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Use of Cooled Radiofrequency Lateral Branch Neurotomy for the Treatment of Sacroiliac Joint-Mediated Low Back Pain: A Large Case Series

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Abstract

Background. The sacroiliac joint (SIJ) complex has been identified as a common source of chronic low back pain. Radiofrequency (RF) neurotomy has been investigated in recent years as a minimally invasive treatment option for SIJ-mediated low back pain. A number of RF neurotomy methodologies have been investigated, including the use of cooled RF.

Objective. To retrospectively evaluate the use of cooled RF lateral branch neurotomy (LBN) to treat chronic SIJ-mediated low back pain in a large European study population.

Study Design. The electronic records of 126 patients with chronic low back pain who underwent treatment with cooled RF LBN were identified. Subjects were selected for treatment based on physical examination and positive response (≥50% pain relief) to an intra-articular SIJ block. Cooled RF LBN involved lesioning the L5 dorsal ramus and lateral to the S1, S2, and S3 posterior sacral foraminal apertures. Visual analog scale (VAS) pain scores, quality of life, medication usage, and satisfaction were collected before the procedure, at 3–4 weeks postprocedure (N = 97), and once again between 4 and 20 months postprocedure (N = 105).

Results. When stratified by time to final follow-up (4–6, 6–12, and >12 months, respectively): 86%, 71%, and 48% of subjects experienced ≥50% reduction in VAS pain scores, 96%, 93%, and 85% reported their quality of life as much improved or improved, and 100%, 62%, and 67% of opioid users stopped or decreased use of opioids.

Conclusions. The current results show promising, durable improvements in pain, quality of life, and medication usage in a large European study population, with benefits persisting in some subjects at 20 months after treatment. These results are consistent with previous study findings on the use of cooled RF to treat SIJ-mediated low back pain.

Key Words. Chronic Pain; Sacroiliac Joint; Cooled Radiofrequency; Intra-articular SIJ Block; L5 Dorsal Ramus (L5DR); Low Back Pain; S1-S3 Dorsal Rami

Introduction

The prevalence of sacroiliac joint (SIJ) pain among patients with chronic axial low back pain is reported to be between 18% and 30% [1,2]. Pain of sacroiliac origin may be difficult to diagnose because it can be confused with referred pain from other low back structures. Diagnosis of SIJ pain typically consists of physical examination, including medical history and a series of provocation maneuvers, followed by diagnostic blocks [3]. Some authors have advocated a single diagnostic block, while others have advocated confirmatory (double) diagnostic blocks with anesthetics of different duration of effect [1,2,4–7].

In early anatomical studies, the SIJ was reported to have both dorsal and ventral innervation [8]. More recent anatomical studies have demonstrated predominantly dorsal innervations from the L5 dorsal ramus (L5DR) and the S1-S3 dorsal rami, with contribution from the S4 level [6,9,10]. The sacral lateral branches exiting the posterior foramina display a variable running course between individuals and from side to side in the same individual. These branches can run along the surface of the sacrum or travel distally into the posterior ligaments [11].

A number of radiofrequency (RF) lateral branch neurotomy (LBN) techniques have been described, with treatment

parameters and outcome reporting varying widely across studies [10,12–17]. Cooled RF is a novel technology whereby internally cooled RF probes can reportedly yield larger tissue lesions than those created by standard RF probes [18]. Theoretically, large lesion size should help target the inconsistent course of the sacral lateral branch nerves. Previously published results on using cooled RF probes to treat chronic SIJ pain have demonstrated ≥50% pain relief in 50% and 64% of subjects at 3–4 months, respectively [18,19]. A retrospective analysis of a large series of patients found the use of cooled RF technology to be the only positive predictor of treatment success [17]. Further, a recent evidence-based review of SIJ pain treatment options has recommended cooled RF LBN for subjects who fail or receive only short-term effects from intra-articular injections [3]. This is the first study to examine the efficacy of cooled RF LBN in a European population and also the first study to report study outcomes up to 20 months in duration.

Methods

The medical charts of consecutive subjects treated with cooled RF LBN between January 7th, 2008 and May 26th, 2009 were reviewed.

