Erector Spinae Plane Block versus Intertransverse Process Block: a Randomized Control Trial in Healthy Volunteers

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Purpose of the Study

Objectives:

To compare the cutaneous sensory block distribution of the Erector Spinae Plane (ESP) block and the Intertransverse Process (ITP) block in healthy adult volunteers, using detailed skin mapping with pinprick, cold stimuli, heat stimuli, and thermographic imaging.

To compare if any differences are found between the ESP and ITP blocks in terms of respiratory dynamics, using pulmonary function testing at baseline and post-block.

Hypothesis:

The ITP block provides a more localized and consistent dermatomal coverage compared to the ESP block, with reduced variability in cutaneous sensory distribution. Additionally, no differences in pharmacokinetic profiles of lidocaine will exist between blocks, both showing equally safe profiles. No differences in respiratory dynamics are found between ESP and ITP blocks.

Background & Significance

Regional anesthesia techniques (or nerve blocks) are used to provide sensory blockade over the chest wall. The most established technique is thoracic epidural. This provides bilateral spread but is also associated with neuraxial complications, which has led to a decrease in clinical usage. Alternative techniques such as the Erector Spinae Plane (ESP) block and Intertransverse Process (ITP) block have emerged as safer and less invasive techniques.

The scientific background of this study lies in the exploration of these blocks, both of which are utilized for thoracic analgesia, mainly following thoracic surgery. The ESP block has gained popularity due to its simple technique. However, one of the key challenges associated with the ESP block is its variable and inconsistent spread of anesthetic, which can lead to unpredictable outcomes in terms of dermatomal coverage, and therefore, it's efficacy and reliability. Even being a standard care block indicated as a first-line technique in some guidelines, this variability has prompted the search for alternative techniques that might provide more reliable and consistent results.

The ITP block was developed with the goal of overcoming some of these limitations. By targeting a different anatomical site, it aims to provide a more controlled spread of anesthetic, potentially resulting in a more predictable and effective blockade. However, despite its theoretical advantages, there is limited research comparing the effectiveness of ITP to ESP, including in terms of cutaneous sensory block distribution and dermatomal spread.

This study is significant because it directly compares these two regional anesthesia techniques in healthy volunteers, providing valuable insights into their relative efficacy and consistency. By using objective

measures such as temperature discrimination, mechanical discrimination, and thermography, the study aims to offer a comprehensive assessment of the cutaneous sensory block produced by both techniques. Furthermore, this research could potentially clarify whether ITP truly offers superior or more consistent outcomes compared to ESP, thus informing clinical decisions and potentially improving anesthesia management for thoracic procedures.

In addition to assessing the distribution and coverage of the ESP and ITP blocks, this study also seeks to investigate the pharmacokinetics (PK) of lidocaine in each technique. Despite the anatomical target being slightly different, a different systemic absorption of local anesthetic is not expected, as local anesthetic is injected in similar compartments. While inferences can be made from studies on other blocks, we seek to obtain clear, specific data for these particular techniques. We, therefore, expect to confirm similar safety profiles for both blocks. Additionally, we aim to compare the absorption behavior of lidocaine between these blocks, as this information could have important clinical implications, particularly regarding onset and block duration. To our knowledge, this aspect has not been previously investigated.

The relevance of this study extends to improving patient care in thoracic anesthesia, where achieving consistent and reliable regional blockade is critical. If the ITP block demonstrates more predictable results, it may be adopted more widely in clinical practice, especially for patients undergoing thoracic surgery or those with conditions requiring reliable pain control in the thoracic region.

Design & Procedures

A participant will be considered enrolled in the study after they have provided written informed consent. Participants will only be eligible to participate in the study if they have consented to participate in the study in accordance with the study procedure. Enrollment in the study will require a time commitment of approximately twelve (12) hours over the course of two visits.

The trial will adhere to the Declaration of Helsinki guidelines and will consist of two visits:
Screening, informed consent, procedure day 1 with block performance and assessment.
Procedure day 2 with block performance and assessment.

Visit 1:
During the first visit, the study designated staff reviews the purpose of the study, discusses potential risk involved with the procedure, goes over the informed consent form (ICF), answers any questions and obtains the subjects signature on the consent form.

Qualified healthy adult volunteers will be used as participants in this study.

Medical History including known allergies to lidocaine or medical adhesive; concomitant medications including the history of prescription and over the counter medication will be carefully noted and recorded (medication name, indication for use, dose, frequency, route of administration start/stop date).

