Prospective Evaluation

A New Radiofrequency Ablation Procedure to Treat Sacroiliac Joint Pain

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Background: Low back pain may arise from disorders of the sacroiliac joint in up to 30% of patients. Radiofrequency ablation (RFA) of the nerves innervating the sacroiliac joint has been shown to be a safe and efficacious strategy.

Objectives: We aimed to develop a new RFA technique to relieve low back pain secondary to sacroiliac joint disorders.

Study Design: Methodology development with validation through prospective observational non-randomized trial (PONRT).

Setting: Academic multidisciplinary health care system, Ohio, USA.

Methods: We devised a guide-block to facilitate accurate placement of multiple electrodes to simultaneously ablate the L5 dorsal ramus and lateral branches of the S1, S2, and S3 dorsal rami. This was achieved by bipolar radiofrequency ablation (b-RFA) to create a strip lesion from the lateral border of the base of the sacral superior articular process (L5-S1 facet joint) to the lateral border of the S3 sacral foramen. We applied this technique in 31 consecutive patients and compared the operating time, x-ray exposure time and dose, and clinical outcomes with patients (n = 62) who have been treated with the cooled radiofrequency technique. Patients' level of pain relief was reported as < 50%, 50 – 80%, and > 80% pain relief at one, 3, 6, and 12 months after the procedure. The relationship between RFA technique and duration of pain relief was evaluated using interval-censored multivariable Cox regression.

Results: The new technique allowed reduction of operating time by more than 50%, x-ray exposure time and dose by more than 80%, and cost by more than $1,000 per case. The percent of patients who achieved > 50% pain reduction was significantly higher in the b-RFA group at 3, 6, and 12 months follow-up, compared to the cooled radiofrequency group. No complications were observed in either group.

Limitations: Although the major confounding factors were taken into account in the analysis, use of historical controls does not balance observed and unobserved potential confounding variables between groups so that the reported results are potentially confounded.

Conclusion: Compared to the cooled radiofrequency ablation (c-RFA) technique, the new b-RFA technique reduced operating time by more than 50%, decreased x-ray exposure by more than 80%, and cut the cost by more than $1000 per case. The new method was associated with significantly improved clinical outcomes despite the limitations of the study design. Thus this new technique appeared to be safe, efficacious, and cost-effective.

Key words: Sacroiliac joint pain, sacroiliac joint, low back pain, radiofrequency ablation (RFA), bipolar radiofrequency ablation (b-RFA), cooled radiofrequency ablation (c-RFA), cost-effectiveness

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Low-back pain is among the most common musculoskeletal conditions worldwide and is estimated to affect nearly two-thirds of the US population at some point in their lives. The sacroiliac joint (SIJ) is a common source of chronic back pain, accounting for 13 to 30% of all cases presenting with axial low back pain (1-5). Among the most common etiologies are rheumatoid arthritis, osteoarthritis, and other degenerative changes of the joint, often precipitated by or associated with trauma, pregnancy, inflammatory bowel disease, and autoimmune disorders. Lumbar or lumbosacral fusion is another cause of SIJ pain (6). One of the challenges in the management of SIJ-mediated low back pain is the lack of efficacious and long-term treatment options. Since the first report of using radiofrequency ablation (RFA) to treat SIJ pain in 2001 (7), a number of pilot and case series studies have been published on RFA of the lateral branches of the dorsal rami of the sacral nerves that innervate the SIJ (8-16). More recently, 2 randomized controlled trials provided evidence supporting this treatment modality (17-19).

The unique innervation of the SIJ, primarily by the lateral branches of the S1, S2, and S3 dorsal rami of the sacral nerves and branches of the L5 dorsal ramus, and the significant anatomic variation in the course of these nerve branches pose significant challenges for consistent and replicable denervation by RFA (16,20,21). The cooled RFA (c-RFA) technique was recently introduced to overcome the challenges posed by the anatomical variations of the lateral branches of sacral dorsal rami (17-19). By creating larger lesions, c-RFA is expected to increase the probability of ablating the anatomically variable lateral branches and achieve more reliable and consistent outcomes. However, the larger lesions are achieved at the cost of much longer procedure time for electrode placement and tissue ablation and higher costs for equipment and disposables. A recent comparative study has failed to reveal superior outcomes of c-RFA over the traditional thermal RFA (22). It is important to perform comparative effectiveness studies when multiple options are available to treat the same disease in order to determine the most efficacious, safe, and cost-effective modality of treatment for clinical applications.

A bipolar radiofrequency ablation technique (b-RFA) was recently described to create a geometrically controlled strip lesion lateral to the sacral foramen to denature the S1, S2, and S3 lateral branches in cadavers (23). Unlike c-RFA and the traditional thermal technique, b-RFA is accomplished by completing the electrical circuit between 2 adjacent needle electrodes. It requires precise placement of multiple electrodes parallel to one another at equal distances to ensure the desired geometric shape of the lesions and effective ablation of the target nerves. We thus devised a guide-block to facilitate this process. In addition to S1, S2, and S3 lateral branches, the guide-block also allows simultaneous ablation of the L5 dorsal ramus which is also a source of SIJ innervation (21,24). Compared to c-RFA, b-RFA does not need a ground electrode and sophisticated cooling system and is easy to perform. Indeed, application of the new technique over a period of 40 months demonstrated a reduction of operating time by more than 50%, x-ray exposure time and dose by more than 80%, and cost by more than $1,000 per case. The clinical outcomes appeared to be superior as well.

Methods

The research protocol was approved by the Institutional Review Board of the Cleveland Clinic (IRB# 09-598).

