Treatment of Pain Using Cervical Radiofrequency Ablation: Outcomes from an International, Prospective Multicenter Study (RAPID)

Joseph Atallah[1], Bradley Holt[2], Michael Danko[3], David Provenzano[4], Maaz Iqbal[5], Binit Shah[6], Albert Singh[7], Harsh Sachdeva[8], Ella Ver Donck[9], Bart Liebrand[10], Erik Shaw[11], Sherri Haas[12], Rajat Sekhar[13], Ann Pan[14], Edward Goldberg[14]

1. The Toledo Clinic, Toledo, OH USA 2. Tucson Orthopaedic Institute, Tucson, AZ USA 3. Premier Pain Treatment Institute, Loveland OH, USA 4. Pain Diagnostics and Interventional Care, Sewickley, PA USA 5. Elite Pain and Spine Institute, Mesa, AZ USA
6. Carolinas Pain Center, Huntersville, NC USA7. Quincy Medical Group, Quincy, IL USA 8. UC Health Pain Medicine, Cincinnati, OH USA 9. AZ Sint-Jan, Bruges, Belgium 10. St Anna Hospital, Geldrop, The Netherlands
11. Shepherd Center, Shepherd Pain Institute, Atlanta, GA, USA 12. Twin Cities Pain Clinic & Surgery Center, Edina, MN USA 13. St. Vincent's Medical Center, Bridgeport, CT USA 14. Boston Scientific Neuromodulation, Valencia, CA USA

BACKGROUND

Chronic axial neck pain with or without headache and/or upper extremity pain is increasingly noted as a source of enduring disability and medical costs, and one of the leading causes of healthcare burden.[1] Several clinical studies, including RCTs and observational studies have demonstrated positive outcomes using radiofrequency ablative (RFA) techniques for a range of chronic neck pain indications.[2-6] Further, a recent meta-analysis of 20 previously published studies showed that evidence collectively published supports the use of therapeutic radiofrequency (RF) techniques for the effective management of chronic neck pain.[7] In light of the on-going opioid epidemic and the need to provide better care to chronic pain patients, recent guidelines (HHS 2019 Best Practices report and 2022 CDC guidelines) have highlighted the need to incorporate interventional techniques including neuromodulation and RF.[8-10] Thus, it is important to continually assess and document clinical effectiveness of contemporary RF devices in real-world patients with chronic neck pain, headaches and proximal upper extremity pain. We assessed patients diagnosed with chronic cervical facet joint pain treated with RFA in a prospectively-enrolled, real-world, multicenter, international study.

METHODS

Study Design	Multicenter, Prospective, International Outcomes Study RAPID Study (clinicaltrials.gov identifier: NCT04673032)
Study Device	Commercially-approved RFA Systems (Boston Scientific)
Subjects	•75-enrolled patients with cervical facet joint pain •73-treated patients with cervical facet joint pain (initial procedure completed)
Study Eligibility Criteria	**Key Inclusion Criteria:** Study candidate is scheduled to be treated with a commercially approved Boston Scientific RF system for pain per local Directions for Use (DFU) **Key Exclusion Criteria:** Meets any contraindications per locally applicable Directions for Use (DFU)

STUDY SCHEMATIC



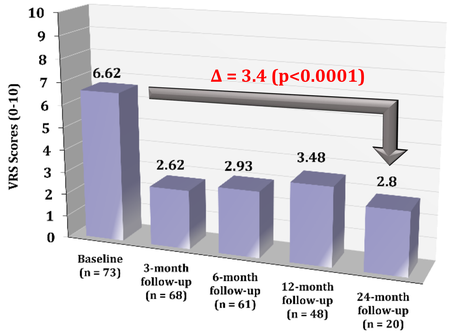
RESULTS

Baseline Characteristics
(n = 73 patients with initial RFA completed)

Gender - Females (%)	60.3% (n = 44/73)
Age (years) [Mean (SD)]	59.6 ± 11.3 years (n = 73)
Pain Duration (years) [Mean (SD)]	13.7 ± 11.5 years (n = 73)
Baseline Targeted Pain VRS Score [Mean (SD)]	**VRS**: 6.62 ± 1.6
Number of Study RF Procedures [Mean (SD)]	2.3 ± 1.4 procedures (n = 73)
Follow-up Duration [Mean (SD)]	498.5 ± 235.4 days (n = 73)
Location Targeted by RFA	**Head, neck, shoulder and upper back** – 75.3% (55/73)
	Mid/Low Back – 24.7% (18/73)
Pain Type Treated by RFA	**Cervical zygapophyseal joints pain** – 100% (73/73)

Targeted Pain is the area of pain intended to be treated with RF

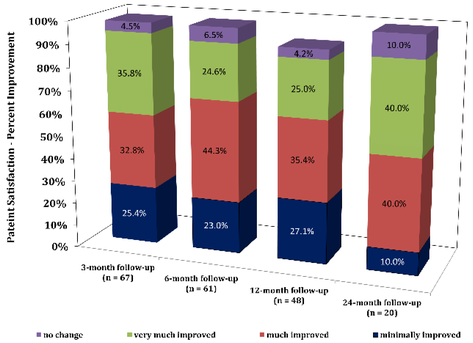
Targeted Pain Scores up to 24-months post-procedure



•**At 3-months, a mean 3.9-point reduction in VRS score was observed (p<0.0001)**
•**At 24-months, a mean 3.4-point reduction in VRS score was observed (p<0.0001**

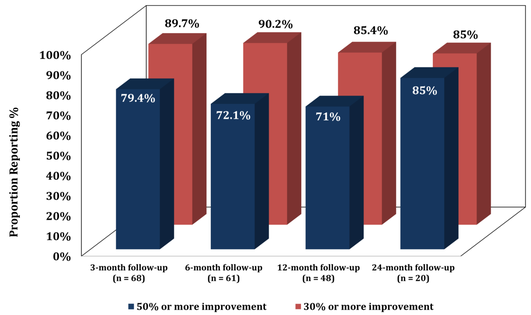
PPR = percent pain relief

Patient Satisfaction (PGIC) post-procedure



~90% of patients reported improvement (very much, much, or minimally improved) up to 24-months post-procedure

Responder Rates post-procedure



At all timepoints:
•**≥85% responder rate (≥30% overall PPR)**
•**≥71% responder rate (≥50% overall PPR)**

CONCLUSIONS

•Preliminary sub-analysis derived from this ongoing, prospective, multicenter, real-world clinical outcomes RF study of 73 patients with chronic cervical pain demonstrates significant improvement in pain scores out to 24-months post-procedure.

•Follow-up outcomes:
- ❑3.4-point VRS pain score improvement out to to 24-months post-procedure
- ❑Responder rate ≥71% (≥50% overall PPR) and ≥85% (≥30% overall PPR) at all time points
- ❑~90% of patients reported improvement (i.e., very much, much or minimally improved)

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DISCLOSURES

Study Sponsored by Boston Scientific.
Drs. Atallah and Provenzano have consulting agreements with Boston Scientific. Ann Pan and Edward Goldberg are employees of Boston Scientific

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