Treatment of chronic sacroiliac joint pain using Conventional Radiofrequency (CRF) and Pulsed Radiofrequency (PRF): A randomized control study.

Tayyaba Wasim¹, Syed Mehmoed Ali², Zahra Asad³, Anum Zeb⁴, Muhammad Oun⁵, Zulqarnain Butt⁶

ABSTRACT... Objective: To determine the effectiveness of conventional radiofrequency (CRF) and pulsed radiofrequency (PRF) in treatment of chronic sacroiliac joint pain. Study Design: Randomized Controlled Trial. Setting: Shaikh Zayed Hospital, Lahore. Period: 2nd August 2022 to 10th February 2023. Methods: A total sample of 60 patients with SIJ pain was screened for this study. This sample was divided equally but randomly into both study groups; conventional radiofrequency (CRF) and pulsed radiofrequency (PRF). Pre-procedure general information on Visual analogue score (VAS) and revised Oswestry Disability Index (ODI) were used to measure the main outcome variables; pain score and physical disability index. Post-procedure information on these two outcome variables was also recorded after 1, 3 and 6 months duration. Paired samples t-test and independent samples t-test was used to assess the effectiveness of these two treatment methods for SIJ pain treatment. Results: The mean pain score in the conventional radiofrequency (CRF) group was reduced to 3.02 ± 0.9 from 8.02 ± 1.13 which is more substantial and statistically significant than pulsed radiofrequency where it was 4.2 ± 1.31 from 7.98 ± 1.20. Similarly, the conventional radiofrequency (CRF) group showed better performance on average scores of the ODI index (20.2± 6.9) as compared to pulsed radiofrequency (31.2± 8.9) in reducing physical disability in SIJ patients. Conclusion: This study concludes that the existing conventional radiofrequency (CRF) method of treatment can be effectively used in treatment of SIJ with its slight complications.

Key words: Chronic Sacroiliac Joint, Oswestry Disability Index, Pulsed Radiofrequency, Sacroiliac Joint Pain, Visual Analogue Scale.

INTRODUCTION
In recent times, one of the most prevalent health issues is chronic low back pain that can even cause disability.¹ Sacroiliac joint (SIJ) pain affects about 40% of people who complains of low back pain, which actually affects 70%–85% of the total population. SIJ pain is the leading contributor to disability and is very common and expensive.² Its causal relationships with disability have been clearly defined. Estimates have shown that a total of 83 million disability-adjusted life years (DALY), or years of life lost due to illness, disability, or early death every year have been associated with this disease.² Many people experience pain in their SIJ but did not consider it, therefore, researchers claim that it is an underestimated source of persistent low back pain.³⁴ The SIJ is a synovial joint whose main job is to transfer weight to the lower extremities from the axial skeleton.⁵ There are currently two main categories of SI joint pain and injury: traumatic and atraumatic. The most frequent traumatic causes include pelvic fractures, car accidents, and atraumatic injuries sustained while carrying large objects, while the most prevalent atraumatic causes are osteoarthritis, pregnancy, and structural disorders of the axial bone.⁶ Both types of SI joint injuries cause inflammation and injury to the SI joint capsule, ligaments, or subchondral bone.⁷ The articular surfaces of the SI joint are identical and are separated by a fibrous capsule. The SIJ contains traits that are unique to it and are not present in other diarthrodial joints as a result.

1. MBBS, FCPS (Anesthesia), FCPS (Pain Medicine), Resident, Shaikh Zayed Hospital Lahore, Senior Registrar Anesthesia, Hameed Latif Hospital, Lahore.
2. MBBS, FCPS (Anesthesia), MSc (Pain Medicine), FIPP, Associate Professor Anesthesia, Shaikh Zayed Hospital, Lahore.
3. MBBS, FCPS (Anesthesia), Senior Registrar Anesthesia, Mayo Hospital, Lahore.
4. MBBS, FCPS (Anesthesia), Senior Registrar Anesthesia, Lahore General Hospital, Lahore.
5. MBBS, FCPS (Anesthesia), Medical Officer Anesthesia, Punjab institute of Neurosciences, Lahore.
6. MBBS, MCPS (Anesthesia), FCPS (Anesthesia), Associate Professor Anesthesia, Hameed Latif Hospital, Lahore.

