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Intra-articular pulsed radiofrequency with methyl prednisolone injection in chronic sacroiliac joint arthritis: A randomized clinical trial

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ABSTRACT

Background: Sacroiliac joint pain (SIJP) is an important cause of low back pain and seriously affects the patients' quality of life. Therefore, it is urgent to find effective treatment methods. The goal of our research was to assess the effectiveness of radiofrequency ablation combined with steroid injection versus steroid injection alone in the treatment of chronic sacroiliac joint arthritis (SIJ) pain.

Methods: Sixty patients with chronic SIJ pain were divided into two groups randomly: Group RF (n = 30) received intraarticular RF + methylprednisolone, while Group C (n = 30) received intraarticular methylprednisolone alone. The Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), and Patient Global Impression of Change Scale (PGIC) were followed up at each observation time (before the intervention, 1 month, 3 months, 6 months, 9 months, and 12 months).

Results: The NRS and ODI reduced following treatment compared to pretreatment values; however, the PGIC increased in both groups. The NRS in the RF group reduced significantly than in the control group after treatment at nearly all time intervals after the third month with $p = 0.015^*$, 0.004^* , 0.049^* , and 0.025^* , respectively. After the first month, the difference in PGIC score between the two groups becomes statistically significant at nearly all time intervals with p < 0.05. At nearly all time intervals, the RF group had higher PGIC scores.

Conclusion: PRF ablation with methylprednisolone injection is a safe and efficient treatment for sacroiliac pain. It has the potential to considerably reduce sacroiliac pain, lower ODI, raise PGIG, and improve physical and mental quality of life.

1. Introduction

Low back pain (LBP) is a significant clinical, social, economic, and public health issue. LBP frequently recurs, despite the fact that the symptoms are usually acute and self-limited. 30% of those who develop acute LBP develop chronic LBP [1].

Sacroiliac joint pain (SIJP) is a common cause of low back pain. SIJP is characterized by acute or chronic injury to the cartilage, joint capsule, peripheral ligament, and soft tissue of the sacroiliac joint (SIJ), as well as pain in the lumbosacral and lower extremities [2,3]. SIJ disease is currently responsible for 15–30% of low back pain [4]. This has a significant impact on patients' quality of life and is the leading cause of early disability. It is caused by a variety of disorders, the pathophysiology of which is unknown, and the diagnosis is challenging [5]. It can be diagnosed by doing many tests such as [6] pressure application to a sacroiliac ligament [7], Gaenslen's test [8], or Patrick test [9], and when the test becomes positive, it will increase the probability of SIJ pain. Patients were also required to show pain decrease of at least 50% for at least 30 min after a diagnostic block using 0.5 mL of 2% lidocaine intra-articularly and 0.3 mL of 2% lidocaine periarticularly for the diagnosis of SIJ pain [10].

There are several techniques that can be used to treat SI joint pain [11]. A traditional therapeutic procedure is SIJ block. It can successfully reduce SIJP, but it has a short maintenance period and a limited longterm therapy impact and requires repeated treatment [12]. Injections of methylprednisolone into the SIJ have been found to decrease inflammation and pain [11].

Radiofrequency (RF) has been used to treat chronic pain that has failed to respond to other treatments [13]. Radiofrequency treatment has increasingly become a standard technique for treating chronic pain, such as neuropathic pain, knee pain, and others [14,15]. Radiofrequency is a minimally invasive procedure. There are two types of radiofrequency: conventional radiofrequency (CRF) and pulsed radiofrequency (PRF) [16].

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CRF acts by interrupting nociceptive signals by blocking the transmission of pain signals by thermal lesion formation [17]. There have only been a few attempts to employ RF current to treat painful joint disorders in the extremities. There have been case studies using RF therapy for hip joint pain [18–20], while pulsed radiofrequency (PRF) is essentially a nonneurolytic procedure. The affected target may be larger than that associated with conventional radiofrequency (RF) due to the enormous electromagnetic field produced [21].

Radiofrequency (RF) neurotomy may be a successful alternative treatment with few complications in patients for whom surgery is contraindicated [22].

Our goal was to see how effective it was to combine intra-articular pulsed radiofrequency (PRF) ablation with traditional intraarticular steroid injection versus intraarticular steroids alone in treating sacroiliac join.

