

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

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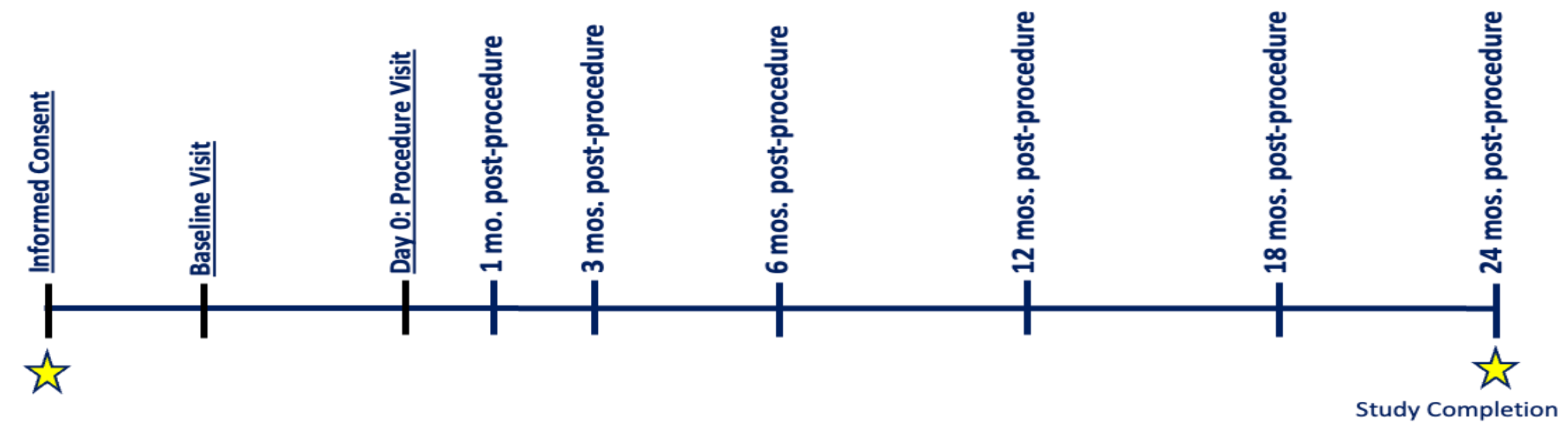
BACKGROUND

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 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 RAPID Study (clinicaltrials.gov identifier: NCT04673032)
Study Device	Commercially-approved RFA Systems (Boston Scientific)
Subjects	297 enrolled subjects; 291 patients treated 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