Correspondence Address:
Dr. Tayyaba Wasim
Shaikh Zayed Hospital Lahore,
Senior Registrar Anesthesia Hameed Latif Hospital,
t.wasim25@gmail.com

Article received on: 09/11/2023
Accepted for publication: 11/01/2024
Chronic Sacroiliac Joint Pain

The most typical patient presentation for SIJ pain is a deep pain that develops after an initiating event, radiating up the back of the knee and down the posterior thigh, and reproducible when sitting, lying on the ipsilateral side, or ascending stairs. This is a crucial distinction from radicular pain, which frequently creeps up on patients.\(^4\) Because of the SIJ’s complexity and breadth, many different aetiologies can contribute to pain in this area, making diagnosis both difficult and elusive. Although the majority of the studies reviewed indicated a point prevalence of about 25% and a false-positive rate for uncontrolled blocks of about 20%, a systematic review of the prevalence and diagnostic accuracy of SIJ interventions\(^8\) discovered a highly variable prevalence ranging from 10% to 60% depending on the setting. Because there is no widely accepted “gold standard” for diagnosing low back pain from various illnesses that cannot be recognized with imaging or clinical examination.\(^9\)

There are several ways to treat SIJ disease that mainly includes therapies (interventional) surgery, physical therapy and conservative methods. The choice of conservative treatment is directly associated with the patient’s health. Some people might have better curative characteristics than others who don’t respond to the standard treatments and consequently prolong their disease. Intra-articular joint injections\(^10\), radiofrequency ablation (RFA)\(^11\), and surgical treatment are all interventional treatments for the management of SIJ pain.\(^12\) RFA is an old technique and was first discussed in the literature in 1975\(^13\) for treating chronic back pain and is now the most commonly used treatment method. For many years, X-ray fluoroscopy-guided percutaneous conventional radiofrequency (CRF) has been used to treat spinal pain.\(^14\) As compared to CRF, pulsed radiofrequency (PRF) consumes less energy and operates at a lower temperature.\(^15\)

The use of pulsed radiofrequency is a novel approach to pain management. It is accomplished by using RFA energy with a pulsed time cycle of 2 ms/s at temperatures no higher than 42\(^\circ\) C.\(^14\) However, there is insufficient evidence in the literature to prove the efficacy of pulsed radiofrequency in the treatment of SIJ. Therefore, this study aims to compare the efficiency of CRF in a conventional way with pulsed radiofrequency which is relatively a novel method to treat SIJ pain. Because of the scarcity of randomized controlled trials, this study tries to assess the efficacy of these treatment methods in terms of pain management and the reduction of physical disability in SIJ pain patients.

METHODS

Selection of Patients
This study was conducted at Shaikh Zayed Hospital, Lahore from 2 August 2022 to 10 February 2023. It is a tertiary care hospital. A randomized controlled trials design was adopted in this study. The randomization process utilized a lottery method, ensuring unbiased allocation of participants to either the Conventional Radiofrequency (CRF) or Pulsed Radiofrequency (PRF) groups (30 patients in each group). This sample size was estimated using previous similar studies\(^16,17\) and statistical reasoning; at least a sample of 30 in each group for the sufficient sample size for comparison purposes.\(^18\) Further, 80% power of the test and 5% margin of error and with a large effect size, were also used to compute the sample size. However, written informed consent was also taken for these procedures before any treatment. This study was approved by an ethical review committee (IRB/SZMC/131) (14-3-22) of the Shaikh Zayed Hospital, Lahore.

Inclusion Criteria
The inclusion criteria of the current study were based on IASP’s\(^19\) definitions for SIJ pain. This definition includes that the span of the pain should be more than 1 month, at the visual analogue scale (VAS) pain should be moderate to severe; pain intensity score > 5 points on average in 24 hours at the VAS scale. This pain should be in one or bilateral lumbosacral regions especially hips, lower extremities and groin. Tenderness and percussion pain should be in the sacroiliac region while having a physical examination. In addition to physical examination, at least one test should be positive; the Patrick sign, compression and distraction test and the Gaenslen sign. Imaging
technology like CT scan or MRI confirm sacroiliac arthritis and intraarticular (IA) block can give relief of 50% and a conservative method of treatment would not be effective.