2. Methods

2.1. Patients

The Medical Research Ethics Committee, Faculty of Medicine, Assiut University, Assiut, Egypt, approved this prospective randomized controlled double-blind (SHAM) study (approval no: 17200203). It follows the Helsinki Declaration and was registered at ClinicalTrials.gov (NCT03564106). From April 2019 to January 2021, researchers at University Hospital Pain Clinic conducted this study.

After obtaining written informed consent from patients suffering from sacroiliac joint (SIJ) arthritis, we included a total of 60 patients ranging in age from 18 to 65 years old.

Patients scheduled for elective adult interventional procedures under local anesthesia signed a written informed consent form.

Patients with persistent SIJ arthritis who had at least three positive diagnostic tests [23] (Distraction, Thigh Thrust, FABER, Compression, and Gaenslen's tests) and had 50% reduction of pain after doing the diagnostic intraarticular block were included in this study. Also, all patients must have had chronic pain for at least 6 months, have a pain intensity >5 on a 10-point Numeric Rating Scale (NRS) (where 0 means no pain and 10 is the worst pain imaginable), and have failed medical treatment.

Patients with a history of coagulation or other bleeding disorders, diabetes, rheumatoid arthritis, ankylosing spondylitis and other degenerative joint diseases, including other possible causes of low back pain, psychiatric illness, opioid addiction, infections, trauma or previous surgery at the injection site, or refusal to participate in the trial were excluded.

2.2. Randomization and blinding

Serially numbered unopened, opaque envelopes were used to hide allocations. After opening the accompanying sealed envelope, each patient was assigned a serial number from a computer-generated randomization table and placed in the proper group. Prior to recruiting, participants received participation counseling. Patients were divided into two groups at random:

2.2.1. Group RF (the study group)

This group had received intraarticular RF for 10 min + intraarticular methylprednisolone (30 mg).

2.2.2. Group C (the control group)

This group had received conventional intraarticular methylprednisolone alone (30 mg) with keeping the RF device turned on without being operated, leaving the needle in its place for 10 min and then was removed.

The intervention was kept blind for the patients and the clinicians who followed up with them.

2.3. Intervention protocol

An IV cannula was placed prior to the procedure, and patients were monitored (pulse oximeter, NIBP, and ECG) before being placed in prone position on the fluoroscopy table and receiving 1 μ g/kg fentanyl immediately before the procedure which was conducted by an experienced physician.

All patients were put prone on the fluoroscopy table, and the SIJ was revealed by tilting the fluoroscope 5 to 15 degrees caudal and 3 to 10 degrees toward the contralateral side and then 3 ml lidocaine 2% was injected at the site of needle insertion after under aseptic and antiseptic precautions (good sterilization by Betadine© solution) and then we used 10-cm -long, 10-mm active tip, 22-gauge, curved radiofrequency cannula (Neurotherm) to target the SIJ at its lower third according to Do et al. method [24].

To validate the needle position inside the joint, contrast dye (0.3 mL omnipaque) was utilized. The joint was then injected with a mixture of steroids and local anesthetic (30 mg methylprednisolone in 1% lidocaine in a total volume of 1.7 ml).

In group RF, five cycles of pulsed radiofrequency 120 s each were done using the Neurotherm 1100 Radio-Frequency Machine. The temperature was set at 42°C. A frequency of 2 Hz and a pulse width of 20 ms were set (large joints as the SIJ will need 10 min of pulsed radiofrequency energy to capture its large surface area).

In group C (intraarticular injection), the RF cannula remained in its place after the injection for 10 min and then removed.

Patients in groups RF and C were observed for 1 h after the intervention and then discharged.

2.4. Assessment parameters

The following data were collected:

- Demographic and anthropometric data included patient's age, sex, weight, and height, and address and contact information were collected.
- In pain assessments using the Numeric Rating Scale (NRS), patients were instructed to rate their worst pain before the procedure on a scale from 0 to 10, where 0 indicates no pain and 10 indicates severe disabling pain.
- All patients answered the Oswestry Disability Index (ODI) [25]. Scoring: 0– 20: Minimal disability, 21–40: Moderate Disability, 41–60: Severe Disability, 61–80: Crippling back pain, 81–100: These patients are either bed-bound or have an exaggeration of their symptoms.
- Patient Global Impression of Change Scale (PGIC) [26] before the intervention.

