Randomized Trial

Comparison of Efficacy of Lateral Branch Pulsed Radiofrequency Denervation and Intraarticular Depot Methylprednisolone Injection for Sacroiliac Joint Pain

Kaustuv Dutta, MD, Samarjit Dey, MD, Prithwis Bhattacharyya, MD, Sharat Agarwal, MS, and Priyanka Dev, MD

From: North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, India

Address Correspondence: Samarjit Dey, MD North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Anaesthesia B 9 E, Faculty quarters NEIGRIHMS, Mawdiangdiang, Shillong, Meghalaya 793018, India E-mail: drsamaroo02@gmail.com

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Background: Sacroiliac joint dysfunctional pain has always been an enigma to the pain physician, whether it be the diagnosis or the treatment. Diagnostic blocks are the gold standard way to diagnose this condition. Radiofrequency neurotomy of the nerves supplying the sacroiliac joint has shown equivocal results due to anatomical variation. Intraarticular depo-steroid injection is a traditional approach to treating sacroiliac joint pain. For long-term pain relief, however, lesioning the sacral lateral branches may be a better approach.

Objective: This study compared the efficacy of intraarticular depo-methylprednisolone injection to that of pulsed radiofrequency ablation for sacroiliac joint pain.

Study Design: This study used a randomized, prospective design.

Setting: Thirty patients with diagnostic block-confirmed sacroiliac joint dysfunctional pain were randomly assigned to 2 groups. One group received intraarticular methylprednisolone and another group underwent pulsed radiofrequency of the L4 medial branch, the L5 dorsal rami, and the lateral sacral branches.

Results: Reduction in Numeric Rating Scale (NRS) for pain at 1 month post-procedure remained similar in Group A, while in Group B few patients reported a further decrease in the NRS score (3.333 ± 0.4880 and 2.933 ± 0.5936, respectively). At 3 months post-procedure, the NRS score began to rise in most patients in group A, while in Group B, the NRS score remained the same since the last visit (4.400 ± 0.9856 and 3.067 ± 0.8837, respectively). At 6 months post-procedure, the NRS score began to rise further in most patients in group A. In Group B, the NRS score remained the same in most of the patients since the last visit (5.400 ± 1.549 and 3.200 ± 1.207). There was a marked difference between the 2 groups in Oswestry Disability Index (ODI) scores at 3 months post-procedure (Group A, 12.133 ± 4.486 vs Group B, 9.133 ± 3.523) and at 6 months post-procedure there was a significant (P = 0.0017) difference in ODI scores between Group A and Group B (13.067 ± 4.284 and 8.000 ± 3.703, respectively). Global Perceived Effect (GPE) was assessed in both groups at 3 months post-procedure Only 33.3% (Confidence Interval (CI) of 11.8- 61.6) of patients in Group A had positive GPE responses whereas in Group B, 86.67% (CI of 59.5- 98.3) of patients had positive GPE responses. At 6 months post-procedure, the proportion of patients with positive GPE declined further in Group A, while in Group B, positive GPE responses remained the same (20% with a CI of 4.30-48.10 and 86.67% with a CI of 59.5- 98.3, respectively).

Limitations: Small sample size.

Conclusion: This comparative study shows that pulsed radiofrequency denervation of the L4 and L5 primary dorsal rami and S1-3 lateral branches provide significant pain relief and functional improvement in patients with sacroiliac joint pain.

Key words: Low back pain, sacroiliac joint dysfunctional pain, radiofrequency, intraarticular injection

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Low back pain (LBP) is an important clinical, social, economic, and public health problem. Although symptoms are usually acute and self-limited, LBP often recurs. Of those who develop acute LBP, 30% develop chronic LBP (1). The sacroiliac joint (SIJ) is an accepted source of LBP with or without associated lower extremity symptoms. SIJ pain is a challenging condition affecting 15% to 25% of patients with LBP, and there is no standard long-term treatment for it (2). SIJ pain is not only disabling for the person affected with it; it is also a burden to society, as it leads to abstinence from work and takes its toll on family members as well. In remote villages in India, people carry heavy objects daily on their backs while traversing hilly and steep terrain, leading to chronic LBP. And yet, there is no research regarding the burden of SIJ pain as a cause of LBP in North East India.