**Exclusion Criteria**
The patients who have the following diseases; lower bone density, autoimmune diseases, leg length discrepancy, variability in auricular surface, and trauma, can show more likelihood of SIJ pain.20

**Conventional Radiofrequency Procedure**
In the conventional radiofrequency (CRF) treatment for SIJ pain, the patient was positioned prone on an examination table. Firstly, venous was identified and its access was ensured. Thirty minutes before treatment, ceftriaxone sodium was given to the patients to avoid any type of infection. 0.5% lidocaine was used as infiltration anaesthesia after the initial local disinfection. After sterilization and local anesthesia, a fluoroscopically guided RF needle was inserted at a 45-degree angle. The needle was advanced medially to target the pain-transmitting nerves. The RF instrument was tested at: 50 Hz, 0.1–0.3 V test sensation and 2 Hz, 0.1 V test exercise, and there was no induction of hips and lower extremity muscle tremors and pain. The RF generator delivers high-frequency alternating current, maintaining temperatures between 80 and 90 degrees Celsius. However, in the CRF group treatment was started at 50°C and steadily increased to the target temperature of 80°C for 3 minutes (180 seconds). Lesion formation typically lasts 60 to 120 seconds. At the end, an amount of 3 ml of an analgesic complex solution (2% lidocaine 1.5 mL + compound betamethasone 5 mg + normal saline 0.5 mL) was also injected.

**Pulsed Radiofrequency Procedure**
In the pulsed radiofrequency (PRF) procedure, the selected patient was positioned prone on an examination table. A specialized pulsed radiofrequency needle was percutaneously inserted using fluoroscopic guidance. pulsed radiofrequency energy was delivered intermittently at a frequency of 2 Hz or lower, with each pulse lasting 20 milliseconds or less. The objective was to create a neuromodulatory effect by interfering with pain signal transmission. In this group, treatment was started at 42°C and pulsed radiofrequency for 600 seconds. After this treatment, an amount of 3 ml of an analgesic complex solution (2% lidocaine 1.5 mL + compound betamethasone 5 mg + normal saline 0.5 mL) was injected. The patient was observed for a further 30 minutes and returned to the ward or discharged from the hospital. This study was mainly before and after the treatment procedure. Therefore, before treatment, the general condition of all patients was recorded. Age, gender, history of pain, VAS, pain side and position were also noted. In this study follow-up measurements were also performed at different times; 1, 3 and 6 months. These evaluations were done by medical staff and followed the procedure of double-blind. These observations include the following assessments prior to and after CRF and pulsed radiofrequency, VAS pain score; ranges from 0 (painless) to 10 (intolerable pain), secondly, physical functions were assessed using a revised Oswestry Disability Index (ODI).21

**Data Analysis Plan**
SPSS version 23.0 was used to analyze the data. Analysis was performed at two levels; descriptive and inferential. The first type of analysis deals with only a description of qualitative and quantitative data. Qualitative variables were presented with their corresponding frequency and percentage, however, mean and standard deviation were reported for the quantitative variables of the study. At the inferential level, the pain score and physical functionality of patients were computed through VAS pain score and ODI scales, respectively and were compared in CRF and pulsed radiofrequency groups through independent samples t-test. However, paired samples t-test was also applied to examine the before and after treatment within groups separately. These tests were used at a 5% level of significance.

