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Randomized controlled trial: lumbar medial branch cryoneurolysis versus radiofrequency ablation for chronic low back pain

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Introduction

Chronic low back pain is a common condition that is often treated with thermal ablation via radiofrequency (RFA), which destroys specific nerves to provide pain relief (refs 1,2). Cryoneurolysis is an alternative treatment to RFA that applies cold temperatures to disrupt nerve conduction pathways via Wallerian degeneration, allowing for nerve regrowth (ref 3). However, data investigating the use of cryoneurolysis to treat chronic low back pain are sparse. This pilot study examined the effect of cryoneurolysis versus RFA for treatment of chronic low back pain.

Materials and Methods

This single-center, randomized controlled trial enrolled participants with facet-mediated chronic low back pain and received institutional review board approval from Advarra, Inc (Pro00062787). Participants underwent cryoneurolysis or RFA of the medial branch nerves at L4, L5, and L5 (dorsal ramus) to S1 (lateral branch). The main outcomes were safety, numerical rating scale (NRS) pain scores (range, 0 [“no pain”] to 10 [“worst possible pain”]), Oswestry Disability Index (ODI; range, 0-50, with lower scores reflecting milder disability) to assess disability status, participant satisfaction with pain management (score range, 1 [“extremely dissatisfied”] to 5 [“extremely satisfied”]), and patient’s global impression of change (PGIC). Follow-up duration was 1 year. Analyses were adjusted for baseline NRS, sex, and tobacco use.

Results/Case Report

Thirty participants were included in this analysis (cryoneurolysis, n=15; RFA, n=15). Baseline characteristics were similarly distributed between groups (Table 1) and all participants were White. After Day 7, adjusted least squares mean (LSM) NRS pain scores were numerically higher with RFA versus cryoneurolysis (Figure 1A). Cryoneurolysis was associated with a significant decrease in NRS pain scores versus RFA (LSM [95% confidence interval (CI)], 3.0 [1.4, 4.7] vs 6.1 [4.5, 7.7]; P=0.01) at Day 360. Adjusted ODI scores were significantly lower compared with RFA at Day 360 (LSM [95% CI], 10.1 [6.0, 14.3] vs 20.6 [16.5, 24.7]; P=0.002) (Figure 1B) with the mean percent decrease from baseline in ODI score being greatest for cryoneurolysis (Figure 1C). Compared with those receiving RFA, more participants receiving cryoneurolysis had “no disability” (1/15 vs 0/15) at Day 360 (Table 2). Cryoneurolysis was associated with significant improvements in PGIC versus RFA (Day 360: LSM [95% CI], 1.7 [0.7, 2.8] vs 4.4 [3.3, 5.4]; P=0.002) (Figure 2A). More participants were satisfied with pain management after cryoneurolysis versus RFA

(90.9% vs 66.7%) at day 360 (Figure 2B). After Day 180, ≥1 additional spinal injection (facet, epidural, spinal trigger point, or other) was required for participants receiving RFA and cryoneurolysis (9/12 [75.0%] and 5/11 [45.5%], respectively; Table 3). One adverse event unrelated to treatment (mild compression fracture in the cryoneurolysis group) was reported; no serious adverse events were observed.

Discussion

Cryoneurolysis had a favorable safety profile and led to significant improvements in pain, functional disability, and overall impression of treatment compared with RFA 1 year after treatment for chronic low back pain. Cryoneurolysis treatment may also reduce the need for additional spinal injections. A confirmatory large multicenter trial is warranted.

