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IRB Protocol Presentation - 8/25/08

Title

"Prospective Evaluation of Teres Minor Hypertrophy in Patients with Rotator Cuff Tears"

Study Purpose and Rationale

Rotator cuff tears are one of the most common conditions affecting the shoulder, though failures of current surgical repair techniques range from 30-90% [1]. Loss of shoulder function in patients with rotator cuff tears is variable and not well understood. Teres minor hypertrophy has been observed in the setting of rotator cuff tears, though little literature exists to explain the possible link between teres minor hypertrophy and sustained function. Biomechanically, the teres minor contributes significantly to the external rotation strength of the shoulder in the abducted position, and may obscure expected decreased shoulder function after rotator cuff tears [2,3]. The post-operative course of patients with relative TM hypertrophy has not been studied to see if it differs from that of patients without hypertrophy. The significance of this is that a better understanding of the clinical picture of patients with rotator cuff tears may lead to improved therapeutic interventions in the future.

Physical exam of the shoulder, including active and passive range of motion, as well as provocative tests, such as the external rotation lag sign, drop sign, and the hornblower's sign, contribute to the diagnosis of a rotator cuff tear [2,4,5]. Walch et al evaluated the drop and hornblower's signs for external rotation strength in patients with known combined supraspinatus/infraspinatus tears. They found that those patients with both positive drop and hornblower's signs had significant correlation with fatty degeneration of the infraspinatus and teres minor, while those patients with a positive drop sign but negative hornblower's had degeneration of the infraspinatus only. Furthermore, seven of these patients actually had hypertrophy of the teres minor. Both negative drop and hornblower's predicted that neither the infraspinatus nor teres minor was degenerated [5]. This implies that the external rotation strength of the teres minor can compensate for some motion in the setting of nonfunctional supraspinatus and infraspinatus.

Other authors have noted preservation of teres minor muscle mass in the setting of supraspinatus and infraspinatus atrophy and fatty degeneration [6,7]. Itoi et al found that no atrophy was seen in either the teres minor or subscapularis after combined supraspinatus/infraspinatus tears. The same group also reported that teres minor volume is preserved in the presence of rotator cuff tears, and others have reported teres minor hypertrophy in the setting of combined supra/infraspinatus tears, also noting preserved function compared to those patients without teres minor hypertrophy [6,7].

Other than these few abstracts, however, there is little literature regarding teres minor hypertrophy either in the setting of rotator cuff tears or following rotator cuff repair. No studies have been done to elucidate which cuff tear patterns are associated with teres minor hypertrophy,

or what other factors contribute to hypertrophy of the muscle. In addition, there is no literature about the degree to which strength, range of motion, and function are preserved with teres minor hypertrophy, and how this affects outcomes after rotator cuff repair.

MRI has been established as the gold standard for identifying rotator cuff tears. This imaging is ideal for visualizing the muscle volumes of the rotator cuff. Lehtinen et al established an accurate and reproducible method of calculating volume of rotator cuff muscles using MRI and imaging software [8,9]. This method would be useful in establishing a correlation between preserved shoulder function and teres minor hypertrophy with rotator cuff tears.

It is our hypothesis that patients with rotator cuff tears who demonstrate teres minor hypertrophy, as measured on MRI, will maintain better shoulder range of motion and function following rotator cuff repair.

References:
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Study Design and Statistical Procedures

To test the hypothesis that hypertrophy of the teres minor preserves both post-operative strength and the ability to forward elevate in patients with rotator cuff, patients will be identified in the private offices of two Orthopaedic surgeons during 2008-2009. The patients will be divided into 3 groups as follows: (1) patients with evidence of large/massive rotator cuff tears who have MRI evidence of teres minor hypertrophy, (2) patients with evidence of large/massive rotator cuff tears who do not have MRI evidence of teres minor hypertrophy, and (3) control patients without evidence of rotator cuff tears, to be made up of patients with SLAP lesions, impingement, or shoulder instability.

Each patient will undergo shoulder MRI as part of the standard diagnostic and/or preoperative workup. The MRIs of each of these groups of patients will then be analyzed with Mimics (Materialise, Ann Arbor, MI), a computer program to create 3D models from MRI data. Careful

attention will be paid to sagittal cuts, at the level of the "y-shaped image" where the scapular landmarks (spine, body, and coracoid process) form a Y, as well as a more medial image twice the distance from the glenoid [8,9]. The muscle bellies of the rotator cuff will be outlined, cross-sectional area will be calculated for all rotator cuff muscles in these cuts, and the software will be used to calculate the volume of each muscle. All of these volumes will be normalized as a percentage of the subscapularis area.

