgery; arthroscopy

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*Reprint requests: Michael J. Codsi, MD, 6541 Chapin Pl N, Seattle, WA 98103, USA.

E-mail address: mikecodsi@gmail.com (M.J. Codsi).

Postoperative images of rotator cuff repairs can be difficult to interpret. The most commonly used modality is magnetic resonance imaging (MRI) because it is easy to obtain, creates images that are portable and can be interpreted by multiple clinicians, and allows the evaluation of

1058-2746/\$ - see front matter © 2014 Journal of Shoulder and Elbow Surgery Board of Trustees. http://dx.doi.org/10.1016/j.jse.2014.01.045 other intra-articular pathology besides the rotator cuff. However, MRI can be difficult to interpret in a postoperative shoulder due to artifact from metallic suture anchors as well as persistent abnormalities in signal intensity and morphology in surgically manipulated tendon. Scar tissue and soft tissue edema can also complicate the interpretation of MRI. The addition of intra-articular contrast may affect tissue contrast, thus making residual partial defects or retears of the rotator cuff easier to see, but it also has its limitations: intra-articular contrast is invasive, and the clinical importance of a small contrast leak is unclear because a rotator cuff repair does not need to be watertight to be functional.

Ultrasound is another imaging modality that has gained popularity among surgeons because it can be used in the clinic and the results can be seen immediately. Unlike MRI, ultrasound allows the rotator cuff repair to be viewed dynamically and without any artifact from the metal implants that are often used for the repair.¹⁷ Numerous studies have shown that ultrasound and MRI are equally accurate at diagnosing rotator cuff tears before surgery.^{3,4,15,18} However, very few studies have reported the sensitivity, specificity, and accuracy of ultrasound for the diagnosis of rotator cuff postoperative healing. These studies have usually taken place in only specialized centers with experienced radiologists, making it difficult to apply the results to the community setting.^{6,12}

It is well-established that ultrasound imaging is operator-dependent. The quality of the images directly relate to the experience of the ultrasonographer. Historically, some clinicians have favored MRI over ultrasound for the evaluation of rotator cuff healing for precisely this reason, believing that ultrasound is more technically demanding and that community radiologists do not have the same experience in interpreting ultrasound images as they do MRI images. A multicenter research study that includes nonspecialized radiologists performing the ultrasounds will be helpful to determine whether the results of ultrasound evaluations of rotator cuff repair can be generalized from tertiary research centers to the community setting.

The purpose of this prospective nonrandomized multicenter concordance study was to correlate the results of ultrasound and MRI assessments used for patients who underwent arthroscopic rotator cuff repair. The orthopedic surgeons or local radiologists with varying degrees of experience performed and interpreted the ultrasounds. The surgeons at the centers and one central musculoskeletal radiologist all independently interpreted each MRI. The results of such a study design may provide useful information to a clinician who works in the community setting.

Materials and methods

We performed a concordance study using the data obtained from a prospective nonrandomized study that was performed at 13 centers

| Table I | Inclusion and exclusion criteria for the study | | |
|---|--|--|--|
| Inclusion criteria | | | |
| Age be | tween 21 and 75 years | | |
| Tear siz | Tear size of the supraspinatus and infraspinatus tendons was | | |
| between 1 and 4 cm | | | |
| Range of motion of the shoulder was at least 140 $^\circ$ of | | | |
| elevation and all motion was within 20 $^\circ$ of the opposite | | | |
| normal shoulder | | | |
| Exclusion | criteria | | |
| Previou | s surgery | | |
| Should | er instability | | |
| Moderate or severe degenerative changes of the | | | |
| glenohumeral joint | | | |
| Avascular necrosis | | | |
| Chondrolysis | | | |
| Inflamı | Inflammatory arthritis | | |
| Treatment within 3 months of surgery with a steroid | | | |
| injec | tion or systemic steroids | | |
| Subscapularis tears | | | |
| Labral tear that required repair | | | |
| Stage 3 or 4 fatty degeneration according to the Goutallier classification | | | |
| Clubb | meation | | |

across the United States between October 2008 and July 2011. Fellowship-trained shoulder surgeons recruited 162 patients with 1to 4-cm-wide tears of the supraspinatus tendon. Of these patients, 155 underwent surgical repair of the rotator cuff, and 113 were deemed evaluable because they met the eligibility criteria of the study (Table I) and received the protocol-defined surgical repair. During the 1-year postoperative period, 665 MRIs and 550 ultrasounds were performed for the 113 evaluable patients.

