

Does Adding Lidocaine to Corticosteroid Injections Reduce Pain Intensity in Hand Surgery?

Date: 7-18-2019

Hypotheses

Primary null hypothesis:

There is a difference in pain intensity during injection (directly assessed after the injection) between patients receiving corticosteroid injections in combination with lidocaine vs without lidocaine, for any hand/wrist injection.

Secondary hypotheses:

- There is a difference in pain intensity 4 hours after injection between patients receiving corticosteroid injections in combination with lidocaine vs without lidocaine, for any hand/wrist injection.

As per some previous studies we will perform our other analyses based on superiority, without margins of non-inferiority, as this is only relevant for the analysis of the primary outcome.

- There are no factors (including adding lido to corticosteroid injection) independently associated with pain intensity, satisfaction with the visit, and perceived empathy.

Background and significance

In patients with carpal tunnel syndrome, injection of glucocorticoids into the region of the carpal tunnel is intended to reduce tissue inflammation and aid recovery. [3] For trigger finger and de Quervain tendinopathy, glucocorticosteroid injection can cure the problem. [4;8] The corticosteroid injection is usually mixed with lidocaine. [3;4] Lidocaine is a local anesthetic commonly used in clinics and it is characterized by a rapid onset of action. [1]

In case of trigger finger, a systematic review including two randomized trials, found that glucocorticosteroid injection was more effective for symptom relief than lidocaine injection alone. [5;6]. Dernek et al. shows no difference in efficacy between treatment for carpal tunnel syndrome with lidocaine and treatment with corticosteroid. [2] There's a lack of evidence about the use of lidocaine injection as an addition to steroids against pain during injections.

The average pain caused by corticosteroid injection for trigger finger is 4.3 on a scale of 10 when given with lidocaine. [7] Among other things, pain is correlated with expected pain, heightened illness concern, pain catastrophizing and depression, but not with prior injection or technique. [7] Adding lidocaine adds to the volume of the injection, which might increase pain. It's possible that injecting cortisone without any lidocaine would be more comfortable than with lidocaine.

The aim of this randomized controlled trial is to assess the difference in pain intensity between patients receiving a corticosteroid injection with or without lidocaine in patients with a hand condition. Secondly, the aim of this study is to assess factors independently associated with pain intensity, satisfaction with the visit, and perceived empathy.

Proposed methods

Study design: Randomized Controlled Trial

Recruitment methods (if applicable):

All patients offered a corticosteroid injection will be invited to enroll in the middle of their visit prior to injection. A research assistant will obtain informed consent. Patients will be randomized, using a random number generator in Microsoft Excel, in two groups for the corticosteroid injection, one group with lidocaine and one group without lidocaine. Then the surgeon will give the corticosteroid injection. The group without the lidocaine will get an injection with only steroids. To make this a double-blind study, the medical assistant will put a piece of tape around the syringe to cover up the volume.

Data will be recorded on tablets using HIPAA compliant REDCap. After the injection, patients will be asked to complete a survey on REDCap in the following order: demographics, prior steroid injection, pain intensity, patient satisfaction with the visit, JSPPE, PCS-4, PHQ-2, and PSEQ-2. This will take the patients 5 minutes to complete. A research assistant will ask the surgeon for the diagnosis, initial treatment, approach of injection and intrasheath or extrasheath injection. The medical assistant will complete the use of lidocaine in addition to corticosteroid injection, any other added substances and the volume of the injection.

After 4 hours, the research assistant will do the follow up call and ask for the pain intensity.

