Lumbar Medial Branch Cryoneurolysis for Facet-Mediated Chronic Low Back Pain: a Prospective Clinical Case Series

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OBJECTIVES

To assess the safety and effectiveness of lumbar medial branch cryoneurolysis in patients experiencing facet-mediated chronic low back pain (CLBP)

CONCLUSIONS

1. This interim analysis of lumbar medial branch cryoneurolysis to treat facet-mediated CLBP using a novel tip for cryoneurolysis administration demonstrated
   - A favorable safety profile (ie, no serious adverse events [AEs] and only 1 mild AE)
   - Rapid and durable pain relief; mean pain intensity score (numerical rating scale [NRS]) decreased by ~75% by day 1 (P<0.0001) with significant reductions in pain intensity maintained through day 150 (P<0.005 for all time points)
   - Complete recovery from disability was observed in ~20%-30% of participants at every monthly follow-up visit through 6 months
2. The overall condition of participants was "much better" throughout the 6-month follow-up period given that median Patient Global Impression of Change (PGIC) scores remained at 1 or 2 following treatment; by day 180 after treatment, ≥50% of participants had a mean PGIC score ≤2
   - Participant sleep quality and restless sleep were significantly improved by day 90 (P<0.05) and substantial improvements continued though day 180
   - Over 70% of participants were satisfied with cryoneurolysis treatment through day 180
3. This case series study is ongoing to determine long-term improvements following cryoneurolysis

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INTRODUCTION

- Lumbar facet joints are reported to be the cause of pain in 10%-15% of patients with CLBP[1]
- Radiofrequency ablation is a standard treatment for facet-mediated CLBP that uses radiofrequency energy to create a precise burn at the target medial branch nerve supplying the facet joint; however, the associated high temperatures can result in vascular injury, procedural pain, and destruction of surrounding tissue[2]
- Cryoneurolysis is a novel approach to CLBP management that uses a coolant (eg, liquid nitrous oxide) contained within a device and closed-end needles to create a precise cold zone at target nerve sites[3]
  - This approach causes a peripheral nerve block based on Wallerian degeneration, which preserves the epineurium, perineurium, and endoneurium, thereby allowing for nerve regrowth[3,4]

METHODS

STUDY DESIGN

- In this open-label, prospective clinical case series study, cryoneurolysis was applied to the lumbar spine at the target medial branch nerves using the iovera° device equipped with the Smart Tip, a 180-mm–long probe that facilitates target nerve location by conducting nerve stimulation from a separate stimulator; participants received fluoroscopy-guided cryoneurolysis in the prone position and were followed for up to 360 (±7) days

PARTICIPANTS AND ELIGIBILITY CRITERIA

- Participants were adults ≥18 years old who had a primary symptom of axial LBP suggesting bilateral facet joint involvement that was
  - Chronic (≥3 months)
  - Moderate to severe (pain intensity score of ≥5 to ≤9 on NRS)
  - Causing functional impairment (≥30% Oswestry Disability Index [ODI] score)
- Eligible participants underwent 2 successful diagnostic medial branch blocks with only local anesthetics, with success defined as ≥80% relief of primary index pain for the duration of local anesthetic activity

ENDPOINTS AND ANALYSIS FOR INTERIM ANALYSIS

- The main outcomes of the study included
  - Safety (eg, AE monitoring)
  - NRS pain intensity score (scores range from 0 ["no pain"] to 10 ["worst possible pain"]); the NRS scale also measured improvement in sleep quality and restless sleep
  - Functional disability on the ODI (score range from 0 to 50; lower scores reflect milder disability)
  - PGIC (score range from 0 to 10; lower scores reflect "much better"/ "much improved")
  - Patient satisfaction with postsurgical pain management
- Change in pain intensity score from baseline was assessed over the first 7 days and then every 30 days (ie, day 30, 90, 120, 150, and 180)
  - A Wilcoxon rank-sum test was used to compare changes from baseline
  - The least squares mean (LSM) for NRS score was estimated over time by a linear mixed-effects model; estimated changes were adjusted for age
- Outcome questionnaires were self-reported using personal electronic devices