To be treated with cooled RF LBN, patients needed to present with the following characteristics: chronic low back pain for equal to or longer than 6 months and a visual analog scale (VAS) pain score of greater than or equal to 5; pain localized in the SIJ region; signs and symptoms of SIJ-mediated low back pain upon physical examination; previous failure to achieve adequate improvement with conservative noninvasive treatments; and received ≥50% relief from a single fluoroscopically confirmed intra-articular SIJ injection (2.5 mL lidocaine 2% and 1-mL bupivacaine 0.5%, plus 0.5- to 1-mL iopamidol 200 mg/mL). Patients were not considered for treatment if they received pain relief for a duration longer than what could be achieved with lidocaine and bupivacaine, and if they had incorrect expectations. Furthermore, patients were asked before treatment about their maximal and minimal daily pain and the relationship between pain increase/decrease during activity. After the test-block, in order to examine the relationship of pain provocation(pain with movement) and the resulting pain reports, patients were required to fill out a pain diary noting their VAS every 30 minutes for about 6 hours.

Patients were treated with cooled RF LBN at Medizinisches Zentrum SchmerzLos Linz, Austria and Medizinisches Zentrum SchmerzLOS, Baden/Vienna, Austria. Minimal sedation was used, allowing subjects to communicate for the duration of the procedure. With the subject prone, the L5/S1 disk space was visualized in anterior-posterior view using a C-arm fluoroscope.

Local anesthesia on all sacral levels and skin entry points (lidocaine 2%/bupivacaine 0.5%, 1:1, total volume 12 cc). Thin-gauge needles were placed into the posterior aspect of the S1, S2, and S3 sacral foramen to mark internal reference points for probe placement. A stainless steel ruler (Epsilon Ruler, Baylis Medical, Inc., Montreal, Canada) was placed on the skin near the insertion site, and the central spoke aligned with the lateral border of the S1 foramen. An introducer with stylet was inserted onto the bone end point of the posterior sacrum, a safe distance dependent on lesion size, to the sacral foramen (foraminal needle) on the sacral gutter, and the stylet was removed and replaced with a RF probe. A lateral fluoroscopic image was examined to ensure that the probe was not within the sacral canal. Tissue impedence was verified, and if above 500 ohms (best between 100–300 ohms), the probe position was slightly adjusted. This was repeated as necessary until both an appropriate impedence and location were achieved. RF energy was then delivered for 2 minutes and 30 seconds to achieve a target electrode temperature of 60°C. This technique was repeated to create three lesions lateral to S1 and S2 sacral foramina and two lesions lateral to the S3 sacral foramen. Only one skin entry point was used at each sacral level, and the introducer with stylet pivoted to reach each of the target sites. The eight sequential lesions, roughly 1 cm apart, produced a strip of lesioned tissue running along the lateral aspect of the S1-S3 sacral foramina.

The L5DR was lesioned by first obtaining an anterior-posterior view to visualize the notch between the ala and the superior articular process of the sacrum. The introducer with stylet was inserted from a point slightly lateral and inferior to the target until contact was made with the target bony end point. Using a lateral view, the needle was confirmed to be no deeper than the anterior-posterior midline of the superior articular process to avoid lesioning the L5 segmental nerve root. The stylet was removed, and a small amount of local anesthetic administered to the target site through the introducer. RF energy was delivered for 2 minutes and 30 seconds with a target temperature of 60°C. Subjects were monitored closely during lesioning for pain in the groin, anterior thigh, lower leg, and foot.

A total of nine lesions were created during the procedure: one at the L5DR, three lateral to the S1 and S2 sacral foramina, and two lateral to the S3 sacral foramen (Figure 1). All lesions were created using the Pain Management SInergy System (Kimberly Clark Corporation, Roswell, GA, USA). Subjects who received bilateral treatment received contralateral treatment a minimum of 2 weeks after the first treatment.

A total of 126 charts were reviewed. Charts were required to have a pain score recorded before treatment and once again between 4 and 20 months after treatment. Of the 126 charts, 21 had incomplete data: nine subjects were lost to follow-up, two had psychological barriers to reporting outcomes, three had incomplete records, and seven had confounding sources of pain or disease states that prevented follow-up (two herniated disk, two rheumatoid arthritis, one spastic paraparesis and full body pain, one inflammation of nerve roots, and one hospitalized with liver disease). The remaining 105 charts were suitable for analysis.