References

1. Airaksinen et al. Eur Spine J. 2006;15(suppl 2):S192-S300.
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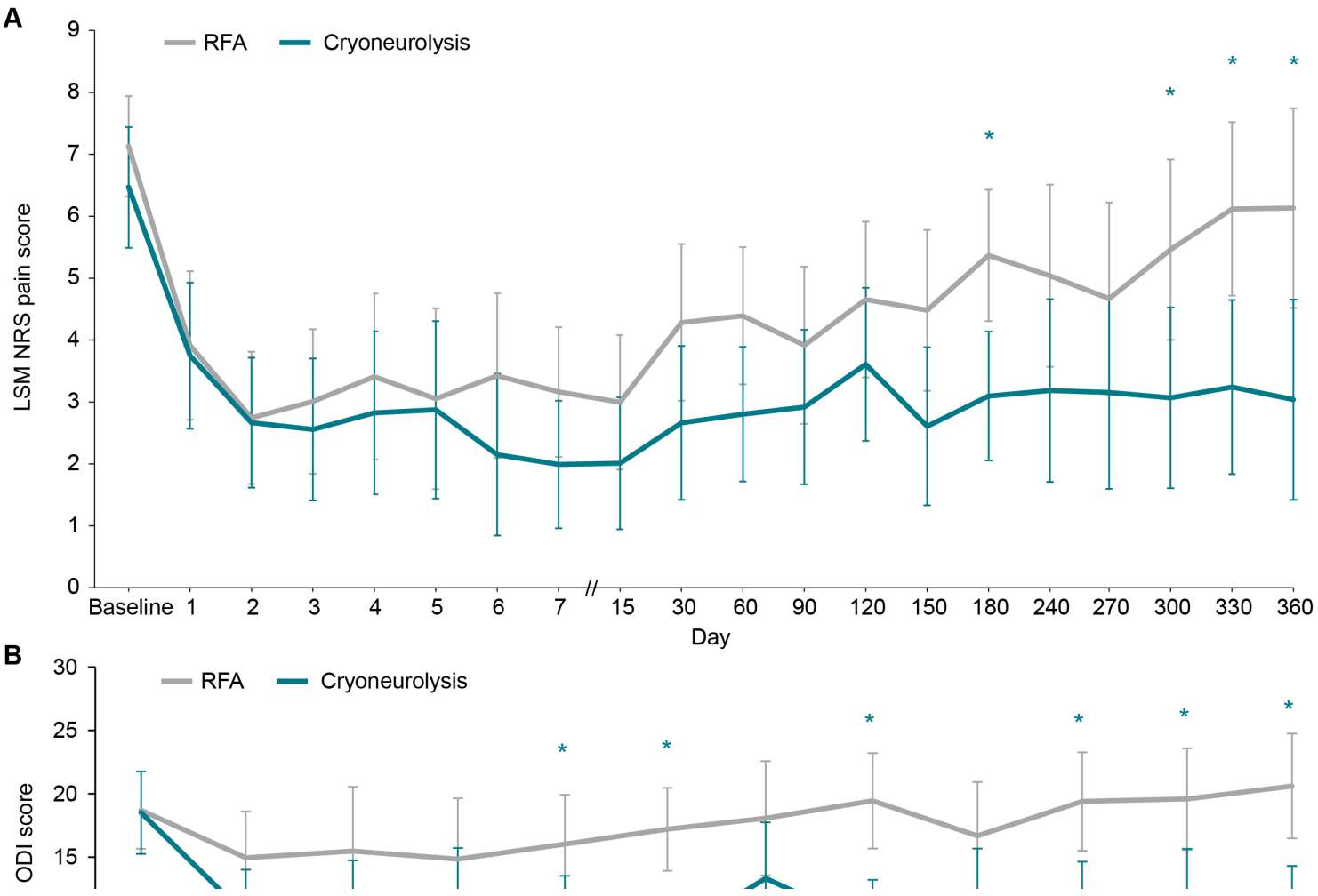
3. Guirguis et al. Cryotherapy. In: Deer et al, eds. Deer's Treatment of Pain. Cham, Switzerland: Springer Nature Switzerland AG; 2019:283-289.

