Pain Outcomes Following Intralesional Corticosteroid Injections

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1. Background

Corticosteroid therapy, including intralesional and topical applications, has many indications within the fields of Dermatology, Plastic Surgery, and Orthopedics. However, these injections can be quite painful, which leads many patients to discontinue treatment.

Often, the injection involves a mixture of local anesthetic and corticosteroids despite a lack of evidence that the use of lidocaine improves pain.[1,2] Due to the acidic pH, the lidocaine component of the injection can actually cause a significant burning sensation during the procedure. Lidocaine does not have anti-inflammatory properties and does not treat the underlying pathology. By including another medication, lidocaine also adds cost and risk to the procedure.

In a double blind, randomized control trial, Osanakornkul and Burusapat studied the benefit of applying topical anesthetics or a 1:1 mixture of 1% lidocaine and triamcinolone acetonide at the injection site to alleviate pain during keloid treatment.[2] While the use of a topical anesthetic 1 hour prior to the injection was able to alleviate the pain from needle stick, the study did not show a statistical difference in pain outcomes with the use of lidocaine. However, this study was limited to the use of intralesional corticosteroid injections for the treatment of keloids. In addition, the study only focused on 3 locations: the shoulder, sternum, and ear. Keloid injections are often more painful than other injections because the horizontal penetration of the needle can pierce a large number of nerve endings. In routine injections, the entry of the needle is either vertical or angled and thus pierces a small number of nerve endings.[3] In addition, the injected material stretches nerve endings and compresses them against unyielding keloid tissue, causing substantial pain that can persist up to several hours after the procedure.[3] This study will examine intralesional corticosteroid injections for keloids, alopecia areata, and other indications while including a wider variety of injection sites.

2. Rationale and Specific Aims

The purpose of this study is to see if removing lidocaine from intralesional injections decreases pain of the injection. We hypothesize there will be no difference in pain outcomes if lidocaine is removed from intralesional corticosteroid injections.

3. Animal Studies and Previous Human Studies

A similar study was conducted in plastic surgery with intraarticular injections for trigger finger. The project examined pain outcomes for injections containing steroid + normal saline vs steroid + local anesthetic. The results indicated that injections containing local anesthetic were significantly more painful. Thus, including a mixed local anesthetic in the injection adds unnecessary cost and risk to the procedure. Because steroid injections in dermatology are also commonly mixed with a local anesthetic, this study design can be applied to these intralesional injections as well.

4. Inclusion/Exclusion Criteria

Inclusion Criteria:
• >12 years old presenting with an indication for intralesional steroid injection

Exclusion Criteria:
• Not a candidate for corticosteroid injection
• Contraindication to lidocaine

5. Enrollment/Randomization

All patients meeting inclusion/exclusion criteria will be offered enrollment. Using a coin flip, patients will have a 50% chance of receiving one of the following treatments:
1. Corticosteroid + lidocaine
2. Corticosteroid + normal saline

6. Study Procedures

Day 1 (In clinic): After diagnosing the need for an intralesional injection, patients will be screened for enrollment. The consent form will be reviewed in depth to describe the purpose and procedures associated with the study. If they agree to be part of the study, we will collect the following demographic information:
• MRN
• Age
• Gender
• Comorbidities (chronic opioid use, smoking, diabetes, neuropathy, fibromyalgia)
• Phone number
• Site of injection (scalp, face, neck, and trunk)
• Indication for injection

The patient will then be randomized to receive one of the following injections:
1. Corticosteroid with normal saline
2. Corticosteroid with lidocaine

A co-investigator will prepare the syringe to ensure blinding. The injection site will be prepped in sterile fashion with an alcohol wipe. The physician will then administer the injection. Immediately following the injection, the patient will be asked to rate the pain of the injection based on the visual analog scale (appendix A). Specifically, the co-investigator will say "Rate the injection experience on a scale of 0 to 10, 0 being no pain and 10 being the worst pain of your life". A bandaid will be placed over the injection site and the patient will be reminded to expect a phone call that afternoon and the next day.

Day 1 (after clinic): Approximately 6 hours after the injection, a different study investigator will call the patient by phone to assess their current pain level with the visual analog scale. Using a different investigator who is unaware of the treatment arm for follow-up will further ensure blinding. Specifically, the investigator will say "Rate your

current pain level from the injection on a scale of 0 to 10, 0 being no pain and 10 being the worst pain of your life". Patients will be called up to three times before being considered lost to follow-up.