Description of the new technique

The objective of the new technique was to denature the lateral branches of the S1, S2, and S3 dorsal rami as well as the L5 dorsal ramus by creating a continuous strip lesion along a straight line lateral to the sacral foramen. The strip lesion starts from the lateral aspect of the superior articular process of the L5-S1 facet joint to the lateral border of the S4 foramen. The desired lesion is approximately 60 mm (or 80 mm) long, 10 mm wide, and 10 mm deep, just above the surface of the sacrum. In order to achieve this goal, we placed 7 or 9 RF needles perpendicular to the surface plane of the sacrum. The needles were placed in such a way that they were parallel to each other with a distance of 10 mm between each pair of adjacent needles. The RF needle was 20 gauge, straight, and with an active tip of 10 mm (Cosman Med Inc., Boston, MA, USA).

Design of the guide-block

The RF probes have to be precisely placed parallel to each other in order to perform b-RFA and sequentially create a geometrically controlled strip lesion. It is technically challenging as well as time consuming to place multiple needles in parallel and at equal distances between each pair of adjacent probes. We thus designed the guide-block (Fig. 1) to facilitate the procedure and standardize the process (25).

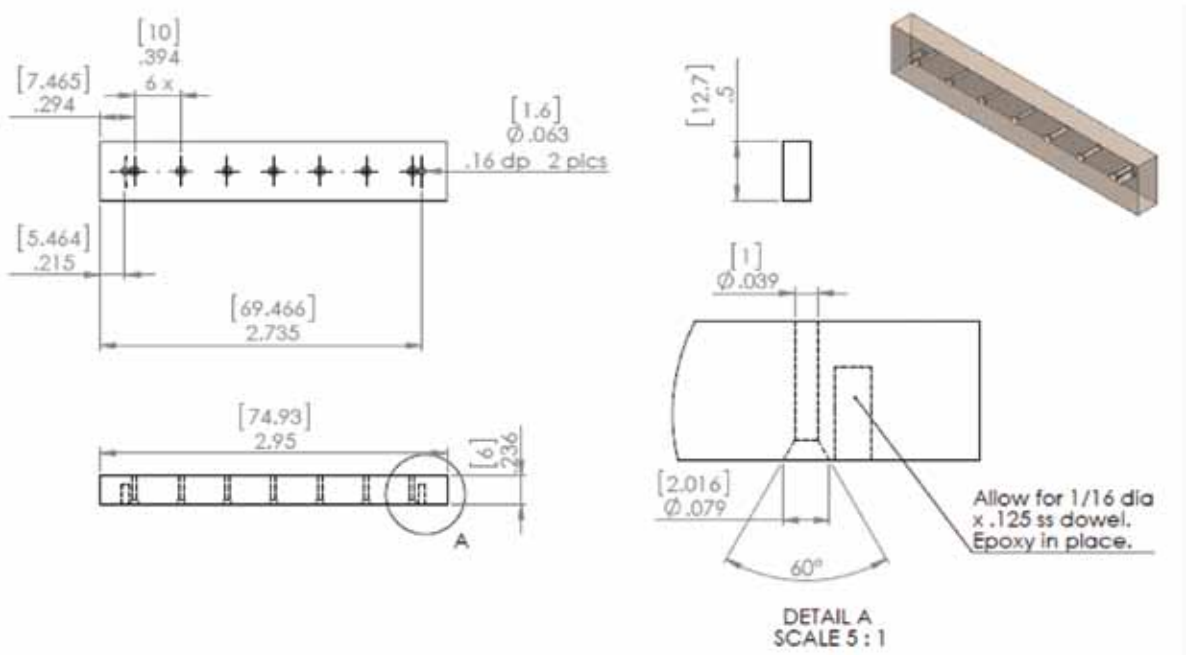

Fig. 1. *Design and blueprint of a guide-block. Dimensions for biomedical engineering of an example guide-block are provided. It gives detailed parameters of the guide-block and its amenities in 3 views as well as the overall appearance of the final product (right upper corner).*

A typical guide-block was a 90 mm long, 10 mm wide, and 6 mm thick rectangular body made of bicarbonate (Fig. 2). There were 9 through-holes along a straight line in the long axis of the guide-block with an equal distance of 10 mm between 2 adjacent RF probes. The diameter of the through-holes was 1 mm, which allows a 20 gauge straight RF needle to pass through easily without waggling space between the needle and the wall of the through-hole. One end of each through-hole has a substantially funnel shaped opening to facilitate easy insertion of the electrodes. The RF needles going through these through-holes can only be parallel to each other at a predetermined distance (10 mm) along a straight line. There were 2 radiopaque markers that were used to guide placement of the guide-block over the skin overlaying the sacrum under the guidance of fluoroscopy. The markers were imbedded in each end of the guide-block in line with the holes, about 1mm away from the first and last through-holes (Fig. 2). The markers were cylinder-shaped and were made of stainless metal with a diameter of 2 mm and a height of 3 mm. The device thus allows precise placement of multiple needles that are substantially parallel to each other at desired predetermined distances. This enables the operator to make controlled lesions via a bipolar radiofrequency configuration to ablate the target nerves. Since the device has no polarity, it can be used on the SIJ of either side. In addition to accuracy, the device and method allows the operator to place multiple RF electrodes more easily, thereby reducing the operating time and x-ray exposure time and dose. A strip lesion was made using 7 through-holes for most patients who are not taller than 200 cm (Fig. 2A). For those with a height of greater than 200 cm, a strip lesion could be made using 9 through-holes (Fig. 2B). The rationale for devising the sequential lesion patterns is to minimize the number of lesion cycles (to 3 or 4 cycles) and to reduce operating time.

