Ticket #:

Statistical Analysis Plan

Dispersion following ESP Versus ITP blocks using Lidocaine (DEVILS) Study

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1. **Introduction:**

   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 firstline 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.

   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.

2. **Study Objective:**

   (1) 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.

   (2) 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.

3. **Hypotheses:**

   (1) The ITP block provides a more localized and consistent dermatomal coverage compared to the ESP block, with reduced variability in cutaneous sensory distribution.
   (2) No differences in respiratory dynamics are found between ESP and ITP blocks.
   (3) Individuals with no mechanical and temperature perception during their first block (either ITP or ESP) are more likely to have no mechanical and temperature perception at their subsequent block (either ITP or ESP).

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4. **Study population or dataset:**

Study design features
This study will be a randomized crossover trail in which all patients will receive both block types. Each block will be performed at separate visits at least 1 week apart. Which block is performed first on each patient will be randomized.

Inclusion Criteria

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

Exclusion Criteria

- BMI > 35kg/m2
- Use of analgesics within 24 hours prior to the procedure
- History of thoracic trauma or surgery
- Thoracic deformities or abnormalities that may prevent proper block performance
- Thoracic tattoos
- Systemic neuromuscular disease
- Contraindication 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 participants ability to successfully complete the study

5. Outcomes:

Hypothesis	Variable names	Description	Specifications (e.g. formula)	Data Source
1	Mechanical Perception	Sensory testing of the chest wall using pinprick discrimination Mechanical perception will be based on surface area.	Performed on the anterior, lateral, posterior areas of the chest wall Performed after ITP and ESP blocks	Redcap/from PI Sensory demarcation lines mapped on skin and documented with digital photography
3	Zero Mechanical Perception at Second Block	Binary Indicator for whether or not patient had zero mechanical perception at their second block (either ITP or ESP) Based on sensory testing of the chest wall using pinprick discrimination Mechanical perception will be based on surface area	Performed on the anterior, lateral, posterior areas of the chest wall 1 = zero surface area 0 = non-zero surface area	Redcap/from PI Sensory demarcation lines mapped on skin and documented with digital photography
1	Temperature	Sensory testing of the	Performed on the	Redcap/from PI

	Perception	chest wall using ice discrimination Temperature perception will be based on surface area.	anterior, lateral, posterior areas of the chest wall Performed after ITP and ESP blocks	Sensory demarcation lines mapped on skin and documented with digital photography
3	Zero Temperature Perception at Second Block	Binary Indicator for whether or not patient had zero temperature perception at their second block (either ITP or ESP) Sensory testing of the chest wall using ice discrimination Temperature perception will be based on surface area.	Performed on the anterior, lateral, posterior areas of the chest wall 1 = zero surface area 0 = non-zero surface area	Redcap/from PI Sensory demarcation lines mapped on skin and documented with digital photography
1	Heat Perception	Sensory testing of the chest wall using a controlled temperature and appropriate device Heat perception will be 3 separate maximum tolerable temperature measurements each from anterior, mid axillary, or posteriorly (total of 9 measurements) compared to baseline maximum temperature measurements.	Performed on the anterior, lateral, posterior areas of the chest wall Performed after ITP and ESP blocks	Redcap/from PI Sensory demarcation lines mapped on skin and documented with digital photography
1	Thermography	Sensory testing of the chest wall using an infrared camera Will be mean cutaneous temperature as measured at the blocked dermatome	Performed on the anterior, lateral, posterior areas of the chest wall Performed after ITP and ESP blocks	Redcap/from PI
2	Pulmonary Function	FEV1 and Percent Expected. Continuous.	Performed after ITP and ESP blocks	Redcap/from PI

6. Primary predictor of interest

Hypothesis	Variable names	Description	Specifications (e.g. formula)	Data Source

1,2	Block Type	Type of regional anesthesia performed: (1) Erector Spinae Plane (ESP) block (2) Intertransverse Process (ITP) block	Binary	Redcap/ from PI
3	Zero Mechanical Perception at First Block	Binary Indicator for whether or not patient had zero mechanical perception at their first block (either ITP or ESP) Based on sensory testing of the chest wall using pinprick discrimination Mechanical perception will be based on surface area	Performed on the anterior, lateral, posterior areas of the chest wall 1 = zero surface area 0 = non-zero surface area	Redcap/ from PI
3	Zero Temperature Perception at First Block	Binary Indicator for whether or not patient had zero temperature perception at their first block (either ITP or ESP) Sensory testing of the chest wall using ice discrimination Mechanical perception will be based on surface area	Performed on the anterior, lateral, posterior areas of the chest wall 1 = zero surface area 0 = non-zero surface area	Redcap/ from PI

7. Candidate covariates for multivariate models/ Table 1 variables

Variables in **BOLD** are for consideration of multivariable models, the rest will be summarized for the cohort in a table.