The control (i.e. no rotator cuff tear) group will be used to define teres minor hypertrophy. Once the normalized teres minor volume is found for a normal population, hypertrophy will be defined as any patient whose normalized teres minor volume is 1.5 standard deviations above the mean. To ensure separation into two distinct groups, normal teres minor volume will be considered to be below 0.5 standard deviations above the mean in a normal population. Thus, patient with rotator cuff tears whose normalized teres minor volume is between 0.5 and 1.5 standard deviations above the mean will be excluded.

Following surgical repair of the patients' rotator cuff, the functional status of each patient will be determined at the 8-week follow-up office visit. The patients will complete a series of subjective pain and function questionnaires, including the SST (Simple Shoulder Test) and ASES (American Shoulder and Elbow Surgeons). Physician assessment measurements will also be recorded, including shoulder active and passive range of motion, the outcome of provocative tests, and isometric strength measured with the Isobex Analyzer system (MDS, Oberburg, Switzerland). Range of motion, measured in degrees, will be measured compared to the contralateral unaffected shoulder by physician exam. The main outcome will be a comparison of forward elevation between the patients with teres minor hypertrophy and without hypertrophy.

Approximately 40-50 patients will be made up of control patients with SLAP lesions, impingement, or shoulder instability, whose MRI analysis will be used to define hypertrophy. We estimate that approximately 100 patients with rotator cuff tears will be seen in the over the course of the study. Some of these patients will be excluded from the study (see Study Subjects section). The remaining patients will be divided into the first and second cohorts (patients with rotator cuff tears with or without teres minor hypertrophy), for an estimated 30 patients in each cohort. From an as yet unpublished retrospective study from our group, we can estimate the standard deviation of the difference in forward elevation between groups to be 41°. With alpha = 0.05, 80% power, and using the formula:

$$n = 1 + 16\left(\frac{std - dev}{effect}\right)^2$$

we can estimate that, given n=30 per group, we should be able to detect a difference of 30°, below our groups clinically desired level of 35°.

Unpaired t-test will be used to compare the two patient types (large tears with hypertrophy, large tears without hypertrophy). Variables to be analyzed will be range of motion (forward elevation as primary outcome, external rotation with the arm at the side, external rotation with the arm in abduction, internal rotation with the arm at the side), isometric strength (as measured with Isobex system). Multiple regression analysis will be performed to determine the effect of age, sex,

handedness, smoking status, and muscle fatty infiltration (as defined by the Goutallier score [2]) on outcome.

Study Procedures

As described

Study Drugs or Devices

Not applicable

Study Questionnaires

ASES, SST

Study Subjects – Inclusion criteria, Exclusion Criteria

Patients seen in the office of two Orthopedic surgeons during 2008-2009 will be divided into three groups: (1) patients with evidence of large/massive rotator cuff tears who have MRI evidence of teres minor hypertrophy, (2) patients with evidence of large/massive rotator cuff tears who do not have MRI evidence of teres minor hypertrophy, and (3) control patients without evidence of rotator cuff tears, to be made up of patients with SLAP lesions, impingement, or shoulder instability. Patients with radiographic evidence of subscapularis tear or abnormal physical exam of the subscapularis will be excluded from the study. Patients with rotator cuff tears whose normalized teres minor volume is between 0.5 and 1.5 standard deviations above the mean will also be excluded.

Recruitment

Patients with suspected rotator cuff tears will be recruited in the private office visits of two orthopedic surgeons in 2008-2009.

Confidentiality of Study Data

Patients will be assigned a study number by the principal investigator. Deidentified data will be stored on the computer of the laboratory.

Potential Risks

There is minimal potential risk associated with this study as the data collected is data that is routinely obtained for patient care, including demographic information and MRI scans. None of the procedures or physical exam differs from standard of care for rotator cuff tears.

Potential Benefits

This study can be used in the future to help predict functional status based on physical exam and radiographic findings, as well as aid in both non-operative treatment and pre-operative planning in patients with rotator cuff tears. The results may also improve understanding of rotator cuff tears. Furthermore, developing improved techniques to use Mimics software to reconstruct 3D models of rotator cuff musculature may improve understanding of hypertrophy patterns, and will establish a model for additional MRI reconstruction based studies.

Alternatives

The alternative is to not participate in the study. Not participating in the study will not change medical care.