The RFA procedure

RFA was performed as an ambulatory procedure using local anesthesia and light intravenous sedation if necessary. C-arm fluoroscopy was used to visualize the sacral ala, the SI joint, and sacral foramen, and to guide the placement of the RF probes. c-RFA was performed using a water-cooled heating system (Pain Management SInergy System, Baylis Medical Company, Montreal, Canada) that involves 17-gauge, 75-mm electrodes with

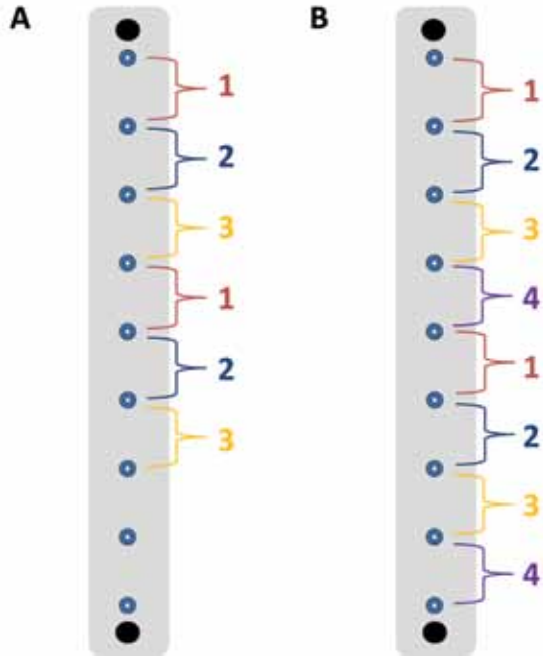

Fig. 2. *Illustration of combinations of electrode connections. A. The most commonly used combinations of connections between adjacent electrodes to make a strip lesion of 60 mm in patients with body heights < 200 cm. Four electrodes were used to make 2 lesions at a time, starting with the combination labeled 1. This process was repeated 2 more times with the combinations labeled 2 and 3. B. The combinations of electrode connections to make a strip lesion of 80 mm in patients with body heights > 200 cm. Four electrodes were used to make 2 lesions at a time, starting with the combination labeled 1. This process was repeated 3 more times with the combinations labeled 2, 3, and 4.*

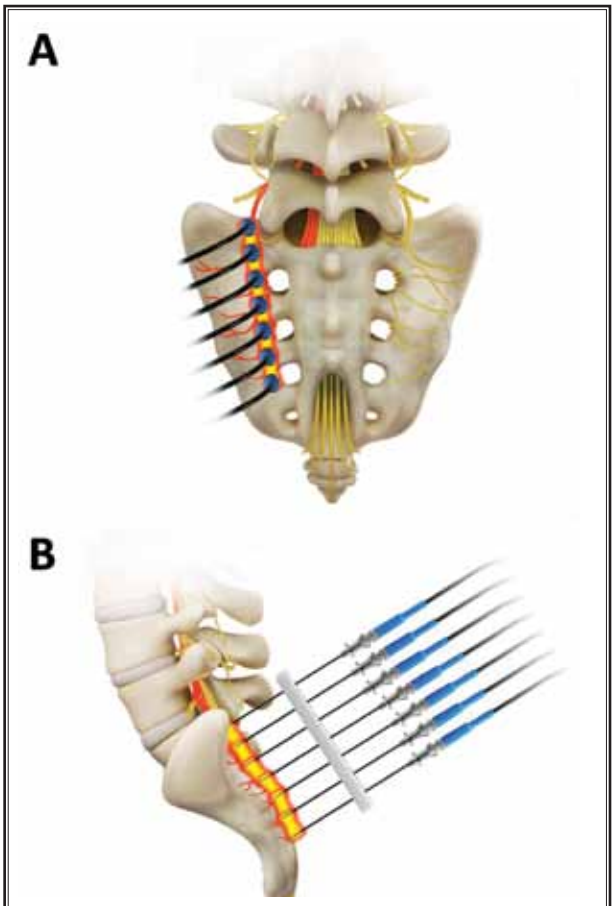

Fig. 3. *Schematic illustration of multiple needle placement and the location and size of the lesion in both anteroposterior (A) and lateral views (B). The target nerves are L5 dorsal ramus and the lateral branches of the S1, S2, and S3 dorsal rami, which are the major innervations of the posterior compartment of the sacroiliac joint.*

4-mm active tips. Since the c-RFA procedure has been described previously (17,18), here we focus our attention on the technical aspects of b-RFA. The patient was placed in the prone position. The skin of the surgical site was prepared and draped with sterile technique. The guide-block was placed on the skin on the side of the operation over the sacrum. Under fluoroscopic guidance in the anteroposterior (AP) view, the guide-block was aligned in such a way that one of the radiopaque markers was on top of the sacral ala, just lateral to the base of the S1 superior articular process of the L5-S1 facet joint and the other was lateral and distal to the lateral border of the S3 foramen (Fig. 3). The location of the guide-block was marked with a marking pen and the guide-block was then removed to expose the skin underneath, so that a local anesthetic (1% lidocaine) could be injected to numb the skin and subcutaneous tissues. The guide-block was then loaded with 7 RF needles, with the tips of the needles barely passing through the through-holes. The guide-block, with the loaded needles, was placed back to its original position.

The needles were advanced about 10 mm into the skin, one at a time. The through-holes were preferably sized such that there was minimal space for the needles to move laterally. The needles thereby effectively act as a fixation mechanism to maintain the position of the guide-block. An AP fluoroscopic image was then taken to confirm the correct location of the guide-block and

the desired trajectories of the needles (Fig. 4A). The trajectory of the needles could be adjusted by manipulating the angle of the guide-block while advancing the needles so that the tip of the needles would take positions as illustrated in Fig. 3. The needles were typically advanced without necessarily using fluoroscopy and the depth of needle insertion was controlled by the tactile indication of the needle touching the bone. Once all of the needles were advanced to the dorsal surface of the sacrum, a lateral view was then taken to confirm that none of the needles went into the sacral foramen (too deep on lateral view) or landed on the posterior iliac crest (too shallow on a lateral view) (Fig. 4B). This ensured that the electrodes reached the posterior surface of the sacrum along a straight line starting from the sacral ala and ending at the lateral border of the S4 foramen. This configuration of the electrodes ensures the most effective bipolar radiofrequency lesions that encompass the L5 dorsal ramus and the lateral branches of the S1, S2, and S3 sacral dorsal rami.