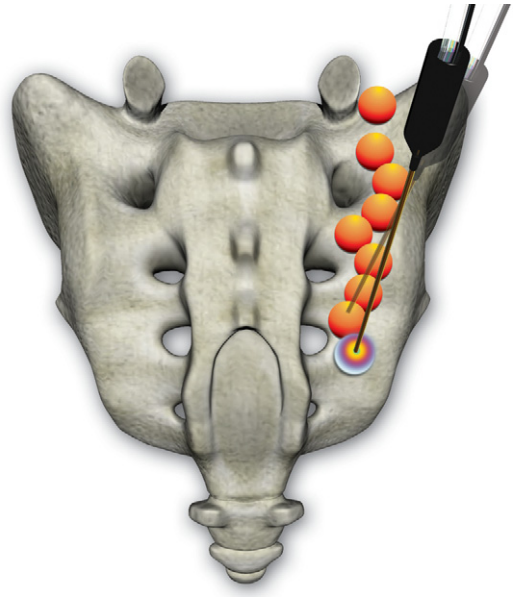

Figure 1 Illustration of lesioning pattern during cooled radiofrequency lateral branch neurotomy. Three lesions were created lateral to the S1 and S2 sacral foramina, two lesions lateral to the S3 sacral foramen, and one lesion to target the L5 dorsal ramus (Source: Kimberly Clark).

Follow-up was conducted once at 3–4 weeks after treatment and subsequently once between 4 and 20 months after treatment. At follow-up, the following outcome instruments were used: VAS for pain and multiple-choice questions for quality of life (much improved, improved, same, worse) for use of medication since treatment (none, less, equal) and for whether subjects would repeat treatment (yes, no, yes if insurance paid more). For pain scores, at inception and follow-up, the mean score and standard deviation were calculated. As well, calculated were the proportions of patients who achieved at least 50% relief of pain, which is a measure used in previous studies [10,14,19] and the proportions of patients who achieved reductions of pain by more than 2/10, which is the minimal clinically important change for back pain [20,21].

Of the 105 charts, 97 had data on pain scores at 3–4 weeks. These were used to assess the association between response to diagnostic block and short-term response to treatment. All 105 charts were used to assess the durability of response to treatment. The subjects were stratified according to the time to final follow-up: 4–6 months (mean 4.9 ± 0.7 months; N = 26), 6–12 months (mean 7.9 ± 1.6 months; N = 45), and more than 12 months (mean 17.5 ± 2.8 months; N = 34).

Comparisons were made using paired and unpaired *t*-tests for continuous data, Fisher's exact test and Pearson's χ^2 test for categorical data, and one-way analysis of variance for comparison of baseline continuous data. Proportions were compared using 95% confidence intervals. All statistics were calculated, and all graphs were generated using Microsoft Excel 2007 (Microsoft, Redmond, WA, USA) and GraphPad InStat (GraphPad Software, Inc., La Jolia, CA, USA).

A number of studies have used a ≥50% reduction in VAS pain scores as a marker of treatment success [10,14,19]. In this study, 86% (73–99), 71% (58–84), and 48% (31–65) of subjects in the 4–6, 6–12, and >12 months of follow-up groups, respectively, achieved ≥50% reduction in VAS pain scores (Table 2).

A clinically significant decrease in VAS has been defined in the literature as a two-point decrease [20,21]. The proportions of patients who achieved at least a two-point reduction in pain were 92% (82–100), 84% (73–95), and 74% (59–98) in the groups at 4–6, 6–12, and >12 months, respectively.

Results

The three groups of patients did not differ significantly with respect to demographic features, presenting features, and early response to treatment (Table 1). Statistically, the groups did differ with respect to pain scores after the diagnostic block, but the magnitude of the difference was not clinically significant (Table 1). Significantly fewer of the patients followed at 4–6 months had a prior history of surgery, but the other two groups had statistically similar proportions with such a history (Table 1).

The results of cooled RF LBN on VAS pain scores reported 4–20 months post-treatment are shown in Table 2. A significant decrease in mean VAS pain score from baseline was observed in all follow-up groups, as follows: 8.52 ± 1.07 to 2.34 ± 2.27 in the 4–6 months group; 8.07 ± 1.11 to 2.64 ± 2.67 in the 6–12 months group; and 7.99 ± 1.44 to 4.10 ± 2.93 in the >12 months follow-up group ($P < 0.001$, for all).

No serious complications were encountered during the course of the study. Recovery after treatment was consistent with that of other RF procedures.

