

Effect of Percutaneous Cryoneurolysis on Pain in Patients With Plateaued or Refractory Upper Extremity Spasticity

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DISCLOSURES

Paul Winston has received educational and research grants and acted on advisory boards and as a consultant for Pacira BioSciences, Inc.; AbbVie; Merz Therapeutics; and Ipsen. All of the relevant financial relationships listed have been mitigated.

Mahdis Hashemi has no relevant financial relationships with ineligible companies to disclose and no non-financial conflicts of interest relevant to this activity.

Eve Boissonnault has received educational grants from AbbVie and received honoraria, acted on advisory boards, and acted as a consultant for Pacira BioSciences, Inc.; AbbVie; Merz Therapeutics; and Ipsen. All of the relevant financial relationships listed have been mitigated.

Daniel Vincent has acted as a consultant for Pacira BioSciences, Inc. and received funding per session from Island Health. All of the relevant financial relationships listed have been mitigated.

Fraser MacRae has no relevant financial relationships with ineligible companies to disclose and no non-financial conflicts of interest relevant to this activity.

Jia Song and **Sandy Shi** are employees of Pacira BioSciences, Inc. and own stock in the company. All of the relevant financial relationships listed have been mitigated.

Introduction



Spasticity results from central nervous system injury and can lead to **painful involuntary muscle contractions**^{1,2}



Conventional spasticity therapies (eg, braces, injection with botulinum toxin,² or surgery³) do not always improve patient outcomes, indicating a **need for new therapies**



Percutaneous cryoneurolysis is a minimally invasive technique that has been used to **reduce pain** associated with knee osteoarthritis,⁴ total knee arthroplasty surgery,⁵ and neuralgia⁶



Currently, there are no prospective studies using cryoneurolysis to treat upper extremity spasticity



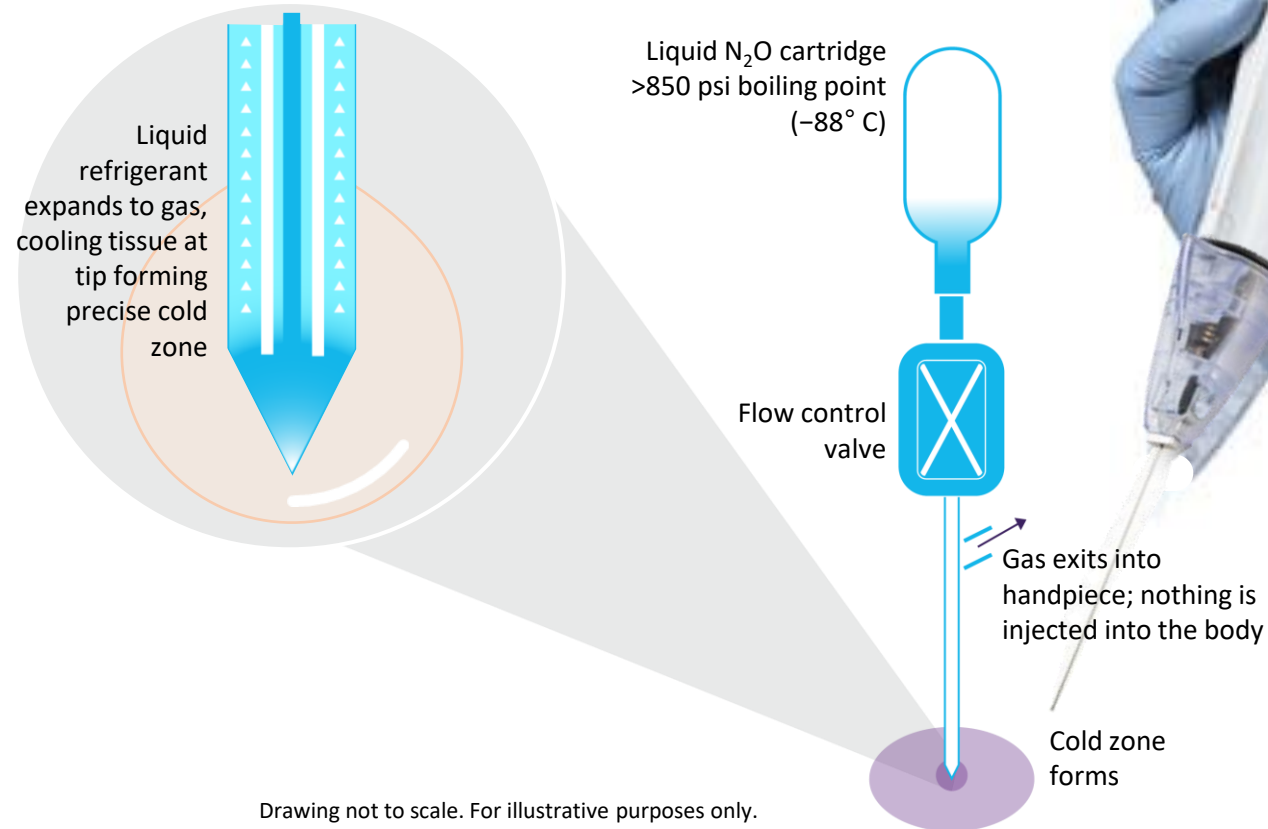
Objective: to evaluate changes in pain after cryoneurolysis in participants experiencing pain associated with upper extremity spasticity