The stylets of the needles were then removed and 2 mL of 1% lidocaine was injected through each needle to numb the tissues to be ablated with RF energy delivered by a RF generator (Four-Electrode Radiofrequency Generator (G4), Cosman Medical Inc., Boston, MA, USA). A strip lesion was created by delivering RF energy (85°C for 150 seconds) through 4 electrodes, making 2 controlled lesions along the strip at a time. Three sequential lesions were made by the combinations of needle connections, as illustrated in Fig. 2A. A longer strip lesion may be made for patients taller than 200 cm by using 4 combinations of RF needle connections, as illustrated in Fig. 2B. This approach would ensure effective and reliable denervation of the posterior aspect of the sacroiliac joint for the purpose of pain relief and functional improvement. The same process could be conducted on the other side of the patient's sacrum (i.e., a bilateral procedure can be performed). Upon completion of the procedure, all the needles were removed. The skin was cleaned with wet and dry gauze, and the site was covered with a sterile dressing (Primapore, Smith & Nephew Medical Limited, USA).

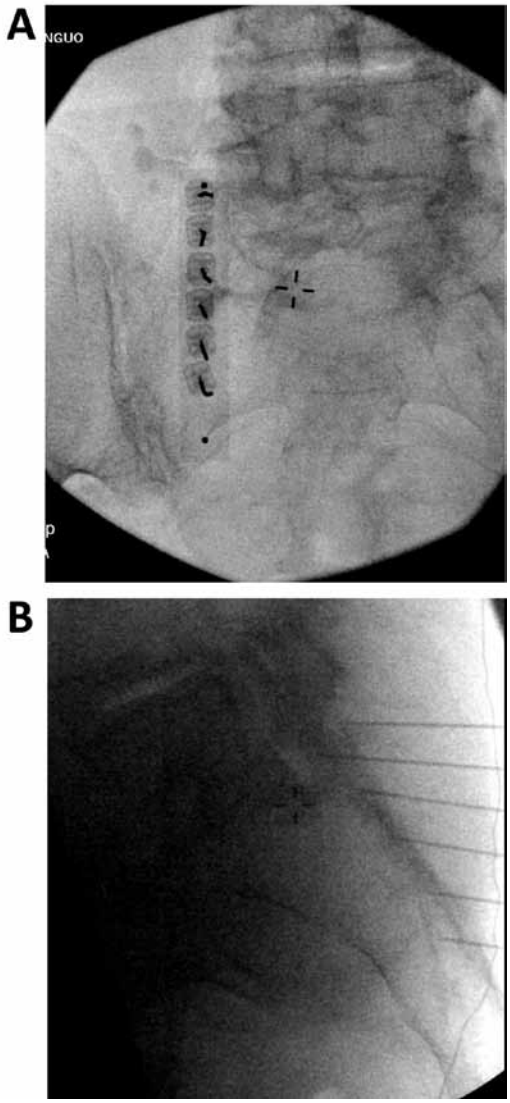

Fig. 4. *Fluoroscopic images of the guide-block and RF needle placement. A. An anteroposterior view of the guide-block and RF needles targeting the L5 dorsal ramus and the lateral branches of the S1, S2, and S3 dorsal rami. B. A lateral view of the RF needles on the dorsum of the sacrum, which has an uneven surface with multiple elevations and depressions.*

Validation of the new treatment

The new method was validated by collecting and analyzing data of operating time (from the first needle insertion for local anesthetic infiltration to removal of the last RF needle), x-ray exposure time and dose for the whole procedure, and clinical outcomes parameters. We collected prospective perioperative data for patients undergoing b-RFA treatment between April 2012 and July 2015 in the main campus of the Cleveland Clinic. Additionally, retrospective perioperative data were collected for comparison from patients undergoing c-RFA treatments between February 2007 and October 2014. In light of the nature of comparison between the 2 groups, this

investigation was not registered as a clinical trial. The decision regarding which modality (c-RFA vs. b-RFA) to use was based on physician's preference. The operating time and x-ray exposure time and dose were collected from the last 10 patients in both groups as these data were routinely collected in each case as a measure of practice quality control since January of 2014.

Patients

All patients met the following inclusion criteria: age 18 years or older, chronic LBP of 3 months' duration or longer, absence of focal neurologic signs or symptoms, and at least 50% pain relief in numeric rating scale (NRS) following 2, fluoroscopically guided SI joint blocks using 3 mL of local anesthetic bupivacaine 0.5% (or 1% lidocaine) and 40 mg triamcinolone. All of the patients who received RFA treatment had previously failed to achieve adequate improvement with conservative treatments including rehabilitation and pharmacological therapies. All patients receiving RFA treatment achieved less than one month of pain relief of > 50% after the SI joint blocks. Typically, patients received one SI joint block before RFA treatment for both groups. Excluded from the study were patients with a known, specific cause of LBP (e.g., spondylolisthesis or significant spinal stenosis), untreated coagulopathy, and concomitant medical (e.g., poorly controlled cardiac condition) or psychiatric illness (e.g., untreated depression) likely to endanger the patient or compromise treatment outcomes. In addition, patients with severe fibromyalgia with multiple and widespread pain complaints were excluded from the prospective part of the study. Of the 93 patients eligible for this study, 31 (33%) were in the prospective cohort of b-RFA patients and 62 (67%) were in the historic retrospective cohort of c-RFA patients (Table 1). All patients receiving c-RFA

Table 1. Comparison of patients undergoing bipolar radiofrequency ablation for sacroiliac joint pain to historic patients undergoing cooled radiofrequency ablation for sacroiliac joint pain on demographic, morphometric, and procedural characteristics.

