

PROTOCOL TITLE: Do Cervical Interlaminar Epidural Steroid Injections with Low-dose Lidocaine Cause Transient Objective Upper Extremity Weakness? A Prospective Randomized Controlled Trial

PRINCIPAL INVESTIGATOR:

David Walega, M.D.
Department of Anesthesiology
(312) 695-2500
d-walega@northwestern.edu

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OBJECTIVES:**1.0 Research Aims:****1. Research Question:**

Is there a detectable difference upper extremity strength as measured with dynamometry after cervical epidural steroid injections when lidocaine is used instead of saline as a steroid diluent in patients with cervical radiculitis?

2. Null Hypothesis:

There is no difference in upper extremity strength when lidocaine is used as a steroid diluent instead of saline for cervical epidural steroid injections.

BACKGROUND:**Literature:**

Cervical radicular pain is a common problem that is often treated by epidural steroid injection (1). While clinical practice guidelines do not specifically recommend or discourage the use of local anesthetic in the epidural injectate (2), the majority of the published literature on clinical outcomes of cervical epidural steroid injection includes the use of lidocaine in the epidural injectate (3-11). Consequently, many practitioners elect to use local anesthetic in the epidural injectate in order to provide immediate pain relief to patients in cases of exquisitely painful radicular symptoms. Local anesthetic may also be used in such cases to gain additional clinical information regarding a patient's analgesic response, which may help pinpoint a precise anatomic source of pain when the clinical presentation and pain generator is not clear.

Local anesthetic injection into the epidural space has the potential to cause transient weakness of the upper extremities. High doses of local anesthetic in the cervical epidural space (12) and inappropriately placed low-dose local anesthetic in the subdural space or subarachnoid space (13,14) are known to cause motor weakness. Appropriately placed, low-dose local anesthetic injected into the epidural space via a transforaminal approach, in close proximity to the exiting spinal nerve root, causes motor block in a small proportion of patients (15). However, the effect of low-dose injection of local anesthetic in the cervical interlaminar epidural space on objective upper extremity strength has not been well characterized in the published literature. This proposition affects post-procedure instructions, as even mild weakness may pose a hazard during performance manual activities that require the upper extremity/extremities such as using a handrail or cane handle for support.

Dynamometry is an established method for assessing muscle strength and motor neuron function with high reliability, and has been used to objectively assess changes in upper extremity strength and has been validated in several patient populations (16-22).

This study aims to determine whether a standard dose of 2 mL 1% lidocaine vs 2mL of saline included as a steroid diluent in a C7-T1 cervical interlaminar epidural steroid injection (CESI) causes an objective change in strength as measured by dynamometry.

We hypothesize that CESI with lidocaine will cause an objective transient decrease in upper extremity strength, consistent with the expected duration of this local anesthetic.

Significance: Cervical radiculitis is a relatively common pain syndrome and is often treated with cervical epidural steroid injection (CESI) when conservative treatments (oral analgesics, physical therapy and activity modification for example) have failed to provide relief of symptoms. There are no universal clinical practice guidelines for the use of or type of diluents when CESI are performed.

Interlaminar CESI may be performed with or without the use of local anesthetics. CESI without the benefit of local anesthetic as a steroid diluent will not provide immediate relief of pain in patients with excruciating radicular symptoms, and also limits clinical information gleaned from the immediate analgesic response. Finally, the lack of immediate pain relief following spine interventions for chronic pain management may decrease patient satisfaction (23).

By evaluating the effects of local anesthetic as a diluent during interlaminar CESI, we will provide information about the potential for objective motor weakness with this commonly performed pain management procedure.

INCLUSION AND EXCLUSION CRITERIA:

Patients who plan to undergo CESI for treatment of cervical radiculitis or the control group (no CESI) will be screened for eligibility by authorized research personnel during their visit to the Northwestern Anesthesiology Pain Medicine Center, 259 E. Erie, Suite 1400, Lavin Pavilion.

CESI Group

Inclusion criteria:

All patients ages 18 years or older who will undergo CESI for treatment of cervical radiculitis.