We performed preoperative screening MRI and an ultrasound to ensure that all patients met the inclusion and exclusion criteria. We enrolled eligible patients in the study and treated them with an arthroscopic surgical repair with a double-row, transosseousequivalent suture bridge technique using metal suture anchors medially and transosseous-equivalent anchors laterally. We allowed additional procedures at the time of repair, including subacromial decompression, biceps debridement, and biceps tenotomy.

We evaluated postoperative tendon healing using MRI and ultrasound assessment at 6, 12, 16, 26, and 52 weeks. Patients also had a clinical evaluation and MRI 2 weeks after surgery, but did not undergo an ultrasound evaluation at that visit because the range of motion needed for a thorough ultrasound examination would be neither possible nor advisable for most patients at that time. We used a standardized immobilization and rehabilitation protocol for all patients after surgery.

The protocol for obtaining MRIs was the same at all of the centers (Appendix 1). At the screening and at 52 weeks, the evaluation consisted of a study-specific MRI scan that included T1, T2, and proton-density imaging in the coronal, sagittal, and axial planes. The oblique sagittal T1-weighted spin echo sequence consisted of slices prescribed on the axial localizer perpendicular to a line parallel to the spine of the scapula. Coverage for this prescription was from the deltoid muscle anterolaterally to beyond where the scapular spine meets the scapular body posteromedially. The oblique sagittal fat-saturated proton-density-weighted fast spin echo (FSE) had the same slice prescription as described for

the T1 imaging. The slices for the axial fat-saturated protondensity-weighted FSE were prescribed from at least 1 cm above the acromioclavicular joint to at least 1 cm below the inferior edge of the glenoid. The bicipital groove of the humerus and the teres minor muscle were included in the image.

At all other visits, the MRI sequence included only the T2weighted and proton-density-weighted oblique coronal view. For the oblique coronal T2-weighted FSE, slices were prescribed on the axial localizer at the level of the supraspinatus tendon. Coronal slices were prescribed parallel to the supraspinatus tendon, and coverage included the subscapularis muscle anteriorly and infraspinatus muscle posteriorly. The oblique coronal fat-saturated proton-density-weighted FSE consisted of the same slice prescription as the oblique coronal T2-weighted FSE. All readings were performed at the time of the visit during the study and were not reread at the conclusion of the study. The operating surgeon reviewed the preoperative MRI and determined patient eligibility.

Fatty infiltration was graded by the Goutallier classification as defined by Fuchs et al.⁵ Grade 0 is no fat seen in the muscle. Grade 1 is trace fat in the muscle. Grade 2 is less than 50% fat in the muscle. Grade 3 is 50% fat in the muscle. Grade 4 is more than 50% fat in the muscle. An independent central radiologist also assessed the tear on the screening MRI, but the central radiologist's readings were not used to determine patient eligibility. The surgeon at each center then assessed the postoperative MRI to determine whether the repair was intact. Repairs with partial-thickness defects, even those smaller than the preoperative tear, were considered a failed repair. The central radiologist performed the same assessment for all postoperative MRIs. The surgeons and the central radiologist were blinded to each other's assessments throughout the study.

The surgeon performed the ultrasounds on 29 of the 113 patients, and the local radiologist performed the ultrasounds for 84 patients. Surgeons were allowed to perform their own ultrasounds if they were already using ultrasound routinely in the office to evaluate the rotator cuff tendon before this study began. The ultrasound was requested for each patient to evaluate the rotator cuff repair and determine whether the repair was intact. Any repair with a partial-thickness defect was considered intact, but any full-thickness defect, regardless of size, was considered to indicate a failed repair. The central radiologist was blinded to the ultrasound results and the previous MRI results. The surgeons and local radiologists who read the ultrasounds at their respective sites were not blinded to the results of the MRIs.