Physical examination including an evaluation of general appearance, cardiovascular, respiratory, musculoskeletal system, skin, neurologic function, and head, eyes, ears, nose and throat will be performed at this time.

Vital signs will be recorded at baseline visit and study visit (height, weight, calculated body mass index (BMI), heart Rate, blood pressure, respiratory rate and oxygen saturation).

The American Society of Anesthesiologist (ASA) physical status classification system is used to evaluate the degree of a patient's "sickness" or "physical state." Only subjects with ASA Physical status 1 or 2 will be enrolled in the study.

A urine pregnancy test will be administered.

An anesthesiologist with regional anesthesia expertise will scan the thorax of the subject to assess the ultrasound-anatomy and identify possible technical difficulties. If the block is technically deemed difficult during this pre-scan (structures are unable to be clearly visualized by. ultrasound), the subject will be excluded from the study. If no difficulties are anticipated, the subject will proceed to receive the block (the order of the blocks being administered will be randomized).

Baseline assessments will be performed before the block procedures. These will include:

- Complete sensory testing of the chest wall (anterior, lateral, posterior)
- Mechanical perception with pinprick discrimination
- Temperature perception with an ice discrimination
- Heat perception with a controlled temperature using an appropriate device
- Thermography using an infrared camera
- Pulmonary function testing

Monitoring will be established right before the procedure. An intravenous (IV) line will be placed in each subject.

Each volunteer will receive a 20 mL injection of 1.5% lidocaine with epinephrine at the T4/T5 level, with ultrasound guidance and a linear transducer used to accurately place the needle. The ESP block will be performed by advancing the needle to the transverse process, with local anesthetic injected between the erector spinae muscle and the transverse process, targeting a caudad-cephalad spread. For the ITP block, the needle will be advanced further into the intertransverse tissue complex between the T4 and T5 transverse processes, and local anesthetic will be injected just above the superior costotransverse ligament. In the period between 60- and 90-minutes post-block, the sensory block will be assessed, with the same tests performed at baseline. The mechanical and temperature discrimination points will be used to use demarcation pens on the skin, to draw a map of the blocked area. This map will be documented in three digital photographs of the anterior, lateral, and posterior chest walls. Images will also be captured using the infrared camera that will analyze the skin temperature (thermography). All images will be de-identified.

The subjects will be discharged 6 hours post-block or before if the block wears out.

This study does not include a placebo control as both ESP and ITP are established regional anesthesia techniques with known effects on sensory blocks, and the volunteers will serve as their own controls, receiving both blocks. No standard therapies are delayed or discontinued in the study, and there is no need for a washout period, as each participant will receive both blocks with independent assessments made after the blocks are performed. The procedures and tests, including the sensory testing and cutaneous sensory block mapping, are conducted exclusively for research purposes and are not part of routine clinical care.

If the patient does not fully recover from the block before discharge, they will be sent home with direct contact access to the principal investigator (PI) and will receive close follow-up via phone call within the first 12 hours, or while deemed necessary. Clear instructions will be provided in case any changes occur. Since these are primarily sensory blocks, complications from prolonged blockade are not expected. If any unexpected complications arise, they are most likely to occur immediately or within the first hour after the block is performed—a period during which the patient will remain under the care of the research team. If necessary, the patient will be directed to the emergency department.

Visit 2:

During the second visit, which will happen at least one week apart from visit 1, the exact same procedures will take place, except for the ones related to screening and consent. The block randomized for this visit will be performed accordingly.

The risks associated with the study, including infection, bleeding, local anesthetic systemic toxicity, are minimal, and the benefit lies in advancing knowledge about the distribution of these regional anesthesia techniques, which may ultimately improve clinical practices for thoracic procedures. There are no alternative therapies or concurrent therapies in use, and volunteers who do not meet the inclusion criteria or have contraindications for regional anesthesia will be excluded. All subjects will be followed up via a phone call 2 days after each procedure.

The investigators plan to perform the blocks and assess eight subjects per visit over a period of two to three months. An additional two to three months are estimated for data analysis, followed by six to twelve months for manuscript preparation, submission, and publication.

Selection of Subjects

Healthy volunteers over 18 years old providing written informed consent will be enrolled in this study. They will be recruited via telephone contact by the primary investigator or other key personnel. The study will be explained in full detail, after which volunteers will be given the opportunity to ask questions about the study. If they are interested in participating, they will be again explained the protocol, and informed consent will be obtained on the first visit.