Substantial proportions of patients in each of the three groups achieved at least 50% relief of pain (Table 2). Although the proportions of patients followed for 4–6 and 6–12 months are not significantly different statistically, the proportion of those followed for 12 months is significantly less than those followed for 4–6 months.

Quality of Life

The results of cooled RF LBN on quality of life at final follow-up are reported in Figure 2. In the 4–6, 6–12, and >12 months follow-up groups, respectively, 79% (63–95), 70% (53–84), and 69% (53–85) rated their quality of life as much improved; 17% (2–32), 23% (11–36), and 16% (3–28) rated their quality of life as improved; and 4%

Table 1 Demographic and clinical characteristics, for the entire study population and stratified by time to final follow-up

Feature	4–6 Months Follow-Up Group (N = 26)	6–12 Months Follow-Up Group (N = 45)	>12 Months Follow-Up Group (N = 34)
Age	66 ± 11.5	67 ± 14.0	70 ± 12.3
Gender	15% male, 85% female	36% male, 64% female	26% male, 74% female
Baseline opioid users	5	13	15
Bilateral	0	0	1
VAS before diagnostic block	8.52 ± 1.07	8.07 ± 1.11	7.99 ± 1.44
VAS after diagnostic block	1.21 ± 1.38	1.42 ± 1.28	2.10 ± 1.40*
VAS at 3–4 weeks after treatment (N = 97)	1.59 ± 1.44 (N = 24)	1.50 ± 1.86 (N = 42)	1.69 ± 1.76 (N = 31)
Surgery before study	92% none; 8% minimally invasive or open surgery; 0% spinal fusion	64% none; 19% minimally invasive or open surgery; 17% spinal fusion**	77% none; 23% minimally invasive or open surgery; 0% spinal fusion

* $P = 0.025$ comparing >12 months with 4–6 months group.
** $P = 0.032$ comparing 6–12 months with 4–6 months group.
VAS = visual analog scale.

Table 2 Percentage of subjects who achieved ≥50–100% visual analog scale (VAS) pain score reduction stratified by time to final follow-up

VAS Decrease at Final Follow-Up (%)	4–6 Months (N = 26) % (95% CI)	6–12 Months (N = 45) % (95% CI)	>12 Months (N = 34) % (95% CI)
100	27 (10–44)	38 (24–52)	15 (3–27)
≥90	35 (17–53)	40 (26–54)	18 (5–31)
≥80	43 (24–62)	44 (30–59)	24 (10–38)
≥70	55 (36–74)	53 (38–68)	33 (17–49)
≥60	82 (67–97)	64 (50–78)	45 (28–62)
≥50	86 (73–99)	71 (58–84)	48 (31–65)

CI = confidence interval.

(0–12), 7% (0–15), and 16% (3–28) rated their quality of life as the same. No subjects in any group reported a worsening in quality of life following treatment. Two subjects in each follow-up group were missing quality-of-life data.

In each of the three groups, similar proportions of patients rated their quality of life as much improved, improved, or the same, with the majority considering themselves much improved (Figure 2). Similar proportions in the three groups ceased or reduced consumption of opioids or nonsteroidal anti-inflammatory drug (NSAID) (Figure 3).

The effect of cooled RF LBN on pain medication use at final follow-up are reported in Figure 2. In the 4–6, 6–12, and >12 months follow-up groups, respectively, 80% (45–100), 31% (6–56), and 20% (0–40) of baseline opioid users reported stopping opioid use, and 20% (0–55), 31% (6–56), and 47% (21–72) of baseline opioid users reported using less opioids. Similarly, in the 4–6, 6–12, and >12

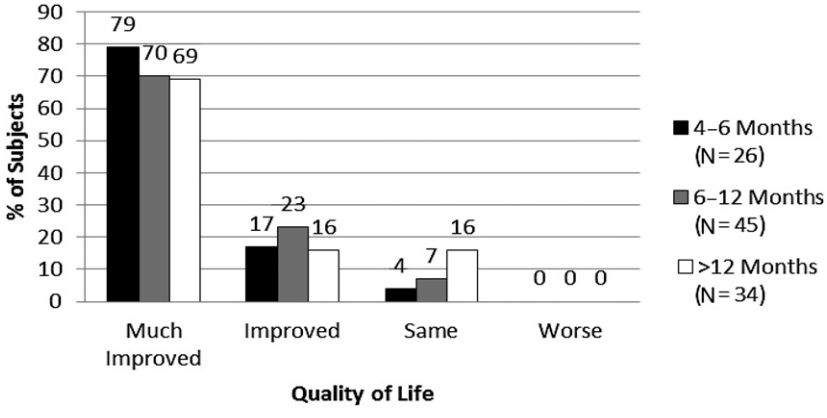

Figure 2 Bar graph demonstrating patient-reported quality-of-life outcomes at final follow-up, with subjects stratified by time to final follow-up.

