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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 - Compared with other Techniques

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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 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 ($\geq 50\%$ pain relief) to an intra-articular SIJ block. Cooled RF LBN involved lesioning the L5 dorsal ramus (L5DR) and lateral to the S1, S2 and S3 posterior sacral foramina. Visual analog scale (VAS) pain scores, quality of life, medication usage, and satisfaction were collected before the procedure, at 3-4 weeks post-procedure ($n=97$), and once again between 4-20 months post-procedure ($n=105$).

Results: When stratified by time to final follow-up (4-6 months, 6-12 months, >12 months, respectively): 86%, 71% and 48% of subjects experienced $\geq 50\%$ reduction in VAS pain scores; 96%, 93%, and 85% reported their quality of life as Much Improved or Improved; and, 100%, 76%, and 70% reported their medication use as Less or None.

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 to 20 months following treatment. These results are consistent with previous study findings on the use of Cooled RF to treat SIJ mediated low back pain.

Keywords: Neurotomy; Sacroiliac joint; Low back pain

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]. Pure SIJ pain 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 innervations [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 radiofrequency (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 running course of the sacral lateral branch nerves. Previously published results on using Cooled RF probes to treat

chronic SIJ pain have demonstrated $\geq 50\%$ pain relief in 50% and 64% of subjects at 3 and 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 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 the following characteristics: chronic low back pain for longer or equal to 6 months; a visual analogue scale (VAS) pain score of greater or equal to 5; pain

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localized in the SIJ region; signs and symptoms of SIJ mediated low back pain upon physical examination; previously failed to achieve adequate improvement with conservative non-invasive treatments; and, received $\geq 50\%$ 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, if they had incorrect expectations.

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 was used on all sacral levels and skin entry points (lidocaine 2%/bupivacaine 0.5%, 1:1, total volume 12 ml). 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. This was positioned at a safe distance 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 impedance was verified, and if above 500 ohms (optimal between 100–300 ohms), the probe position was slightly adjusted. This was repeated as necessary until both an appropriate impedance 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.

The following outcome tools were used at follow-up: visual analogue scale (VAS) pain scores, a quality of life multiple-choice question (Much Improved, Improved, Same, Worse), a multiple-choice question about medication used since treatment (None, Less,

Equal), and a multiple-choice question on whether subjects would repeat treatment (Yes, No, Yes-if insurance paid more). Follow-ups were conducted once at 3-4 weeks post treatment and subsequently once between 4 and 20 months post-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.

VAS pain score data was available in 97 of 105 charts. Data analysis for short-term response and diagnostic block predictive ability was performed on the 97 subjects at this time point. To assess the durability of response to treatment over time, 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 >12 months (mean 17.5 ± 2.8 months) ($n=34$) (Figure 2).

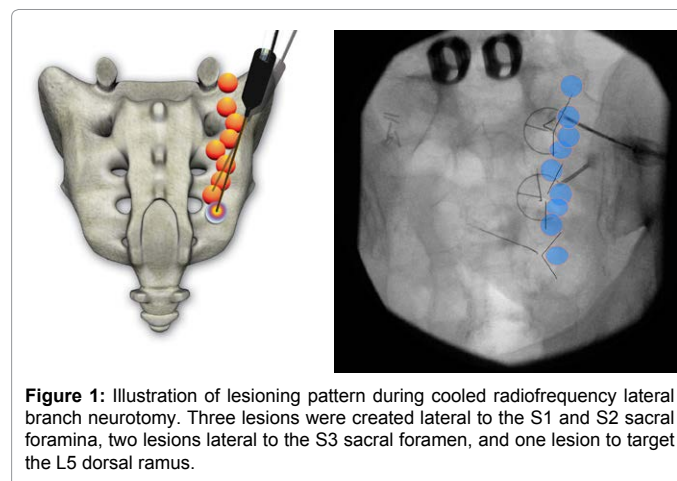
Results

No serious complications were observed during the course of the study, and post-procedural recovery was consistent with other RF procedures. Mean VAS pain score dropped significantly at 3-4 weeks after treatment ($P<0.001$) (Figure 3).

