



Ultrasound-Guided Percutaneous Cryoneurolysis of Intercostal Nerves Following Traumatic Rib Fractures: An Interim Analysis of a Randomized, Observer-Masked, Controlled, Parallel-Arm, Clinical Trial

John J. Finneran IV, MD,¹ Adam N. Schaar MD,¹ Leslie Kobayashi, MD, FACS,² Jessica Weaver, MD, PhD,² Todd W. Costantini, MD, FACS,² Allison E. Berndtson, MD, FACS,² Laura Haines, MD, FACS,² Jay Doucet, MD, FACS,² Laura Adams, MD,² Jeanne Lee, MD, FACS,² Jarrett Santorelli,² MD, Brian M. Ilfeld, MD, MS¹

Departments of Anesthesiology¹ and Surgery², University of California, San Diego



INTRODUCTION

- Rib fractures occur in ~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 rib fracture patients.²
- Duration of analgesia provided by single injection peripheral nerve blocks is limited to less than 24 hours, while pain duration is multiple months.
- Cryoneurolysis employs extreme cold (-20 to -100°C), applied to peripheral nerves to produce longer duration nerve block—usually measured in months.³
- RCT comparing ultrasound-guided percutaneous cryoneurolysis of the intercostal nerves to a sham procedure demonstrated reduction in acute pain and transition to chronic pain following mastectomy.⁴
- Case series have suggested potential benefits of intercostal cryoneurolysis following traumatic rib fractures⁵ but there are currently no RCT comparing cryoneurolysis to sham for rib fracture pain

METHODS

- Enrollment: patients 18 years or older admitted with 1-6 rib fractures.
- After providing written consent, subjects randomized to one of two groups:
- Active cryoneurolysis** (plus sham local anesthetic block) –The cryoneurolysis device 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.
- 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 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

- 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]) (**Spirometry Panel, Figure 1**)

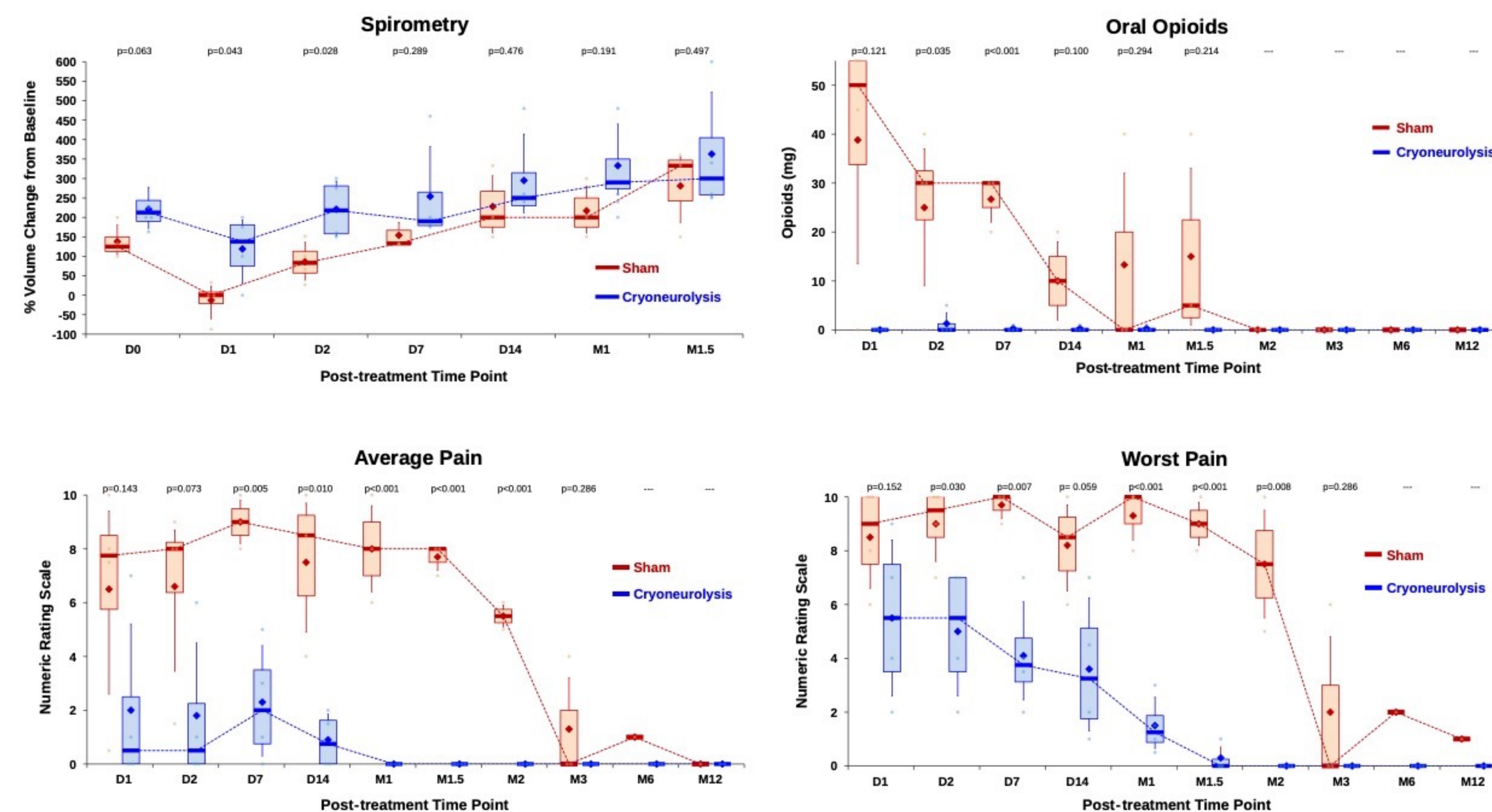


Figure 1. Spirometry, Oral Opioids, Average Pain and Worst Pain at Post-treatment time points days 1, 2, 7, 14, 30, 45, 60, 90, 180, 365

- 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 1**).

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

- Ziegler DW, Agarwal NN. The morbidity and mortality of rib fractures. *J Trauma* 1994; 37: 975-9.
- Osinowo OA, Zahrani M, Softah A. Effect of intercostal nerve block with 0.5% bupivacaine on peak expiratory flow rate and arterial oxygen saturation in rib fractures. *J Trauma* 2004; 56: 345-7.
- Ilfeld BM, Finneran JJ: Cryoneurolysis and percutaneous peripheral nerve stimulation to treat acute pain in the time of the opioid crisis: A Review. *Anesthesiology* 2020; 133: 1127-1149
- Ilfeld BM, Finneran JJ, Swisher MW, Said ET, Gabriel RA, Sztain JF, Khatibi B, Armani A, Trescot A, Donohue MC, Schaar A, Wallace AM. Preoperative ultrasound-guided percutaneous cryoneurolysis for the treatment of pain following mastectomy: A randomized, participant- and observer-masked, sham-controlled study. *Anesthesiology* 2022, 137(5):529-542.
- Finneran IV JJ, Gabriel RA, Swisher MW, Fiallo A, Chiu MJ, Berndtson AE, Godat LN, Costantini TW, Ilfeld BM. Ultrasound-Guided Percutaneous Intercostal Nerve Cryoneurolysis for Analgesia following Traumatic Rib Fracture: A Case Series. *Korean J Anesthesiol* 2020; 73 (5): 455-459.