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Assessment of real-world, prospective outcomes in patients treated with lumbar radiofrequency ablation for chronic pain (RAPID)

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ABSTRACT

Background: Lumbar facet joint syndrome (LFJS) is one of most common forms of chronic low back pain. Despite several decades of real-world use and a plethora of published studies, debate still exists regarding the effectiveness of Radiofrequency Ablation (RFA) as a therapy in LFJS-diagnosed patients.
Objective: Here, we sought to evaluate real-world clinical outcomes in RFA-treated patients with chronic lumbar facetogenic pain participating in one of the largest studies of its kind published to date.
Methods: The RAPID study (Clinicaltrials.gov identifier: NCT04673032) is an international, multicenter, prospective study of patients using a commercially-available radiofrequency ablation system for the treatment of chronic pain, provided per standard of care. Patients were assessed at pre-specified study follow-up visits (1-, 3-. 6-, 12-, and 24-months post-index procedure). Key clinical endpoint measures collected and evaluated include NRS (pain score), Oswestry Disability Index (functional disability, ODI), EQ-5D-5L (quality-of-life), and Patient Global Impression of Change (PGIC).
Results: To date, 193 patients have been enrolled in this lumbar facetogenic pain patient cohort. Evaluation of pain relief amongst patients assessed out to 24-months demonstrated a mean NRS score of 3.4 (baseline NRS: 6.6, $p < 0.0001$). Consistent functional improvement out to 24-months was observed per an 8.6-point mean ODI score reduction (baseline ODI: 38.0, $p < 0.0001$). Following RFA treatment at 1-month and out to 24-months, 77.0% and 79.0% of patients were observed to be treatment responders (i.e., ≥50% pain relief), respectively. Enhanced levels in measures of quality-of-life (EQ-5D-5L) and self-reported health-related change (PGIC) were also consistently noted.
Conclusions: Clinically meaningful and durable improvements in pain relief, functional disability, quality-of-life and treatment satisfaction were observed across all RAPID study follow-up visits. The results of the RAPID study provide for the potential clinical outcomes amongst selected patients with lumbar facetogenic pain within the real-world clinical setting.

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1. Introduction

Chronic low back pain (CLBP) is a leading cause of disability which imposes direct costs on healthcare utilization and indirect costs through loss of productivity. Additionally, due to the opioid drug crisis, greater emphasis is now placed on the use of alternative and/or companion therapies when treating patients with chronic pain, including interventional techniques [1–3]. As such, when conservative treatments such as NSAIDs and physical therapy fail to ameliorate facetogenic pain, radiofrequency ablation (RFA) of the lumbar medial branch nerves (a minimally invasive, outpatient treatment consistently demonstrated to alleviate chronic pain, improve function, and decrease healthcare utilization) is often considered [4–8].

While CLBP makes up an overwhelming fraction of the total source costs of healthcare worldwide, further assessment of specific indications within the CLBP population reveals that chronic lumbar facetogenic pain (i.e., lumbar facet joint syndrome, LFJS), arising from degeneration or dysfunction of the lumbar facet joints, represents a sizable proportion (with estimates ranging from 10 to 45% depending on age) of all CLBP cases [9–12].

Although several published RFA-based studies have reported substantial efficacy and durability when treating patients with chronic lumbar facet pain, there still remains controversy regarding the validity of RFA has an effective long-term treatment approach for LFJS [12–16]. Moreover, prior RFA research has primarily focused on pain relief, with minimal data collected on long-term quality of life outcomes [10]. This study therefore aims to address that gap by assessing real-world, long-term outcomes following treatment with RFA for lumbar facet joint syndrome with focus on pain relief, functional improvement, and quality-of-life. Here, we present our findings from 12 participating RAPID study treatment centers.