2.4.1. Scoring

1 = no change, 2 = almost the same, 3 = a little better, 4 = somewhat better, 5 = moderately better, 6 = better, and 7 = a great deal better. A significant favorable change is a score of 5–7, and no significant change is a 1–4 response. Note that this is a dichotomous scale (5–7 = yes; 1–4 = no). A 2-point change is significant from their last reported score.

All the previous scores had been answered by the patients at 1, 3, 6, 9 and 12 months after the intervention. For example, PGIC: how would you describe the change (if any) in activity limitations, symptoms, emotions and overall quality of life, related to your painful condition?

- Satisfaction score was recorded on the sixth months using Likert score: 1 = strongly unsatisfied, 2 = moderately unsatisfied, 3 = neutral, 4 = moderately satisfied, and 5 = strongly satisfied [27].
- Any complications or complaints whether related to the intervention or sedation.

2.5. Follow-up

All patients were contacted for a year after the intervention, at the 1st, 3rd, 6th, 9th, and 12th months, to rate their pain and progress using the NRS, PGIC score, and ODI Index, as well as to report complications and analgesic consumption. The rescue analgesia was administered with oral paracetamol 1 g as required or whenever the NRS score was >5 over a period of 12 months.

Before the trial began, a successful outcome was defined as a 20% reduction in numerical pain score [28] and a 10–12-point decrease in ODI score [29].

2.6. Outcome

The Numeric Rating Scale (NRS) was used to assess pain severity as the primary outcome measure (NRS). The Patient Global Impression of Change Scale (PGIC), the Oswestry Disability Index (ODI), patient satisfaction, the incidence of complications, and analgesic consumption were used as secondary outcome measures.

2.7. Sample size

Based on results from previous study [30], we need 30 patients in each group to detect a 20% decrease in the NRS score after 6 months of treatments, with an alpha error of 0.05 and 0.8 power of the study. To compensate for dropouts, four patients were added to each group.

2.8. Statistical analysis

Data was expressed as mean \pm standard deviation (SD) or number (%) of patients. For the statistical analysis, SPSS version 20.0 (SPSS Inc., Illinois) was used. Independent *t*-test or Mann–Whitney test was used to compare the continuous variables among the groups. Categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate. A *p* value of less than 0.05 was considered statistically significant.

3. Results

Eighty-seven patients were assessed for eligibility. Fifteen of them did not meet the selection criteria, and four patients refused to participate in the study. Sixty-eight patients were enrolled in the study, but eight patients were lost during the follow-up period (Figure 1).

Figure 2 shows the spread of the dye inside the SIJ with the presence of RF needle.

Age, sex, height, weight, and disease duration were all similar between the two groups; there were no significant intergroup variations in these variables (Table 1).

3.1. Pain scores

There was no significant difference between the two groups in terms of pain score (NRS) before and after the intervention (p > 0.05) up to the 3rd month. There was a significant difference between the two groups after 3, 6, 9, and 12 months (p < 0.05). At nearly all time periods, the RF group had lower NRS scores (Table 2).

According to PGIC score (Patient Global Impression of Change Scale), before the intervention, after 1 m, and after 3 m, there was no significant difference between the two groups (p > 0.05). There was

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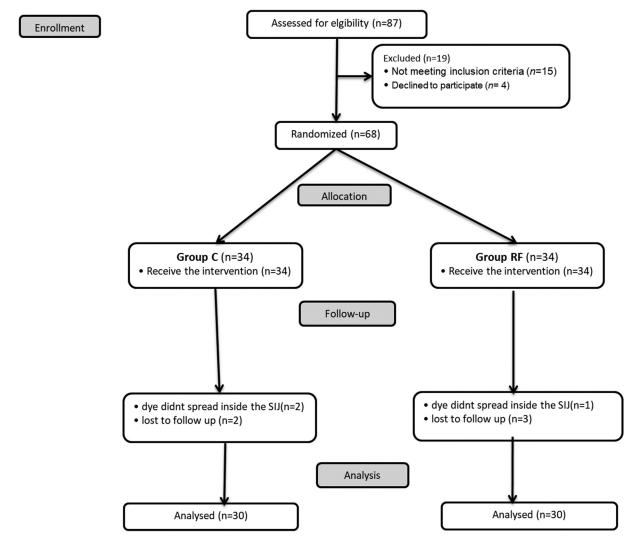


Figure 1. The CONSORT flow chart.

a significant difference between the two groups after 6, 9 and 12 months (*p*<0.05). At nearly all time periods, the RF group had higher PGIC ratings (Table 2).