Several approaches to treating SIJ pain have been used. In patients with sacroiliitis, injection of corticosteroids into the SIJ with fluoroscopic control or with CT guidance has proven its efficacy (3,4). Methyl prednisolone injected into the SIJ has been shown to reduce inflammation and pain (5). In addition, it has been reported that intraarticular corticosteroid injections may provide long-term pain relief (5). Pulsed radiofrequency (PRF) is essentially a nonneurolytic procedure. Due to the large electromagnetic field created, the affected target may be larger than that associated with conventional radiofrequency (RF) (6). Our study aimed to compare the efficacy of intraarticular depo-methylprednisolone injection with PRF ablation for SIJ pain.

Table 1. *Inclusion and exclusion criteria.*

Inclusion Criteria	Exclusion Criteria
Age > 18 yrs	Patient's refusal
Low back pain ≥ 3 mos in duration	Focal neurological signs or symptoms
Patients not responding to conservative therapy (drugs and physiotherapy)	History of bleeding diathesis
Tenderness overlying the sacroiliac joint(s) or positive response to any of the three provocative clinical tests, few of which include: Gaenslen Test FABER Test Gillet test Thigh Thrust Test Anterior Superior Iliac Spine Compression and Distraction tests	Medical illnesses a) History of coronary artery disease or unstable angina b) Diabetes mellitus c) Hypertension d) Peptic ulcer disease e) Chronic kidney disease
Positive result to the diagnostic block	Patients with a history of any psychiatric illness

Methods

The study was conducted in the pain clinic of the Department of Anaesthesiology in the North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences (NEIGRIHMS), Shillong from March 2012 to July 2013 after receiving clearance from the Institute's Ethics Committee. All patients with complaints of LBP were evaluated on their first visit to the hospital; this process involved taking a proper history and conducting an examination and investigations relevant for LBP evaluation. The Numeric Rating Scale (NRS-11) (7) for pain was used to measure pain intensity. The definitive diagnosis of SIJ pain was made using a combination of clinical tests along with the pain referral pattern (unilateral low back or buttock pain, which may or may not radiate down the leg and without associated paraesthesia) and a positive response to fluoroscopy-guided intraarticular local anaesthetic injection in the SIJ. The inclusion and exclusion criteria are shown in Table 1.

Thirty patients were included in the study. On the first visit to the pain clinic, patients were assessed for history of trauma or any inciting event that could have led to back pain; duration, intensity, and character of pain; and aggravating and relieving factors. To assess pain using the NRS-11, patients were instructed to rate their worst pain on a scale from 0 to 10, where 0 indicates no pain and 10 indicates severe disabling pain. Oswestry Disability Index (ODI) (8) scores (Chiropractic "Revised Oswestry Pain Questionnaire") were calculated using the standard questionnaire.

Patients were assessed for range of movements, reflexes, and muscle strength. Other relevant organ systems were also examined. Pain in SIJ dysfunction was examined for the following characteristics: location, referral, and aggravating and relieving factors (9). The following tests to detect SIJ dysfunction were used: Straight Leg Raising Test (SLRT), Compression Test/ Distraction Test, FABER (Patrick's) Test, Gaenslen test, Fortin Finger Test, Gillet Test (One-leg Stork Test), Shear Test (Midline Sacral Thrust), Goldthwait's Test, and the Pump-handle test (10). SLRT was done to exclude the other causes such as nerve root irritation, spondyloithesis, and tumor of the buttock. After a detailed examination, routine, and relevant radiographic investigations were done. Patients were randomized in a 1:1 ratio to either Group A (intraarticular depo-methylprednisolone injections) or Group B (PRF ablation of SIJ).

A total of 42 patients were screened. After a positive response to a diagnostic block, 30 patients were included in the study. Patients were asked to randomly pick a sealed envelope that contained a group assignment. A pain physician unaware of which group patients had been randomly assigned to later evaluated the patients in his clinic at 15 days, 1-, 3-, and 6-months post-procedure.

Diagnostic SIJ Injection

After providing informed consent, those patients who had a positive response to 3 or more provocative SI joint manoeuvres proceeded to undergo the diagnostic SIJ injections with a local anesthetic solution. A positive response was indicated by a more than 80% reduction in pain (compared to the pre-procedure level) for a minimum of 5 hours post-procedure. Only those patients who had fulfilled this criterion were included in the study and proceeded to undergo either PRF ablation of the SIJ or intraarticular depo-methylprednisolone injection.