2. Methods

2.1. Study collection

This is an analysis of patients with chronic lumbar facetogenic pain participating in a prospective, multicenter, international study (RAPID) designed to collect real-world outcomes associated with the use of commercially-available radiofrequency ablation systems for the treatment of chronic spinal and musculoskeletal peripheral pain (ClinicalTrials.gov Identifier: NCT04673032). Criteria for inclusion in the RAPID study was defined by "real-world" clinical practice consisting of patients scheduled to be treated with a commercially-approved RFA system (manufacturer: Boston Scientific, Marlborough, MA USA) for pain, per locally approved Indications for Use, a signed informed consent form, and 18 years of age and older. Patients were excluded from study participation should a cognitive impairment or other characteristic(s) limit their ability to assess pain relief or to complete study assessments, or should they be found to have any other contraindication for RFA. Institutional Review Board (IRB) approval was obtained from each site and the study was conducted in accordance with GCP (ISO14155) guidelines and the Declaration of Helsinki.

2.2. Device description

The commercially-available RFA system (G4 RF Generator, cannulae and electrodes; Boston Scientific) utilized by patients in the RAPID study is designed to transfer oscillating electrical current as derived from a Radiofrequency Generator via an electrode to the desired nerve target. The G4 RF Generator is temperature-controlled system capable of treating up to four anatomical sites simultaneously and is compatible with a wide-range of reusable and disposable cannulas and electrodes. No internally cooled electrodes or side port cannulae were utilized. The study protocol did not specify the cannulae size, active tip lengths, and RFA approach; these (and overall RFA treatment plan) were determined by the investigator at each site according to best clinical judgement.

2.3. Data collection and analysis

Upon enrollment (i.e., a signed Informed Consent Form [ICF]), patients were scheduled for their baseline visit where demographics, medical history and other baseline information were collected. Following the baseline visit, a lumbar RFA procedure was performed. Patients were classified as having received bilateral lumbar RFA if they underwent bilateral treatment at the index procedure or alternatively had two separate unilateral procedures at the right or left sides within 30 days of initial treatment. Repeat RFA procedures targeting the same facet joint(s) treated during the index procedure were permitted. Information specific to the area treated and type of devices used was recorded. Follow-up visits occurring after the initial RFA procedure were conducted at 1- (30 + 14 days), 3- (90 ± 14 days), 6- (180 ± 30 days), 12- (365 ± 30 days), and 24-months (730 ± 30 days). Clinical endpoints collected at baseline and subsequent follow-up visits included the following: Targeted Pain Intensity (Numerical Rating Scale, NRS), Function (Oswestry Disability Index, ODIv12.1a), Health-related Quality of Life (EQ-5D 5-Level), Percent Pain Relief (PPR), and Patient Global Impression of Change and (PGIC). Additionally, related serious and non-serious adverse events were collected through 24-months follow-up. Study sites were selected based on a requirement that investigators have extensive experience with RF procedures. The protocol did not characterize the type of diagnostic procedure to be performed to establish a diagnosis of lumbar facetogenic pain. However, data on diagnostic medial branch blocks was collected including ≥50% and ≥80% pain relief, and type of anesthetic used. Where pertinent, means and standard deviations were calculated for demographic and clinical endpoint data. A paired *t*-test with two-sided 0.05 significance level was used to determine whether a given mean change compared with baseline was statistically significant for continuous outcomes.

3. Results

Patient Baseline Demographics and Procedural Characteristics. From December 2020 to January 2024, a total of 193 patients (55% female) with lumbar facetogenic joint syndrome (LFJS) were enrolled and received RFA treatment. Of these, greater than 80% of patients reported chronic low back pain lasting for a minimum of two years, and greater than 85% of patients was associated with moderate to crippling disability at baseline as assessed by Oswestry Disability Index (Table 1). Diagnostic medial branch blocks were recorded in 189 patients (97.9%, 189/193), of which 99.5% and 95.8% of patients reported ≥50% and ≥80% relief from their facet-joint mediated pain, respectively. Most

Table 1
Baseline demographics.

