Measuring the Efficacy of Percutaneous Cryoneurolysis in the Management of Patients With Plateaued or Refractory Shoulder Spasticity

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OBJECTIVES

To evaluate the outcomes of cryoneurolysis in patients with spastic shoulder who had plateaued in prior treatments, including botulinum toxin therapy

CONCLUSIONS

1. Percutaneous cryoneurolysis of the medial and lateral pectoral nerves and/or suprascapular nerve was associated with improvements in shoulder ROM, spastic tone, and satisfaction out to 12 months after treatment
2. Improvements in shoulder ROM and spastic tone were maintained at later time points; longer follow-up is ongoing to confirm sustainability of improvements

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FUNDING: This study was funded by Pacira BioSciences, Inc. Assistance with poster preparation was provided under the authors' direction by Emma Hinkle, PhD, and David Boffa, ELS, of MedThink SciCom and funded by Pacira BioSciences, Inc.

DISCLOSURES: PW declares having educational and research grants and acting on advisory boards and as a consultant for AbbVie; Ipsen; Merz Therapeutics; and Pacira BioSciences, Inc. **MH** declares no conflicts of interest. **EB** declares receiving educational grants and honoraria from AbbVie, acting on advisory boards and acting as a consultant for AbbVie; Ipsen; Merz Therapeutics; and Pacira BioSciences, Inc. **DV** declares acting as a consultant for Pacira BioSciences, Inc., and receiving funding per session from Island Health. **FM** declares no conflicts of interest. **JS**, **M-HS**, and **SS** are employees of Pacira BioSciences, Inc., and **JS** and **SS** own stock in the company.

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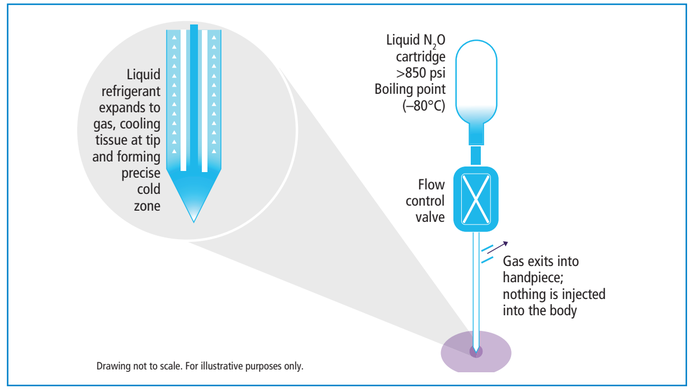
Presented at the World Stroke Congress; October 10-12, 2023; Toronto, ON, Canada

INTRODUCTION

- Conventional treatments for spasticity are costly and have limited duration for some patients[1,2]
  - In the United States, the use of botulinum toxin to control shoulder girdle spasticity is off-label
  - There is a need for novel treatment options to improve patient outcomes
- Percutaneous cryoneurolysis is a minimally invasive technique to freeze target nerves (Figure 1)
  - The probe is cooled to between –60°C and –88°C near the targeted nerve[3-5]
  - Cooling causes secondary axonotmesis and Wallerian degeneration, allowing for axonal regrowth[6]
  - Effects can be prolonged for several months in some cases[7]
- Cryoneurolysis has been used to reduce pain associated with knee osteoarthritis,[7] total knee arthroplasty surgery,[8] and neuralgia[9]
  - A previous case series suggested that cryoneurolysis may be a promising treatment for spasticity, but additional data are needed[3]

Figure 1: Cryoneurolysis overview.



METHODS

STUDY DESIGN

- This repeated-measures pilot study (NCT04670783) included eligible participants (Table 1) who underwent cryoneurolysis to the lateral and/or medial pectoral nerves
  - In some cases, neurolysis was applied to the suprascapular nerve to manage pain

Table 1. Participant Eligibility Criteria

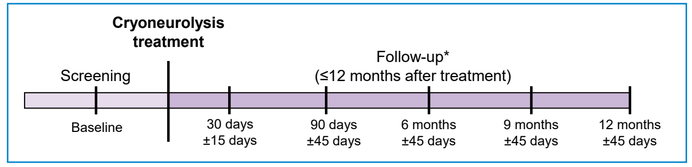
Inclusion Criteria	Exclusion Criteria
Adults with upper extremity spasticity causing functional impairment, who have plateaued in outcomes, in which clinical examination suggested further interventions can be trialed	Being unable to attend the treatment schedule
Upon clinical examination, upper extremity V1 and V3 demonstrated that further range may be possible (versus management of contracture)	Underwent prior neurolytic procedure to the nerve, such as phenol or cryoneurolysis, in the past 2 years
Reducible spasticity (versus contracture) in a diagnostic nerve block to determine whether cryoneurolysis would be beneficial	
Participants were offered a cryoneurolytic procedure and consented to undergo the procedure	

V1, maximal passive stretch; V3, fast catch.

STUDY OUTCOMES

- Outcome measurements during abduction, external rotation, and flexion included mean active range of motion (ROM), maximal passive stretch (V1), and modified Ashworth scale (MAS; score range 0-4). Participant satisfaction was determined with goal attainment scale (GAS) (score range, –2 to +2, transformed into a T-score [mean=50])
- Outcome measurements were examined at baseline and follow-up time points (Figure 2)

Figure 2: Study timeline.

