Protocol

1. Project Title:

Predicting Response to Intra-Articular Corticosteroid Injection in Patients with Osteoarthritis of the Glenohumeral Joint

2. Investigators:

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3. Abstract

In 2009, the AAOS made formal recommendations for osteoarthritis of the glenohumeral joint, but was unable to formally recommend physical therapy, pharmacotherapy or corticosteroid injection. Despite a lack of clinical evidence, orthopedic surgeons continue to recommend conservative treatments prior to considering surgical intervention for primary osteoarthritis of the glenohumeral joint. Generally, activity modification, over the counter analgesics, and intraarticular corticosteroid injections (IACSI) are offered prior to considering arthroplasty.[5,6] The scientific literature remains limited regarding IACSI success for glenohumeral arthritis, with practices largely being adopted from the lower extremity literature. There remains only one small study assessing outcomes following IACSI, where success was indicated as significant pain reduction, improvement in the Constant-Murley scale, Shoulder Pain and Disability Index (SPADI) scores and satisfaction with treatment.[3] The purpose of this study is to assess the effectiveness of IACSI for glenohumeral arthritis by 1) measuring clinical and radiographic parameters and 2) identifying predictors of IACSI success.

4. Background and Significance

Research regarding IACSI for glenohumeral OA is limited. While many articles have assessed the role of hyaluronic injections for this condition, only one study has assessed the effectiveness of IACSI. [4,3,7,2] In this study, IACSI was retrospectively compared to intra-articular hyaluronic acid (HA) injections.[3] All injections were administered in an unguided fashion. Corticosteroid dose for each injection was 40 mg of Depomedrol. Both groups received three injections one week apart, including the steroid group. Within the IACSI group, pain relief was only found to be significant at one month (6.25 vs 4.4, p=0.04). The clinical significance of this change remains debatable. This improvement was significant for both pain at night, as well as pain with activity. No significant differences remained at three months or six months. SPADI scores showed no significant changes over time. The range of motion

subscore of the Constant-Murley score remained significantly improved. They were unable to associate the grade of OA to pain relief following IACSI.

This study differs dramatically from clinical practice, where IACSI is normally administered as a single injection. Repeat injections are often delayed, with some surgeons recommending a three month break between injections. Presently, there is an evidence gap with respect to evidence of the effectiveness of single-injection IACSI on clinical and patient-reported outcomes in patients with glenohumeral OA.

5. Specific Aims

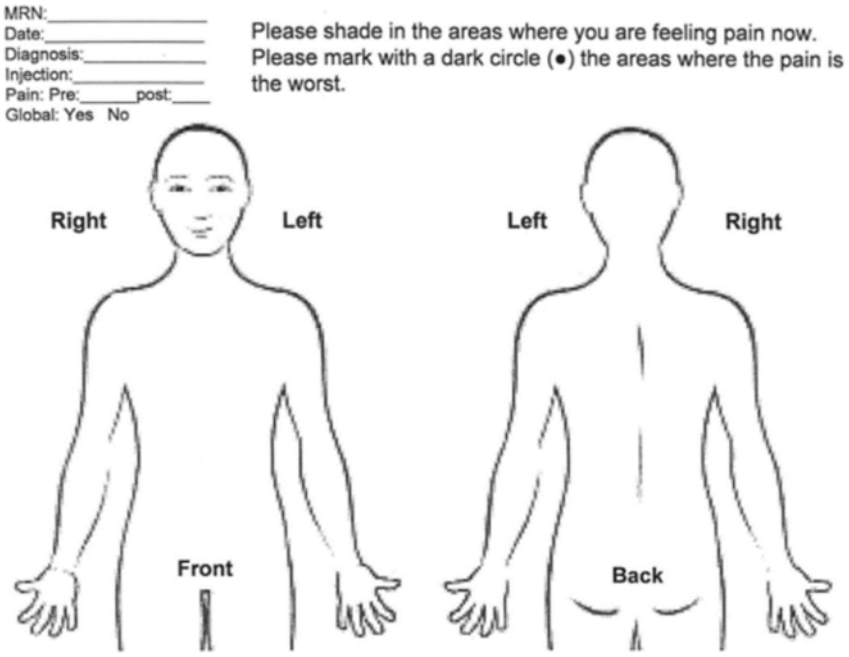
To address this deficit in the literature, there are two specific aims:

1. Assess the effectiveness of IACSI in patients with primary osteoarthritis in the shoulder. This will be determined through three patient-reported outcomes measures:
    - ASES (American Shoulder & Elbow Surgeon) score improvement > 20.9 points[8]
    - VAS (Visual Analog Scale) pain score improvement > 1.4 points
    - SST (Simple Shoulder Test) score improvement > 2.4 points
2. Assess clinical and radiographic predictors of success (outlined below) in patients who elect to receive IACSI as treatment for primary osteoarthritis in the shoulder.
    - Clinical
        - Duration of Symptoms
        - Location of pain (Anatomic Diagram, Figure 1)
            - Pain diagrams will be analyzed using a computer overlay protocol and analyzed in a binary matter according to region. Image software (NIH, Bethesda, MD) will be used. Proportions of the patients responding to injection in each anatomic region and groups of regions will be calculated. 95% confidence intervals will be determined.[1]
        - History of prior injection
        - Range of motion (Forward elevation in the scapular plane, ER at 0^o abduction, IR at 0^o abduction)
        - Standardized pain and function scores (VAS pain, SST, ASES)
        - Prior analgesia (OTC, Narcotic)
        - Initial response to anesthetic component (VAS 5-10 min post-injection)
    - Radiographic
        - Joint space narrowing (measured)
        - Subluxation
        - Walch classification
        - Subchondral cysts
        - Samilson & Prieto Radiological Classification
            - Mild Arthrosis: inferior humeral and/or glenoid exostosis < 3mm in height