PRF Ablation of SIJ

An intravenous (IV) line was established and a sedative (midazolam 1 mg) was given. Blood pressure, electrocardiogram (ECG), and pulse oximetry were monitored. A dispersive return electrode pad was placed on the patient on one of the lower extremities. The patients were positioned prone, and under aseptic and antiseptic precautions, skin was prepped and draped. All procedures were done under fluoroscopic guidance for optimal visualization of the target areas. Lignocaine 1%, 2-3 mL, was used for skin and subcutaneous infiltrations. A 21-gauge, 10 cm long, 10 mm active tip RF needle, Baylis Medical Company, USA) was used. For blockade and lesioning of the L4 medial branch and L5 dorsal rami, a 22-gauge spinal needle was inserted until bone was contacted just superior and medial to the junction between the superior border of the transverse and superior articular processes for procedures done at L4, and at the junction of the ala and articular process of the sacrum for L5 procedures (11,12). At each level, both sensory and motor testing were done. For sensory testing, the correct placement of the electrode relative to the nerve was confirmed using electro stimulation at 50 Hz, with sensation achieved at ≤ 0.5 V. The patients were asked whether they felt sensory symptoms like pressure, tingling, pain, or burning sensation. This was followed by motor testing for which a frequency of 2 Hz and 2 V was used, and absence of any contractions of the leg was verified. After confirmation of correct placement of the needles, 3 PRF lesions (Pain Management Generator, Baylis Medical Company, Version 3.11, Montreal, QC, Canada) were made at pre-designated levels similar to previous studies that performed RF ablation of the SIJ (13).13 For right-sided S1 and S2 procedures, these levels corresponded approximately to the 1:00 (Fig.1) , 3:00, and 5:30 positions of a clock. For the left-sided S1 and S2 procedures, the target sites were at the 6:30, 9:00, and 11:00 positions. At S3, 2 PRF lesions were made using needles placed at 1:30 and 4:30 on the right side, and 7:30 and 10:30 on the left. For L4 and L5, 2 lesions were made at each level. PRF parameters were 45 V for 180 s at all levels using the RF generator (Baylis Medical Company, Montreal). The registered temperatures while doing the procedure varied from 38°C to 42°C. The patients were observed in the post-op intensive care unit (ICU) and discharged 6 hours after observation. The average duration of the PRF was 68 ± 12.21 minutes.

Intraarticular Depo-methyl Prednisolone Injection in SIJ

An IV line was established and a mild sedative drug (midazolam 1 mg) was given. Blood pressure, ECG, and pulse oximetry were monitored. The patients were positioned prone. Under aseptic and antiseptic precautions, skin was prepped and draped. All procedures were done under fluoroscopic guidance for optimal

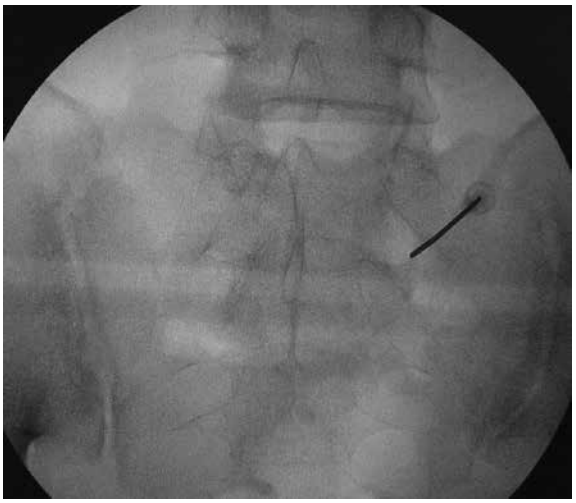

Fig. 1. *PRF lesioning of lateral branches on Right side at S1 level.*

visualization of the target areas. The C-arm image intensifier was rotated cephalad about 20 degrees to open up the SIJ view; then an oblique view was taken until the widest view of the SIJ was observed. A target point was selected 1-2 cm cephalad of the inferior end of the joint line. After infiltration of local anaesthetic (lidocaine 2%) on skin, a 22-gauge, 100 mm spinal needle was targeted to hit the sacrum. Once the needle struck the sacrum, it was withdrawn slightly and redirected towards the joint space. Entry was recognized by loss of bony resistance as the tip slipped between the sacrum and the ilium. The tip was inserted less than a few mm into the joint. Its position was checked by a lateral view image. Once inside the joint, its position was further confirmed by injecting 0.3-0.5 mL contrast medium (IOHEXOL), which outlined the joint space (Fig. 1A). Following confirmation of joint penetration, a 3 mL solution containing 2 mL of bupivacaine 0.5% and 1 mL of 40 mg/mL DEPO-MEDROL (Methylprednisolone Acetate, Injectable Suspension) was administered. The average duration of the PRF was 18 ± 5.10 minutes. Patients were observed in the post-op ICU and discharged 6 hours after observation.