RESULTS

PATIENT CHARACTERISTICS AND DEMOGRAPHICS AT BASELINE

- Of 20 total participants who received cryoneurolysis, all completed assessments at the day-30 follow-up visit; of these, 19 (95%) completed day-90 assessments, 16 (80%) completed day-120 assessments, and 7 (35%) completed day-180 assessments at the time of this interim analysis (December 16, 2025)
  - The first participant first visit was May 10, 2025
- Most participants were female (65.0%), white (80.0%), and not Hispanic or Latino (85.0%); none of the participants had a change in medical or surgical history since screening or had a documented history of opioid or illicit drug abuse (Table)
- The mean (standard deviation [SD]) duration since CLBP diagnosis was 7.31 years; the mean (SD) pain intensity score over the last 30 days was 5.9 on the NRS
- Most participants (55%) expected cryoneurolysis to result in less pain, while 40% expected no pain; same pain was expected by 5% of participants

Table. Key Participant Demographics and Baseline Characteristics

	Baseline (N=20)
Age, mean (SD) [range], y	55.6 (16.2) [24-80]
Female sex, n (%)	13 (65)
Not Hispanic or Latin ethnicity, n (%)	17 (85)
Race, n (%)	
Black or African American	1 (5)
Other/multiple/not reported/unknown	3 (15)
White	16 (80)
Body mass index, mean (SD) [range], kg/m^2	29.8 (7.6) [18.6-41.9]
Duration of low back pain diagnosis, mean (SD) [range], y	7.3 (9.8) [0.5-31.6]
Average pain intensity score (NRS) in the last 30 days, mean (SD) [range]	5.9 (2.0) [2-10]
Expectations with treatment as it relates to pain, n (%)	
No pain	8 (40)
Less pain	11 (55)
Same pain	1 (5)
Expectations with treatment as it relates to activities of daily living, n (%)	
No problems	10 (50)
Fewer problems	10 (50)
No change in medical or surgical history since screening, n (%)	20 (100)
No documented history of opioid or illicit drug abuse, n (%)	20 (100)

NRS, numerical rating scale; SD, standard deviation.

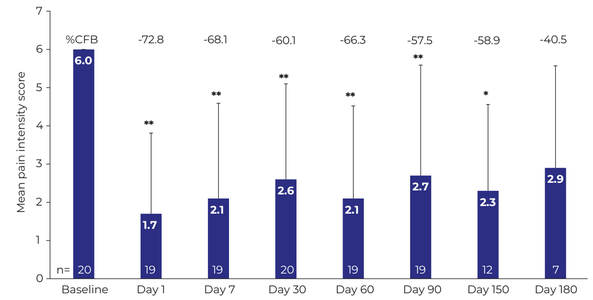
SAFETY

- No serious AEs were observed
- One mild AE was deemed likely related to cryoneurolysis (acute on chronic sciatic nerve pain aggravated by the iovera° device) and was ongoing at the time of interim analysis following treatment

PAIN OUTCOMES

- Mean pain intensity score (NRS) decreased by 72.8% (6.0 to 1.7; P<0.0001) within 24 hours of cryoneurolysis (Figure 1)
- Significant reductions in pain intensity were maintained through day 150 (Figure 1)

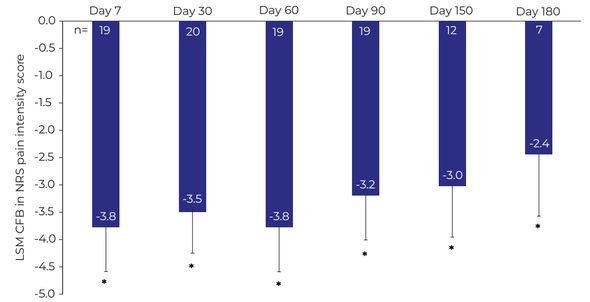
Figure 1. Pain intensity over time (NRS).