Baseline Demographics	All Patients Mean (SD) N
Age (years)	62.9 (12.1) 193
Sex	
Male	44.6%
Female	55.4%
Duration of low back pain (years)	12.2 (12.5) 180
unknown	6.7%
<2 years	10.4%
2–5 years	30.1%
>5 years	52.8%
NRS Score	6.6 (1.9) 187
ODI Score	37.9 (14.0) 191
Crippled	5.7%
Severe Disability	36.1%
Moderate Disability	45.6%
Minimal Disability	12.6%
EQ-5D-5L Score	0.65 (0.14) 191
Morphine Milligram Equivalents (MME)	11.7 (28.7) 193

enrolled patients underwent radiofrequency ablation of two facet joints, with the most common levels treated being L3/4, L4/5, and L5/S1 (Table 2). Additionally, most patients (84%) were treated with a lesion time of 90 s as well as a majority (89%) at a temperature of 80 °C. Tables 1 and 2 provide additional baseline demographic and procedural characteristics (as was available) collected from across all patients assessed in the lumbar facetogenic pain sub-cohort. To date, 76 patients have exited the study at various times since their initial enrollment primarily due to voluntary patient withdrawal (42.1%, 32/76), investigator discretion (28.9%, 22/76), or loss of follow-up (19.7%, 15/76). Of those patients who withdrew from the study, none were found to have done so due to an adverse event or device deficiency.

Pain reduction (NRS). Baseline pain among all assessed participants as measured by the mean numerical rating scale (NRS) score prior to treatment was determined to be 6.6 (Fig. 1). This improved following lumbar RFA to 3.2 at 1-month follow-up (n = 178). The mean NRS score was similarly reduced to 3.6 and 3.4 at 12- (n = 133) and 24-months follow-up (n = 70), representing statistically and clinically significant improvement ($p < 0.0001$) [17].

Percent Pain Reduction (PPR). The mean percent pain relief among all patients at the following study visits was the following: 1-month (67.3%), 3-month (64.9%), 6-month (64.9%), 12-month (64.6%), and 24-month (69.8%).

Responder Rates. At 1-month follow-up, 86% and 77% of patients achieved at least a 30% and 50% (or greater) reduction in pain, respectively (n = 177) (Fig. 2). The 50% responder rate was 72% at both three (n = 172) and six months (n = 151), 69% at 12-months (n = 133), and 79% at the 24-month follow-up visit (n = 70). All of the 30% responder rates observed at the 3-, 6-, 12-, and 24-month follow-up visits were found to be within a range of 83%–88%.

Oswestry Disability Index (ODI). Measure of back pain-related disability was performed using the ODI across at all evaluated time-points. The mean baseline ODI score among all participants was determined to be 38.0 (n = 191), signifying moderate disability. At 1-month, the mean ODI score was reduced by 11-points, and at 3, 6, 12, and 24-months the mean ODI remained improved by >20% relative to baseline, corresponding to a mean ODI score reduction of 8.6-points out to 24-months follow-up ($p < 0.0001$). Across all follow-up visits there was a reduction in the number of patients classified with "crippling" or "severe" disability, while those categorized with "no to minimal" disability increased over time as compared to baseline (Fig. 3).

Quality-of-Life (EQ-5D-5L). Health-related quality of life was assessed using the EQ-5D-5-level (EQ-5D-5L) questionnaire. The EQ-5D-

Table 2
Index procedural characteristics.

Index Procedural Characteristics	
Number of facet joint levels treated	
1	4.7%
2	58.0%
3	30.1%
4	7.3%
Lumbar Facet Joint Levels Treated[a]	
L1/2	0.5%
L2/3	4.1%
L3/4	52.3%
L4/5	100.0%
L5/S1	79.3%
RF Approach[b]	
Parallel	90.2%
Perpendicular	10.4%
Laterality	
Bilateral	65.8%
Cannula Gauge	
22 ga	3.1%
20 ga	24.8%
18 ga	60.9%
16 ga	11.2%
Cannula Length	
15 cm	11.8%
10 cm	88.2%
Active Tip Length	
10 mm	82.6%
5 mm	17.4%

[a] Multiple facet joints levels could be treated at index procedure.
[b] Multiple approaches could be reported at index procedure.

