STUDY TITLE: Randomized Clinical Trial of Erector Spinae Plane (ESP) vs. Paravertebral Nerve Blockade for Video Assisted Thoracoscopic Surgery (VATS)

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STUDY PROTOCOL – 08/28/2019

ESP vs. PVB Nerve Blocks for Video Assisted Thoracoscopic Surgery (VATS) Research

Protocol

Continuous paravertebral analgesia and erector spinae plane blockade (ESP) are accepted techniques at UPMC for pain management in thoracic surgery. This is a prospective randomized study intended to assess the efficacy, safety and side-effect profile of continuous ESP block Vs continuous paravertebral block for VATS procedures.

Methods:

Once the patient has agreed to have peripheral nerve blocks as part of the analgesia technique and meets inclusion criteria, the patient will be asked to participate in the study. If they agree to participate, informed consent will be obtained and we will proceed with randomization.

Patient selection and Inclusion/Exclusion criteria

Inclusion criteria:

* Patients undergoing VATS agreeable to have a nerve block as analgesic technique

* Age: 18 years old and older.

* ASA I-IV

Exclusion criteria:

* Cognitive impairment that would not allow effective nerve block placement or gathering information related to the study (ex. pain score).

* Contraindications for nerve block placement such as coagulopathy, use of clopidogrel in the past 48hs, patients on dual antiplatelet therapy, infection at the site of puncture, patient refusal, allergy to local anesthetics.

* Chronic opiate consumption (>30 OME/day)

* Patient expected to be on therapeutic anticoagulation post procedure.

* Pregnancy

* Comorbid conditions: Any comorbid condition that in the judgment of the anesthesiologist would preclude the patient from any aspect of the study (ex. sepsis, possibly abnormalities of the thoracic spine or paravertebral anatomy such as neoplastic mass occupying the space, empyema, increased intracranial pressure)

Randomization: Patients will be randomized 1:1 into one of the study groups. The groups will be defined as Group 1: ESP block; Group 2: PVNB.

The goal is to include 80 patients (40 in each arm).

Before insertion of catheter, ropivacaine 0.5% will be injected incrementally prior aspiration to decrease the risk of intravascular injection every 5ml. The dose will be left at discretion of the

anesthesiologist performing the nerve block, with a volume that would provide effective dermatome coverage and considering the maximum possible dose to avoid local anesthetic toxicity. After administration of LA catheter will then be placed and left 5cm beyond the needle tip.

Continuous Infusion: bupivacaine 0.0625% will be started at 6ml/h and will be titrated up to a max of 12ml/h.

Bolus: patients will have access to rescue boluses of 3ml every hour, through the catheter with bupivacaine 0.0625% if needed.

All patients will be assessed daily by the acute pain service. Additional pain medication will be available to all patients per standard of care. All patients will have access to acetaminophen 1g every 6hs, ketamine infusion, and opiates as needed to provide adequate analgesia.

Data collection

Preoperative period:

In addition, to treat breakthrough pain, all patients will receive multimodal analgesia per routine.

An excel sheet will be available to collect the patient information from EMR and the patient.

- Data to be collected: age, gender, type of surgery, type of anesthesia (including medications and type regional anesthesia received).
- Incentive spirometer baseline measure prior to surgery
- dermatomal spread (pinprick and or changes in temperature (cold or hot) sensation) after 15-20mins of initial bolus will be documented.

Postoperative period:

In PACU:

- Intraoperative opiate consumption in (morphine equivalent dose) and while in PACU.
- pain scores using the numeric rating scale.
- insertion site and number of catheters will be documented
- dermatomal spread (pinprick and or changes in temperature (cold or hot) sensation) will be documented.
- number of chest tubes and sites

Postoperative period

- total opioid consumption (in morphine equivalents) and pain scores on the numeric pain rating scale will be documented every 6hs for the first 24hs.
- Incentive spirometer daily score postoperatively
- Length of stay,

- Duration of catheter
- Use of additional pain medication will be recorded
- Document adverse events or complications related to nerve blocks
- dermatome spread with infusion infusion will be documented.