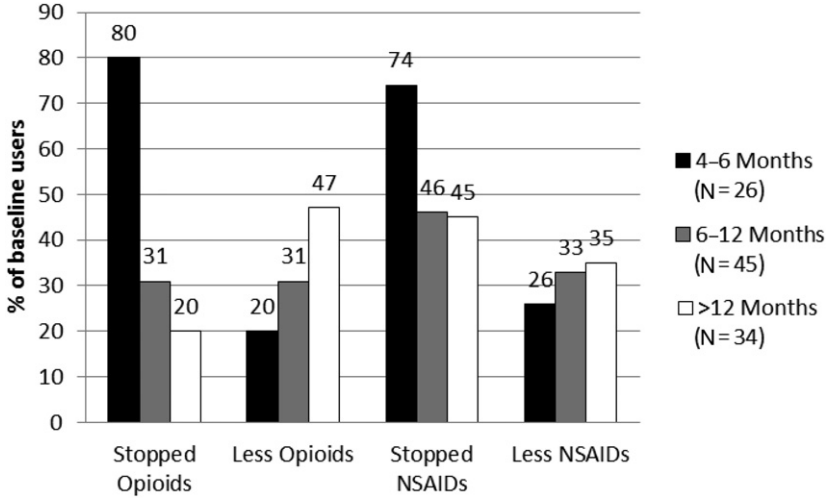

Figure 3 Percentage of baseline opioid and nonsteroidal anti-inflammatory drug (NSAID) users who stopped or decreased use, with subjects stratified by time to final follow-up.

months follow-up groups, respectively, 74% (54–93), 46% (26–66), and 45% (23–67) of baseline NSAID users reported stopping NSAID use, and 26% (7–46), 33% (14–52), and 35% (14–56) of baseline NSAID users reported using less NSAIDs. Data were missing for two subjects in the 4–6 months follow-up group, three subjects in the 6–12 months follow-up group, and four subjects in the >12 months follow-up group.

At final follow-up, of the patients followed for 4–6, 6–12, and >12 months respectively, 79% (63–95), 77% (65–90), and 71% (55–87) reported that they would repeat the treatment, and 21% (5–37), 18% (7–30), and 19% (5–33) would repeat the treatment if insurance coverage was better. Only 0%, 5% (0–11), and 10% (0–20) of patients reported that they would not repeat the treatment.

The diagnostic utility of intra-articular SIJ injections was evaluated in this study. A trend was detected between the pain score after diagnostic block and the pain score at 3–4 weeks after treatment (Figure 4). The Pearson's product moment correlation coefficient for this relationship was 0.58, reflecting a moderate-to-strong correlation. This means that response to blocks explains only about 34% of the variance in response to treatment (Figure 4).

Discussion

In this study, the proportion of subjects who achieved a ≥50% decrease in VAS pain scores was the same or greater than what has been observed in other retrospective studies of LBN [10,12,14,16,17,19]. Furthermore, the success rate of LBN reported in the present study is similar to the retrospective study results on RF neurotomy for lumbar facet joint pain [22]. The majority of subjects in this study, regardless of duration of follow-up, achieved a minimum two-point drop in VAS pain score, which has been defined as a clinically meaningful reduction in pain [20].

The results of this retrospective case series suggest that cooled RF LBN is an effective treatment option for chronic back pain originating in the SIJ complex. LBN aims to ablate the dorsal innervation of the SIJ, which consists of the L5DR and the S1-S3 sacral lateral branches [10]. The inconsistent course of the sacral lateral branch nerves