According to ODI score (Oswestry Disability Index), there was no significant difference between the two groups before the intervention, (p > 0.05). After 1, 3, 6, 9 and 12 months, there was significant difference between the two groups ($p \le 0.05$). RF group had lower scores of ODI at nearly all time intervals (Table 2).

3.2. Total analgesic requirement

According to total paracetamol dose and its number of doses in the studied groups, there was no significant difference between the two groups before the intervention and up to 3rd months (p > 0.05), but it differed significantly at the 6th, 9th and 12th months ($p \le 0.05$), where the median paracetamol amount required as rescue analgesia in RF group was 1 (0–3) g/day and in control group was 3 (0–3) g/day (Table 3). The rescue analgesia was administered with oral paracetamol 1 g as required or whenever the NRS score was >5 over a period of 12 months.

3.3. The outcome data

36.7% of patients reached the successful outcome in RF group, while 16.7% only in control group (Figure 3).

3.4. Patients' satisfaction

Patients' satisfaction was assessed using Likert scale; the satisfaction score was adequate (very satisfied, satisfied, and neutral) in 95% of the RF group as compared with 45% in the control group (p = 0.037) (Figure 4).

3.4.1. Side effects

Finally, none of the patients in Group RF has developed any complications (infection, hemorrhage, or thermal injury) or related to sedation during the period of follow-up.

4. Discussion

The current study uses the Numeric Rating Scale (NRS), Patient Global Impression of Change Scale (PGIC), and Oswestry Disability Index to demonstrate the efficacy

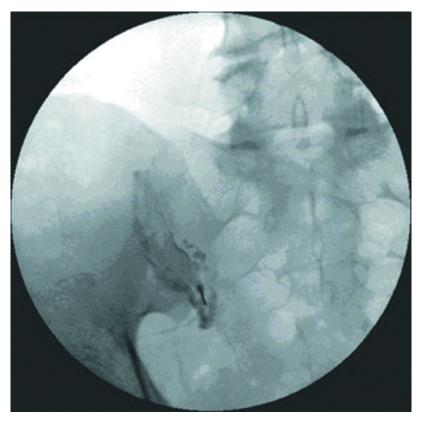


Figure 2. Spread of the dye inside the SIJ.

Table 1. Demographic data from the two studied groups.

ltem	Control group $(n = 30)$	RF group (<i>n</i> = 30)	<i>p</i> -Value
Age (years)	42.20 ± 11.12	44.37 ± 13.35	0.497
Gender (n) %			
 Male 	9 (30)	7 (23.3)	0.386
 Female 	21 (70)	23 (76.7)	
Weight (kg)	83.07 ± 9.51	77.73 ± 14.04	0.090
Height (cm)	170.63 ± 6.50	168.97 ± 7.12	0.348
Duration of disease (months)	22.17 ±7.89	19.70 ±8.25	0.241

Data were presented as mean \pm SD or No. (%).

p Value is significant if <0.05.

Independent-student t test, Fisher's exact test, or Mann–Whitney U test was used.

Table 3. Total dose of paracetamol in (g/day) the two studied groups.

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	Control group ($n = 30$)	RF group ($n = 30$)	<i>p</i> -Value
Pre-intervention	2 (1–3)	3 (1–3)	0.574
After 1 month	2 (0-3)	2 (0-3)	0.963
After 2 months	1 (0–3)	2 (0-3)	0.23
After 3 months	1.5 (0-3)	1 (0–3)	0.72
After 4 months	2 (0-3)	1 (0–2)	0.024*
After 5 months	2 (0-3)	1 (0–2)	0.011*
After 6 months	2 (0-3)	1.5 (0-3)	0.03*
After 9 months	2 (0-3)	1 (0–2)	0.009*
After 12 months	2 (0–3)	1 (0–3)	0.044*

Data were presented as median (IQR).