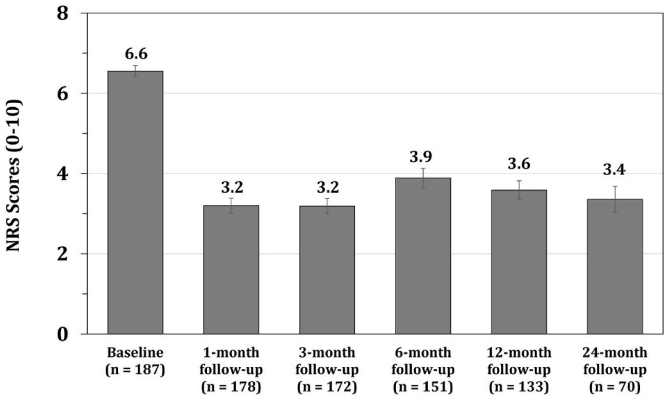

Fig. 1. NRS pain score reduction out to 24-months among all RFA-treated LFJS patients. All assessed follow-up NRS scores: $p < 0.0001$ (vs. Baseline score) at all follow-up visits. Error bars: standard error of the mean, SEM.

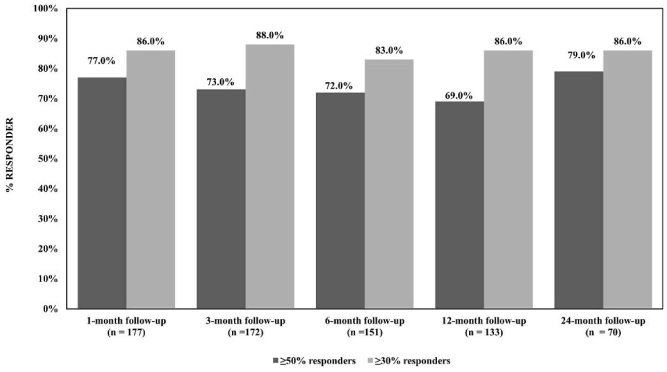

Fig. 2. Responder Rate out to 24-months follow-up among all RFA-treated LFJS patients. Responder rate is defined as proportion of patients reporting ≥30 and ≥ 50% pain relief.

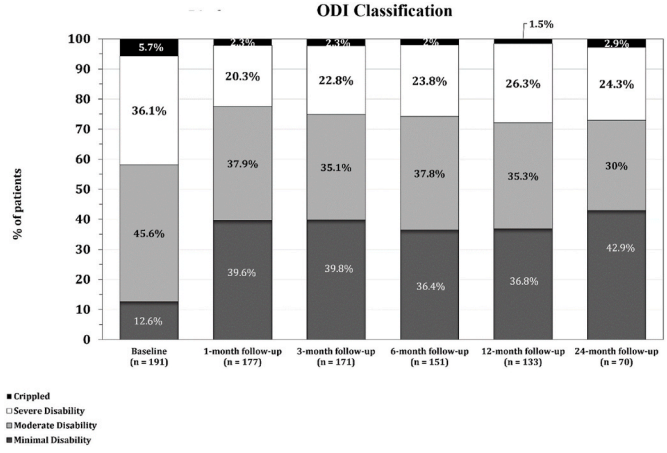

Fig. 3. Disability Improvement (ODI) among all RFA-treated patients. Descriptive classification of disability across all patients out to 24-months follow-up.