Exclusion criteria:

- Subject refusal
- Subject unwilling to provide written consent
- History of a hypersensitivity to amide local anesthetics
- Any medical contraindication to CESI
- Inability of the subject to communicate in English with research personnel
- Inability of the subject to perform handgrip or arm strength testing
- Cervical spinal cord lesions
- Cerebrovascular, demyelinating or other neuromuscular muscular disease
- Subject request for or requirement of intravenous conscious sedation for the injection procedure

Pregnancy
Breast feeding

Non CESI Group (control)

Inclusion Criteria:

All patients ages 18 years or older who will undergo trigger point injections (TPI)
TPI include: Occipital facet or cervical facet injection

Exclusion Criteria:

Subject refusal
Subject unwilling to provide written consent
Pregnant
Breastfeeding
History of a hypersensitivity to amide local anesthetics
Inability of the subject to communicate in English with research personnel
Inability of the subject to perform handgrip or arm strength testing
Cervical spinal cord lesions
Cerebrovascular, demyelinating or other neuromuscular muscular disease

STUDY-WIDE NUMBER OF PARTICIPANTS:

Sample Size Calculation

Group 1: n = 60 (CESI with Lidocaine Diluent)
Group 2: n = 60 (CESI with Saline Diluent)
Group 3: n = 20 (no CESI, control group)

A power analysis was performed based upon previous observations of changes in UE strength (24,25) using Fisher's Exact Test. Sample sizes of 52 in each of the two treatment groups will achieve > 80% power to detect a group different in proportions, assuming 20% of patients in the Lidocaine group will demonstrate a motor deficit after the CESI and those in the Saline group will demonstrate no difference in motor strength after the CESI, and further assuming a 2% measurement error with the strength testing method described. The alpha level of this test statistic is set at 0.05, but the significance level actually achieved by this study design is 0.0004. To allow for drop outs, a total of 130 subjects will be enrolled in group 1 and 2. Group 3 will enroll a convenience sample of 20 control subjects based on available patients. Total of 150 subjects for the study will be enrolled.

Statistical analysis: The primary outcome (UE strength by dynamometry will be compared between the lidocaine and control group using Fisher's Exact Test. Secondary outcomes will be compared using the Mann-Whitney test for continuous data and a chi-squared statistic. A $P < 0.05$ will be required to reject the null hypothesis.

STUDY-WIDE RECRUITMENT METHODS: N/A

MULTI-SITE RESEARCH: N/A

STUDY TIMELINES:

Each enrolled subject will receive a follow up telephone call 24 hours and one week after the procedure. The anticipated duration for study enrollment is 6 months.

STUDY ENDPOINTS:

Primary outcome:

Change in upper extremity strength defined by dynamometry measurements for each individual in each treatment group before and 30 minutes after the procedure (CESI or no CESI).

Secondary outcomes:

Mean arterial pressure

Heart rate

Numeric Rating Scale (NRS) pain score

Upper Extremity Functional Index (UEFI) score

Procedure complications

PROCEDURES INVOLVED:

Study design:

Prospective, randomized, controlled, double blinded trial in patients undergoing CESI for symptoms of cervical radiculitis.

Group #1: Interlaminar cervical ESI at the C7-T1 level with triamcinolone 80 mg + 2 mL 1% lidocaine (total volume 4 cc).

Group #2: Interlaminar cervical ESI at the C7-T1 level with triamcinolone 80 mg + 2 mL preservative saline (total volume 4 cc).

Group #3: Control group (No CESI) cervical or occipital facet injection

Adults who are eligible to have a CESI for treatment of cervical radiculitis at the Northwestern Anesthesiology Pain Medicine Center will be approached by authorized research personnel prior to a patient's CESI is performed and will obtain informed consent from patients who agree to participate.

A pre-procedure NRS pain score and presence of subjective or objective symptoms of UE weakness will be recorded by a blinded authorized study team member. Bilateral handgrip, wrist extension, elbow flexion, and elbow extension strength (myotomes C5-T1) will be measured prior to the injection procedure using a handheld JAMAR® PLUS+ digital dynamometer (Sammons Preston, Bolingbrook, IL) for hand grip strength and a push/pull handheld hydraulic dynamometer (Balego and Associates Inc., St. Paul, MN) for arm strength assessment. Three baseline strength measurements will be recorded for each strength test. Measurements will be taken prior to and 30 minutes following the

injection procedure. Participants will also be queried with the Upper Extremity Functional Index (UEFI) before the injection procedure and again 1 day and 1 week after the procedure (administered via telephone).