Factor	b-RFA (N = 31)	c-RFA (N = 62)	ASD*
Male sex (%)	6 (19)	16 (26)	0.155
Age (years; mean ± SD)	56 ± 15	53 ± 13	0.215
Body mass index (kg/m2; mean ± SD)	28 ± 6	30 ± 7	0.189
Location of pain: back (%)	30 (97)	59 (95)	0.082
Location of pain: radiating to the leg (%)	19 (61)	51 (82)	0.479
Gradual onset (vs. sudden) (%)	30 (97)	46 (74)	0.677
Pain with extension or axial rotation (%)	10 (32)	36 (58)	0.537
Tenderness over sacroiliac joint (%)	15 (48)	57 (92)	1.082
Duration of pain (years)	5 [4, 8]	4 [2, 8]	0.269
Chronic opioid use (%)	18 (58)	43 (69)	0.236
Previous spine surgery (%)	10 (32)	22 (35)	0.068
Multiple pain complaints (%)	17 (57)+	55 (89)	0.771
Employed full time (%)	9 (29)	29 (48)+	0.388
Disabled (%)	5 (16)	6 (10)+	0.188
Diabetes (%)	5 (16)	6 (10)	0.193
Smoker (%)	7 (23)	18 (29)	0.148
NRS pain score before RFA (mean ± SD)	6 ± 2	7 ± 2	0.156
Levels of RFA (%)			0.907
S1,2,3	0 (0)	6 (10)	
L5, S1,2,3	31 (100)	56 (90)	
Use of steroids after RFA (%)	0 (0)	40 (65)	1.907
Year (median [quartiles])	2014 [2013, 2014]	2008 [2008, 2009]	2.983

b-RFA = bipolar radiofrequency ablation; c-RFA = cooled radiofrequency ablation; ASD = Absolute standardized difference; RFA = radiofrequency ablation; NRS = numeric rating scale.

* Absolute standardized difference, defined as the absolute difference in means, mean ranks, or proportions divided by the pooled standard deviation.

+ Data missing for one patient.

were included as long as the outcomes data were complete through office visits and/or documented phone correspondence.

In addition to treatment outcomes, other demographic and clinical variables recorded for analysis were age, gender, location of pain, referral pattern (i.e., exclusively axial, radiating above the knee, or extending below the knee), mode of onset, duration of pain, opioid usage, body mass index, history of diabetes, multiple pain complaints, previous surgery, employment status, workers' compensation or disability status, smoking, presence of SI joint tenderness, response to provocative maneuvers (extension or axial rotation, Patrick and Gaenslen tests), numeric rating scale (NRS) pain scores before RFA, number of levels ablated, number of lesions at each level, RFA technique (c-RFA or t-RFA), use of steroid after RFA, and complications (Table 1).

Clinical Outcome Measures

All pain scores were measured using 0- to 10-point NRS, recorded as average pain score at the time of the evaluation. Scheduled follow-up assessments occurred at one, 3, 6, and 12 months after the RFA procedure. The duration of pain relief, defined as the time until the patient reported < 50% pain relief, served as our primary outcome. We chose time to < 50% pain relief as our primary outcome because pain relief of 50% or greater is clinically significant and has been used as a benchmark by which the efficacy of RFA treatments are judged in other studies (17,18). NRS may be a more accurate measure for a specific point in time. However, report of percent pain relief is preferable for the overall evaluation of the responses to the procedure because it takes into account of the patient's experience in the whole interval between the time of the procedure and the time of the follow-up, including the best and worst pain intensity levels. The duration of the pain relief is defined as the interval between the time of the procedure and the time when the patient reported < 50% pain relief. In addition to treatment outcomes, demographic and morphometric characteristics corresponding to each patient's first RFA treatment, as well as procedural characteristics corresponding to all RFA treatments, were summarized and analyzed using standard descriptive statistics and univariable tests, as appropriate (Table 1). Any complications of the procedures were to be followed up and documented.

Statistical Analysis

Student t tests were employed to compare the operating time and x-ray exposure time and dose between the b-RFA and c-RFA groups at a significance level of < 0.05.

Our primary clinical outcome, duration of pain relief, was interval-censored because patients could have reached < 50% relief any time between scheduled follow-ups. Censoring intervals were defined as the interval between the last observed follow-up with > 50% relief and either the first observed follow-up time with < 50% relief or infinity if < 50% relief was never observed. For example, if < 50% pain relief was observed at 3 months, the patient would be interval censored at (1, 3) since the event could have occurred anywhere between one and 3 months. If a missing follow-up occurred but the patient reported > 50% pain relief at the next available contact, we assumed that the patient had > 50% relief at the time of the missing follow-up. For those patients who had a subsequent RFA procedure for the contralateral side, duration of pain relief was right-censored at the time of the procedure (i.e., assumed to have some value greater than the time until the subsequent procedure). For those who had repeat RFA procedures, only the first RFA procedure per patient was included in the analysis.

The distribution of duration of pain relief was estimated for each RFA technique univariably using Turnbull nonparametric maximum likelihood estimation for interval-censored data (26). We calculated multiplicity-adjusted confidence intervals for each RFA technique's Turnbull distribution using a modified bootstrap technique (i.e., Bonferroni correction; 0.05/8). We univariably assessed the extent to which bipolar versus cooled RFA techniques differ in duration of pain relief using the Sun log rank test for interval-censored data (27). However, this univariable test does not account for differences in baseline patient characteristics between patients receiving bipolar and cooled RFA that could influence the results.