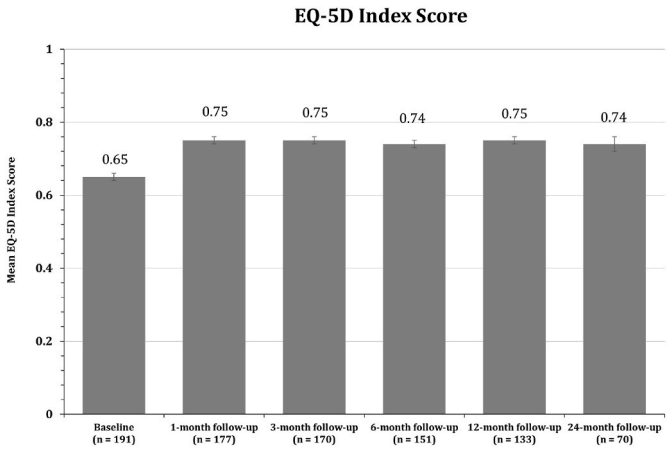

Fig. 4. EQ-5D-5L. Health-related quality of life measurement among all RFA-treated patients out to 24 months follow-up: $p < 0.0001$ (versus Baseline measurement) at each follow-up visit. Error bars: standard error of the mean, SEM.

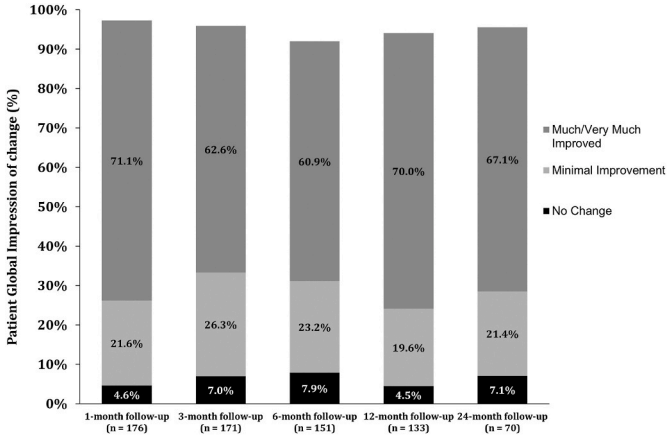

Fig. 5. Patient Global Impression of Change (PGIC) among all RFA-treated patients.

5L mean index score increased from 0.65 at baseline to 0.75 at 1-month ($p < 0.0001$) which represents an improvement exceeding a reported minimum clinically important difference of 0.069 (Fig. 4) [18]. This level of improvement in health-related quality of life was consistent across all timepoints including out to 24-months follow-up ($p < 0.0001$).

Global Impression of Change. The Patient Global Impression of Change (PGIC) provides a subjective assessment of a patient's overall perception of improvement or worsening in their condition over time. The majority of treated patients indicated that they were "very much" or "much improved" across all follow-up visits (1-month: 71%, 3-months: 62.6%, 6-months: 60.9%, 12-months: 69.9%, 24-months: 67.1%) (Fig. 5).

Repeat RFA Procedures. Repeat radiofrequency ablation procedures are sometimes needed in a subset of patients to manage facetogenic pain due to the natural tendency of the medial branch nerves to regenerate [4]. To evaluate the clinical outcomes following a repeat RFA, the average duration until occurrence of a repeat RFA procedure and average reductions in NRS and ODI scores were evaluated following a repeat intervention in 52 patients with available follow-up data (a total 71 patients underwent a repeat RFA but 19 of these were without follow-up data). The average (standard deviation ± 95% confidence interval) time until a repeat RFA took place was 380.6 (153.3 ± 15.1) days. The average NRS and ODI scores improved from 6.1 and 37.8 at baseline (prior to the first RFA) to 3.0 and 30.7, respectively, as measured at the next scheduled study visit following the repeat RFA, which on average occurred 111.7 (56.8 ± 19.12) days post-repeat RFA. There were 8 (out of 52) patients who were observed to have undergone more than one repeat RFA procedure.

Safety. There were no device or procedure-related serious adverse events reported in the study. Related non-serious adverse events included 1 event of procedure-related nausea, 1 event of procedure-related migraine, and 1 device-related burn occurring at a grounding pad site.

