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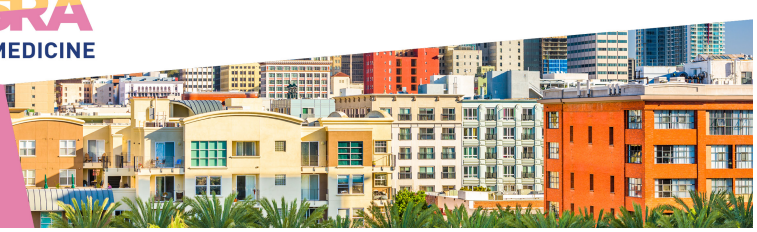

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Ultrasound-Guided Percutaneous Cryoneurolysis of Intercostal Nerves following Traumatic Rib Fracture: An Interim Analysis

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Introduction

Rib fractures occur in approximately 10% of trauma patients and are associated with significant pain, morbidity, and mortality.1 Local anesthetic-based intercostal nerve blocks decrease pain and improve peak expiratory flow rate and arterial oxygen saturation in patients with rib fractures.2 However, the duration of analgesia provided by single injection peripheral nerve blocks is limited to less than 24 hours, while the duration of pain is often prolonged for multiple months.

Cryoneurolysis is an analgesic modality in which extreme cold (-20 to -100□C) is applied to peripheral nerves to produce a much longer duration nerve block—usually measured in months—than can be achieved with local anesthetics.3 Utilizing ultrasound-guidance, a percutaneously inserted cryoprobe may be used to treat individual intercostal nerves. Randomized trials comparing ultrasound-guided percutaneous cryoneurolysis of the intercostal nerves to a sham procedure have demonstrated reduction in acute pain and transition to chronic pain following mastectomy.4 Case series have suggested possible benefits of intercostal cryoneurolysis following traumatic rib fractures; however, there are currently no randomized data comparing cryoneurolysis to sham procedures for rib fracture pain. We undertook this randomized, observer- and participant-masked, controlled, parallel-arm clinical study to evaluate intercostal cryoneurolysis for traumatic rib fractures. Per study protocol, the results were unblinded following completion of the first eight participants for the purposes of a grant submission (subsequently funded: HT9425-23-2-0013), which we present now.

Materials and Methods

This study was IRB approved and registered at ClinicalTrials.gov (NCT04198662) prior to enrollment and study interventions. Enrollment was offered to patients 18 years or older admitted with 1-6 rib fractures. After providing written consent, subjects were randomized to one of two groups using computer generated randomization lists:

(1) Active cryoneurolysis (plus sham local anesthetic block) –The cryoneurolysis device (PainBlocker, Epimed International, Dallas, TX) was triggered using 2 cycles of 2-minute gas activation separated by 1-minute defrost periods for the target intercostal nerves. Normal saline (3 mL) was injected into the muscle superficial to each

targeted nerve to provide the sham peripheral nerve block.

(2) Sham Cryoneurolysis (plus Active local anesthetic block) – The nitrous oxide was vented prior to reaching the probe shaft, resulting in a lack of tissue temperature change. Ropivacaine 0.5% (with epinephrine, 3 mL) was injected perineurally to provide the active peripheral nerve block.

Participants were positioned either prone or seated and standard American Society of Anesthesiologists monitors applied. If required for participant comfort, midazolam and/or fentanyl was titrated to facilitate patient positioning and reduce anxiety while ensuring participants remained responsive to verbal cues. Using either a large curvilinear or linear ultrasound probe, the ribs were counted and numbered. Based on the participant's randomization, the appropriate treatment was applied to each intercostal nerve associated with a fractured rib as well as the intercostal nerves above and below (e.g., if the 3rd through 5th ribs were fractured, the 2nd through 6th intercostal nerves were treated).

Study related follow-up was conducted either in person, while patients remained hospitalized, or by telephone by an investigator blinded to treatment group assignment. Participants were contacted on post-procedure days 1, 2, 7, and 14; and months 1, 1.5, 2, 3, 6, and 12 following the study procedure. The primary outcome measure was the maximum voluntary inspiration volume between baseline (prior to the procedure) and the following day.

Results/Case Report

Eight participants were enrolled, randomized, and successfully treated at the time of unblinding for the purposes of grant submission. For the primary endpoint, expressed as maximum inspiratory volume change from baseline, the median [IQR] change on post-procedure day 1 for the Active group (n=4) was 1125ml [750 ml to 1375 ml and 0 ml [-162.5 ml to 125 ml] for the Sham group (n=4; P-value: 0.055 [95% CI -31.9 ml to 2107ml]) (Figure 1). At nearly all time points during the first two months following the study intervention, average and worst pain scores, opioid consumption, and incentive spirometry values were improved in the Active cryoneurolysis group compared to the Sham group (Figure 2). Spirometry data is limited to 1.5 months because participants did not keep and use their spirometeres beyond this time point.

No study related complications were observed in either group.

Discussion

At this interim analysis time point, ultrasound-guided percutaneous cryoneurolysis of the intercostal nerves appears to be a viable option for extended duration analgesia following traumatic rib fractures.

References

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Disclosures

No

Tables / Images