

Cooled vs. Standard Radiofrequency Ablation of the Medial Branch Nerves in the Management of Chronic Facetogenic Low Back Pain

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BACKGROUND

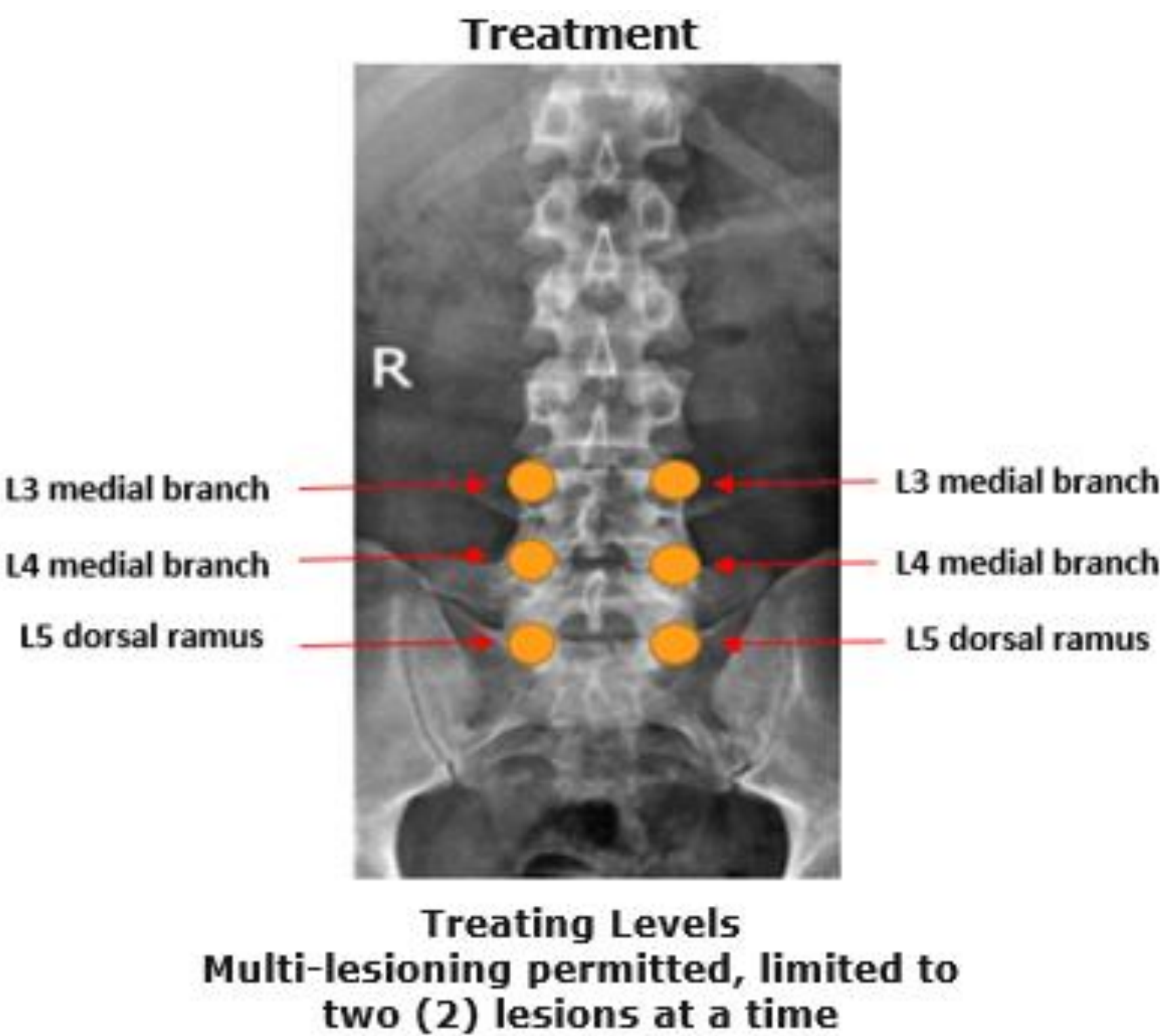
- Lumbar facetogenic back pain has been estimated as high as 45% of all chronic low back pain (LBP) causes (range 15-45%).¹
- With both U.S. and global populations aging, chronic LBP is a major cause of disability and responsible for a sizeable portion of overall healthcare costs.¹
- Radiofrequency ablation (RFA) of the lumbar medial branches is a commonly performed treatment and has been used for this indication since 1975.²

OBJECTIVE

- This study compared Cooled RFA (CRFA) to Standard RFA (SRFA) to evaluate efficacy and durability of analgesia in the management of chronic lumbar facetogenic back pain.