In Table 1, demographic characteristics are stratified by time to final follow-up.

The results of Cooled RF LBN on VAS pain scores reported 4-20 months post-treatment are shown in Figure 4 and Table 2. A significant decrease in mean VAS pain score from baseline was observed in all follow-up groups, at all time points, as illustrated in Figure 4. A number of studies have used a $\geq 50\%$ 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 months, 6-12 months, and >12 months follow-up groups, respectively, achieved $\geq 50\%$ reduction in VAS pain scores (Table 2).

A clinically significant decrease in VAS has been defined in the literature as a 2-point decrease [20,21]. In this study, 92% (82-100), 84% (73-95), and 74% (59-89) of the 4-6 months, 6-12 months, and >12



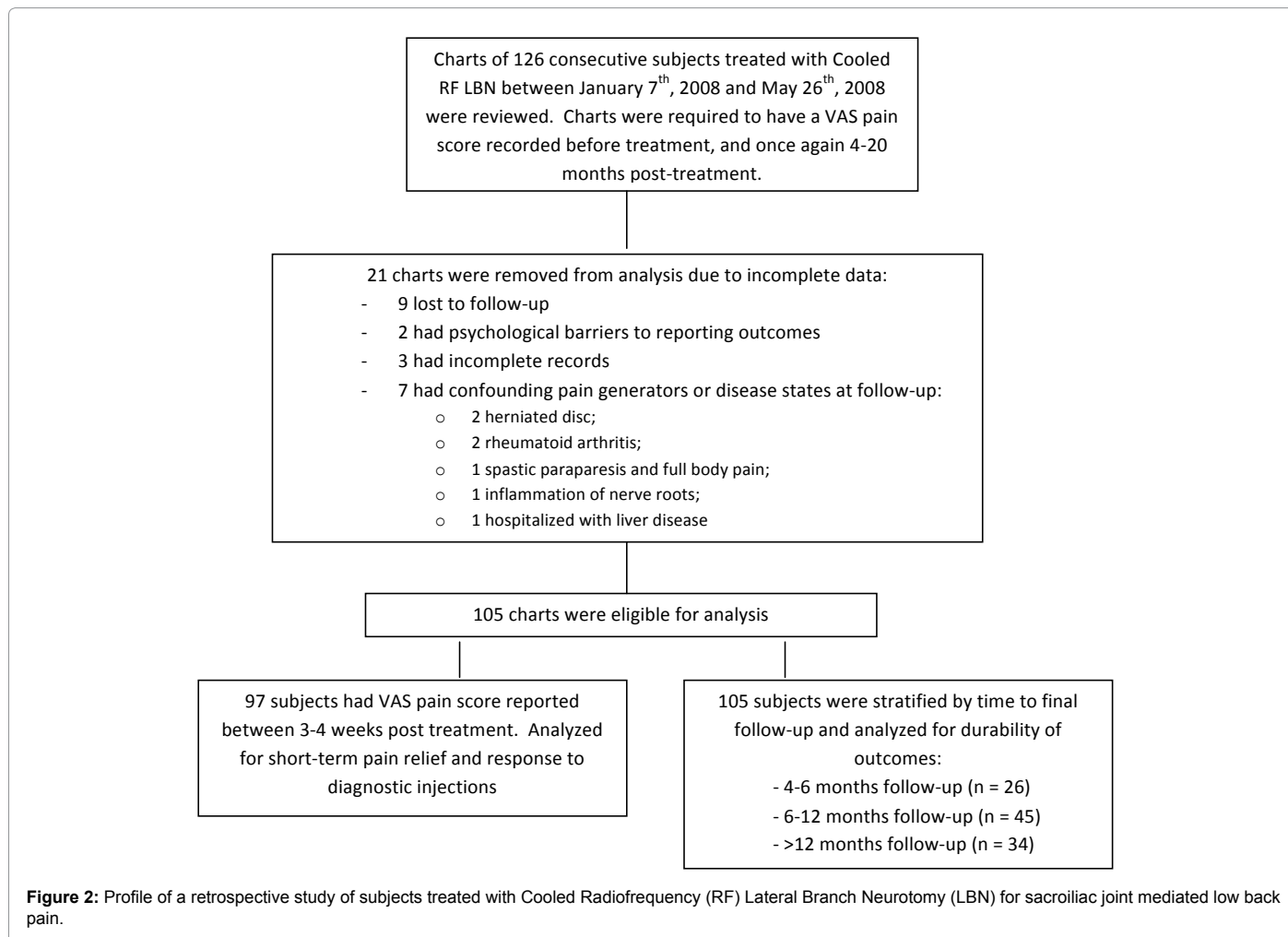


Figure 2: Profile of a retrospective study of subjects treated with Cooled Radiofrequency (RF) Lateral Branch Neurotomy (LBN) for sacroiliac joint mediated low back pain.

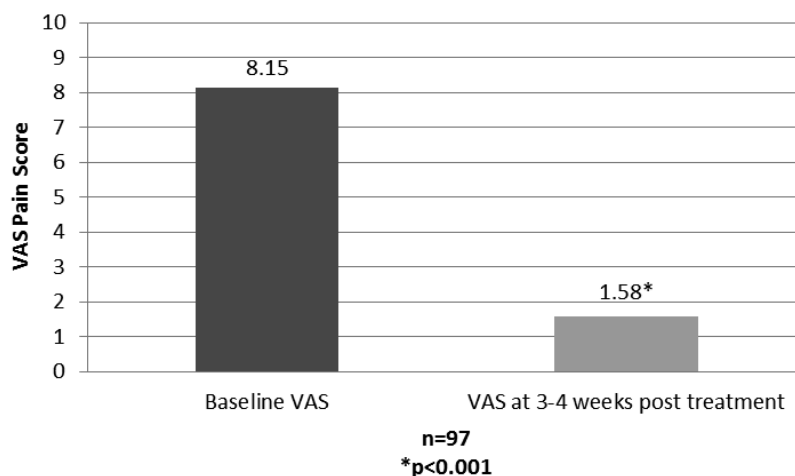