Inclusion criteria:

Ability to provide written informed consent
Ability and willingness to comply with the study procedures and duration requirements
ASA physical status 1 or 2
Age ≥ 18 years

Exclusion criteria:
BMI > 35kg.m2
Use of analgesics within 24 hours before the procedure
History of thoracic trauma or surgery
Thoracic deformities or abnormalities that may prevent proper block performance
Thoracic tattoos
Systemic neuromuscular disease
Contraindications to regional anesthesia (e.g., infection, allergy, challenging sonoanatomy)
Structures are unable to be visualized by ultrasound
Pregnancy*
Other known health conditions that would affect the participant's ability to successfully complete the study

*Note: The physiological effects of pregnancy may influence key aspects of the study intervention due to altered lidocaine metabolism, which results in an overall increased susceptibility to the drug.

Subject Recruitment and Compensation

Potential subjects will be primarily recruited by the use of the Healthy Volunteer Data Repository (Pro00091879) principal investigator or designee will send an email to participants with a link to a dedicated REDCap study survey which includes a series of straight-forward eligibility questions. A Quick Response (QR) code within the advertisement will also direct the participants to the dedicated REDCap study survey website. A description of the Human Pharmacology and Physiology Lab (HPPL), as well as a quick summary of the planned study, and link to a PDF version of the informed consent form (ICF) is also available for the participants for a review at their leisure. A member of the research team will review the submitted screening survey form to determine if the subject is eligible for the screening visit.

The study will incur no cost to the subject. The subject will be paid $400 in total compensation, $200 for completing the first visit, and the remaining $200 for completing the second visit. The subjects will receive $25 if they screen failure for difficult anatomy.

Risk/Benefit Assessment

This study is for research purposes only. There is no direct benefit to participants participating in the study. Information from this study may help other people in the future.

Lidocaine: the risks associated with use of this local anesthetic, may include discomfort or pain (burning or stinging) with injection; and allergic reaction to medication (extremely rare: < 0.1%). There is the risk of Local Anesthetic Systemic Toxicity (rare <0.1%), with symptoms that include dizziness, tinnitus, metallic taste, seizures, or cardiac arrhythmias. Risk is mitigated by slow aspiration and adherence to dosing limits.

Lidocaine is a well-established local anesthetic. The dose used in each procedure day (300 mg) corresponds to 4.2 mg/kg for a 70 kg adult, as it will be used with added epinephrine, it will be below the recommended maximum dose of 7 mg/kg. Additionally, lipid emulsion, the therapy to treat toxicity will be on-site at all times.

Regional anesthesia techniques potential risks: the risk for serious adverse events is extremely low (a meta-analysis of 64 randomized controlled trials showed no difference in complications' incidence between ESP and placebo or no block. However, the rare complications include:

- Pneumothorax: Very rare during thoracic block procedures (<0.5%). Can cause chest pain, dyspnea, and hypoxia.
- Pain at Injection Site: Common (10-20%). Typically mild and self-limiting.
- Hematoma: Rare (<1%).
- Transient Nerve Injury: Rare (<1%). Can cause temporary paresthesia or weakness; usually resolves within weeks.
- Infection at Injection Site: Very rare (<0.1%). Prevented by sterile technique.

Ultrasound: utilizes high frequency sound waves to produce images of internal body structures. There are no anticipated risks. The ultrasound will be used identify anatomical structures and see both the needle and the local anesthetic spread in real time, with direct visualization. The blocks will be performed under sterile conditions following standard practice. Subjects will be excluded if they have a known severe allergy to the ultrasound gel.

The risk in the use of ECG electrodes is believed to be minimal.

Risks associated with intravenous line placement: infection, bruising, bleeding.

Data Management, Analysis and Statistical Considerations

No formal power calculation will be performed; the sample size is based on convenience and prior studies.

Data Presentation:
Continuous variables: Median and standard deviation (SD)
Categorical variables: Proportions

Data & Safety Monitoring

In accordance with federal regulations the PI will monitor for, review, and promptly report to the IRB, appropriate institutional officials, sponsor, coordinating center and the appropriate regulatory agency head all unanticipated problems involving risks to subjects or others that occur in the course of a subject's participation in a research study (45 CFR 46.103(b)(5)(i) and 21 CFR 56.108(b)(1)), all AE reports will be reported per the DUHS IRB policies. PI will be monitoring all AEs and submitting reports to the IRB per DUHS IRB policy.