*p value is significant if <0.05.

Mann–Whitney U test was used.

of applying intra-articular Pulsed RF with methylprednisolone injection to the SIJ in patients with chronic sacroiliitis (SIJ). In patients with SIJ pain, we discovered that intra-articular pulsed RF with methylprednisolone

Table 2. Follow-up of study scales in both groups.

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Variables	Control group ($n = 30$)	RF group ($n = 30$)	<i>p</i> -Value			
NRS score						
Pre-intervention	9 (4–10)	8.5 (6–10)	0.946			
After 1 month	2.5 (0-10)^	3 (0-8)^	0.917			
After 3 months	3.5 (1–10)^	2 (0-6)^	0.015*			
After 6 months	3.5 (0–10)^	1.5 (0–5)^	0.004*			
After 9 months	4 (0–10)^	2 (0–9)^	0.049*			
After 12 months	4 (0–10)^	2.5 (0–7)^	0.025*			
PGIC score						
Pre-intervention	2 (1–3)	1 (1–3)	0.301			
After 1 month	6 (1–7)^	6 (1–7)^	0.824			
After 3 months	6 (1–7)^	6 (1–7)^	0.366			
After 6 months	5 (1–7)^	6.5 (2–7)^	0.001*			
After 9 months	4 (1–7)^	6.5 (2–7)^	<0.001*			
After 12 months	3 (1–7)^	6.5 (1–7)^	0.001*			
ODI score						
Pre-intervention	53.5 (20-77)	56.5 (30-85)	0.296			
After 1 month	40 (20-67)^	22 (15–70)^	0.019*			
After 3 months	34.5 (20-70)^	21.5 (20-66)^	0.056*			
After 6 months	27.5 (20-70)^	20 (20-65)^	0.005*			
After 9 months	30 (20–70)^	20 (20-70)^	0.028*			
After 12 months	34 (20–70)^	20 (20–69)^	0.010*			
Data were presented as median (IOP)						

Data were presented as median (IQR).

*p Value is significant if <0.05.

Mann–Whitney U test was used.

^p value is significant if <0.05 when compared between baseline value and follow-up values at each group separately by Wilcoxon signed-rank tests.

injection offers considerable pain alleviation and functional improvement. Up to 12 months following intervention, the RF group showed an increase in PGIC and a drop in ODI score.

Our findings are consistent with numerous studies that have shown the benefit of RF in reducing painful symptomatology [31,32]. The pain alleviation lasted

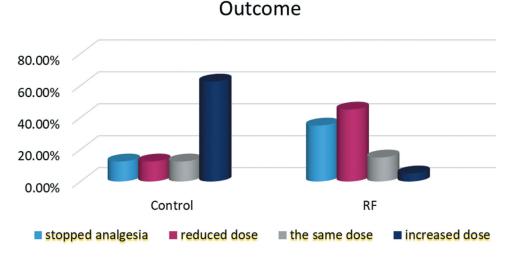
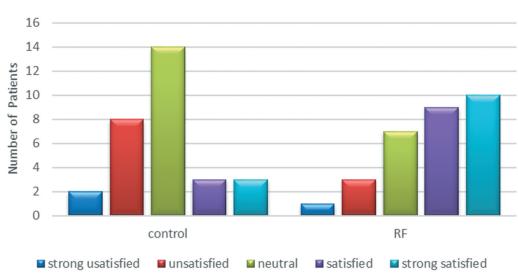


Figure 3. Outcome data.



Likert scale

Figure 4. Patients' satisfaction scale.

considerably longer than would have been expected with just steroid injections. In addition, Group RF had higher patient satisfaction than Group C.

Despite the fact that the control group exhibited considerable improvement, the subjects who received medications had higher NRS scores than the RF group throughout the trial period.

Sacroiliac pain can be treated with a variety of methods, including conservative treatment, interventional therapy, and surgery. The treatment is chosen based on the patient's condition, with conservative treatment being the preferable option. The majority of patients may have a better curative effect. However, some patients do not respond well to conservative treatment, and the disease is prolonged. Interventional therapy can be considered at this time. Interventional therapy has the advantages of a minimal trauma, quick recovery, short operation time, and short postoperative hospital stay, whereas surgery is generally the final option because of its large trauma [12].