4. Discussion

In this real-world evaluation, the RAPID study demonstrated sustained improvements in pain relief, functional disability, quality-of-life, and patient satisfaction as assessed out to 24-months follow-up, and represents one of the largest observational studies to date to report data derived from the real-world clinical setting in patients with low back (lumbar) facetogenic-based pain treated with radiofrequency ablation. More specifically, treatment responders rates of up to 79% were observed out to 24-months follow-up, while additionally, measures of percent pain relief (≥64% at all study visits) and quality-of-life (EQ-5D-5L) were observed to be durable in the long-term. Further, the incidence and types of adverse events reported were in accord with what is reasonably to be expected in the context of real-world clinical practice.

Although controversy still exists regarding the quality of evidence as well as cost-effectiveness of RFA for chronic low back pain, there is nonetheless a considerable amount of published data that supports its safety and efficacy [19,20]. A recent published meta-analysis of placebo-controlled RCTs concluded that RF therapy for lumbar facet joint pain exhibits significant long-term benefits with regard to pain relief and improvement in disability [10]. However, it is now understood that medical interventions can perform quite differently in the context of strictly regimented controlled trials versus that of the real-world clinical setting [21]. In this regard, the manner of collection and volume of data acquired via the RAPID study is designed to allow for a more representative "snapshot" of what is thought most likely to occur in the context of routine, properly-conducted clinical practice (in accordance with established practice guidelines) in patients utilizing RF therapies for chronic low back (facetogenic) pain. Furthermore, where there is disagreement concerning the collective value of efficacy data derived from RCTs due to the significant heterogeneity in trial design and execution, it becomes all the more important to supplement RCT data with high-quality Real-World Evidence (RWE), so as to strive for a more complete understanding of the safety and effectiveness of a particular intervention [11,21]. In this way, integration of RCT and RWE data may very well be key to undertaking a more holistic approach toward the generation of clinical evidence for which neither study approach alone can exclusively provide.

Historically, on the basis of data described from several prior studies, the estimated responder rate in patients treated with RF therapy for lumbar-based chronic low back pain has typically been recognized to fall within a range of 50%–60% (i.e., proportion of those who report at least 50% or greater pain relief) [11,22]. The determined responder rates at follow-up derived from this RAPID study lumbar-specific cohort were in fact found to exceed this estimated range. Moreover, the relatively high proportion responders with ≥50% pain relief (≥69%; range: 69%–79% out to 24-months) was in line with consistent and statistically significant decreases in mean NRS scores documented at each examined follow-up visit. These data are undoubtedly in part a consequence of the increased adoption of properly conducted technique which is known to be critical for successful outcomes in patients treated for chronic pain using RF [23]. For example, most patients in the RAPID study, in accordance with previously published reports, were treated with a parallel RF approach technique (>90%), per a caudal to-cranial cannula trajectory, thereby providing for more optimal ablation and coagulation of the lumbar

medial nerves. Additionally, over 70% of cannulae used were 18-gauge or larger, with over 80% having an active tip length of 10 mm. Data from a recent *ex vivo* study suggest that these equipment selections could produce larger lesion sizes, potentially addressing some technical limitations of RFA and optimizing lesion size to ensure effective targeting of the intended nerve (i.e., medial branch or dorsal ramus of L5) [23]. Notably, a highly publicized study (MINT) – which reported less than satisfactory clinical outcomes in patients using RF therapy for chronic pain – was found to have conducted procedures using questionable techniques (including use of perpendicular approaches and small 22-gauge needles) as well as other aspects leading to poor patient selection [23,24]. In this regard, sites selected for participation in the RAPID study were deliberately chosen in part on the basis of center/provider board-certification, practical experience, and expertise in performing RF procedures as well as selection of patients who are most appropriate for RFA therapy.