Our primary analysis used a multivariable proportional hazards regression model for interval-censored data that adjusted for potentially confounding patient characteristics (28). *A priori*, we defined previous spine surgery, chronic opioid use, multiple pain complaints, body mass index, and duration of lower back pain as the most important potentially confounding factors. We verified the proportional hazards assumption using graphical methods. The primary analysis assumes that censoring is independent from duration of pain relief. However, it is possible that censoring is not independent (e.g., if patients with unsuccessful RFA treatment

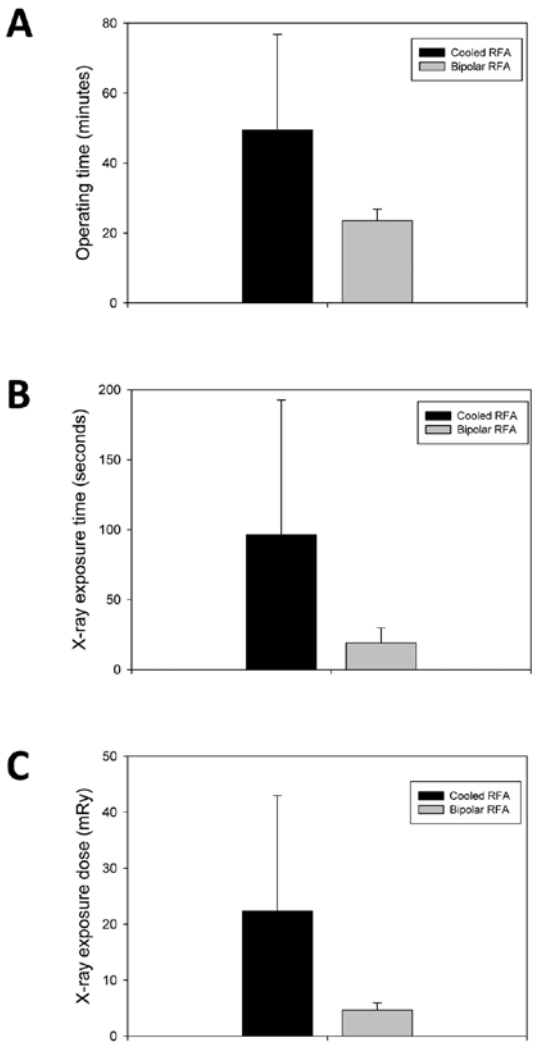

Fig. 5. *Comparisons of the operating time, x-ray exposure time, and x-ray exposure dose between the bipolar radiofrequency ablation (b-RFA) and the cooled radiofrequency ablation (c-RFA) techniques. Application of the b-RFA technique allowed dramatic reduction of the operating time (A), x-ray exposure time (B), and x-ray exposure dose. The differences were all statistically significant (Student t tests, P < 0.01).*

are more likely to be lost to follow-up). Therefore, we conducted a sensitivity analysis defining the censoring interval as the interval between the last observed follow-up with > 50% relief and the first observed time with either < 50% relief or a missing follow-up. This approach conservatively assumes that all loss to follow-up occurs due to treatment failure. All analytical approaches were the same in the sensitivity analysis.

We used a significance criterion of 0.05 for each analysis. All analyses were completed using R statistical software version 3.2.1 (The R Foundation for Statistical Computing, Vienna, Austria) with the "interval" and "Epi" packages for interval-censored analyses (29,30).

Results

There was a more than 53% reduction of operating time for the new b-RFA technique (23.5 + 3.27 minutes) compared to the c-RFA technique (49.5 + 27.25 minutes) ($P < 0.01$) (Fig. 5A). Notably, the standard deviation around the mean operating time for c-RFA was widely variable, reflecting large variations in the level of difficulty with which the procedure was performed in different patients. It also reflected the level of the operators' skills and experience. In contrast, the standard deviation of the mean operating time for the new b-RFA technique was 8 times less, indicating that the new technique was easy to master and was less affected by the anatomical variations and visualizations under fluoroscopy between different patients.

There was a more than 80% reduction of x-ray exposure time for the new b-RFA technique (19.1 + 4.7 seconds) compared to the c-RFA technique (96.3 + 96.2 seconds) ($P < 0.01$) (Fig. 5B). In addition, there was an 80% reduction of x-ray dose for the new b-RFA technique (4.66 + 1.26 mRy) compared to the c-RFA technique (22.36 + 20.61) ($P < 0.01$) (Fig. 5C). Similarly, the standard deviations from the mean x-ray exposure time and mean x-ray dose for c-RFA were about 20 times larger than those for the b-RFA technique. These striking differences were results of the high level of difficulty to visualize the relevant anatomical structures, often in the presence of gases in the colon, under fluoroscopy to precisely place the RF needles for the c-RFA approach. In contrast, the b-RFA technique was much easier to perform with minimal exposure to x-rays. The outcomes data provided support for the validity of the new treatment. Of the 93 patients eligible for this study, 31 (33%) were in the prospective cohort of b-RFA patients and 62 (67%) were in the historic retrospective cohort of c-RFA patients (Table 1). Factors that were well balanced between the 2 groups included gender, location of pain, referral pattern, mode of onset, duration of pain, opioid usage, body mass index, diabetes, multiple pain complaints, employment status, disability status, smoking, presence of SI joint tenderness, response to provocative maneuvers, and NRS pain scores

before RFA. The c-RFA treatment group had a significantly greater likelihood of receiving supplement injection of steroid (triamcinolone acetate) than the b-RFA group. b-RFA patients experienced a longer duration of > 50% pain relief based on the nonparametric maximum likelihood estimates (Fig. 6). At 3 months, 74% of b-RFA patients had > 50% pain relief, compared to around 38% of c-RFA patients. At 6 months, 69% of b-RFA patients reported > 50% pain relief compared to 19% of c-RFA patients. At 12 months, 50% of b-RFA patients and 9% of c-RFA patients had > 50% pain relief. No patients with either treatment had any significant adverse events or serious complications. Before adjusting for imbalanced potentially confounding characteristics, we found that b-RFA was associated with significantly longer duration of pain relief than c-RFA ($P < 0.001$).

