Blind vs. Ultrasound-guided Corticosteroid Injections for de Quervain's disease: A Prospective Study

NCT02038634

February 6, 2018

Background:

De Quervain's disease is the stenosing tenosynovitis and tendinitis of the abductor pollicis longus (APL) and extensor pollicis brevis (EPB) tendons in the first dorsal compartment of the wrist. While the prevalence of de Quervain's is not yet well-established, previous studies have shown that women can be affected by the disease up to six times more frequently than men.^{5, 6} Conservative treatments include splinting and corticosteroid injections, but surgery is an option when such therapy fails. One study⁶ compared the improvement rates of patients treated with splinting alone, injection and splinting, and injection alone, and found the rate of improvement to be 19%, 57%, 67%, respectively. This confirmed the good results reported in previous studies^{1, 3} and recommends corticosteroid injection to clinicians as a reliable treatment for de Quervain's disease.

A seminal study performed by Zyngas *et al.*⁷ correlated the accuracy of corticosteroid injection with pain relief by including X-ray dye in the injection. The results of the study suggested a strong correlation between accurate injection of the first dorsal compartment and pain relief. Since then, the use of ultrasonography (US) to guide steroid injection has been suggested as a possible clinical practice, but little research has been done on the technique. A 2009 study⁴ reported a 93.75% rate of significant pain relief after the use of US-guided injections, but there was no control group with which to compare results. The current standard practice for steroid injection in de Quervain's patients is a blind injection without imaging guidance. To our knowledge, no study has compared the clinical outcomes of blind injections to US-guided injections. We hypothesize that the US-guided injections will result in greater pain relief for patients than blind attempts

Study Design:

This is intended to be a prospective study. Patients will contact the PI for a standard clinical evaluation, which includes palpation of the first extensor compartment and application of the Finkelstein test.² Those diagnosed with de Quervain's disease and who fit all inclusion criteria will receive a detailed verbal description of the study from one of the doctors, who will then attain written, informed consent from willing participants. The PI will then administer either a blind or US-guided injection. The patient will return for follow-up appointments at 6-8 weeks and 12-16 weeks and will undergo another physical exam to determine pain relief. A phone call follow-up will also be placed one year after the injection in order to determine long-term effectiveness. Once 20 study subjects in each group (40 total) have been enrolled and completed treatment, the data will undergo statistical analysis.

This study poses minimal or no physical risk to study subjects, as the US-guided injection should show better accuracy and pain relief for patients than the current standard treatment (blind injection).

All Injections will consist of 6 mg betamethasone and 4 cc 1% lidocaine without epinephrine, which is standard of care treatment.

In summary, we aim to perform a prospective study to evaluate the effectiveness of blind corticosteroid injections to US-guided injections for the treatment of de Quervain's disease. The results of the study will be used to validate current injection protocols or support the incorporation of ultrasonography to treat the disease.

Risk to Subjects:

A minimal physical risk is temporary inflammation around the wrist which accompanies any steroid injection. There is no risk involved with the addition of ultrasound. There is a slight risk of loss of confidentiality.

Data Analysis:

The mean DASH scores from the control group (blind injection) and the treatment group (US-guided injection) will be compared with a t-test to discern any significant statistical difference.

Plan for evaluating problems and adverse events (AEs):

The PI will address any unforeseen problems or events related to the study and the study coordinator will report promptly to the IRB.

References:

- 1. Anderson BC, Manthey R, Brouns MC. Treatment of de Quervain's tenosynovitis with corticosteroids. A prospective study of the response to local injection. Arthritis Rheum 1991; 34:793–798.
- 2. Elliott BG. Finkelstein's test: a descriptive error that can produce a false positive. J Hand Surg [Br] 1992; 17(4): 481–482.
- 3. Harvey FJ, Harvey PM, Horsley MW. De Quervain's disease: Surgical or nonsurgical treatment. J Hand Surg 1990;15A:83–87.
- 4. Jeyapalan K , Choudhary S. Ultrasoundguided injection of triamcinolone and bupivacaine in the management of De Quervain's disease. Skeletal Radiol 2009; 38(11):1099 1103.
- 5. Piligian G, Herbert R, Hearns M, Dropkin J, Landsbergis P, Cherniack M. Evaluation and management of chronic work-related musculoskeletal disorders of the distal upper extremity. Am J Ind Med. 2000;37(1):75–93.
- 6. Weiss AP, Akelman E, Tabatabai M. Treatment of de Quervain's disease. J Hand Surg 1994;19A:595–598.
- 7. Zingas C, Failla JM, van Holsbeeck M. Injection accuracy and clinical relief of the Quervain's tendonitis. J Hand Surg 1998;23:89–96.