Figure 3: Mean visual analogue scale (VAS) pain scores at baseline and at 3-4 weeks after treatment with Cooled Radiofrequency Lateral Branch Neurotomy, for 97 subjects with 3-4 week follow-up data.

months follow-up groups, respectively, achieved a 2-point decrease in VA pain scores (Table 3).

The results of Cooled RF LBN on quality of life at final follow-up are reported in Figure 5. In the 4-6 months, 6-12 months, 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% (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

	4-6 months follow-up group (n=26)	6-12 months follow-up group (n=45)	>12 months follow-up group (n=34)	P Value
Age	66 ± 11.5	67 ± 14.0	70 ± 12.3	0.437
Gender	15% male, 85% female	36% male, 64% female	26% male, 74% female	0.184
Bilateral	0	0	1	---
VAS Before Diagnostic Block	8.52 ± 1.07	8.07 ± 1.11	7.99 ± 1.44	0.209
VAS After Diagnostic Block	1.21 ± 1.38	1.42 ± 1.28	2.10 ± 1.40	0.025
VAS at 3-4 Weeks After Treatment (n=97)	1.59 ± 1.44	1.50 ± 1.86	1.69 ± 1.76	0.898
Surgery before study	92% none; 8% not defined; 0% intervention	64% none; 19% not defined; 17% intervention	77% none; 23% not defined; 0% intervention	0.032
	with artificial implants	with artificial implants	with artificial implants	