All patients were prescribed aceclofenac tablets for 3-5 days to manage post-procedure pain and instructed to report to the physician unaware of the randomization (study group) in his clinic at 15 days post-procedure; then at 1-, 3-, and 6-month intervals.

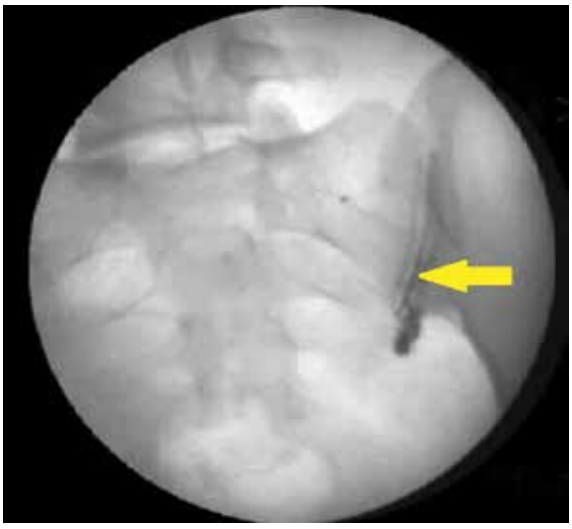

Fig. 1A. Intraarticular Si injection with dye spread.

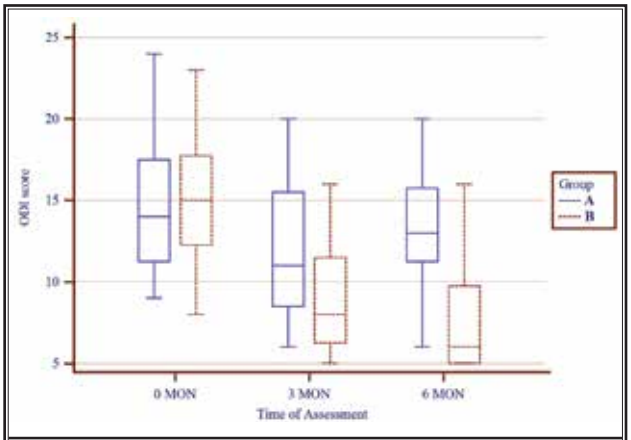

Fig. 2. *Comparison of ODI between groups.*

Outcome Measures and Follow-up

All patients were followed-up in the pain clinic 15 days post-procedure; then at 1-, 3-, and 6-month intervals. The primary outcome measure was a NRS (0–10) pain score, which was evaluated both prior to receiving the treatment and post-procedure at 1-, 3-, and 6-month intervals. Secondary outcome measures included the ODI score evaluated prior to receiving the treatment and at 3- and 6-month intervals post-procedure, and the Global Perceived Effect (GPE) (13) evaluated at 3- and 6-month intervals post-procedure. A positive GPE was defined as a positive response to the following 3 questions:

1. My pain has improved/worsened/stayed the same since my last visit
2. The treatment I received improved/did not improve my ability to perform daily activities
3. I am satisfied/not satisfied with the treatment I received and would recommend it to others.

A negative response to any of these questions con-

Table 2. *Comparison of NRS scores between groups over 6 months.*

Time of Assessment	A (n = 15)	B (n = 15)	*P* value
Pre-procedure	7.133 ± 1.06	7.067 ± 1.033	0.8641
15 days post-procedure	3.333 ± 0.4880	3.200 ± 0.4140	0.4265
1 mo post-procedure	3.333 ± 0.4880	2.933 ± 0.5936	0.0535
3 mos post-procedure	4.400 ± 0.9856	3.067 ± 0.8837	0.0005
6 mos post-procedure	5.400 ± 1.549	3.200 ± 1.207	0.0002

stituted a negative outcome. A successful outcome was defined before the initiation of the study as a ≥ 50% reduction in numerical pain score, a positive GPE, and a 5-point decrease in (ODI) score. Continuous variables were compared between groups using unpaired t tests; values for each group are expressed as mean ± standard deviation.