1. Winston P et al. *Arch Rehabil Res Clin Transl*. 2019;1(3-4):100030; 2. O'Brien CF. *Clin J Pain*. 2002;18(6 suppl):S182-S190; 3. Yang E et al. *J Clin Med*. 2021;10(20):4723; 4. Radnovich R et al. *Osteoarthritis Cartilage*. 2017;25(8):1247-1256; 5. Urban JA et al. *Arthroplast Today*. 2021;10:87-92; 6. Kim CH et al. *Pain Physician*. 2015;3:E363-E368.

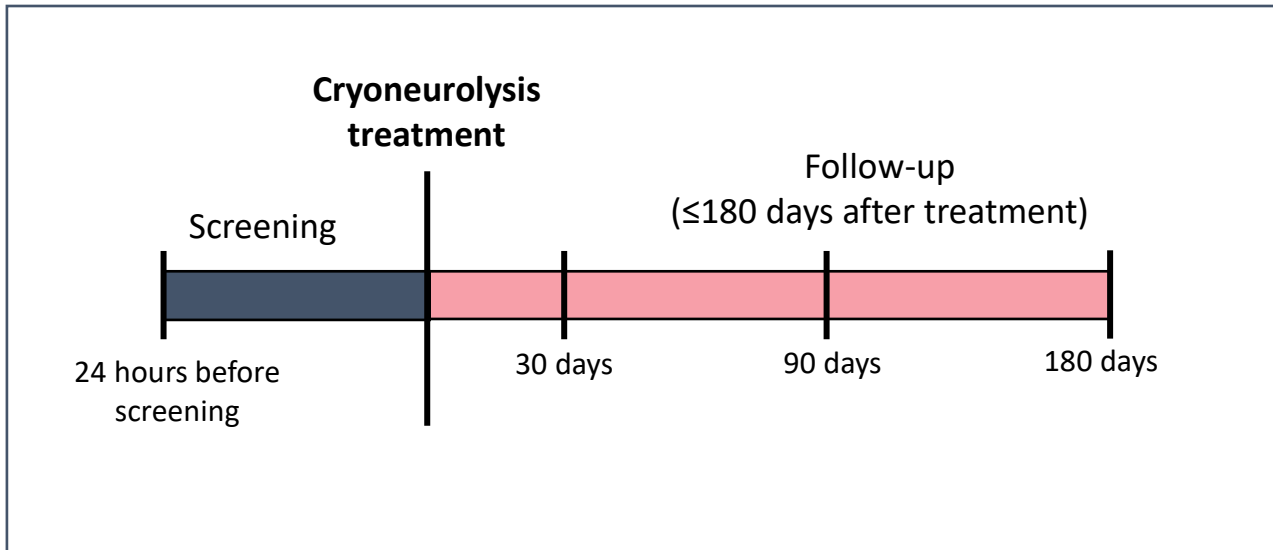
Methods: Cryoneurolysis Procedure

Percutaneous cryoneurolysis was applied to multiple nerves to treat upper extremity spasticity in this repeated-measures pilot study (NCT04670783)

- Probe cooled to between -60°C and -88°C near the targeted nerve¹⁻³
 - Cooling causes secondary axonotmesis and Wallerian degeneration, allowing for axonal regrowth⁴
- Effects can be prolonged for several months in some cases⁵



Drawing not to scale. For illustrative purposes only.