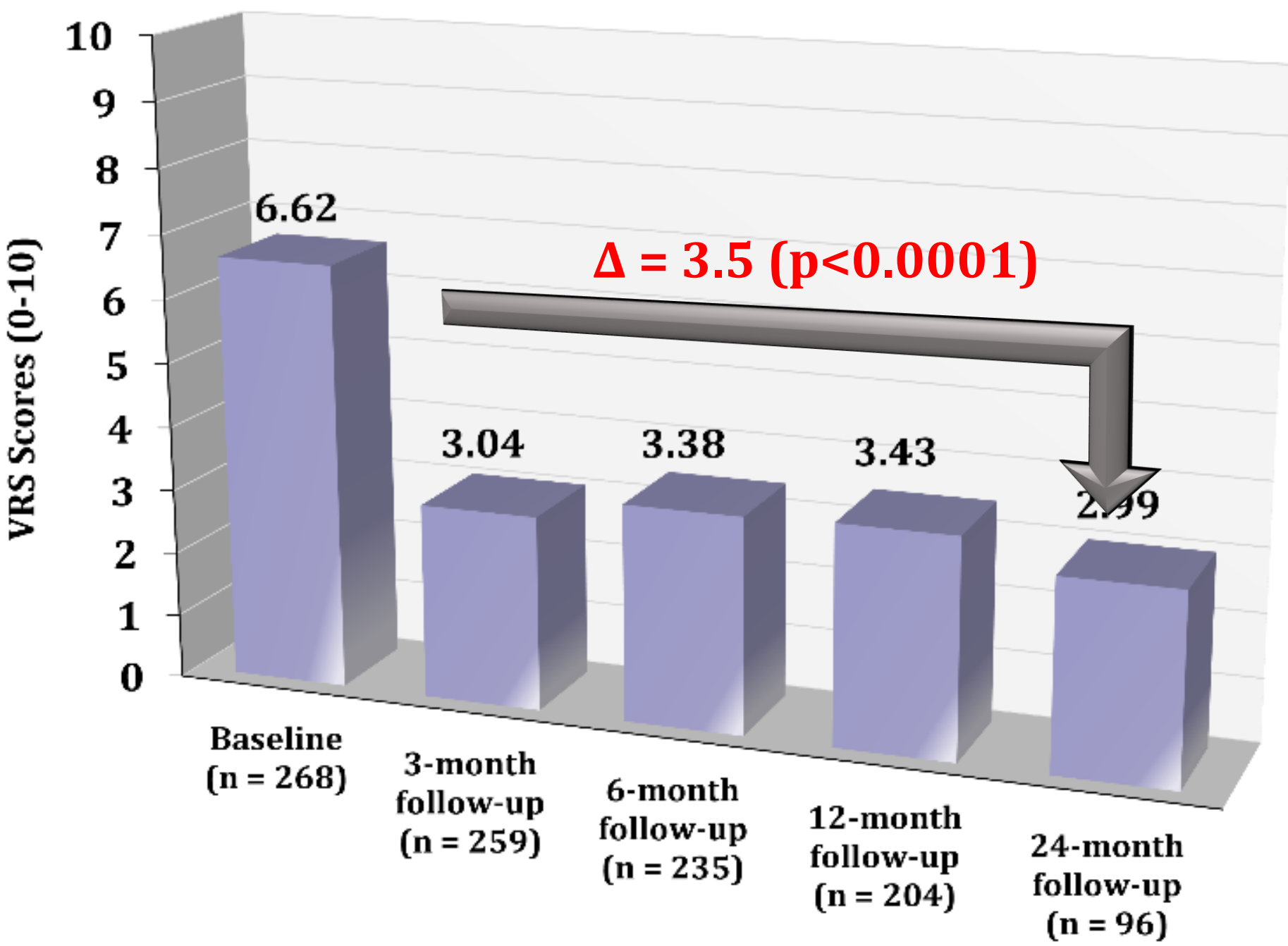


RESULTS

Baseline Characteristics (n = 291 patients with initial RFA completed)	
Gender - Females (%)	56% (n = 163/291)
Age (years) [Mean (SD)]	61.4 ± 12.9 years (n =291)
Pain Duration (years) [Mean (SD)]	12.6 ± 12.5 years (n = 281)
Baseline Targeted Pain VRS Score [Mean (SD)]	6.62 ± 1.74 (n = 268)
Number of Study RF Procedures [Mean (SD)]	2.2 ± 1.2 procedures (n =291)
Follow-up Duration [Mean (SD)]	542.2 ± 226.2 days (n = 291)
Location Targeted by RFA	Head, neck, shoulder and upper back – 20.6% (60/291)
	Mid/Low Back – 69.1% (201/291)
	Knee – 6.5% (19/291)
	Other – 4.4% (13/291)
Type of Pain Treated by RFA	Head pain – 7.6% (22/291)
	Cervical zygapophyseal joints pain – 25.1% (73/291)
	Thoracic zygapophyseal joint pain – 5.2% (15/291)
	Lumbar pain – 67.7% (197/291)
	Sacroiliac joint pain – 20.3% (59/291)
	Hip pain – 8.9% (26/291)
	Knee pain – 13.1% (38/291)
	Other – 7.6% (22/291)