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

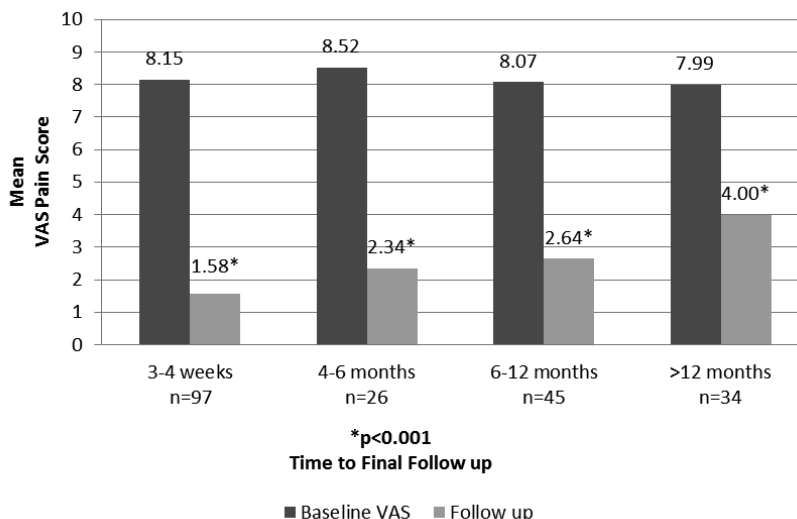


Figure 4: Mean visual analogue scale (VAS) pain scores at baseline and at final follow-up, with subjects stratified according to time to final follow-up. *P < 0.001 compared with baseline of the respective group.

VAS Decrease at Final Follow-Up	4-6 Months (n=26) % (95% Confidence Interval)	6-12 Months (n = 45) % (95% Confidence Interval)	>12 Months (n = 34) % (95% Confidence Interval)
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)

Table 2: Percentage of subjects who achieved ≥ 50-100% visual analogue scale (vas) pain score reduction, stratified by time to final follow-up.

life following treatment. Two (2) subjects in each follow-up group were missing quality of life data.

The effect of Cooled RF LBN on medication use at final follow-up are reported in Figure 6. In the 4-6 months, 6-12 months, and >12 months follow-up groups, respectively, 67% (48- 86), 43% (28-58) and 40% (22-58) of subjects reported their medication use as None; 33% (14- 52), 33% (19-48) and 30% (14-46) of subjects reported their medication use as Less; and, 0%, 24% (11-37), and 30% (14-46) of

subjects reported their medication use as the Same. Data was missing for 2 subjects in the 4-6 months follow-up group, 3 subjects in the 6-12 months follow-up group, and 4 subjects in the >12 months follow-up group.

To measure satisfaction, subjects were asked if they would repeat the procedure. At final follow-up, in the 4-6 months, 6-12 months, and >12 months follow-up groups, respectively, 79% (63-95), 77% (65-90) and 71% (55-87) of subjects reported that they would repeat the

Feature	4-6 months follow-up group		6-12 months follow-up group		>12 months follow-up group	
	n	(95% CI)	n	(95% CI)	n	(95% CI)
5-Point VAS Decrease	77	(61-93)	67	(53-81)	32	(16-48)
2-Point VAS Decrease	92	(82-100)	84	(73-95)	74	(59-89)

CI=Confidence Interval

Table 3: Proportion of subjects achieving 5-point decrease in visual analogue scale (vas) pain scores, and 2-point decrease in vas pain scores, with subjects stratified by time to final follow-up.