Results

Out of 15 patients in Group A, 10 (66.67%) were men and 5 (33.33%) were women. In Group B, 4 (26.67%) were men and 11 (73.33%) were women. The patients presenting with SIJ pain in Group A were aged between 27-60 years (mean age = 41.6 years). In Group B, patients were between 19-76 years (mean age = 43.1 years).

NRS scores before and after the procedure are summarized in Table 2. GPE was assessed in both groups at 3 and 6 months post-procedure. Using the binomial model of statistical analysis, the 95% confidence interval for the proportion of each group with a positive GPE was compared at each time period (Table 3). The ODI score was assessed both pre-procedure and at 3 and 6 months post-procedure (Table 4 and Fig. 2).

In our study we found that the baseline NRS scores for Group A (7.133 ± 1.060) and Group B (7.067 ± 1.033) were comparable. At 15 days post-procedure, the mean NRS scores were significantly lower (> 50%) than at baseline in both Group A (3.333 ± 0.4880) and Group B (3.200 ± 0.4140). The mean NRS score at 1 month post-procedure remained stable in Group A (3.333 ± 0.4880), but declined in Group B (2.933 ± 0.5936), with a few patients reporting a further decrease in their NRS scores. At 3 months post-procedure, the mean NRS score was higher in Group A (4.400 ± 0.9856), with 3 patients having scores that remained the same since their last visit. In Group B, there was no change in mean score since last visit (3.067 ± 0.8837), with only 2 patients having slightly higher NRS scores. This difference in mean NRS scores at 3 months was significant (2-tailed $P = 0.0005$; Table 2 and Fig. 3). Mean NRS scores at 6 months post-procedure were significantly higher in Group A (5.400 ± 1.549), in which the same 3 patients had unchanged scores since their last visit, than in Group B (3.200 ± 1.207), in which only 2 patients had further increases in their NRS scores since their last visit (2-tailed $P = 0.0002$).

ODI scores for Group A (14.667 ± 4.639) and Group B (15.220 ± 4.263) were also comparable at baseline. By 3 months post-procedure, mean ODI scores for Group A (12.133 ± 4.486) and Group B (9.133 ± 3.523) had diverged. At 6 months post-procedure, mean ODI scores of Group A (13.067 ± 4.284) and Group B (8.000 ± 3.703) were significantly different ($P = 0.0017$).

At 3 months post-procedure, 33.3% (Confidence Interval (CI) 11.8 - 61.6) of patients in Group A had positive GPE responses, whereas in Group B, 86.67% (CI of 59.5 - 98.3) of patients had positive GPE responses. At 6 months post-procedure, the proportion of patients in Group A with positive GPE responses had declined further (20% with a CI of 4.30 - 48.10), while in Group B, the proportion of patients with positive GPE responses

Table 3. *Comparison of GPE between groups.*

Time of Assessment	A (n = 15)	B (n = 15)
3 mos post-procedure 95% CI	5 33.3 (11.8 - 61.6)	13 86.67 (59.5 - 98.3)
6 mos post-procedure 95% CI	3 20 (4.30 - 48.10)	13 86.67 (59.5 - 98.3)

($P < 0.05$ at 6 months)

Table 4. *Comparison of ODI between groups.*

Time of Assessment	A	B	*P* value
Pre-procedure	14.667 ± 4.639	15.220 ± 4.263	0.7455
3 mos post-procedure	12.133 ± 4.486	9.133 ± 3.523	0.0512
6 mos post-procedure	13.067 ± 4.284	8.000 ± 3.703	0.0017