Group 1 and 2 participants will be randomized to treatment group based on a random computer-generated schedule (<https://www.randomizer.org>) and will be blinded to the group to which they are assigned. Blinding will not occur with Group 3. Providers will not be blinded to randomization; blinded research personnel will collect all outcome measures in this study.

All standard Pain Center procedures for CESIs will be followed (standard practice) including time out, skin prep, hemodynamic monitoring, image guidance, post-injection instruction etc.

Group 1 and Group 2 group randomization, triamcinolone acetonide 80 mg (Kenalog, E. R. Squibb & Sons Limited, Uxbridge UK) will be combined with 2mL Lidocaine 1% or 2 mL preservative free saline and will be injected during the CESI procedure. In all cases, the total injectate volume will be 4 mL. All injections will be performed with fluoroscopy guidance (current standard practice).

Group 3 will receive standard treatment intramuscular injection of bupivacaine .25% 10-20 mL and methylprednisolone 20 mg.

All participant's will be recovered for approximately 20 minutes following the procedure (and will be discharged from the clinic with standardized written discharge instructions given to all patients who receive an injection in this practice (includes bathing instructions, activity following the procedure, signs and symptoms of neurologic compromise, for example).

All participants will be contacted by telephone by authorized study team member on Day 2 and again 1 week after the procedure (CESI or No CESI) to assess for residual subjective weakness in the hands or arms as well as any other adverse reactions. As the clinical duration of effect for 1% lidocaine is 1-2 hours in most patients, we do not expect to see sustained subjective weakness at 24 hour and 1 week post-CESI assessments as a result of this diluent. As above, the Upper Extremity Functional Index will be administered.

Group 1 and 2 participants will only be recruited for this study for a single CESI. Those who require repeat injections will not be recruited for this study a second or third time.

DATA AND SPECIMEN BANKING: N/A

DATA AND SPECIMEN MANAGEMENT:

The data will be collected by the research study team. Subject data will be stored in the Northwestern University REDcap data collection system accessible only by using a secured password protected departmental computer at Northwestern University Department of Anesthesiology Pain Center, Lavin Pavilion 14th floor.

Data are backed up every night using Northwestern University Department of Anesthesiology (NM) servers which are stored on the 5th floor Arkes Pavilion and only accessible by the departmental IT administrator using key card and hard key as well as passwords.

Completed paper data collection forms will be stored in locked cabinets in the office of the principal investigator on the 14th floor Lavin Pavilion, Department of Anesthesiology. Only study team members will have access to review the data.

Each study subject will be assigned a study code number. The code will be used to link study data to participant identification (name) in a separate database and this will be kept in a dedicated Department of Anesthesiology password-protected computer in a locked office located on the 10 floor of Arkes Pavilion, Department of Anesthesiology offices.

Strict measures will be in place to ensure that no loss of confidentiality occurs. Only study team members will have access to the data. The principal investigator will be oversee the handling and management of the data.

Data both electronic and paper will be destroyed 5 years after manuscript preparation using current department protocol and current vendor.

PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF PARTICIPANTS:

The data collected will be periodically evaluated by a data monitoring committee consisting of the Department of Anesthesiology Director of Research, the Statistician and the Pain Center Medical Director regarding both harms and benefits to determine whether participants remain safe.

Safety data and adverse event data will reviewed.

- The frequency of data collection, including when safety data collection starts. Safety data collection occurs when completing the data collection form and reviewing the side effect profile of study drug.
- Data will be reviewed by the research study team and the data monitoring committee.
- The data will be reviewed every 15 subjects or if one of the study subjects experience a rapid response team intervention and review.
- The statistical tests for analyzing the safety data to determine whether harm is occurring. Adverse events are rare with CESI. Therefore, the analysis for harm would be a simple assessment of the number and types of adverse events in this small study, if they are to occur.