Statistical analysis

The study took into account the following comparisons: (1) the central radiologist's MRI reading vs the investigator's MRI reading, (2) the central radiologist's MRI reading vs the ultrasound reading, and (3) the investigator's MRI reading vs the ultrasound reading. We used SAS 9 software (SAS Institute Inc, Cary, NC, USA) to calculate all of our statistics. Concordance was calculated for every comparison between the 3 imaging interpretations. A κ coefficient was calculated to determine the repeatability of image interpretation. Perfect agreement showed a κ coefficient of 1.0, and no agreement beyond chance showed a κ coefficient of 0.0. A κ coefficient greater than 0.7 showed excellent agreement beyond chance, and greater than 0.5 showed good agreement beyond

Table II Concordance and κ values for all image comparisons between the central radiologist's magnetic resonance imaging reading and the investigator's reading

| Time after surgery | Central radiologist's MRI reading vs investigator's MRI reading | | | |
|-----------------------|--|---------|---------------|--|
| | Concordance, % | κ value | CI (95%) | |
| 2 weeks | 96 | 0.49 | -0.10 to 1.00 | |
| 6 weeks | 94 | 0.27 | -0.15 to 0.70 | |
| 12 weeks | 90 | 0.37 | 0.07-0.66 | |
| 16 weeks | 92 | 0.66 | 0.42-0.89 | |
| 26 weeks | 92 | 0.66 | 0.46-0.87 | |
| 52 weeks | 93 | 0.65 | 0.43-0.87 | |
| Overall | 89 | 0.60 | 0.40-0.81 | |
| | | | | |

CI, confidence interval; MRI, magnetic resonance imaging.

chance. A ϕ statistic was also calculated to account for the possibility of skewed data distribution.

Results

The concordance between the central radiologist's and investigator's MRI readings at all time points was 89%, with a κ coefficient of 0.60 and a φ coefficient of 0.60. The concordance at 2, 6, 12, 16, 26, and 52 weeks was 96%, 94%, 90%, 92%, 92%, and 93%, respectively. Although the concordance was high at 6 weeks, at 92%, the κ coefficient was the lowest at 0.27. The κ value at 2, 6, 12, 16, 26, and 52 weeks was 0.49, 0.27, 0.37, 0.66, 0.66, and 0.65, respectively (Table II).

The concordance between the central radiologist's MRI and ultrasound readings at all time points was 85%, with a κ coefficient of 0.40 and a ϕ coefficient of 0.40. The concordance at 6, 12, 16, 26, and 52 weeks was 95%, 88%, 89%, 89%, and 87%, respectively. The κ value at 6, 12, 16, 26, and 52 weeks was 0.43, 0.30, 0.42, 0.48, and 0.37, respectively (Table III).

The concordance between the investigator's MRI and ultrasound readings at all time points was 92%, with a κ coefficient of 0.70 and a φ coefficient of 0.70. The concordance at 6, 12, 16, 26, and 52 weeks was 97%, 93%, 92%, 93%, and 91%, respectively. The κ value at 6, 12, 16, 24, and 52 weeks was 1.00, 0.64, 0.71, 0.74, and 0.59, respectively (Table IV).

Discussion

This prospective study used MRI and ultrasound imaging to evaluate rotator cuff integrity after a standardized repair and demonstrated good agreement between the central radiologist's and site investigator's evaluations of MRI findings. The concordance between the MRI and ultrasound readings was only modest for the central radiologist, but

Table III Concordance and κ values for all image comparisons between the central radiologist's magnetic resonance imaging reading and the ultrasound reading

| Time after | Central radiologist's | MRI reading | g vs ultrasound |
|------------|-----------------------|-------------|-----------------|
| surgery | Concordance, % | к value | CI (95%) |
| 6 weeks | 95 | 0.43 | 0.03-0.83 |
| 12 weeks | 88 | 0.30 | -0.01 to 0.60 |
| 16 weeks | 89 | 0.42 | 0.14-0.70 |
| 26 weeks | 89 | 0.48 | 0.23-0.73 |
| 52 weeks | 87 | 0.37 | 0.09-0.64 |
| Overall | 85 | 0.40 | 0.16-0.63 |

CI, confidence interval; MRI, magnetic resonance imaging.

