Pulsed Radiofrequency Ablation for Treatment of Chronic Pain: Real-world Outcomes in Europe

Background and Aims Collection of real-world data can offer the aggregation of additional evidence and help drive discovery of new therapeutic aspects for evaluation in future clinical studies. In this report, we describe real-world outcomes from a cohort of patients who received pulsed radiofrequency (PRF) ablation as a treatment method for the treatment of chronic pain.

Methods This is a real-world, retrospective, observational, case-series study of patients in Europe who used a device capable of pulsed radiofrequency ablation (Boston Scientific, Marlborough, MA, USA) for treatment of chronic pain. Key data and clinical assessments include demographic characteristics, pain diagnosis, baseline and post-treatment pain scores, and percent pain relief.

Results To date, 31 patients have been assessed with an average age of 69.3 ± 10.6 years (n = 23). At post-procedure and last follow-up (mean=289 ± 338 days, median 119 days), significant improvement (p < 0.0001) in pain intensity scores was documented. In particular, a 3.1-point NRS score improvement versus baseline (7.9) was observed at last follow-up (2.8). In addition, the proportion of patients with >50% pain relief (responder rate) at last follow-up was also determined to be 74.2% (23/31).

Conclusions PRF ablation as a therapeutic modality for treatment of chronic pain may be particularly helpful in patients who have not achieved a sought after level of pain relief using conventional drug medications or other traditional pain management approaches. This observational case-series seeks to track and assess clinical outcomes of patients who used PRF to help manage their chronic intractable pain.

Background and Aims Minimally invasive interventional pain procedures, such as thermal radiofrequency (TRF) ablation, have steadily progressed to become a key segment of the therapeutic armamentarium now available to the chronic pain patient population. Here, we report real world-collected outcomes from a study of patients treated with TRF for management of chronic pain.

Methods This is a real-world, retrospective, observational, case-series study of patients in Europe who used a device capable of thermal radiofrequency ablation (Boston Scientific, Marlborough, MA, USA) for treatment of chronic pain. Key data and clinical assessments include demographic characteristics, pain diagnosis, baseline and post-treatment pain scores, and percent pain relief.

Results Fifty-four patients have been assessed to date with an average age of 58.2 ± 17.2 years who received thermal RF for treatment of chronic pain. Significant improvement (p<0.0001) in pain scores was noted at post-procedure and last follow-up. A 5.5-point NRS score improvement (8.1 [baseline] → 2.6) was noted at last follow-up (mean = 314.9 ± 233.7 days, median 224 days). A higher responder rate (proportion of patients with >50% pain relief) post-procedure at last follow-up was also observed (79.5%; 43/54).

Conclusions The data collected from this clinical investigation aims to accrue additional real-world evidence regarding the use of TRF as a strategy for use in the treatment of chronic pain.

Real-world Outcomes Using Thermal Radiofrequency (TRF) Ablation for Chronic Pain

Background and Aims In this study, we will report prospectively-collected outcomes from a multicenter, international study of patients treated with Radiofrequency Ablation (RFA) for management of chronic pain.

Methods RAPID (ClinicalTrials.gov: NCT04673032) is an international, prospective, multicenter, observational outcomes study of up to 1500 patients using a commercially-approved radiofrequency ablation system (Boston Scientific, Marlborough, MA), as indicated per local directions for use, for chronic pain. Key data and clinical assessments will include demographic characteristics, pain diagnosis, baseline (and post-treatment) pain scores, percent pain relief, patient global impression of change, change in disability, change in use of opioid medications, and occurrence of adverse events. Study participants will be evaluated out to 24 months. This study was approved by Institutional Review Board (IRB) for each site and is registered at Clinicaltrials.gov: NCT04673032.

Results To date, 104 subjects (mean age = 60.5 ± 12.7 years) have been enrolled. Of the 100 subjects that completed their procedure, 74 and 56 subjects reached their 1- and 3-months post-procedure visit. In addition, at 1-and 3-months post-procedure, a mean targeted pain score of 2.9 and 2.6 (0–10 scale) were reported, respectively. Seventy-seven percent of subjects reported ≥50% targeted pain relief at 1-month (75%) at 3 months). Updated data will be presented.

Conclusions The data collected from this multi-national, prospectively-enrolled clinical investigation aims to offer a