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

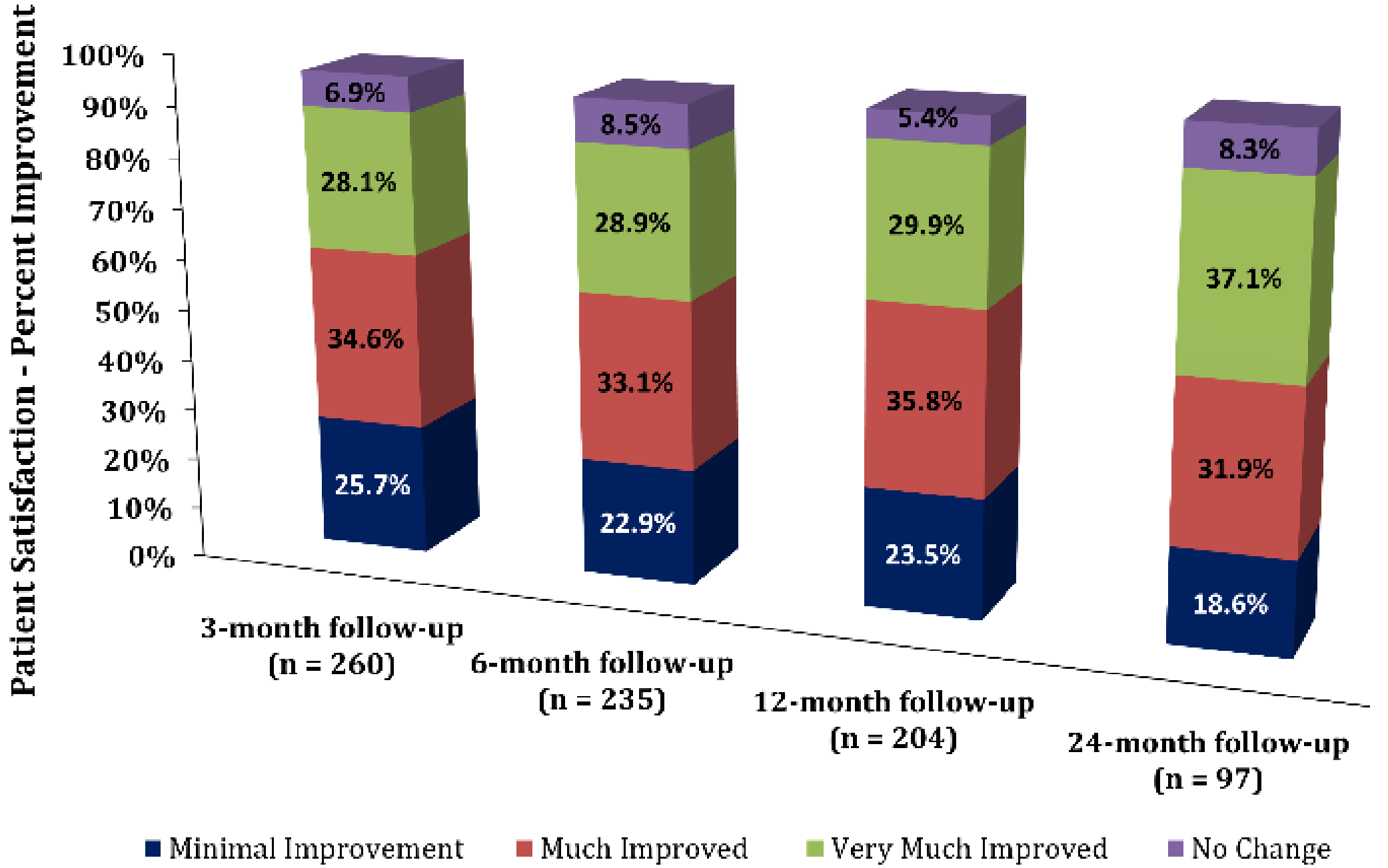
Targeted Pain Scores up to 24-months post-procedure



- At 3-months, a mean 3.5-point reduction in VRS score was observed (p<0.0001)
- At 24-months, a mean 3.5-point reduction in VRS score was observed (p<0.0001)