Functional improvement following treatment for chronic low back pain, as assessed using the Oswestry Disability Index (ODI), has been conventionally thought to be therapeutically successful when at least a difference of 10-points is recorded between pre- and post-treatment ODI score [25]. However, to date, no standardized method for determination of minimal clinically important difference (MCID) for ODI in patients with chronic low back pain has ever been formally adopted [26,27]. As such, several prior studies assessing patients using RF approaches for chronic pain have utilized different methods to calculate thresholds ranging from a mean change from baseline of 5-points (at a minimum) to 15-points (at a maximum) for use in defining an MCID as a classification for a successful outcome [28–31]. Moreover, an array of MCIDs for mean change in ODI score have been utilized across several different types of studies (that utilized a variety of therapeutic approaches) in patients treated for chronic low back pain (range: 4- to 15-points from baseline measurement) [31]. As observed in the RAPID study, ODI scores across all patients evaluated (n = 193) were consistently improved versus baseline ranging from 7.5- to 10.9-points out to 24-months follow-up (baseline ODI score: 38.0) representing magnitudes of change that fall in or near the middle range of MCIDs calculated in previous reports.

RFA as a procedure not only exhibits a low rate of associated adverse events but also has been shown to be cost-effective and associated with reduced opioid use [4,5,32,33]. Thus, in light of the socioeconomic costs associated with treatment of chronic low back pain, including the risk of opioid addiction and/or risk of poor outcomes linked with more invasive methods, the data derived from the RAPID study described here provides further evidence to support the notion that RFA is an indispensable therapeutic approach for use in the management of chronic low back facetogenic pain in appropriately selected patients. Even so, limitations of observational studies such as that described in this report must be acknowledged. First, unidentified confounders within an observed study population could introduce bias into the collected data. This may occur as a result of the manner in which some patients are selected and/or treated, or as the result of un-documented co-morbidities. For example, because the block technique (i.e., single vs dual) or percent pain relief required to progress to RFA were not defined in the RAPID study, this could potentially bias data to appear as though the therapy is more or less effective than it genuinely may be. However, we observed that diagnostic medial branch blocks (MBBs) were recorded in approximately 98% of patients that underwent RFA, with over 95% of RFA--treated patients reporting more than 80% relief from their facetogenic pain during the blocks (note: overall proportion of all MBB responders was not collected). This aligns with the diagnostic block percent pain relief requirement as defined in the Centers for Medicare and Medicaid (CMS) local coverage determination (LCD) [34].

Second, the nature of an observationally-based study design is such that data is obtained from routine healthcare settings (typically per standard of care). One of the challenging aspects of large, real-world observational studies is the number of patients that can be lost to follow-up. Notably however, retention of patients in the RAPID study out to 6- and 12-months remained high at 81% (151/187) and 71% (133/187), respectively. Moreover, in any large, multicenter study, the manner in which some participating treatment centers conduct patient visits and procedures may introduce a degree of variability or skew into the data, in turn theoretically disrupting the ability to fully reflect widespread practice (and outcomes) in accordance with what is likely to occur in the real-world clinical setting. Altogether, limitations of varying study designs (i.e., RCT, RWE, other), including those that may exist in the context of the RAPID study, will always behoove the need to assess clinical data in aggregate across a compendium of similarly- and differentially-designed studies, so as to cumulatively reveal the likely efficacy, effectiveness, and value of any therapy.

5. Conclusions

The RAPID study is one of the largest prospective, multicenter observational studies ever to be conducted in patients treated with RFA for chronic low back facetogenic-based pain as assessed out to 1- and 2-years follow-up. In this lumbar-specific (lumbar face joint syndrome, LFJS) cohort, clinically meaningful and durable improvements in pain relief, functional disability, quality-of-life and treatment satisfaction were observed across all follow-up visits, including no unanticipated serious adverse events. The clinical evidence provided by the RAPID study offers an indication of the representative clinical outcomes in appropriately selected patients treated according to standardized, guideline-driven RFA techniques for chronic low back, lumbar facetogenic pain.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Pain Diagnostics and Interventional Care (Sewickley, PA) reports research support was provided by Boston Scientific Corporation. Joseph Atallah reports research support was provided by Boston Scientific Corporation. Ann Pan reports a relationship with Boston Scientific Corporation that includes: employment. Daniel S. Halperin reports a relationship with Boston Scientific Corporation that includes: employment. Edward Goldberg reports a relationship with Boston Scientific Corporation that includes: employment. This study is sponsored by Boston Scientific. All other authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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