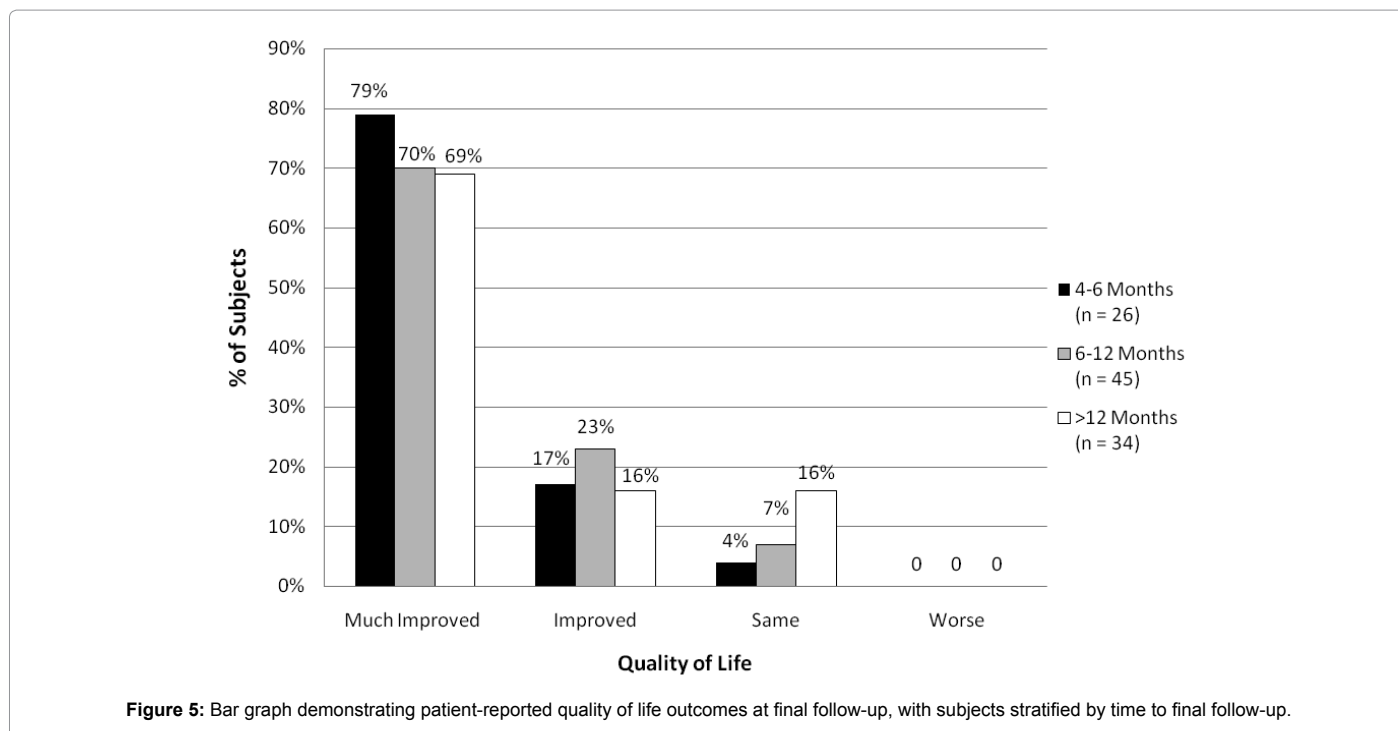


Figure 5: Bar graph demonstrating patient-reported quality of life outcomes at final follow-up, with subjects stratified by time to final follow-up.