Our findings are also corroborated by Dutta et al., who compared intra-articular injections of depomethylprednisolone to pulsed radiofrequency ablation for sacroiliac joint pain and found that the RF group had a significantly lower NRS and ODI score than the other group. They concluded that pulsed radiofrequency denervation can enhance joint function and analgesia in patients with sacroiliac joint pain in a safe and effective manner, but it has many complications [31].

IA injection of local anesthetics and cortisol directly into the joints can reduce inflammation in and around the joints, relieve pain, and promote tissue repair immediately, but the maintenance time is brief, and repeated therapy always has more side effects [12].

PRF does not cause nerve injury; nevertheless, pain alleviation may be due to reversible neurons momentarily inhibiting nerve impulses in the nerve conduction pathway. In the spinal cord, PRF inhibited MAPK activation (mitogen-activated protein kinase), reduced cytokine release, and inhibited the release of excitatory amino acids [33]. Furthermore, PRF may reduce JNK (C Jun-N-terminal Kinases) activation in the dorsal horn of the spinal cord [34], inhibited spinal cord sensitization, and regulated the expression of multiple genes in the pathway. The expressions of anti-inflammatory factor genes (GABA_B-R1, Na/K-ATPase, and 5-HT3r) were enhanced, while the expressions of pro-inflammatory factor genes (TNF-a and IL-6) were decreased [35], so the pain was relieved [36]. As a result, PRF's analgesic effect was slow, and its long-term analgesic effect could be linked to neuromodulation.

Steroids reduce redness and swelling (inflammation) in the vicinity. This can help relieve pain and stiffness. The effects of a cortisone injection can last between 6 weeks and 6 months.

The increased success rate with PRF ablation with intraarticular steroid injection in our study could be explained in part by the fact that both of them work together as neuromodulation and anti-inflammatory as shown in improving NRS and reducing ODI from the first month of follow-up.

RF denervation for SIJ pain has been reported using a variety of techniques. The use of RF denervation with bipolar electrodes for thermoablation along the SIJ line was reported by Ferrante et al. In their research, 36.4% experienced a 50% reduction in pain for at least 6 months [37].

Cohen et al. used RF denervation in their patients with SIJ pain in the medial branch of L4, the dorsal rami of L5, and the lateral branches of S1–S3. Eight out of nine patients experienced pain reduction that lasted more than 9 months [38].

The different procedures utilized or anatomic variance of the sensory fibers innervating the SIJ could explain differences in success rates for RF denervation of the SIJ [31].

In regards to safety, no complications have been reported by our participants during the follow-up period. The biological effects of pulsed RF have been studied in several studies. Interestingly, they discovered that RF does not result in irreversible tissue damage [39,40], and this was an important concern in the management of our patients. Based on this information, we believe that additional RF interventions can be safely allowed in cases where there is a medical necessity.

The novelty factor is that it is the first to compare the efficacy of intraarticular PRF ablation with methylprednisolone injection to that of intraarticular methylprednisolone injection in patients with SIJ pain. In adequately screened patients with chronic painful sacroiliac joint, PRF ablation with methylprednisolone injection is superior to the conventional intraarticular steroid injection, in the early and late stages. It is recommended for SIJ pain.

5. Limitations

In addition, some of the study's limitations should be considered. First, a small group of participants was recruited. Second, pain intensity was not assessed in various situations or positions, such as resting, walking, or standing. It is suggested that more research be done to solve these constraints. However, larger, randomized, controlled and multicenter studies with long-term follow-up and comprehensive outcome measures are needed to confirm our findings and establish the efficacy of PRF ablation with methylprednisolone injection in the management of SIJ pain.

We may consider putting more than one radiofrequency needle in the SIJ to allow larger impact, but putting the RF needle in the upper third of the joint is technically difficult.

6. Conclusion

In summary, PRF ablation with methylprednisolone injection is a safe and efficient treatment for sacroiliac pain. It has the potential to considerably reduce sacroiliac pain, lower ODI, raise PGIG, and improve physical and mental quality of life.

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Disclosure statement

The authors declare that they have no conflicts of interest".

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