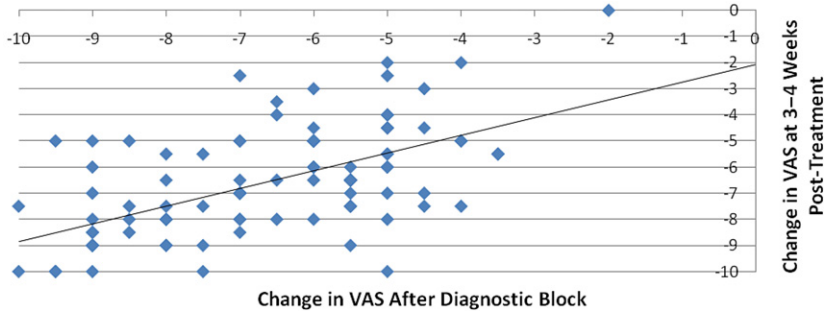

Figure 4 Scatter plot showing change in visual analog scale (VAS) pain scores after intra-articular sacroiliac joint diagnostic block plotted against change in VAS pain scores 3–4 weeks after treatment with cooled radiofrequency lateral branch neurotomy for the 97 subjects with data collected at 3–4 weeks.

necessitates a lesion profile that encompasses as much of the area lateral to the S1-S3 posterior sacral foraminal apertures as is possible and safe. The use of cooled probes allows target tissue temperature to reach 75°C, while the temperature immediately surrounding the electrode remains at 60°C [23]. This prevents tissue charring at the electrode, thereby providing minimal postprocedure pain and dysthesia, and produces lesions from 8 to 10 mm in diameter [18]. Using cooled RF probes for LBN should theoretically help target the inconsistent running course of the lateral branch nerves by creating a large, confluent strip of lesioned tissue lateral to the posterior sacral foraminal apertures. The positive short-term results and durability of outcomes seen in this study could be explained by the larger lesioning pattern afforded by the cooled RF technology.

The durability of pain relief reported in this study is consistent with other studies of RF neurotomy for SIJ-mediated back pain and lumbar facet pain, with mid- to long-term follow-up [10,14,17,18,22,24]. Relief was maintained beyond 6 months, but a trend toward decreasing benefit for VAS pain scores, quality-of-life scores, and medication use was seen as time to final follow-up increased. Despite this trend, many subjects in the >12 months follow-up group (mean 17.5 months follow-up) had pronounced improvements, with some exhibiting benefits at 20 months post-treatment. Return of pain is presumably due to regeneration of afferent nociceptive pathways.

The durability analysis in this study presumed that the subject groups were equivalent in their baseline characteristics. This is a reasonable assumption because the subjects were consecutive from the authors' practices. Furthermore, the three follow-up groups (4–6, 6–12, and >12 months follow-up) did not differ significantly in baseline characteristics (age, gender, baseline VAS pain scores) or in VAS pain scores at 3–4 weeks post-treatment (Table 1). There was a statistically significant weaker response to the diagnostic blocks in the >12 months follow-up groups, and there were significantly fewer surgeries performed on subjects prior to the study in the 4–6 months group. These differences, however, are likely statistical artifacts and should have no bearing on the interpretation of results, as there was no difference in short-term outcomes (3- to 4-week data) between the three long-term follow-up groups (Table 1).

Limitations of this study are those that apply to all retrospective studies: no control group to account for confounders, such as the placebo effect; difficulty in contacting certain subjects; and missing data for some subjects. A unique limitation of this study was the variable length of time to final follow-up. However, homogeneity among the follow-up groups allows a reasonable assessment of procedural durability.

A single intra-articular diagnostic block was used in selecting patients to undergo cooled RF LBN. Despite the recommendation of the International Spine Intervention Society to perform comparative local anesthetic blocks, the authors preferred the use of a single block in their practices. This study demonstrated a moderate positive correlation between pain relief from diagnostic block and pain relief at 3–4 weeks of follow-up. In the context of this study, the use of single intra-articular blocks was effective in selecting patients to undergo cooled RF LBN. Additionally, it is worth noting that during the course of the study, a total volume of 3.5 mL of local anesthetic was used for blocking, but as of 2010, the authors have adopted the newer recommendation of a total volume of 1.5 mL.

This is the first published study on cooled RF LBN to report outcomes in a European population and the first to report outcomes up to 20 months in duration. Many regions in Europe have yet to adopt this treatment modality, but these results are encouraging and in line with, if not more positive, than those reported in American studies of cooled RF LBN [18,19]. These results further support the recommendation of cooled RF LBN as the treatment option for subjects who are not able to achieve adequate benefit from conservative medical management or therapeutic SIJ injections [3]. The decreases in chronic pain and medication usage, along with the improvement in quality of life and high amount of treatment satisfaction, may justify the use of cooled RF equipment in a broader population.

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