Disclosures

Yes

Tables / Images



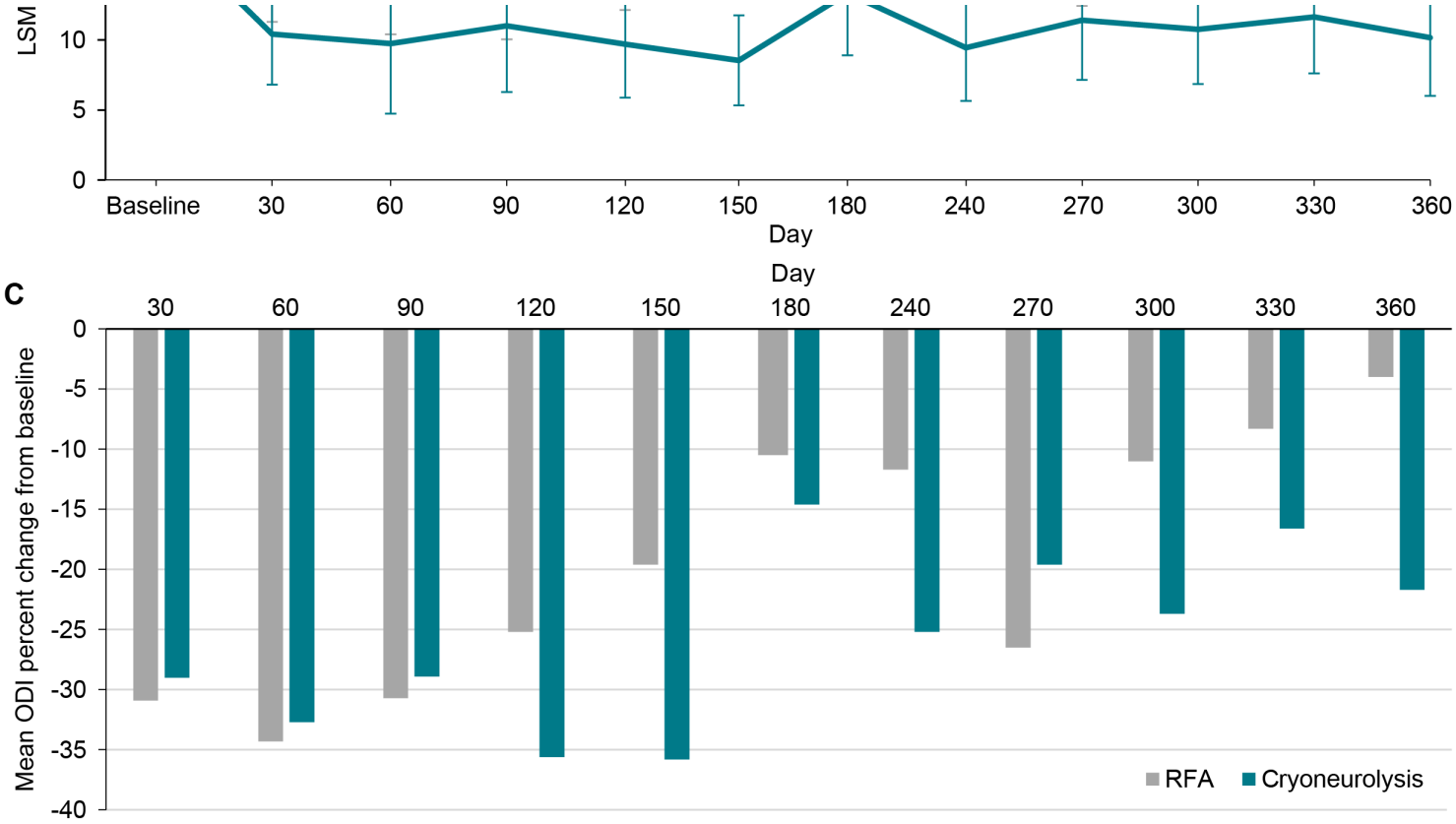


Figure 1. (A) Adjusted LSM NRS pain scores through 360 days.[a,b] **(B)** Adjusted LSM ODI scores through 360 days.[a,b] **(C)** Mean ODI percent change from baseline through 360 days.[a] Error bars are the 95% confidence interval. **P*<0.05. [a]Data for Day 210 were excluded because the request to extend the study was under evaluation. [b]Baseline mean was not adjusted for covariates, including baseline NRS, sex, and tobacco use status. LSM, least squares mean; NRS, numerical rating scale; ODI, Oswestry Disability Index; RFA, radiofrequency ablation.