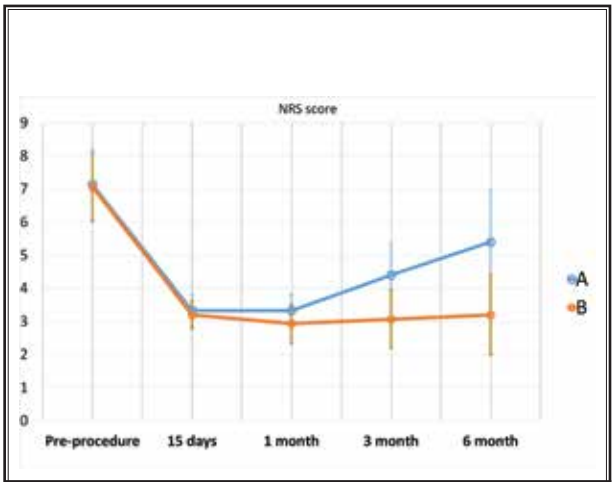

Fig. 3. *Please provide a caption.*

remained the same (86.67% with a CI of 59.5- 98.3) (Table 3 and Fig. 4).

Discussion

Performing RF lesions at the superior lateral portion of the S2 and S3 foramina, at the medial branches of the higher dorsal rami in the lumbar region, at the sacral ala and SIJ junction, and along the posterior SIJ long axis is a suggested technique for SIJ dysfunctional pain. The results of this study provide evidence that PRF denervation of the L4 and L5 primary dorsal rami and S1-3 lateral branches provide significant pain relief and functional improvement in patients with SIJ pain. At 1-, 3- and 6-months post-procedure, 100%, 86.7%, and 86.7% of patients, respectively, obtained ≥ 50% pain relief and functional improvement. In contrast, patients who received intraarticular depo methylprednisolone injection had only short-term pain relief. At 3- and 6-months post-procedure, only 20% of patients obtained ≥ 50% pain relief and functional improvement. This is a rather low success rate compared to other reports (14,15).

The long-term effectiveness of SIJ steroid injection has been reported as the proportion of patients with sustained pain relief at 6 months being 58%, or the average duration of sufficient pain relief being 9.3 months (14). This is likely because Maugars et al (15) conducted the study in patients with spondyloarthropathy, in which the inflammatory component of spondyloarthropathy must have been more overpowering than a mechanical or traumatic cause.

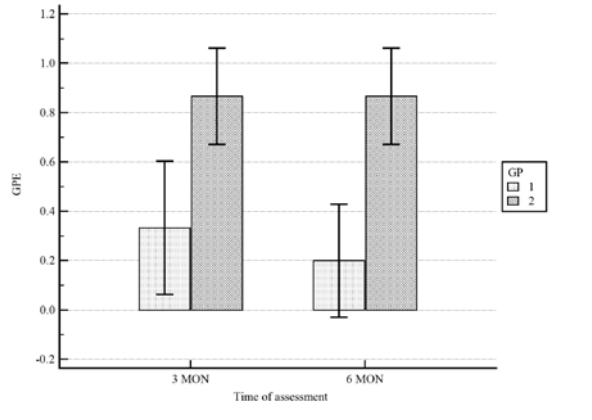

Fig. 4. *Comparison of GPE between groups..*

Hawkins et al (14), in their report of a practice audit of serial therapeutic SIJ injections, showed that SIJ corticosteroid injections appear to be an effective palliative treatment for selected patients with SIJ pain. However, most patients in this study whose pain was responsive to SIJ steroid injections improved sufficiently and remained well only after more than 1 injection, and some required frequent injections on a long-term basis. Over a period of almost 2 years of follow-up of the 155 patients, 77% were positive responders. The positive responders had received a mean of 2.7 injections per patient. In addition, different criteria for a positive response to a diagnostic block may have affected the reliability of the diagnostic block, which may in turn have affected the success rate of the therapeutic injections.

van der Wurff et al (16) found that positive responses to a SIJ diagnostic block may occur with extravasation of an anesthetic agent out of the joint due to defects in the joint capsule.

The review of provocative testing and clinical examination by Laslett et al (17) suggest that 6 commonly performed provocative tests may be useful to select patients for further study, provided 3 or more of them are positive. These include the distraction, compression, thigh thrust, Gaenslen's test, and sacral thrust test. Diagnostic injection into the SIJ can provide data on an intraarticular source of pain, but not on pain arising from the extraarticular ligaments (17,18).