Outcome	Measure
Average pain	• BPIQ¹ (range, 0 [least pain] to 10 [highest pain]) • The BPIQ contains 4 items – “Worst pain in the last 24 hours” – “Least pain in the last 24 hours” – “Average pain in the last 24 hours” – “Current pain”

Methods: Study Design and Outcomes

- Change in average daily pain scores from baseline using the BPIQ was assessed at days 30, 90, and 180
 - Only participants with nonzero pain scores at baseline were included in final analysis
 - A Wilcoxon signed rank test was used to compare changes from baseline
 - LOESS models evaluated trends in pain severity over time

BPIQ, Brief Pain Inventory Questionnaire.

1. The Brief Pain Inventory. <https://www.mdanderson.org/research/departments-labs-institutes/departments-divisions/symptom-research/symptom-assessment-tools/brief-pain-inventory.html>. Accessed July 18, 2023.

Methods: Eligibility Criteria

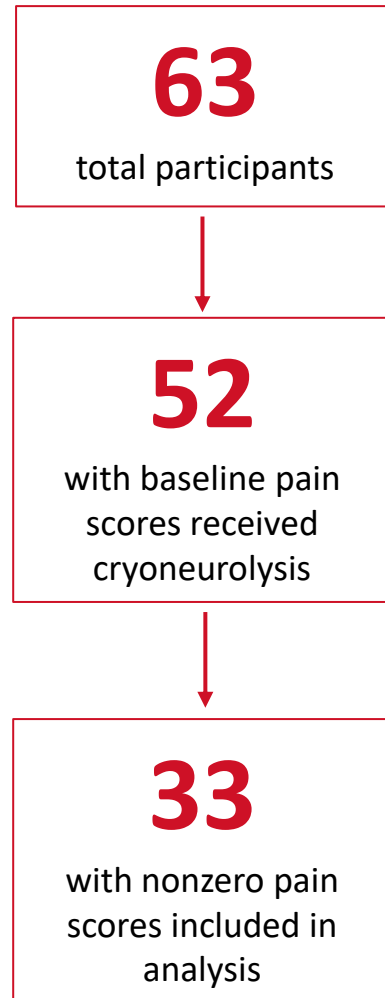
Inclusion criteria

- Adults ≥ 18 years old with upper extremity spasticity impairing function and who have plateaued in outcomes
- Clinical examination of upper extremity V1 and V3 demonstrates a possibility of further range of motion after treatment
- Participant undergoes a diagnostic nerve block to determine whether cryoneurolysis would be beneficial
- Participant was offered a cryoneurolytic procedure and consented to procedure

Exclusion criteria

- Participant unable to attend treatment schedule
- Participants who previously underwent neurolytic procedure such as phenol or cryoneurolysis in the past 2 years