Day 2: Approximately 24 hours after the injection, the study investigator will again call the patient by phone to assess their current pain level with the visual analog scale. Specifically, the investigator will say "Rate your current pain level from the injection on a scale of 0 to 10, 0 being no pain and 10 being the worst pain of your life". Patients will then be thanked for their involvement in the study and encouraged to reach out to the principle investigator or clinic should any problems arise. Patients will be called up to three times before being considered lost to follow-up.

7. Risks

This study is categorized as less than minimal risk. We are comparing two treatment methods that are accepted as standard of care, and are already used on the clinic population being studied on a daily basis. There is no new experimental intervention that would put patients at greater than minimal risk. Although rare, the risks of a corticosteroid injection include hypopigmentation, skin atrophy, and hyperglycemia in patients with diabetes. There is also a small risk of an allergic reaction to the lidocaine component. There may be unknown or unanticipated adverse effects.

8. Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

Adverse events will be reported to the IRB immediately through standard reporting mechanisms.

9. Study Withdrawal/Discontinuation

There are no anticipated circumstances under which subjects would be withdrawn from research without their consent. If subjects withdraw, there will be no penalty or consequences.

10. Statistical Plan

We are planning a study of a continuous response variable from independent control and experimental subjects with 1.1538 control(s) per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.3. If the true difference in the experimental and control means is 0.2, we will need to study 34 experimental subjects and 39 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

11. Privacy/Confidentiality Issues

Private health information (PHI) will used in the study, but not disclosed. All PHI will be stored on a secure, password-locked server. All participants in the study have obtained Human Research certification to have the necessary authorization to PHI. When collecting patient data, only medical record numbers will be used to identify patients.

12. Follow-up and Record Retention

The study will last for approximately 1 year after initiation or until the enrollment goal is met. At the study conclusion, all identifiable data will be destroyed and de-identified data will be kept for analysis.

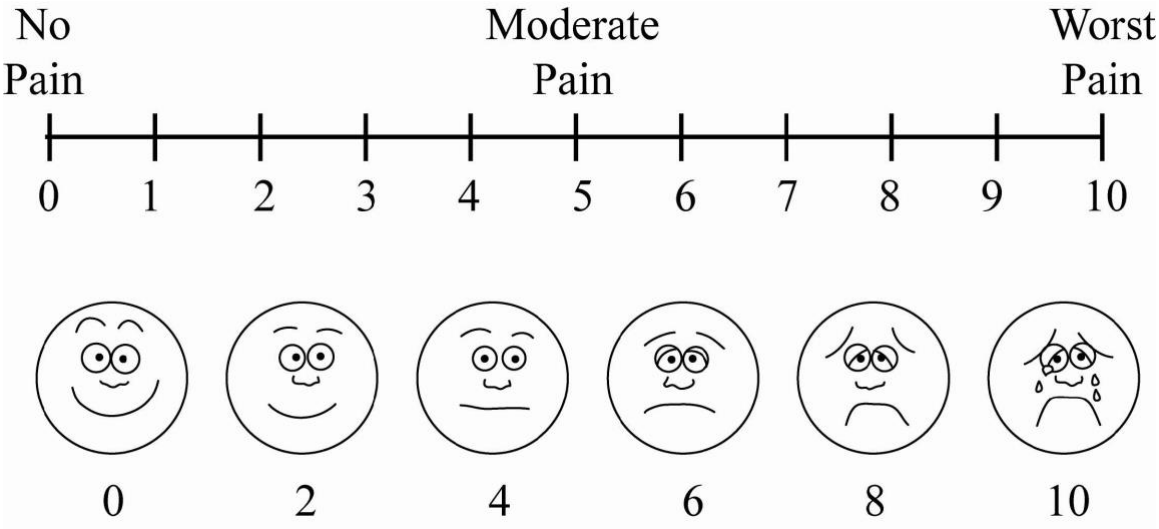
13. References:

1. Osterne RL, Araújo PM, de Souza-Carvalho AC, Cavalcante RB, Sant'Ana E, Nongueira RL. Intralesional corticosteroid injections in the treatment of central giant cell lesions of the jaws: A meta-analytic study. Medicina Oral, Patología Oral y Cirugía Bucal. 2013;18(2):e226-e232. doi:10.4317/medoral.18345.

2. Usanakornkul, A., & Burusapat, C. (2017). A Topical Anesthetic and Lidocaine Mixture for Pain Relief During Keloid Treatment. Dermatologic Surgery, 43(1), 66-73. doi:10.1097/dss.0000000000000932

3. Mishra S Safe and less painful injection of triamcinolone acetonide into a keloid—a technique. J Plast Reconstr Aesthet Surg 63:e205

Appendices:



Appendix A