Randomized Prospective Clinical Analysis of Ultrasound-guided vs. Landmark-guided Biceps Corticosteroid Injections

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Introduction

Biceps tendinitis typically includes pain in the anterior shoulder that is reproduced with provocative maneuvers. Corticosteroid injections have been a mainstay of conservative management of biceps tendonitis. Many physicians have recently added ultrasound guidance to the injection to ensure accurate placement in the tendon sheath. Studies have shown that ultrasound guidance is more accurate than landmark guidance. However, the clinical significance of the accurate placement of the injection into the sheath is not clear.

Study Aim

Using randomization, prospectively determine superiority of either ultrasound-guided or landmark-guided biceps corticosteroid injections with regard to various clinical variables described at three weeks and three months.

Hypothesis

There will be a significant clinical difference in outcomes with ultrasound-guided being superior tolandmark-guided biceps corticosteroid injections at threeweeks and threemonth follow up.

Inclusion Criteria

Pain at intertubercular groove
Anterior humeral pain
Positive Speed's Test
Bicep's tendinitis is primary diagnosis for patient
Patient agrees to follow up and consent

Exclusion Criteria

Prior biceps surgery or injections
Prior SLAP or labral repair
Concomitant shoulder arthroplasty

Methods

Patients are diagnosed with biceps tendinitis in the outpatient clinic. After diagnosis, all the patients that meet inclusion/exclusion criteria will be offered to enroll in the study. Study will be described to the patient with regard to protocol and consent. All questions regarding the study will be answered, and it will be explicitly described that the

study involvement will not change clinical care. It will be explained that we expect a follow up appointment in three weeks and three months.

After collection of informed consent, the patient will be randomized to either ultrasound-guided or landmark-guided injection. The patient will complete clinical scores at the initial visit prior to the injection. After injection, the patient will have follow up scheduled for three weeks and three months. To ensure patient blinding, an ultrasound will be placed on the patient for both groups, but only active imaging with be performed for the ultrasound-guided patient group. For clinician blinding, a different clinician than the injecting clinician will perform the follow up examinations. The patient is instructed to not seek additional injections during the study.

Enrollment:
40-60 patients will be enrolled

Data collection will be performed as described below:

Pre-Procedural Data:

- Clinical Assessment Information (Symptomatic and asymptomatic side)
- Clinical Questionnaires
    - Pain VAS
    - ASES
    - SST
    - SANE
- Biceps Specific Questions
    - Fatigue pain
    - Anterior Shoulder Pain (0-10)
    - Presence of spasms
- Provocative Maneuvers
    - Tenderness at the bicipital groove with arm at neutral
    - O'Brien's, Speeds, Yergason's test

Post-Procedural Evaluation (same data as pre-operative visit)

- 3weeks
- 3 months

All data will be stored on a dedicated research computer on a local hard drive that requires password access, which only study personnel will possess. All patient identifying data will be removed and only demographic information will be included with an anonymous patient ID being ascribed. Statistical analysis will be performed in a blinded manner until results are final. These will include non-parametric comparison of groups with regard to all outcomes.