WITHDRAWAL OF PARTICIPANTS:

If the PI has determined that it is in the best interest of the subject, the PI will discuss the reason for withdrawal from the study with the subject. Data collected to that point will be included in the data analysis.

RISKS TO PARTICIPANTS:

Group 1 and 2

Risks of study participation are the same as those for any fluoroscopically guided cervical ESI performed for management of cervical radiculitis when more conservative methods have been exhausted or failed. The duration of recovery for study participants is no longer than that of a standard CESI performed in this practice.

Procedure risks:

Localized infection

Epidural hematoma or abscess

Dural puncture and potential post-dural puncture headache

Paresthesia during needle placement

Pain at the injection site

Failure of technique to decrease pain levels

Allergy to latex, chlorhexidine, adhesives or any medications used during the procedure

Risks of Triamcinolone acetonide 80 mg total dose (Kenalog 40 mg/mL)**Common (less than 10%)**

Aggression

Agitation

Anxiety

Blurred vision

Decrease in the amount of urine

Dizziness

Fast, slow, pounding, or irregular heartbeat or pulse

Headache

Irritability

Mental depression

Mood changes

Nervousness

Noisy, rattling breathing

Numbness or tingling in the arms or legs

Pounding in the ears

Shortness of breath

Swelling of the fingers, hands, feet, or lower legs

Trouble thinking, speaking, or walking

Troubled breathing at rest

Weight gain

Incidence rate unknown:

Abdominal cramping and/or burning (severe), abdominal pain, backache, bloody, black, or tarry stools, cough or hoarseness, darkening of skin, decreased vision, diarrhea, dry mouth, eye pain eye tearing, facial hair growth in females, fainting, fatigue, fever or chills, flushed, dry skin, fractures, fruit-like breath odor, full or round face, neck, or trunk, heartburn and/or indigestion (severe and continuous), increased hunger, increased thirst, increased urination, loss of appetite, loss of sexual desire or ability, lower back or side pain, menstrual irregularities, muscle pain or tenderness, muscle wasting or weakness, nausea, pain in back, ribs, arms, or legs, painful or difficult urination, skin rash, sleeplessness, sweating, trouble healing, trouble sleeping, unexplained weight loss, unusual tiredness or weakness, vision changes, vomiting, vomiting of material that looks like coffee grounds

Risks of 1% Lidocaine

Common (less than 10%):

Hypotension
Hypertension
Nausea
Vomiting
Paresthesia
Dizziness
Bradycardia (slowed heart rate)

Less Common (less than 5%):

Convulsions
Paresthesia
Circumoral numbness
Hyperacusis
Visual disturbances
Tremor
Tinnitus
Dysarthria
CNS depression

Rare (less than 1%):

Cardiac arrest
Cardiac arrhythmias
Allergic reactions
Anaphylactic reaction/shock
Respiratory depression
Neuropathy
Diplopia

Group 3:

Risks of study participation are the same as those for any trigger point injections performed for pain management.

Localized infection
Epidural hematoma or abscess
Pain at the injection side

There is the potential for loss of confidentiality even though there are strict measures in place to prevent occurrence. There is the potential for feeling uncomfortable completing the testing and questionnaires. There is the potential for feeling uncomfortable answering the follow up questions.

POTENTIAL BENEFITS TO PARTICIPANTS:

There are no direct benefits to the individual by participating in this study. The patients will be presented with the same treatment options whether they enroll in the study or decide not to participate.

The information gained from this study may provide the investigators a better understanding of a patient's pain and strength response following a cervical epidural steroid injection.

SHARING OF RESULTS WITH PARTICIPANTS:

After the study is completed and the randomization schedule becomes known to the research study team, if requested, we will notify the patient by telephone of the study group he or she belonged to.

SETTING:

Potential participants will be recruited for the study in the Northwestern Anesthesiology Pain Medicine Center, 259 E. Erie, Suite 1400 (Lavin Pavilion). The research study team member will review the consent document with the subject on the day of the procedure.

The study drug will be administered during the procedure in the treatment area of the Pain Center. Study drugs are obtained from a password protected Omnicell machine in the Pain Center. Post procedure care will take place in the Pain Center recovery room.