| Table IV | Concordance and κ values for all image comparisons |
|-------------|---|
| between the | e investigator's magnetic resonance imaging reading |
| and the ult | rasound reading |

| Time after | Investigator's MRI reading vs ultrasound | | | |
|------------|--|---------|-----------|--|
| surgery | Concordance, % | κ value | CI (95%) | |
| 6 weeks | 97 | 1.00 | 1.00-1.00 | |
| 12 weeks | 93 | 0.64 | 0.35-0.93 | |
| 16 weeks | 92 | 0.71 | 0.47-0.95 | |
| 26 weeks | 93 | 0.74 | 0.56-0.92 | |
| 52 weeks | 91 | 0.59 | 0.35-0.83 | |
| Overall | 92 | 0.70 | 0.51-0.88 | |

CI, confidence interval; MRI, magnetic resonance imaging.

concordance was better between the MRI and ultrasound readings for the investigator. This finding may be explained by the fact that the site investigator often read the MRI and the ultrasound, and was not, like the central radiologist, blinded to the results of the ultrasound.

There is growing interest in the orthopedic community in the use of musculoskeletal ultrasound to diagnose rotator cuff tears, as well as evaluate repairs.^{2,5,7,8,10,11,13,14,17,19} Previous ultrasound studies have shown the importance of experience and equipment in increasing the accuracy of ultrasound evaluation. There have been recent improvements in ultrasound equipment and image quality; however, sensitivity, specificity, and accuracy still rely on the experience of the ultrasonographer who interprets the images. A recent study demonstrated that orthopedic surgeons without previous ultrasound experience can reliably evaluate rotator cuff integrity using ultrasound within 50 to 100 scans.^{1,9} Although ultrasound is fairly comparable with MRI in diagnosing full-thickness tears, ultrasound is less accurate for partial-thickness tears. Recent studies have shown that when arthroscopic evaluation is used as the gold standard, ultrasound is less accurate than MRI arthrography for detecting partial-thickness tears.¹⁰

In addition to determining the integrity of rotator cuff repair, ultrasound evaluation allows for assessment of subacromial bursal thickness, tendon vascularity, and capsular thickness. These changes are common after surgical repair¹⁶ and generally normalize in 6 to 12 months for an intact repair. Ultrasonography may also allow for the evaluation of fatty infiltration of the rotator cuff muscles.¹⁹ Although the original Goutallier classification was established using computed tomography and later modified for MRI evaluation,⁵ surgeons are increasingly aware of the importance of fatty infiltration in making clinical decisions regarding the treatment of rotator cuff injuries. It has been recommended that rotator cuff tears with Goutallier classifications of grade 2 and above not be repaired because the likelihood of an unsuccessful repair is high. For this reason, this study did not include any rotator cuff tears with grade 3 or 4 fatty infiltration.

This study had several important limitations. The site investigator was not blinded to the results of the ultrasound when interpreting the MRI, but the central radiologist was blinded to the results of the ultrasound. Also, the ultrasound protocol may have varied slightly among centers, because the ultrasounds were to be read according to the standard practice of each location and were dependent on the ultrasonographer at each institution. The advantage of this study design, however, is that the results are more generalizable to the average clinical situation.

Another limitation of the study is the assumption that MRI is the gold standard for evaluation of the healing rotator cuff. We did not perform second-look arthroscopy to confirm imaging findings because a repeat surgery is impractical. This limitation could be addressed by evaluating the accuracy of ultrasound vs MRI in patients who undergo revision rotator cuff repair. Very few studies have used arthroscopic grading as the standard for comparison.^{1,12,15}

Conclusions

Ultrasonography has evolved as a comparable alternative to MRI for evaluating rotator cuff injuries. Our study demonstrated good agreement between ultrasound and MRI evaluations of rotator cuff repair. These findings will be important when designing future prospective studies. However, despite the agreement between both imaging modalities shown in our study, we believe that clinical investigators should compare their postoperative ultrasound results against their postoperative MRI results for a certain time period to establish the accuracy of ultrasound before relying solely on ultrasound to evaluate the integrity of their rotator cuff repairs.

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Supplementary data

Supplementary data related to this article can be found online at http://dx.doi.org/10.1016/j.jse.2014.01.045.

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