Candidate Covariates	**Description**
Age	**years**
Biological Sex	**Male, Female**
Height	cm
Weight	kg
BMI	m/kg2
ASA status	Categorical (1,2,3,4,5)

8. Statistical Methods and results

8.1. Data management:

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Data will be handled in accordance with institutional policies and procedures for protected health information (PHI) and other sensitive information. All analyses will be run within a secure drive behind Duke's firewall under a folder dedicated specifically to this study and accessible only by study personnel/analysts with enterprise authentication. Identifiers will be removed before generating final tables and figures. The original dataset with identifiers will remain within the secure drive. All analyses will be performed in R 4.4.0 or SAS 9.4.

8.2. Descriptive statistics:

Descriptive statistics of patient demographics and clinical characteristics will be reported for each analgesic approach. Normally distributed continuous variables will be reported as mean (SD) and non-normally distributed continuous variables will be reported as median [Q1-Q3]. Use of parametric methods for continuous variables will be determined through visual inspection of generated histograms and shapiro-wilk tests. Categorical variables will be reported as counts and percentages, N (%). A threshold of 0.05 will be used to determine significance. The rate of missingness for each variable of interest will be determined and missing rates greater than 5-10% will be considered for imputation.

8.3. Hypothesis I Analysis Plan: [Include File: (location and filename)]

Descriptive statistics for each continuous outcome of interest will be generated for each block type and missing rates will be reported as counts and percentages, N (%). Univariate comparisons between block types will be assessed via paired t-tests while multivariable comparisons will be assessed through mixed-effect linear regression models adjusting for age and sex. Alternative methods will include using a Wilcoxon singed rank test for univariate comparisons and a transformation of the outcome prior to multivariable modeling (z-score normalization, log-transformation, etc.) or the use of robust standard errors. Results will be reported as beta coefficients (β) or mean ratios (MR) with 95% confidence intervals.

8.4. Hypothesis II Analysis Plan: [Include File: (location and filename)]

Descriptive statistics for pulmonary function after each block will be generated and missing rates will be reported as counts and percentages, N Univariate comparisons between block types will be assessed via paired t-tests while multivariable comparisons will be assessed through mixed-effect linear regression models adjusting for age and sex. Alternative methods will include using a Wilcoxon singed rank test for univariate comparisons and a transformation of the outcome prior to multivariable modeling (z-score normalization, log-transformation, etc.) or the use of robust standard errors. Results will be reported as beta coefficients (β) or mean ratios (MR) with 95% confidence intervals.

8.5. Hypothesis III Analysis Plan: [Include File: (location and filename)]

First, we will create a contingency table of the binary classifications (zero vs non-zero) of the surface area measurements for mechanical and temperature discrimination. We will use McNemar's test to evaluate whether the proportion of participants with zero mechanical/temperature perception differed between the two visits following the administration of the block assigned for that visit. We will report the percent of patients that maintained zero and non-zero values between the two visits as well as the percent of patients that changed between the two. Finally, we will assess the association between zero discrimination after the first block and second block through a logistic regression model and report the odds ratio (OR) with a 95% confidence interval. In the event of heavy separation, we will apply a Firth correction and report estimates from both our standard and First-corrected logistic regression models.

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9. Supplementary

Table Shells:

	ESP	ITP	P-value
Age			
Sex			
Height (cm)			
Weight (kg)			
BMI (kg/m2)			

Table 1. Demographic and baseline clinical characteristics

	ESP	ITP	Beta (95% CI)	P-value
Mechanical Perception				
Anterior				
Posterior				
Lateral				
Temperature Perception				
Anterior				
Posterior				
Lateral				
Heat Perception				
Anterior				
Posterior				
Lateral				
Thermography				
Anterior				
Posterior				
Lateral				
Pulmonary Function				
FEV1				
Percent Expected				

Table 3. Multivariable regression results