RESOURCES AVAILABLE:

The research study team will be fully informed about the research protocol. Copies of the protocol will be available for review in the Pain Center. After enrollment, the study will be conducted in Pain Center. Research study team will collect procedure and post procedure data. The follow up will be by telephone at 24 hours and again 1 week following the procedure (CESI and Non CESI).

PRIOR APPROVALS:

This protocol has been reviewed and approved by the Department of Anesthesiology Research Committee

RECRUITMENT METHODS:

Patients will be seen in the Pain Center, with a diagnosis of cervical radicular pain and scheduled to undergo CESI (Group 1 and 2) or no CESI (Group3) procedure by Anesthesiology Pain Center personnel will be recruited. If the subject meets the inclusion criteria and is interested to participate, the subject will be given a copy of the consent form to read on paper or on the Department of Anesthesiology Research password protected encrypted tablet. Research study team members will be present to answer all study related questions, after which the patient will sign the HIPAA compliant electronic consent form in REDcap.

NUMBER OF LOCAL PARTICIPANTS:

Size of study groups:

Group 1: n = 60

Group 2: n = 60

Group 3: n = 20

CONFIDENTIALITY:

Data will be stored in a Northwestern University Department of Anesthesiology dedicated computers which are only accessible to the research study team. The computers are password protected and are located on the 10th floor Arkes Pavilion Department of Anesthesiology administrative office and the 14th floor Pain Center in the Lavin Pavilion. The computers are backed up every night to the Department of Anesthesiology server located on the 5th floor Arkes pavilion. A key card and key are required and is only accessible by the Department of Anesthesiology IT administrator. The server is remotely backed up nightly.

Each study subject will be assigned a study code number. The code will be used to link study data to patient identification (name) in a separate database. Data access will be password protected and only available to study investigators.

PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF PARTICIPANTS:

The subject will have multiple interactions with the study team. The first interaction will be to discuss and obtain written informed consent; then 24 hours and 1 week following the injection for a brief period by telephone. These brief interactions limit the amount of intrusion into the subject's post-injection recovery.

Procedures will be completed by a study team member who will remind the participant why this encounter is occurring with the study team.

The research study team may only view the data sheets and the subject's medical record in Powerchart and EPIC for selected data within the parameters of the study.

COMPENSATION FOR RESEARCH-RELATED INJURY:

No compensation will be provided to participants for research related injury.

ECONOMIC BURDEN TO PARTICIPANTS:

There is no additional cost charged to patients who participate in this study, as compared to those patients not in a study who receive a CESI.

CONSENT PROCESS:

Potential subjects will be approached by study team members in the Pain Center. They will be able to review the consent document either on paper or on the dedicated (encrypted and password protected) study tablet owned by the Department of Anesthesiology. They will be consented before their planned procedure. The consent will be stored in HIPAA compliant REDcap. The subject's copy of the signed consent will be forwarded electronically to their individual E-mail account. If they do not have E-mail access a paper copy will be provided. A copy of the consent document will also be available in REDcap. A copy of the consent will also be uploaded to Enotis. The research study team will be following SOP: Informed Consent Process for Research (HRP-090). The study team will spend greater than 10 minutes discussing the consent document and the procedures involved.

Ample time will be allowed for patient to ask questions regarding the study and the consent document. The subject will also be informed that there is no conflict of interest between the PI and the protocol. The PI will not receive financial remuneration nor will the study participation affect the subject's medical bills.

Waiver or Alteration of Consent Process: No waiver of consent is being sought.

Participants who are not yet adults (infants, children, teenagers) and adults unable to provide consent will not be included in this study.

PROCESS TO DOCUMENT CONSENT IN WRITING:

SOP Written Documentation of Consent (HRP-091) has been reviewed. Consent document will be attached to the IRB application. HIPAA compliant REDcap will host the electronic version of the consent document to allow electronic signatures of participants on the consent document.

DRUGS OR DEVICES:

The research study team will be blinded to the participant's group assignment in this study. Drugs are stocked in an Omnicell machine in the Pain Center. The provider will administer the study drug to the patient during the CESI.

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