b-RFA patients typically had a longer history of pain, lower incidence of chronic opioid use, and lower incidence of multiple pain complaints compared to c-RFA patients (Table 1). These factors, BMI, and the incidence of previous spine surgery were included in the primary multivariable model because of their potential confounding effects. After adjusting for variables, we found that the b-RFA technique was associated with a significantly longer duration of pain relief compared to the c-RFA technique, with an estimated hazard ratio (95% confidence interval) of 0.25 (0.13, 0.48) ($P < 0.001$). Thus, the hazard of reaching < 50% relief was 75% lower among b-RFA patients compared to c-RFA patients at any given time. The sensitivity analysis assuming loss to follow-up occurred due to pain returning was consistent with these results. Thus, results were consistent even if all of the patients lost to follow-up was caused due to reaching < 50% pain relief. One b-RFA patient had missing data and was thus excluded from the multivariable analysis, but conclusions were consistent when we included this patient assuming no response to the treatment.

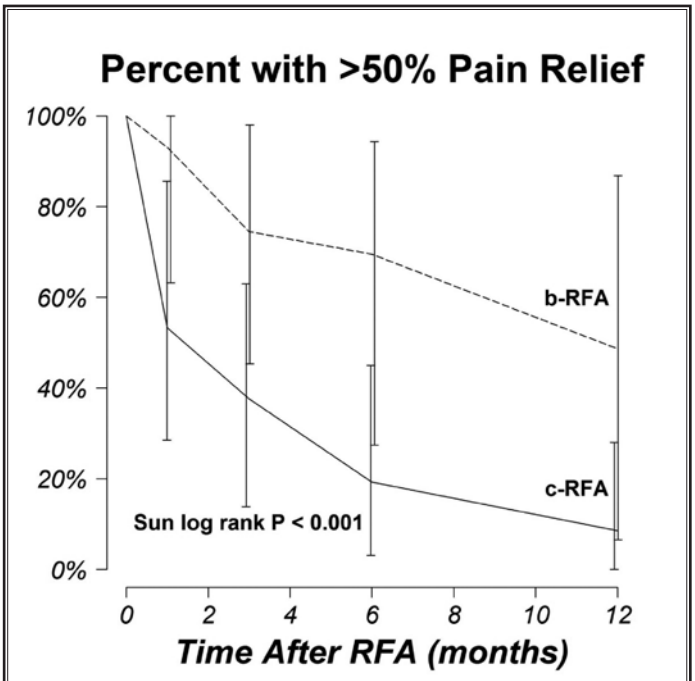

Fig. 6. *Turnbull estimates and adjusted 95% confidence intervals of the distribution of duration of pain relief, defined as the time until pain reaches < 50% of pretreatment levels for 93 patients undergoing radiofrequency ablation (RFA) (31 patients with bipolar RFA (b-RFA) and 62 patients with cooled RFA [c-RFA]). Bipolar RFA was associated with longer duration of pain relief in both the univariable Sun log rank test for interval censored data ($P < 0.001$) and the multivariable model ($P < 0.001$; Wald test). Censoring intervals were defined as the interval between the last observed follow-up with > 50% relief and the first observed follow-up time with < 50% relief.*

Discussion

In this study, we developed a new b-RFA method to treat low back pain due to SIJ disorders. We have designed and utilized a guide-block to facilitate precise and easy placement of the RF needles to simultaneously ablate the L5 dorsal ramus and the lateral branches of the S1, S2, and S3 sacral dorsal rami, which are the predominant sensory innervation of the posterior compartment of the SIJ (Figs. 1 – 3). This new technique is based on studies that systematically and elegantly investigated the geometry of the lesion by determining the key physical parameters that affect the shape and size of the lesion (23). These factors include the configuration of the electrodes (parallel tip spacing), the length of the active tip, the distance between 2 adjacent electrodes (spacing), the temperature, the duration of tissue ablation, and the interplay between these parameters. Our data from this investigation demonstrate that the new b-RFA technique using the guide-block is safe, efficacious, and cost-effective.

The new b-RFA technique used less than half of the operating time required for c-RFA, which is currently the most commonly used and the best studied modality (Fig. 5A)

(17,18). There was an 8-fold reduction of standard deviation from the mean operating time compared to the c-RFA technique. The small standard deviation from the mean operating time for b-RFA suggests that this new method is easy to master by operating physicians and is less affected by patient variables. The operating time was primarily reduced by virtue of the simplicity of b-RF needle placement compared to c-RFA, which involves time-consuming visualization of the landmarks for accurate, multiple needle placement due to anatomical variability and the presence of gases in the colon. The dramatically shortened operating time and reduced variation in operating time help to reduce patient discomfort, increase operating room efficiency, and decrease costs related to the operating suite and personnel utilization. In addition, the cost of the guide-block is 10 times less than the disposables required by c-RFA (special RF probes and ground electrode). Furthermore, unlike the c-RFA technique, the b-RFA technique does not require special and expensive cooling system, thus adding more savings. The total saving from reduced operating time, reduced costs associated with disposables (~$700) and equipment cost, and increased operating room efficiency is estimated to be more than $1000 per case.

Application of the new b-RFA technique reduced the x-ray exposure time and x-ray exposure dose by more than 4 fold compared to the c-RFA technique (Fig. 5B and 5C). The reduction of standard deviation from the mean x-ray exposure time and dose was more than 20 fold compared to the c-RFA technique. Such dramatic reductions of harmful x-ray exposure are desirable for the patients, the physicians, and other personnel in the operating room alike. Even though effective protection from x-ray exposure is available, one cannot underestimate the value of minimizing harmful and unnecessary exposures to patients and health care providers (31). It would also be interesting to perform the b-RFA technique through ultrasound guidance, thus completely avoiding x-ray exposures. Such an approach is feasible for b-RFA as the bony landmarks are easily identifiable to guide accurate placement of the guide-block, which will further facilitate placement of the RF needles.