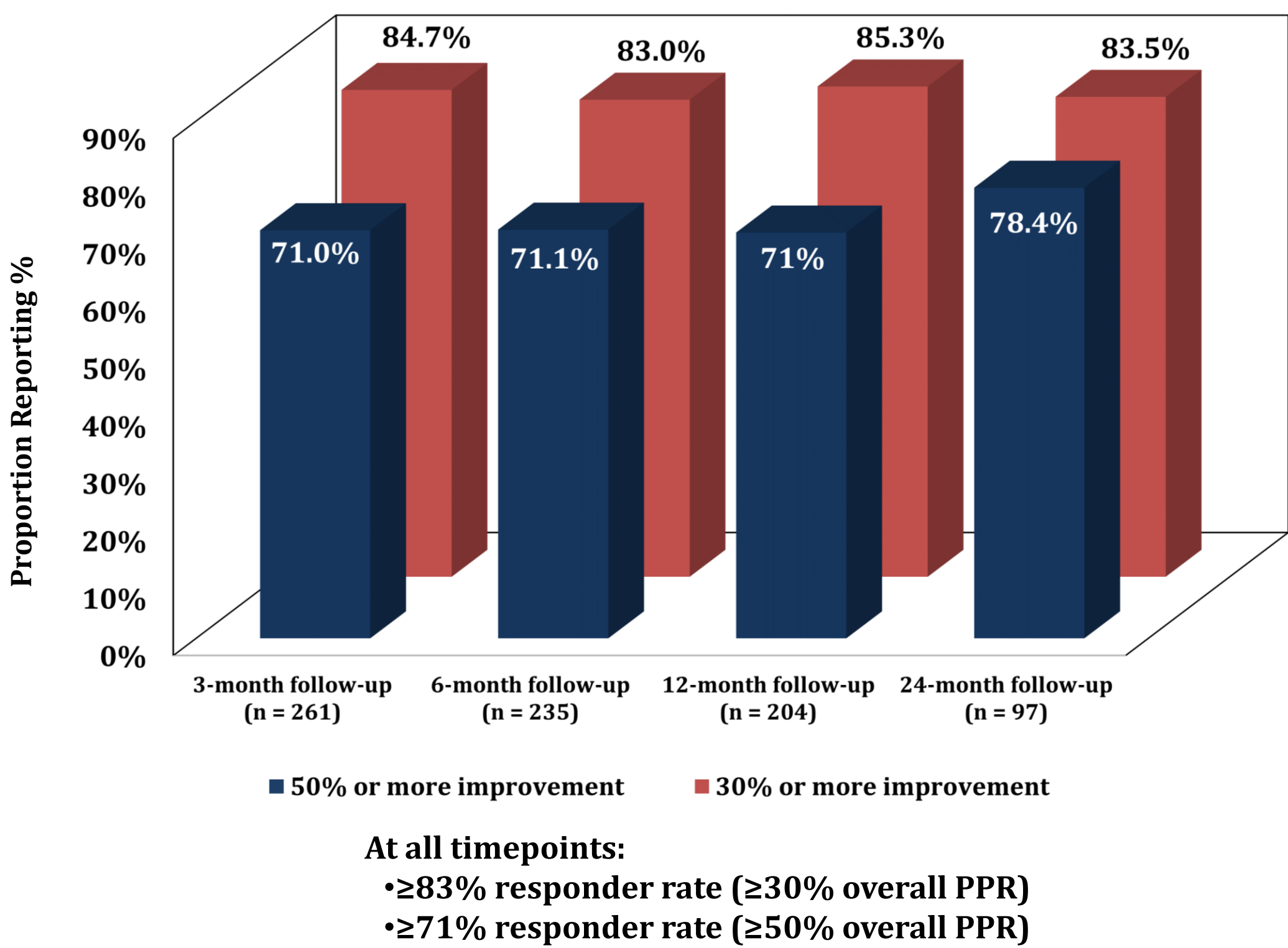
PPR = percent pain relief

Patient Satisfaction (PGIC) post-procedure



~88% of patients reported improvement (very much, much, or minimally improved) up to 24-months post-procedure

Responder Rates post-procedure



CONCLUSIONS

- The data from this prospective, multicenter, real-world outcomes radiofrequency ablation (RFA) study of 291-patients treated with RFA describes clinical outcomes out to 24-months.
- Significant improvement in pain scores up to 24-months post-procedure were observed. Repeat RFA procedures were permitted during the study.
- High treatment responder rates and patient satisfaction were noted during long term follow-up.
 - ~88% of patients reported very much, much or minimally improved at 24-month post-procedure follow-up.
 - ≥83% responder rate (≥30% PPR) and ≥71% responder rate (≥50% PPR) at all time points.

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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..