**RESULTS**
The demographic characteristics of the study subjects have been reported in Table-I. These characteristics were noted at the time of enrollment in the study. Therefore, these are pre-procedure attributes of enrolled patients.
Both groups have an equal sample size of 30. Gender-wise distribution in both groups of study is slightly different. In the pulsed radiofrequency groups males were 63.3% as compared to 56.6% in the CRF group. The average age of patients diagnosed with SIJ pain was almost similar in both groups. It is ideal to control the confounding effects of such background demographic variables. Further, the duration of pain history (in months) was also observed and noted that average pain history time was also similar in both groups. In the CRF group, 43.34% of patients reported that they had pain on the left side. However, 26.6% of patients complained that they felt pain on both sides. The presence of pain in pulsed radiofrequency patients was mostly observed on the left side or both sides (36.67% each). According to pain position, all patients reported that they had pain in their hips region; as it is the basic characteristic of SIJ pain. VAS and ODI scores were the main outcome scores in these two groups of comparison. At VAS average score, it was observed that patients in both groups; CRF and pulsed radiofrequency, have very high pain scores; 8.02 and 7.98, respectively. Further, the average physical functioning scores in both groups were almost 50. It means patients have severe levels of disability (40-60 points’ means a severe form of disability).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CRF</th>
<th>PRF</th>
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<tbody>
<tr>
<td>Patients (n)</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Gender (n, %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17 (56.6)</td>
<td>19 (63.3)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (43.3)</td>
<td>11 (36.6)</td>
</tr>
<tr>
<td>Age in years (mean ± SD)</td>
<td>47.62 ± 8.71</td>
<td>48.01± 8.51</td>
</tr>
<tr>
<td>Pain history before treatment (mean ± SD) in months</td>
<td>11.2 ± 2.7</td>
<td>10.9 ± 2.8</td>
</tr>
<tr>
<td>Pain Side (n, %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>9 (30.0)</td>
<td>8 (26.66)</td>
</tr>
<tr>
<td>Left</td>
<td>13 (43.34)</td>
<td>11 (36.67)</td>
</tr>
<tr>
<td>Both</td>
<td>08 (26.66)</td>
<td>11 (36.67)</td>
</tr>
<tr>
<td>Position of Pain (n, %)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hips</td>
<td>30 (100)</td>
<td>30 (100)</td>
</tr>
<tr>
<td>Groin</td>
<td>12 (40.0)</td>
<td>10 (33.33)</td>
</tr>
<tr>
<td>Lower Extremities</td>
<td>6 (20.0)</td>
<td>5 (16.7)</td>
</tr>
<tr>
<td>VAS Score</td>
<td>8.02 ± 1.13</td>
<td>7.98 ± 1.20</td>
</tr>
<tr>
<td>ODI Score</td>
<td>50.2± 10.2</td>
<td>50.78± 9.98</td>
</tr>
</tbody>
</table>

Figure-1. Comparison between VAS pain score and ODI disability scores in CRF and PRF Treatment Groups

Table-II is comparison between CRF and PRF treatment methods concerning to pain management and reduction in disability levels. At the initial level, without any treatment average VAS score and ODI score were statistically insignificant having p-values, 0.8943 and 0.8238, respectively. It shows that both groups of patients have similar characteristics. Therefore, there were minimum chances of confounding effects. This comparison is performed in further two ways; within-group and between-group comparisons.
The within-group comparison was performed to evaluate the role of each treatment method with the time. Paired samples t-test was used for this purpose. However, between groups comparison is performed through two-independent samples t-test and assesses the statistically significant difference between two methods of treatment for SIJ pain if any. Paired samples t-tests results (row-wise) have shown that CRF and PRF both methods performed significantly to reduce SIJ pain and its related disability levels. Results were statistically significant at a 5% level of significance. The initial VAS score in the CRF group was 8.02 which reduced to 3.02 after 6 months and this difference was significant. However, this difference was also found significant after 1 month and 3 months. Similarly, in the PRF group, before treatment, VAS score was 7.98 which significantly reduced to 4.2. However, reduction of VAS score in the conventional radiofrequency group was more substantial as compared to the PRF group. A similar pattern was also observed in the ODI score which was observed only once at the end of the study. The conventional radiofrequency method showed a more significant reduction in physical disability score as compared to the PRF method at both time frames; after 3 months and 6 months. Figure 1 is the more elaboration of these findings and showed a smooth pattern of reduction in pain and disability scores with the course of time.

**DISCUSSION**

Sacroiliac joint (SIJ) pain is one of the main reasons of low back pain and can cause a severe form of disability. There are various methods in the literature which can be used to manage this disease. However, conventional radiofrequency (CRF) is generally considered an effective method, however, pulsed radiofrequency (PRF) can also be an option. There is a scarcity of literature about the comparison of these two method of treatment of SIJ pain, especially in local context of developing countries. This study examines the efficacy of these two treatment methods in two dimensions; reduction in pain score and disability. Overall this study found that conventional radiofrequency method of treatment is superior to PRF in both dimensions; reduction in pain scores and disability scores.

Initial findings of study showed that average age of the patients of SIJ was around 48 years. It showed that this disease is more prevalent in middle-aged people. There can be multiple reasons behind this finding. Generally, low physical inactivity, dietary issues, bone quality, and lifestyle can be associated with this disease in this age group. This study finding is consistent with previous study which also reported almost similar average age (46.72 years) for SIJ pain. Further, it was also observed that average pain history was almost 11 months. This long duration showed that people generally ignore this disease at initial level and visit to physicians and practitioners when they have to face the severe problem in their routine life activities like standing, sleeping, walking, social life etc. This continuous habit of delaying leads to physical disability which was observed in this study. This study finding also augmented the researchers who claimed that this disease is generally under-estimated. