**COVER PAGE**

**Study title:** The erector spinae plane block and its effect on respiratory status and pain management in rib fracture patients

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**NCT number:** not yet assigned

**Virginia Commonwealth University Study ID number:** HM20014264

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STUDY DESIGN:

The study will be a prospective, randomized, double-blinded, two-arm study, which will assess the effect of the ESP block on pulmonary function and pain management. The control group will receive a “sham” ESP injection with saline and the experimental group will an ESP injection with local anesthetic. Primary outcomes will measure change in vital capacity and change in pain score after the intervention.

Notably, incorporation of a nerve block for rib fracture pain management is within standard of care but is not considered until other less invasive options have proven inadequate. The step-wise layered approach is as follows: initial therapy includes oral medications such as acetaminophen, non-steroidal anti-inflammatory drugs, and opioids such as oxycodone. If this is not adequate, intravenous medications are added, which include ketamine, dexmedetomidine, and opioids such as hydromorphone. Next, subcutaneous infiltration of local anesthetic may be considered. Finally, acute pain service consultation allows for evaluation of nerve block options such as epidural placement, paravertebral nerve block, or ESP block. Performance of an ESP block is considered within standard of care. The acute pain service consultation will trigger the initial screening process to determine patient eligibility for the study.

PROTOCOL

Consent will be obtained by one of the research investigators in the trauma intensive care unit, where medical management takes place for all patients with significant injuries that include rib fractures. A randomizer will be used to prepare envelopes that will designate which study arm the patient will be placed. After consent is obtained, each participant will be given a numerical designation that will allow for blinding but also allow for easy identification between study arms (data collection sheet attached). The investigator that performs consent and randomization will prepare the study medication; for the control group, the investigator will transfer saline from a vial into two 20cc injection syringes, and for the experimental group, the investigator will transfer 0.5% ropivacaine from a vial into two 20cc injection syringes. The syringes will be labeled as "rib fracture study medication" along with the numerical designation of the participant. The consenting investigator will deliver the medication syringes to the team that is performing the procedure.

A second investigator will obtain baseline measurements and perform the procedure. Neither the second investigator nor the research participant will know the contents of the study medication. All equipment required for the ESP block will be brought to the participant's bedside. The participant will perform a baseline incentive spirometry (IS) exercise in a sitting position on the side of the bed; the

participant will take the deepest breath possible by inhaling through the IS device, and the second investigator will record highest vital capacity volume that the patient can reach. The investigator will also record the participant's reported numerical pain score before the IS exercise and pain score after

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STUDY DESIGN (continued)

the IS exercise (data collection sheet attached). These baseline measurements will be taken for research data collection and will not be documented in the patient's medical record.

The process for performing the ESP block procedure is as follows: the patient will be placed in a seated position and vital sign monitors will be connected. Per standard of care, either an ICU nurse or acute pain service nurse will be present to assist. Intravenous midolazam will be available and administered if necessary to make the patient more comfortable and less anxious. Full aseptic precautions will be taken with personal protective equipment and bactericidal preparation with chlorhexidine. An ultrasound probe will be placed lateral to the patient's upper back and the ideal location of medication injection will be identified on an ultrasound image (which is superficial to the transverse processes of the thoracic vertebral bodies and deep to the erector spinae muscle). The skin will be made numb with lidocaine prior to insertion of a larger needle (Tuohy needle); the proceduralist will direct the Tuohy needle to the desired target under ultrasound guidance and the study medication will be delivered through that needle (either 25 cc saline or 25 cc 0.5% ropivacaine). A continuous nerve catheter will then be inserted through the Tuohy needle to allow for delivery of medication after the study data is collected. The Tuohy needle will be removed and the nerve catheter will be secured in place with adhesive dressing. After the procedure is performed, continuous vital sign monitoring will occur over 15 minutes, which is the standard of care after completion of a nerve block procedure. To reduce confounders, the participant will not be permitted to receive oral or intravenous pain medication for 45 minutes after the nerve block is performed; this is an alteration of routine care that would be discussed with the patient prior to initiation of the study.

The full effect from a ropivacaine nerve block can take up to 45 minutes and is expected to last a few hours. Data measurements will be obtained by the second investigator 45 minutes after the completion of the ESP block. For these data measurements, an IS exercise will be performed with the patient is a sitting position on the side of the bed, and maximum vital capacity volume will be recorded. Numerical pain scores before and after the IS exercise will be recorded.

Research data collection will be complete at this point and the participant's care will be continued by the acute pain service. After the data is collected, the acute pain service and the research participant will be updated by the first investigator about which treatment was delivered for the research study. The nerve catheter that was inserted will be used for continuation of ropivacaine delivery and will likely provide benefit for the participant during their hospitalization.

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STATISTICAL ANALYSIS AND JUSTIFICATION OF SAMPLE SIZE

Based on three patients at our institution where ESP blocks were performed, incentive spirometry values before the block were 500cc, 750cc, and 1000cc; after the block, the values were 1500cc, 1200cc, and 2000cc, respectively.

Using these numbers, based on the equation in An Intro to Medical Statistics (Bland, 2015) and an online statistical calculator (http://clinicalc.com/stats/samplesize.aspx), the sample size needed to produce an alpha of 0.05 and beta of 0.2 was only 2 participants.

We believe that for clinical justification of our findings, 2 participants are not adequate. 20 participants would make our findings more relevant and likely to encourage a change in practice at other institutions. Therefore, we will aim to recruit 24 participants to account for a 20% dropout rate.

Statistical significance in the primary outcomes will be determined with a paired sample t-test, since change will be assessed using paired observations on the same subject before and after an ESP block is performed.