The differences in procedure time and x-ray exposure time could result from either the procedures or the practitioners. However, since the investigation took place in a major academic center with the largest training program in the US, experienced attending physicians were supervising the same pool of pain fellowship trainees, who were, for the most part, responsible for carrying out the procedures. In fact, it took only approximately 12 minutes for b-RFA or approximately 35 minutes for c-RFA when the procedures were personally performed by the attending physicians. In such scenarios, the reduction of operating time was more than 75% and the reduction of x-ray exposure was more than 90%. We did not make these claims because the sample size was too small. The purpose of designing and using the needle guide-block was to facilitate accurate placement of the needles, reduce x-ray exposure, and save operating time. As a result, the new procedure appeared to be safe, efficacious, and cost-effective. It is conceivable that efficacy outcomes were likely related to the effectiveness of the method of ablation (b-RFA), while the operation outcomes were related to the use of the needle guide device.

RFA denervation of the SIJ is widely accepted as a safe procedure, without significant adverse events or complications reported during its application for over a decade (32). Transient numbness in areas of the buttock was observed in only a few patients and was consistently self-limited to a few days following procedure. Although both techniques are safe to use, b-RFA has an additional advantage as it causes less patient discomfort by significantly reducing the procedure time and the RF needle gauge (20g vs. 17g). In addition, by limiting the electrical current to the 2 closely positioned needles, this technique minimizes the risk of interfering with other implanted devices such as pacemakers and defibrillators, which is a contraindication to traditional radiofrequency treatment. This new treatment option allows access to effective RFA therapy by an increasingly larger population of patients with existing heart diseases and chronic low back pain. We have safely utilized this technique to effectively treat facetogenic pain in patients with an Automatic Implantable Cardioverter Defibrillator (AICD) (33,34).

The efficacy of the new technique seems to be validated in clinical application to patients with SIJ pain (Table 1 and Fig. 5). By comparing the clinical outcomes, we found that patients receiving b-RFA experienced a longer duration of > 50% pain relief based on the non-parametric maximum likelihood estimates. The percent of patients who had > 50% pain relief was significantly higher in the b-RFA group at all follow-up intervals. It was 2 times higher at one month, 3 times higher at 6 months, and 5 times higher at 12 months compared to the c-RFA group. Even after adjusting for potential confounding variables, the b-RFA technique was strongly associated with a significantly longer duration of pain

relief compared to the c-RFA technique, with an estimated hazard ratio of 0.25 (0.13, 0.48) ($P < 0.001$). Thus, the hazard of reaching < 50% relief was 75% lower among b-RFA patients compared to c-RFA patients at any given time. The superior outcomes of b-RFA over c-RFA were evident even with the relatively small sample size, most likely due to the large treatment effects that have strengthened the power of this comparison. Although not ideal, comparing to historical data is a practical way of initial assessment of the efficacy of a new treatment. It closely reflects the real-world clinical practice where inclusion or exclusion of patients from the procedures was judged by physicians in their daily practice.

It is also interesting to compare the current data with those reported in a randomized trial of c-RFA (n = 34) that was elegantly conducted by Patel and colleagues (18,19). More b-RF patients achieved > 50% pain reduction than those receiving c-RFA in the randomized controlled trial, 74% vs. 47% at 3 months, and 69% vs. 38% at 6 months respectively. It is noticeable that our historical c-RFA data have slightly lower success rates compared to the randomized controlled trial report. The small differences could be readily explained by differences in patient characteristics between the 2 studies. In our c-RFA cohort, 35% of patients had previously spine surgeries, 69% were on chronic opioid therapy, and 89% had multiple pain complaints. These factors may have contributed to the lower success rates of c-RFA. We recognize this comparison is between data collected in 2 different settings, daily practice vs. clinical trials. Thus the differences between the 2 cohorts may reflect a gap between clinical trials and daily clinical practice. Such a gap may never be recognized without comparisons of this kind. Therefore it is a necessary practice given that all preclinical and clinical studies are intended to apply their findings to improve patient care in daily medical practice.

The findings of this study are significant because managing of SIJ-mediated low back pain remains to be a challenge despite many modalities of treatment have been tested in the last 30 years. The results of pharmacotherapy, viscosupplementation, prolotherapy, chiropractic manipulation, intraarticular injections, and surgical fusion have been mixed and largely unsatisfactory (35-40). Thus, a new efficacious, safe, and cost-effective treatment is needed to alleviate patient suffering and avoid surgical fusion of the joint (41-43).

It is important to recognize the limitations of the outcomes data. Use of historical controls does not balance observed and unobserved potential confounding variables between groups, so the reported results are potentially confounded. Groups of patients (b-RFA and c-RFA) differed on several baseline and procedural characteristics (Table 1), but we could only adjust for the most important confounders in our analysis due to the relatively small sample sizes for both groups. Thus, the observed difference between groups may be distorted by observed or unobserved confounding factors. In addition, the reported results are subject to temporal bias because of our use of historical controls. We could not adjust for the year of procedure due to minimal temporal overlap between the 2 groups. Observed and unobserved patient and procedural factors may have changed over time, such as operator experience, decreasing our confidence in the reported results. The observed association between b-RFA and longer duration of pain relief is potentially stronger than what we would observe in a randomized trial due to the above limitations. Thus, further research using randomized controlled trials is important to establish the extent to which b-RFA truly increases duration of pain relief.

Conclusion

In conclusion, compared to the currently used c-RFA technique, the new b-RFA technique reduced operating time by more than 50%, decreased x-ray exposure by more than 80%, cut the cost by more than $1000 per case, and is significantly associated with improved clinical outcomes despite of the limitations of the study design. Thus this new technique appeared to be safe, efficacious, and cost-effective. It deserves further investigation in randomized controlled clinical trials to determine its superiority over the existing RFA procedures.

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