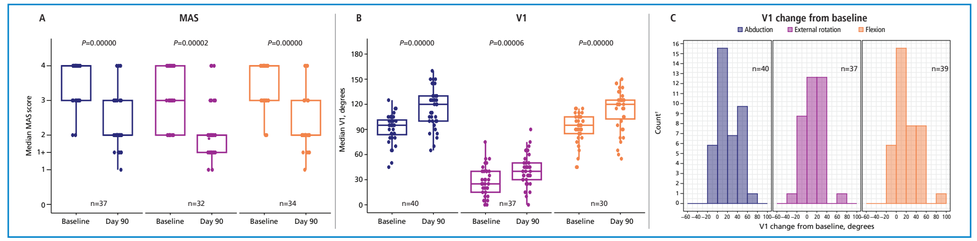


*All participants have a least 6 months of follow-up.

RESULTS

- 47 participants underwent cryoneurolysis of the shoulder, and 40 participants completed the 90-day follow-up at the time of this analysis
- At baseline, participants had reduced median active ROM and high median MAS scores during abduction, external rotation, and flexion, suggesting severe spasticity with possible musculotendinous contracture
- At 90 days, significant improvements were observed in MAS scores and V1 for abduction, external rotation, and flexion ($P<0.001$ and $P<0.0001$, respectively) (Figure 3A,B). These changes resulted in a 3-dimensional change in ROM
- There was a numerical increase in mean improvement per patient in GAS scores at 90 days (10.5 points)
- 44%, 38%, and 44% of participants experienced >20° improvements in V1 abduction, external rotation, and flexion at 90 days, respectively (Figure 3C)

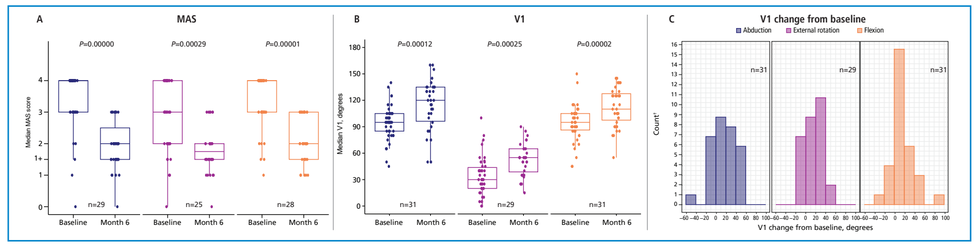
Figure 3: MAS scores (A) and V1 (B) at baseline and 90 days* and distribution of V1 change from baseline at 90 days (C).



*Wilcox *P* value reported. †4 participants died, with 3 having negative results; 1 participant had severe pain (complex regional pain syndrome, impingement syndrome, capsulitis). MAS, modified Ashworth scale; V1, maximal passive stretch.

- At 180 days, improvements in MAS scores and V1 were sustained ($P\leq0.0003$) (Figure 4A,B). There was a numerical increase in mean improvement per patient in GAS scores at 180 days (13.8 points)
- 45%, 45%, and 32% of participants experienced >20° improvements in V1 abduction, external rotation, and flexion at 6 months, respectively (Figure 4C)
  - 1 participant had a humerus fracture resulting in low abduction values (–60°)

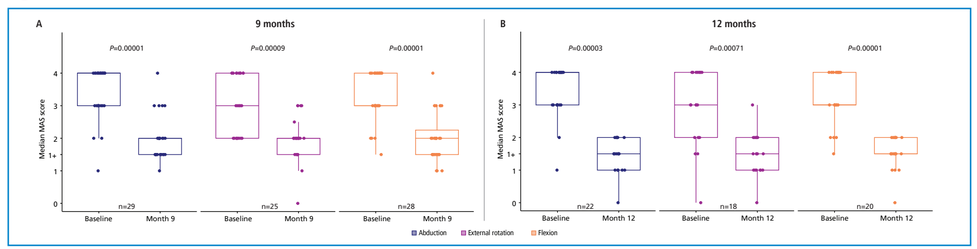
Figure 4: MAS scores (A) and V1 (B) at baseline and 180 days* and distribution of V1 change from baseline at 180 days (C).



*Wilcox *P* value was reported. †1 participant had fracture, 3 had severe pain (complex regional pain syndrome, impingement syndrome, capsulitis), and 1 was referred for surgery. MAS, modified Ashworth score; V1, maximal passive stretch.

- Participants with follow-up data at 9 months and 12 months had sustained significant improvements in MAS scores at 9 ($P\leq0.00009$) and 12 months ($P\leq0.00071$) (Figure 5A,B)
- Significant sustained improvements were also observed in V1 at 9 ($P\leq0.00028$) and 12 months ($P\leq0.0013$) across abduction, external rotation, and flexion
- There was a numerical increase of 11.6 points (31.66%) from baseline in mean GAS scores at 12 months

Figure 5: MAS scores* at baseline and 9 months (A) and baseline and 12 months (B).



*Wilcox *P* value is reported. MAS, modified Ashworth scale.