Results: Mean BPIQ Scores



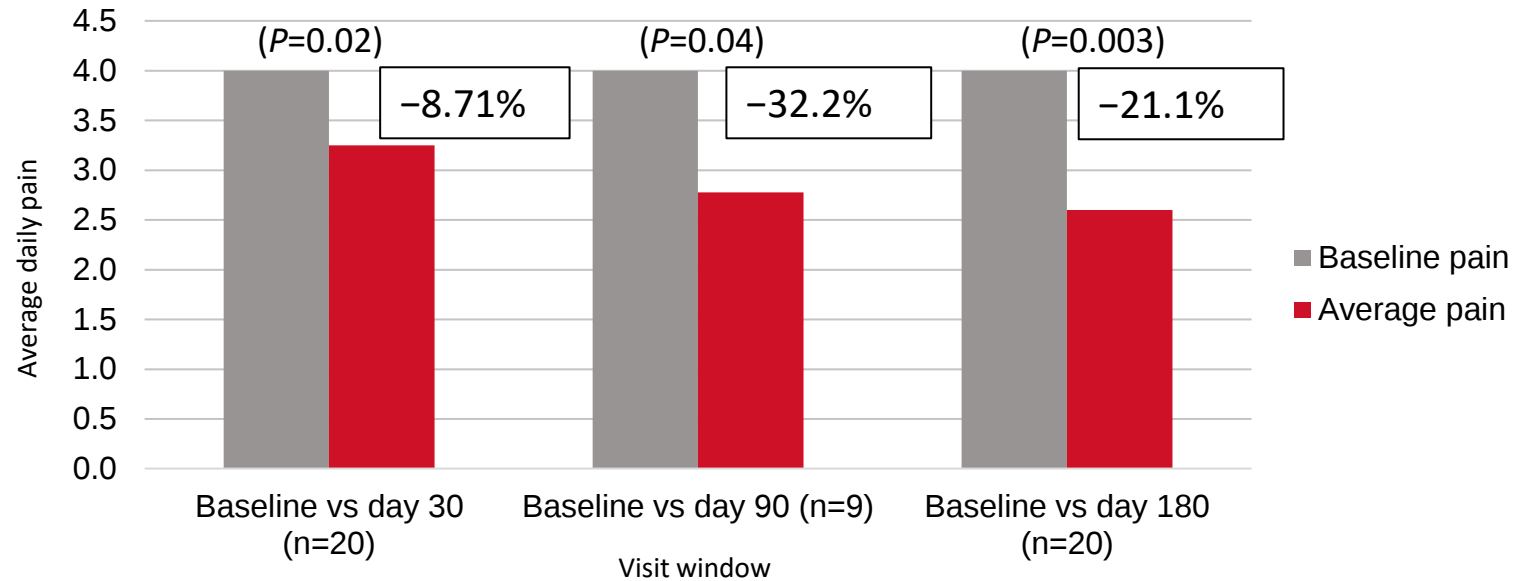
BPIQ Scores	Baseline n=33	Day 30 n=20	Day 90 n=9	Day 180 n=20
Average pain in the last 24 hours, mean	4.00	3.25	2.78	2.60
Worst pain in the last 24 hours, mean	5.58	4.95	4.11	4.40
Least pain in the last 24 hours, mean	1.76	1.60	1.33	1.30
Pain right now, mean	2.27	1.90	2.00	1.90

The mean pain score for “average pain during the last 24 hours” at baseline was 4 and at day 180 was 2.6

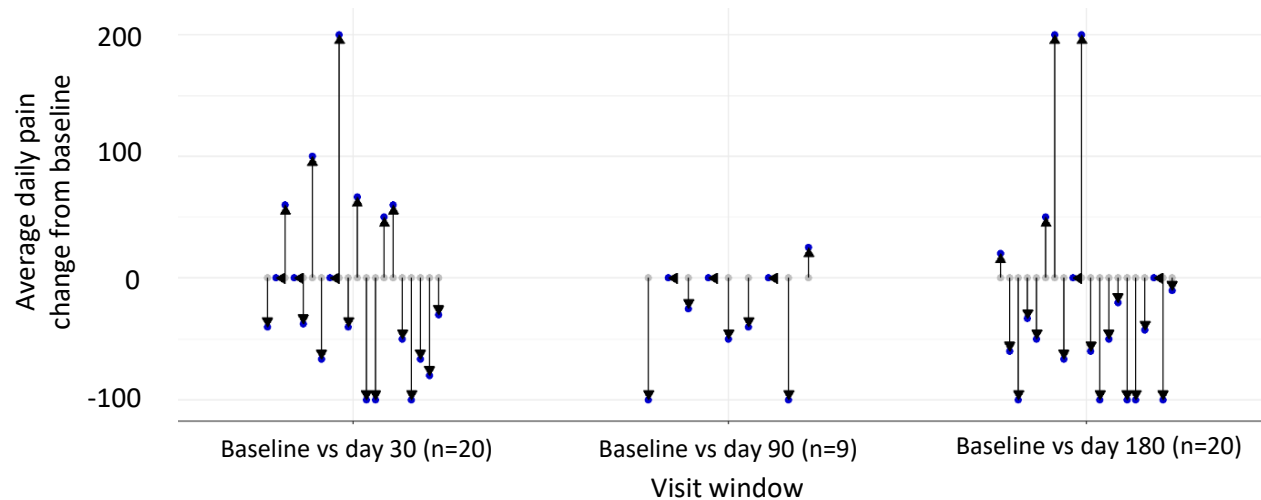
Results: Average Daily Pain

Average daily pain was **significantly reduced from baseline at all timepoints**, including a 32% reduction at day 90 and a 21% reduction at day 180