Error bars are the standard deviation. *P<0.005. **P<0.001. %CFB, percent change from baseline; NRS, numerical rating scale.

- On average, NRS pain intensity score was significantly reduced by ≥3.4 points from baseline through day 60, with significant reductions sustained through day 180 (P<0.001 for all time points; Figure 2)

Figure 2. LSM change from baseline in NRS pain intensity score over time.

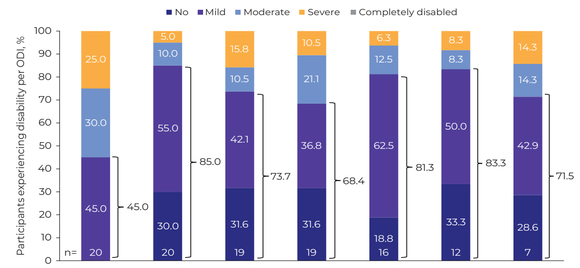


Error bars are the 95% confidence interval. *P<0.001. CFB, change from baseline; LSM, least squares mean; NRS, numerical rating scale.

DISABILITY OUTCOMES

- At baseline, 45% of the 20 participants (n=9) experienced mild disability; the remaining 55% experienced moderate (n=6) or severe (n=5) disability as assessed by ODI before receiving cryoneurolysis (Figure 3)
- Complete recovery from disability was observed in ~20%-30% of participants at every monthly follow-up visit through 6 months (Figure 3)
  - Over two-thirds of participants had either complete recovery or mild disability
  - No participant was completely disabled at any time point assessed

Figure 3. Change in functional disability status (Oswestry Disability Index [ODI]) over time.

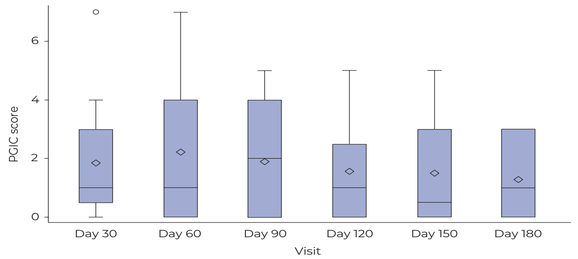


The ODI categories are as follows: 0%-20% = minimal; 21%-40% = moderate; 41%-60% = severe; 61%-80% = crippled; and 81%-100% = bedbound/exaggerated symptoms.

PARTICIPANT IMPROVEMENT AND SATISFACTION

- The overall condition of participants was "much better" throughout the 6-month follow-up period given that median PGIC scores remained at 1 or 2 following cryoneurolysis
  - PGIC improvements were seen by day 30 after treatment, and by day 180, ≥50% of participants had a mean PGIC score ≤2 (Figure 4)

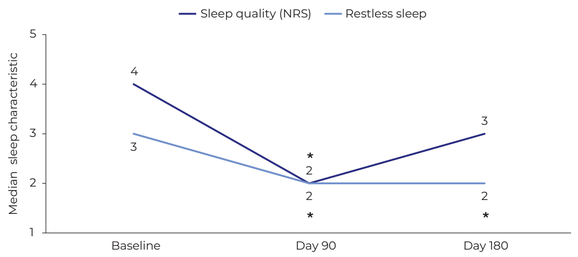
Figure 4. PGIC scores over time.



Data are shown as box plots, representing the 10th, 25th, 50th (median; represented by lines), 75th, and 95th percentiles; circles represent outliers and diamonds represent the mean. PGIC scale 2 categories are as follows: 0 = much better; 5 = no change; and 10 = much worse. PGIC, Patient Global Impression of Change.

- Cryoneurolysis resulted in significant improvements in sleep quality and restless sleep at day 90 (P<0.05); these improvements continued through day 180 (Figure 5)

Figure 5. Improvement in sleep characteristics over time.



*P<0.05. NRS, numerical rating scale.

- Over 70% of participants were satisfied with the pain management at all time points through day 180 (Figure 6), indicating that cryoneurolysis met the treatment expectations of a majority of patients

Figure 6. Participant satisfaction with pain management over time.