Inclusion Criteria:

- All patients offered a steroid injection in a hand surgeon's office
- Aged 18-89 years
- English speaking patients
- Able to provide informed consent

Exclusion criteria:

- Non-English/Spanish speakers

Measured variables

Response variables:

- Pain intensity in the last 7 days
 - o 11-point ordinal scale, with 0 for no pain at all and 10 for worst pain ever
- Pain intensity during injection
 - o 11-point ordinal scale, with 0 for no pain at all and 10 for worst pain ever
- Pain intensity 5 minutes after injection
 - o 11-point ordinal scale, with 0 for no pain at all and 10 for worst pain ever
- Pain intensity 4 hours after injection
 - o 11-point ordinal scale, with 0 for no pain at all and 10 for worst pain ever
- Patient satisfaction with the visit, direct after visit and after 4 hours
 - o 11-point ordinal scale, with 0 for not satisfied at all and 10 for most satisfied)
- Perceived empathy

- JSPPPE

Explanatory variables:

- Use of lidocaine in addition to corticosteroid (Yes / No)
- Total volume of injection
- Approach of injection
- Intrathecal or extrathecal injection
- Diagnosis
- Initial treatment
- Prior steroid injection anywhere
 - Prior steroid injection at that site
- Abbreviated Pain Catastrophizing Scale (PCS 4)
- Patient Health Questionnaire (PHQ 2)
- Pain Self-efficacy Questionnaire (PSEQ 2)
- Patient demographics
 - Sex (female, male)
 - Age (text)
 - Race/ethnicity (1. White, 2. Black/African American, 3. Latino, 4. Other.
 - Marital status (1. Married/Unmarried Couple, 2. Divorced/Separated, 3. Widowed, 4. Single.)
 - Level of education (1. High school or less, 2. 2-year college, 3. 4-year college, 4. Post-college graduate degree)
 - Work status (1. Employed, 2. Out of Work, 3. Unable to Work, 4. Retired)
 - Insurance status (1. Medicare/Medicaid, 2. Commercial, 3. Uninsured, 4. Worker compensation, 5. Other)

Statistical analysis

Intention to treat analysis may bias a non-inferiority trial towards finding no difference. Therefore, we will perform both an intention to treat and per protocol analysis.

Primary and secondary null hypothesis

Unpaired t-test for hypothesis testing and MV linear regressions for other hypotheses.

A priori power analysis

The primary outcome will be the difference in pain immediately after the injection after randomization between corticosteroid shots without lidocaine compared with adding lidocaine.

We aim to assess the non-inferiority of corticosteroid shots without lidocaine compared with adding lidocaine. The difference in pain score will be compared by unpaired t-test. We will also report the mean, with SD and 95% CI and the mean difference with 95% confidence interval. We anticipate a mean pain score of 8.0 (95% CI 7.6 to 8.4) with a standard deviation of 1 for the shots with lidocaine. Non-inferiority will be considered if

the pain score after shots without lidocaine is no more than 0.5 points lower. We aim to achieve 90% power to confirm non-inferiority, with a one-sided confidence level of 95%. Power calculation shows we need to include 138 patients (69 per group). Accounting for 5% loss, we aim to include 145 patients, with 72-73 patients per group.

Stata command: `ssi 8.0 7.5, sd1(1) alpha(0.05) non power(0.9)`

References:

1. Lidocaine Test Increases the Success Rates of Corticosteroid Injection in Impingement Syndrome. Kim et al. Pain Med. 2016 Oct;17(10):1814-1820. Epub 2016 Mar 5.
2. Comparison of the efficacy of lidocaine and betamethasone dipropionate in carpal tunnel syndrome injection. Dernek et al. J Back Musculoskelet Rehabil. 2017;30(3):435-440. doi: 10.3233/BMR-150477.
3. Up to date; Carpal tunnel syndrome: Treatment and prognosis
4. Up to date; Trigger finger (stenosing flexor tenosynovitis)
5. Lambert MA, Morton RJ, Sloan JP. Controlled study of the use of local steroid injection in the treatment of trigger finger and thumb. J Hand Surg Br 1992; 17:69.
6. Peters-Veluthamaningal C et al. Corticosteroid injection for trigger finger in adults. Cochrane Database Syst Rev 2009; :CD005617.
7. Abhishek. Et al. Predictors of pain during and the day after corticosteroid injection for idiopathic trigger finger. The journal of hand surgery Volume 37, Issue 2, February 2012, Pages 237-242
8. Up to date; de Quervain tendinopathy