Clinical And Functional Outcomes After Radiofrequency Ablation Using a Deployable Large-Lesion Cannula

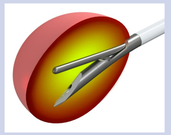
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BACKGROUND

Radiofrequency (RF) techniques in chronic pain management are used to modulate sensory nerve transmission usually by producing thermal lesions. The aim is to lesion a targeted nerve that innervates a structure believed to be contributing to pain. To optimize the outcomes, and because the lesion is not selective to specific tissue types, RF needle technology and placement as well as RF parameters need to be carefully selected to optimize precise and complete coverage of the neural target.[1, 2] For lumbar facetogenic pain, consensus guidelines and clinical data indicate that larger lesions drive better outcomes.[3] A new RF cannula** was recently developed to produce larger lesions, up to 2x larger than a standard cannula, without the need for additional equipment or procedure time. This cannula includes a unique deployment design that was engineered to help achieve larger lesions and reduce the need for multiple burns. We have conducted a real-world study to evaluate clinical outcomes when using this new cannula as per standard practice.

METHODS

Study Design	Multicenter, Consecutive, Observational, Case-Series. Data collected by site personnel (ClinicalTrials.gov identifier NCT01550575)
Study Device	RF equipment (Boston Scientific) including G4 Generator and cannulae with deployment design 
Cohort	Consecutive patients undergoing thermal RF procedure with study device for chronic pain.

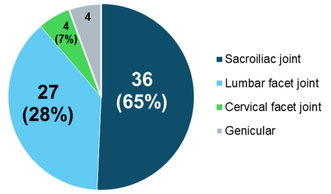
RESULTS

Baseline characteristics (N=71)

Age (yrs.) - Mean (SD) n	67.8 (12.3) 71
Gender (Female) - % (n/N)	61% (43/71)
Pain areas – n/N (multiple areas possible) Low back Lower limbs Upper limb & neck Knee	 64 15 4 4
Overall Pain (NRS)- Mean (SD) n	8.0 (1.1) 71
Oswestry Disability Index (ODI) – Mean (SD) n	49.3 (12.7) 34
Follow-up duration (months)- Mean (SD) n; Median	5.4 (4.9) 71; 4.6

Radiofrequency procedure (N=71)

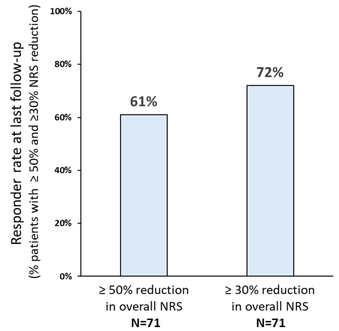
Ablation target



Ablation parameters

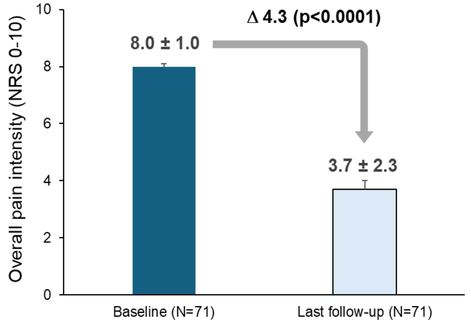
Procedure duration (minutes)- Mean (SD) n	20.0 (9.5) 58
Burn temperature (°C)- Mean (SD) n	83.8 (3.6) 72
Burn time (seconds)- Mean (SD) n	127 (38) 66

Responder rates



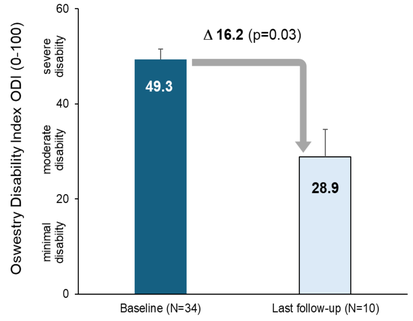
Up to 72% of the patients had a substantial pain relief

Overall pain (NRS 0-10)



Significant mean reduction of overall NRS pain score out to 5.4 months follow-up

Functional disability (ODI 0-100)



ODI score reduced from “severe” to “moderate” disability, more than the established MCID[4]

CONCLUSIONS

Our preliminary results suggest that the use of a new cannula designed for producing larger lesions is effective for RF treatment. Our study included various target locations which may benefit from the use of larger ablation lesions, such as lumbar facet joints and sacroiliac joints.

More than 5 months after the procedure, up to 72% of the patients reported clinically significant levels of pain relief. Overall pain decreased by 4.3-points on average, from 8.0 to 3.7 (N=71, p<0.0001). Preliminary results also showed substantial improvements in disability.

Our study in ongoing and future analysis will be conducted to confirm these findings and evaluate consistency with published prospective evidence.[5, 6]

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DISCLOSURES

Study Sponsored by Boston Scientific.
Edward Goldberg is employee of Boston Scientific.

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