A randomized study by Kim et al (19) using an active-control design compared the effectiveness of prolotherapy to steroid injections for SIJ pain. The authors found no significant differences between the groups at 3 months; however, on a long-term basis, prolotherapy was more effective. Liliang et al (20) showed only short-term effectiveness for intraarticular steroid injections. In that study, 12 patients had a history of lumbar/lumbosacral fusion. The block worked in 5 of the 12 patients (42%), but not in the remaining 7. Conversely, the block worked in 21 of 27 (78%) patients without lumbar/lumbosacral fusion and not in 6, but the duration of the efficacy of the SIJ blocks was shorter in patients with a history of lumbar/lumbosacral fusion. Borowsky et al (21) compared intraarticular injections with a combination of intra- and periarticular injections. The results were suboptimal with both techniques, but were somewhat better in the combined injection group.

In the only published study on PRF for SIJ pain, Vallejo et al (6) reported the results of a prospective case series on the treatment of intractable SIJ dysfunc-

tion with PRF denervation of lateral branches from L4-S2, in which 126 patients with presumptive SIJ dysfunction (based on history and physical examination) underwent arthrographically-confirmed steroid/local anesthetic SIJ injections. Among the 52 patients with a positive response (41.3%), 22 failed to respond and underwent pulsed radiofrequency denervation (PRFD). Sixteen patients (72.7%) experienced either "Good" (> 50% reduction in VAS), or "Excellent" (> 80% reduction in VAS) pain relief lasting at least 6 months. In positive responders, the mean duration of pain relief was 20 weeks. In addition, quality of life scores improved significantly in all measured categories.

In our study, the higher success rate with PRF ablation may be partially explained by the fact that, unlike Vallejo et al (6), who made 2 RF lesions at each level (L4-S2) for a period of 120 s, we aimed to create a lesion with a continuous volume of tissue lateral to the S1-3 foramina at predesignated positions, as done by Cohen et al (13). Various methods of RF denervation for SIJ pain have been reported in the literature. Ferrante et al (22)reported the use of RF denervation with bipolar electrodes for thermoablation along the SIJ line. In their study, 36.4% of patients had a 50% reduction in pain for a period of at least 6 months. In a pilot study, Cohen et al (23) performed RF denervation at the medial branch of L4, the dorsal rami of L5, and the lateral branches of S1–S3 in their patients with SIJ pain. Eight of 9 patients had more than 50% pain relief that lasted for more than 9 months.

Discrepancies in the success rates for RF denervation of the SIJ may be related to the different techniques used or to anatomic variation of the sensory fibers innervating the SIJ. The failure of 2 patients to obtain pain relief in our PRF group may be explained by this fact. In a cadaveric study by Yin et al (24), the anatomic locations of the lateral sacral branches varied greatly, exiting the sacral foramen between the 2 o'clock and 6 o'clock positions on the right, and between the 6 o'clock and 10 o'clock positions on the left. Even within each segmental level, the number, location, and path of the lateral branches to the SIJ were not consistent. Dreyfuss et al (25) also reported that multi-site, multi-depth lateral branch blocks do not effectively block the intraarticular portion of the SIJ. Multi-site, multi-depth lateral branch blocks are physiologically effective at a rate of 70%. Comparative multi-site, multi-depth lateral branch blocks should be considered a potentially valuable tool to diagnose extra-articular SIJ pain and determine if lateral branch RF neurotomy may help alleviate SIJ pain.

The use of cooled RF has been done in a number of studies. Ho et al (26) achieved good long-term outcomes at 24 months in 20 patients using cooled RF denervation of the lateral sacral branches for SIJ pain. Kapural et al (27) published a case series of 26 patients who underwent SIJ intervention using cooled RF denervation with positive outcomes, as measured by a reduction in pain scores and functional improvement at 3–4 months after the procedure.

The merit of our study is that it is a randomized and single-blinded study with a larger sample size compared to the previous study on PRF. The novelty factor is that it is the first to compare the efficacy of PRF ablation to that of intraarticular depo-methylprednisolone injection in patients with SIJ pain.

Conclusion

The results of this randomized, prospective, single-blinded comparative study provide evidence that PRF denervation of the L4 and L5 primary dorsal rami and S1-3 lateral branches provide significant pain relief and functional improvement in patients with SIJ pain. No complications or side effects were observed in our patients throughout the study period. Thus, PRF ablation is more effective than intraarticular depomethylprednisolone injection for SIJ Pain in selected patients with similar demographics. However, larger, randomized, controlled and multi-centre studies with long-term follow-up and comprehensive outcome measures are needed to confirm our findings and establish the efficacy of PRF ablation in the management of SIJ pain.

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