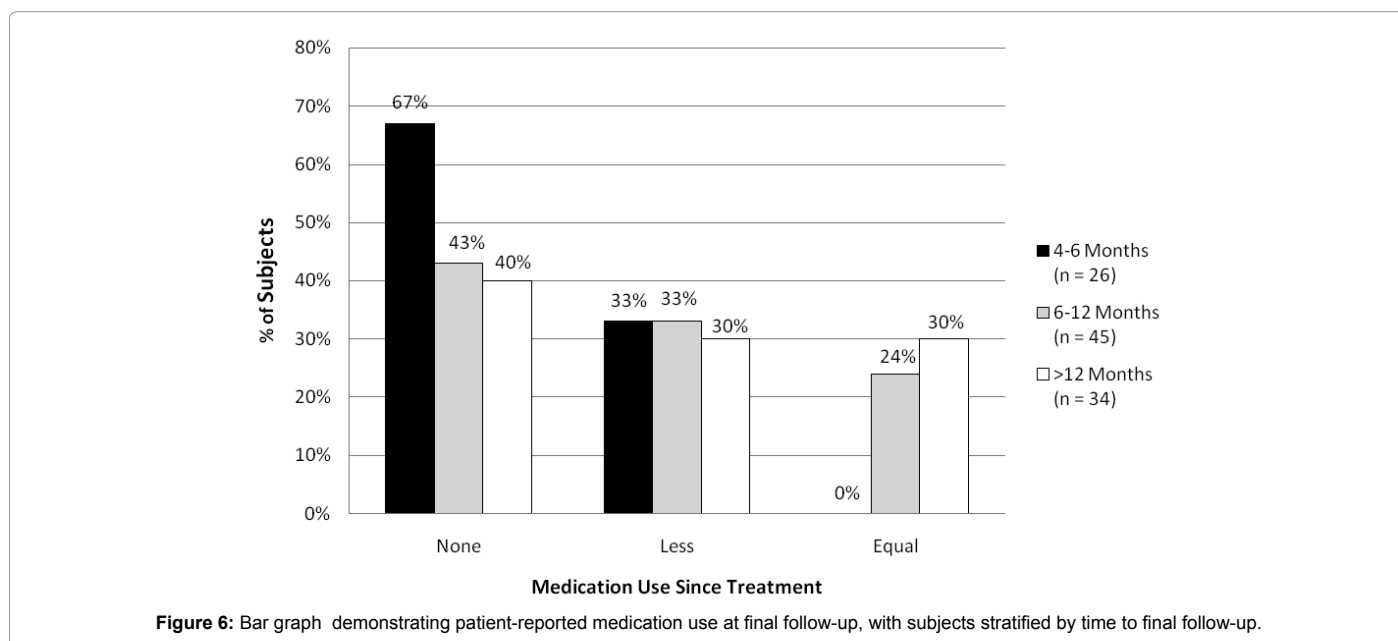


Figure 6: Bar graph demonstrating patient-reported medication use at final follow-up, with subjects stratified by time to final follow-up.

procedure; 21% (5-37), 18% (7-30), and 19% (5-33) of subjects reported that they would repeat the procedure if insurance coverage was better; and, 0%, 5% (0-11) and 10% (0- 20) of subjects reported that they would not repeat the procedure.

The diagnostic utility of intra-articular SIJ injections was evaluated in this study. A trend was observed between VAS pain score response to the intra-articular SIJ diagnostic block and pain at 3-4 weeks following treatment. The Pearson product moment correlation coefficient (r) for this relationship was 0.58, suggesting a moderate-to-strong positive correlation.

Discussion

In this study, the proportion of subjects who achieved a $\geq 50\%$ 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 this study is similar to 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 2- 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. Lateral branch neurotomy aims to ablate all known dorsal innervation of the SIJ, which consists of the L5 dorsal ramus and the S1-S3 sacral lateral branches [10]. The inconsistent running course of the sacral lateral branch nerves necessitates a lesioning profile which 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 post-procedure pain and dyesthesias, 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 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]. 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 [24] months post-treatment. Return of pain is presumably due to regeneration of afferent nociceptive pathways.

In comparison to other published results with standard RF techniques where the authors report with monopolar sensory stimulation ($n=14$), 64%-88% subjects with $>50\%$ pain relief at 6-9 month follow up and 36% pain free at 6 month [16,25,26] bipolar perforaminal RF ($n=9$) 33% of subjects report $>50\%$ pain relief, an ODI decrease of 18, and 67-89% satisfied at 6/9 months [27]; and bipolar "Palisade" technique ($n=4$) where the results were not provided in the paper but the authors stated that "clinical outcomes are positive, but have so far only been assessed informally over a short time [28]". These

reports lack the patient numbers needed to make clinical decisions on the value and efficacy of the various therapies. Our data illustrates a high response rate to the use of a cooled RF technique up to 20 months in duration with a patient population at each time point of substantial numbers to make a clinical determination of success.

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 months, 6-12 months, 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 (3-4 week data) between the three long-term follow-up groups (Table 1).

Limitations of this study are those present for 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 lateral branch neurotomy. This study demonstrated a moderate positive correlation between pain relief from diagnostic block and pain relief at 3-4 weeks follow-up. In the context of this study, the use of single intra-articular lateral branch blocks was effective in selecting patients to undergo Cooled RF lateral branch neurotomy.

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 24 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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