Average daily pain change from baseline

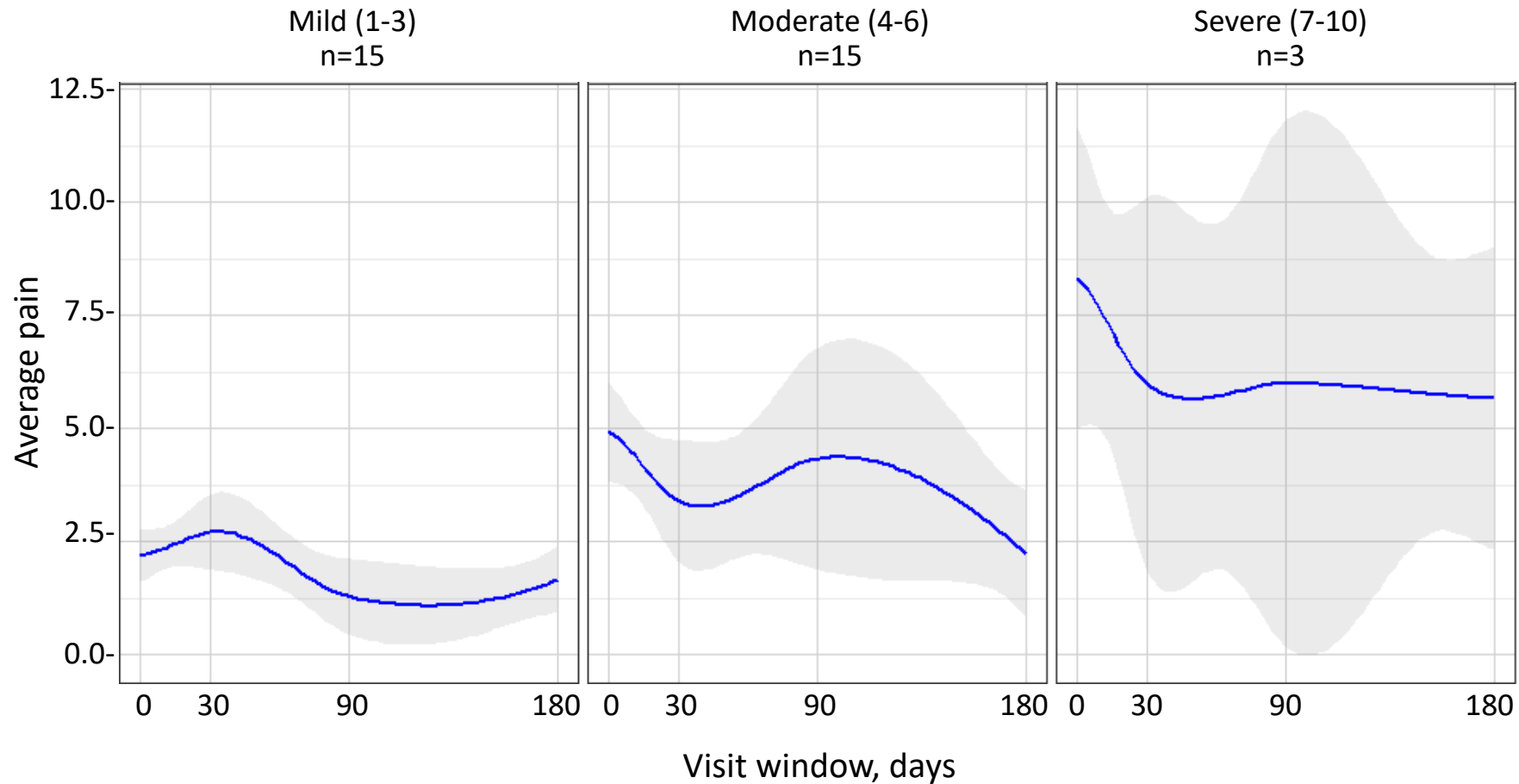


Individual participant average daily pain change from baseline



Results: Average Pain Across 3 Pain Levels

Participants had a **decreasing trend in average pain across varying pain levels at all 3 time points** using a LOESS model



Conclusions

- 1 Percutaneous cryoneurolysis of multiple nerves to treat upper extremity spasticity was associated with **significant reductions in average daily pain** and **decreased trends in pain severity over time**
- 2 **Significant reductions in average daily pain** from baseline were observed **at 30, 90, and 180 days** after treatment
- 3 Additional investigation is ongoing to determine long-term improvements following cryoneurolysis

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