Significant Pain Relief and Treatment Satisfaction Following Radiofrequency Ablation - Prospective, Multicenter Study (RAPID)

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BACKGROUND

Patients suffering with chronic pain typically undergo a variety of treatment approaches including medications, physical therapy, and surgery. Notably however, a recent meta-analysis of 96 randomized trials involving over 26,000 subjects with chronic pain demonstrated that use of opioid drugs was not associated with significant improvements in pain and physical function, nor associated with outcomes that were significantly better than that achieved using conventional treatments (i.e., antidepressants, nonsteroidal anti-inflammatory drugs, anticonvulsants, cannabinoids, or usual care).[1] Radiofrequency ablation (RFA) is minimally invasive, outpatient treatment that has been demonstrated to alleviate pain, improve function, decrease healthcare utilization, and eliminate the need for opiates.[2-6] Additionally, RFA has been progressing as a key approach to managing chronic pain. Here, we assess patients treated with RFA for chronic pain as part of a prospectively-enrolled multicenter, international study.

METHODS

Study Design	Multicenter, Prospective, International Outcomes Study with consecutive enrollment
Study Device	Commercially-approved RFA Systems (Boston Scientific)
Subjects	289 enrolled subjects at 11 sites; 281 patients with initial RFA 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

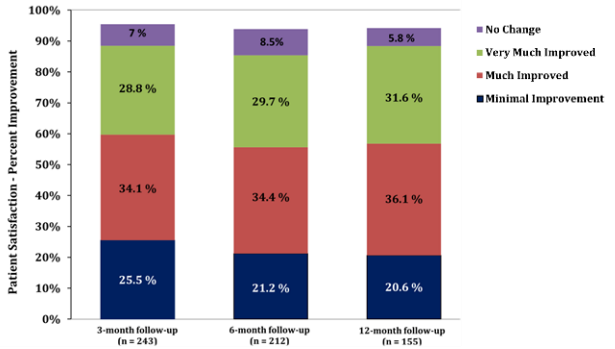
RESULTS

Baseline Characteristics (n = 289)

Gender - Females (%)	56.4% (n = 163/289)
Age (years) [Mean (SD)]	61.4 ± 12.9 years (n = 289)
Pain Duration (years) [Mean (SD)]	12.86 ± 12.63 years (n = 281)
Baseline Targeted Pain Score [Mean (SD)]	6.63 ± 1.76 (n = 258)
Number of Study RF Procedures [Mean (SD)]	1.97 ± 0.99 procedures (n = 281)
Regions treated with RF (with initial procedure completed)	Lumbar – 69.8% (n = 196/281)
	Cervical – 24.2% (n = 68/281)
	Sacroiliac – 21.0% (n = 59/281)
	Hip – 9.25%% (n = 26/281)
	Knee – 13.5% (n = 38/281)
Follow-up Duration [Mean (SD)]	353.2 ± 202.5 days (n = 281)

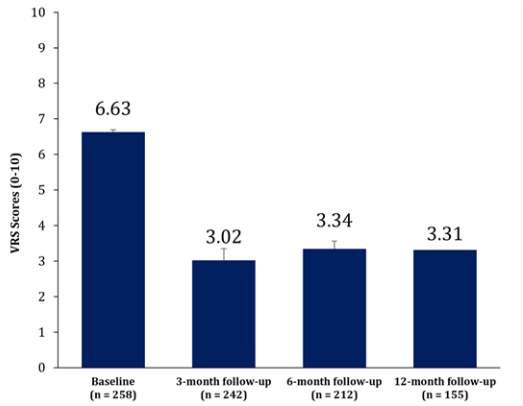
Targeted Pain is the area of pain intended to be treated with RF

Patient Satisfaction (PGIC) post-procedure

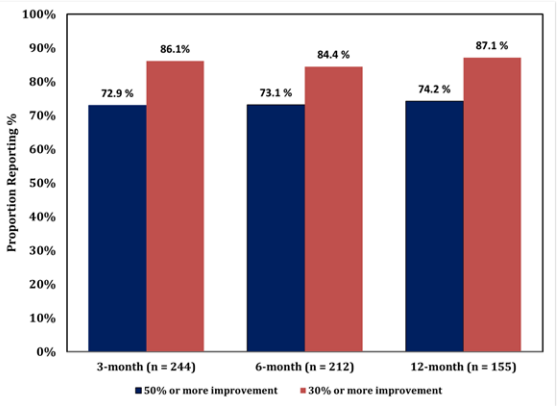


Over 85% of patients reported improvement (very much, much, or minimally improved) up to 12-months post-procedure

Targeted Pain Scores up to 1-year post-procedure



Responder Rates (Targeted Pain) post-procedure



At 12-months post-procedure:

- Significant improvement ($p<0.0001$) in pain scores was noted.
  - 3.58-point improvement (6.63 → 3.02) at 3-months and sustained long-term (Δ = 3.2-point improvement)
- High Responder rates were noted

CONCLUSIONS

- Data from this prospective, multicenter, real-world outcomes radiofrequency ablation (RFA) study of 289 enrolled patients (281 patients with initial RFA procedure complete) shows significant improvement in pain scores up to 12-months post-procedure.
- High responder rates and high patient satisfaction was noted during long term follow up.
  - More than 85% of patients reported very much, much or minimally improved at 12-month post-procedure follow-up.

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DISCLOSURES

This study is sponsored by Boston Scientific.
Drs. Atallah, Shah, and Provenzano have consulting agreements with Boston Scientific.
Yu Pei and Nilesh Patel are employees of Boston Scientific.

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Indications

US Indications for Use: The Boston Scientific Radiofrequency Generators, associated Radiofrequency Lesion Probes and RF Cannula are indicated for use in procedures to create radiofrequency lesions for the treatment of pain or for lesioning only peripheral nerve tissue for functional neurosurgical procedures. The Boston Scientific RF Injection Electrodes are used for percutaneous nerve blocks with local anesthetic solution or for radiofrequency lesioning of peripheral nerve tissue only. The Boston Scientific LCED and Stereotactic TCD Electrodes are indicated for use in radiofrequency (RF) heat lesioning of nervous tissue including the Central Nervous System.

Warnings: The Boston Scientific RF devices may cause interference with active devices such as neurostimulators, cardiac pacemakers, and defibrillators. Interference may affect the action of these active devices or may damage them. For appropriate guidance, consult the instructions for use for these active devices. Refer to the Instructions for Use provided with Boston Scientific generators, electrodes and cannulas for potential adverse effects, warnings and precautions prior to using these products. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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