- Moderate Arthrosis: inferior humeral and/or glenoid exostosis measuring 3mm to 7mm slight gleno-humeral irregularity
- Severe Arthrosis: inferior humeral and/or glenoid exostosis measuring > 7mm gleno-humeral joint narrowing and sclerosis

6. Research Plan

Subjects: Five hundred patients, both male and female, age 18-100 years, with a diagnosis of symptomatic primary osteoarthritis of the shoulder will be recruited from the patient population seeking treatment at the Orthopaedics Sports Medicine Institute. Subjects enrolled into the study will be those who have failed previous treatment including over-the-counter analgesics and activity modification, and have elected to receive a medically-indicated, ultrasound-guided IACSI in the shoulder. Two or three plain film views of the shoulder (including a Grashey and axillary lateral) obtained in accordance with standard of care prior to enrollment in the study will be reviewed. Once written informed consent has been obtained, subjects will complete the pre-procedural pain chart (Figure 1), ASES, VAS pain (at rest, with activity, at night), and SST scores. Upon completion of all outcomes measures, the ultrasound-guided IACSI (5cc of 1% lidocaine, 2cc of depomedrol (40mg/mL)) will be administered. Subjects will be asked to repeat the VAS pain score (at rest) 5-10 minutes following administration of the injection to assess the response to the anesthetic component of the injection. Upon conclusion of the visit, no clinical follow-up appointment will be scheduled, and subjects will be instructed to follow-up with their physician as needed; this is in accordance with standard of care for this patient population.



(Figure 1: Pre-procedural pain chart, anatomic diagram)

Subjects will be contacted via email through the REDCap survey function or a phone call at two weeks, one month, two months, three months, and six months following the injection to complete the ASES, VAS pain (at rest, with activity, at night), and SST scores. If an email survey is not completed in REDCap, a reminder email will be sent every two days, up to two

times. If, after the final email reminder, the REDCap survey is still incomplete, a member of the study staff will call the subject and complete the survey via telephone call.

Exclusion Criteria: Patients will be excluded from the study for any of the following reasons:

- Post traumatic osteoarthritis
- Inflammatory osteoarthritis
- Imaging confirmed rotator cuff tear
- Prior ipsilateral shoulder surgery
- Memory loss or inability to complete study measures
- History of allergy to injection medications
- Diabetic patients with patient-reported fasting blood glucose >200
- Prior injection in the ipsilateral shoulder within three months

Data Collection: The following data points and information will be collected for later analysis:

- Patient name
- MRN
- Gender
- Date of birth
- E-mail address
- Telephone number
- Location of pain (pre-procedural pain chart)
- Duration of symptoms
- History of prior IACSI in ipsilateral shoulder
- Prior analgesia
- Shoulder Range of Motion (Forward elevation, External rotation, Internal rotation)
- Radiographic findings
- Date of IACSI
- Date of each follow-up survey
- Results of each standardized pain and function survey

Confidentiality: Once all enrolled subject data is collected, subject PHI will be removed and the data will be maintained by using assigned research identification numbers that uniquely identify each individual. Date of birth will be converted to age, and dates will also be converted to time frames. Coded data will be stored on a secure online database such as REDCap and an Excel spreadsheet on a password protected computer within the Department of Orthopaedics and Rehabilitation. Data will be converted to a SPSS file for analysis which will also be stored on a secure department server. Data will be used only in aggregate and no identifying characteristics of individuals will be published or presented. Only the study team members will have access to these files. After the study is completed, local data will be stored with other completed research studies in a secured storage room until the appropriate time when the research files may be purged according to university policy.

Data Analysis:

Each patient-reported outcome measure will be assessed at each time point pre- and post-injection and grouped according to the grade of shoulder osteoarthritis. Groups will be compared using a one-way ANOVA analysis. Groups with a response to injection (VAS score improvements greater than the minimal clinically important difference) will be compared to those without a significant response. Single multi-level regression analysis will be performed to assess for clinical and radiographic risk factors outlined in Aim Two that may predict corticosteroid injection failure.

7. Possible Discomforts and Risks

Subjects may experience the standard discomforts and risks associated with any intraarticular injection independent of this study.

Although a minimal risk, completing the study questionnaires may cause stress to some participants who may believe that they are not providing correct answers to the research team. To reduce this stress, the investigators will reassure subjects that all survey answers are based on what they feel, and there is no "correct" answer.

Follow up surveys will be completed by phone or via email with a secure link to surveys in REDCap, thus a loss of confidentiality is a potential risk.

8. Possible Benefits

There is no direct benefit to patients who take part in this study. This study may benefit future patients by identifying factors to assist providers in predicting a patient's response to an IACSI.

9. Conflict of Interest

No conflict of interest for this study.

10. References

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