MATERIALS & METHODS

- Participants were eligible if they had a positive response from dual medial branch blocks (MBB).
- If participant met the diagnostic criteria, then bilateral lumbar medial branch RFA was performed targeting the left and right L3 and L4 medial branches L5 dorsal ramus to treat the L4 – L5 and L5 – S1 facet joints with either CRFA (17 gauge with a 4mm active tip) or SRFA (20 gauge curved probe with a 10mm active tip).
- Follow-up visits were performed at 1, 3, 6, 9 and 12 months post-procedure.
- The primary effectiveness endpoint was defined as the proportion of subjects whose back pain was reduced by >50% based on Usual NRS (average daily pain over the last 7 days) at 6 months.



	ITT Population*							
	Baseline		1 Month		6 Months		12 Months	
	CRFA	SRFA	CRFA	SRFA	CRFA	SRFA	CRFA	SRFA
NRS Pain Score								
N	37	37	37	37	27	34	15	20
Mean (SD)	6.9 (1.22)	6.8 (0.83)	2.8 (2.49)	2.9 (2.13)	2.7 (2.88)	3.4 (2.29)	2.0 (2.20)	3.1 (2.47)
P-Value (Change Between Groups)	-		0.6442		0.1234		0.1880	
Responder Rate (%)**								
N	-	-	37	37	27	34	15	20
n (%)			26 (70.3)	23 (62.2)	20 (74.1)	22 (64.7)	12 (80.0)	12 (60.0)
P-Value (Between Groups)			0.0053		0.0069		0.0058	

*ITT defined as anyone who received treatment and had effectiveness observation (1 Month).
**Response is defined as ≥50% improvement from baseline.

	ITT POPULATION*							
	Baseline		1 Month		6 Months		12 Months	
	CRFA	SRFA	CRFA	SRFA	CRFA	SRFA	CRFA	SRFA
SF-36 (Physical Function Domain)	N=37	N=37	N=37	N=37	N=27	N=34	N=15	N=20
Mean Score (SD)	19.4 (4.59)	19.7 (4.21)	24.1 (5.13)	23.8 (5.57)	24.8 (5.12)	23.8 (4.32)	24.8 (4.62)	23.2 (5.08)
Mean Change from Baseline (SD)	-	-	4.7 (5.57)	4.1 (4.01)	5.1 (6.81)	4.1 (3.62)	4.9 (4.04)	4.0 (4.52)
P-Value (Between Groups)			0.6389		0.4805		0.5318	
Oswestry Disability Index (ODI)	33	30	33	29	24	27	13	15
Mean Score	18.7 (6.30)	17.2 (6.44)	9.3 (6.28)	9.3 (7.84)	8.0 (6.87)	10.2 (8.57)	7.4 (7.67)	8.2 (8.53)
Mean Change from Baseline (SD)	-	-	-9.7 (6.37)	-7.1 (7.63)	-10.1 (8.63)	-6.6 (8.50)	-9.8 (5.37)	-7.9 (8.98)
P-Value (Between Groups)			0.1663		0.1677		0.5118	
EQ-5D-5L Index Score	37	37	37	37	27	33	15	20
Mean Score (SD)	0.47 (0.27)	0.57 (0.24)	0.77 (0.21)	0.75 (0.23)	0.81 (0.21)	0.75 (0.21)	0.82 (0.23)	0.81 (0.15)
Mean Change from Baseline (SD)	-	-	0.29 (0.26)	0.18 (0.18)	0.35 (0.36)	0.19 (0.28)	0.31 (0.23)	0.24 (0.26)
P-Value (Between Groups)			0.0341		0.0643		0.4282	
Global Perceived Effect (GPE)	-	-	37	37	27	34	15	20
Mean Score (SD)			5.5 (0.93)	5.3 (0.91)	5.5 (1.12)	5.3 (1.14)	5.5 (1.13)	5.6 (1.15)
P-Value (Between Groups)			0.4508		0.5238		0.8315	

*ITT defined as anyone who received treatment and had effectiveness observation (1 Month).

RESULTS

- At 6 months in the CRFA group, 20 out of 27 (74.1%) were responders and in the SRFA group, 22 out of 34 (64.7%) (p = 0.0069 between groups).
- Both groups demonstrated a reduction in pain of greater than 2 points on NRS, from baseline to 6 months.
- The mean NRS at baseline for the CRFA group = 6.9 (SD = 1.22) and at 6 months = 2.7 (SD = 2.88), a 4.2 drop in pain score with 27 participants reporting.
- The mean NRS at baseline for the SRFA group = 6.8 (SD = 0.83) and at 6 months = 3.4 (SD = 2.29), a 3.4 drop in score, with 34 participants reporting (p = 0.1234 between groups).

DISCUSSION

- A difficulty in finding participants to meet dual medial branch block criteria challenged enrollment early on.
- Given difficulty in enrollment, the goal of 150 patients (power of 80%) was not achieved.
- A single treatment of RFA of the lumbar facetogenic joints improves a patient’s pain and function, ability to perform daily activities, increases quality of life, and improves their perception of how they are doing.
- Although sample size was small, responder rates were higher and statistically significant in the CRFA cohort.

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