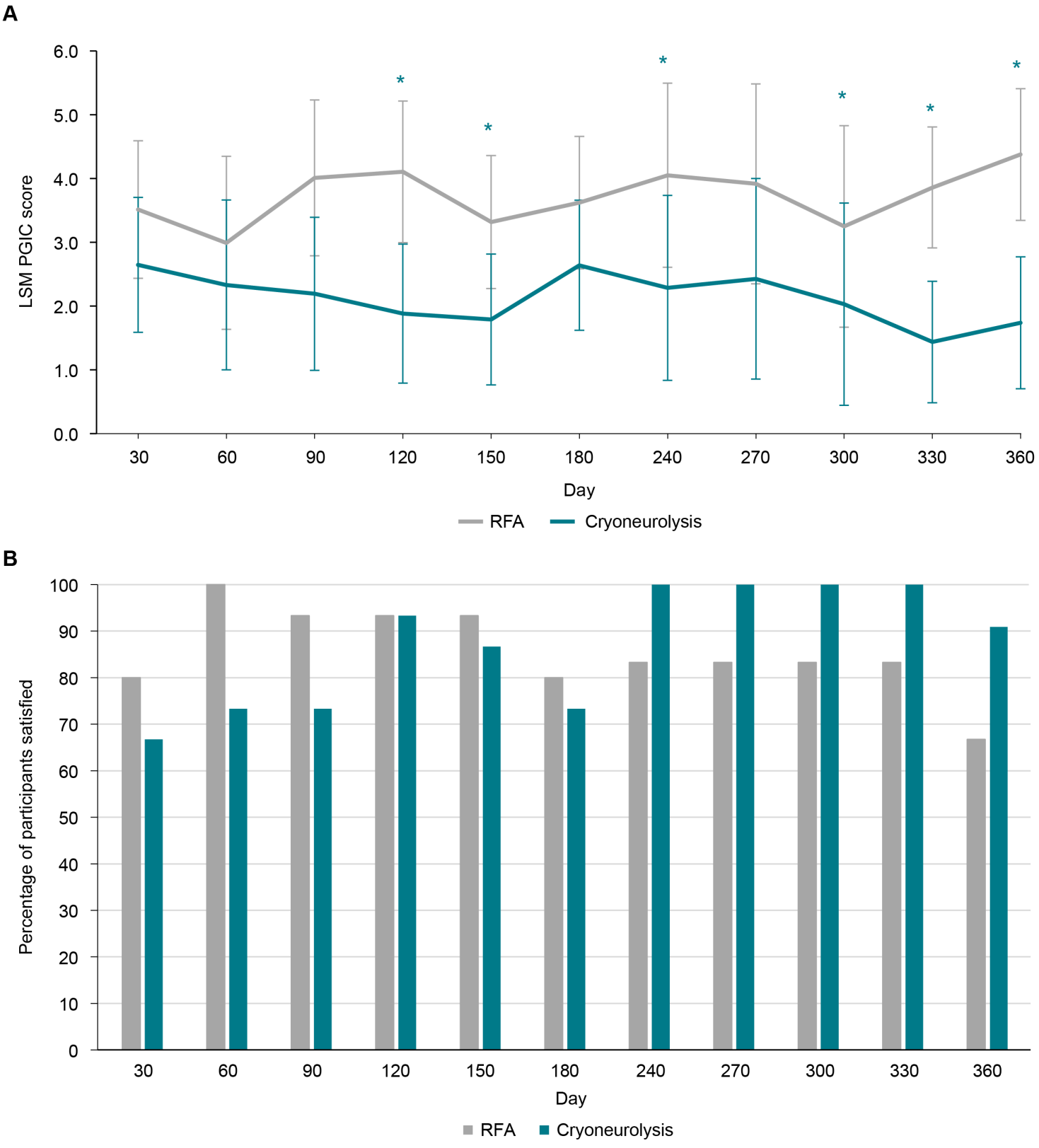


Figure 2. (A) Adjusted LSM PGIC score through 360 days.[a] Error bars are the 95% confidence interval. *P<0.05. **(B)** Participant satisfaction with pain management through 360 days.[a] [a]Data from Day 210 were excluded because the request to extend the study was under evaluation. LSM, least squares mean; PGIC, patient's global impression of change; RFA, radiofrequency ablation.

Table 1. Participant Demographics and Baseline Characteristics

	RFA (n=15)	Cryoneurolysis (n=15)	Total (N=30)
Age, mean (SD), y	63.1 (12.7)	66.0 (17.1)	64.5 (14.9)
Female, n (%)	8 (53.3)	6 (40.0)	14 (46.7)
BMI, mean (SD), kg/m^2	28.1 (5.0)	26.5 (6.4)	27.3 (5.7)
Duration of low back pain, mean (SD), y[a]	19.6 (16.2)	24.9 (19.7)	22.7 (18.2)
ODI score, mean (SD)	18.7 (5.9)	18.5 (7.1)	18.6 (6.4)
Average pain score over 24 hours on NRS, mean (SD)	7.1 (1.6)	6.5 (1.9)	6.8 (1.8)
Any spine injections, n (%)	14 (93.3)	15 (100.0)	29 (96.7)

BMI, body mass index; ODI, Oswestry Disability Index; RFA, radiofrequency ablation; SD, standard deviation. [a]RFA (n=10); cryoneurolysis (n=14); total (n=24).

Table 2. ODI Over Time

	n	No disability, n (%)	Mild, n (%)	Moderate, n (%)	Severe, n (%)	Completely disabled, n (%)
Baseline						
RFA	15	0	3 (20.0)	10 (66.7)	2 (13.3)	0
Cryoneurolysis	15	0	5 (33.3)	6 (40.0)	4 (26.7)	0
Day 360						
RFA	12	0	5 (41.7)	5 (41.7)	2 (16.7)	0
Cryoneurolysis	11	1 (9.1)	5 (45.5)	5 (45.5)	0	0

ODI, Oswestry Disability Index; RFA, radiofrequency ablation.

Table 3. Additional Spinal Injections After Day 180[a]

	RFA (n=12)	Cryoneurolysis (n=11)
Additional spinal injection, n (%)	9 (75.0)	5 (45.5)
Lumbar spine, n	8	7
Cervical, n	3	0
Thoracic, n	1	0

RFA, radiofrequency ablation. [a]Some participants received ≥1 injection.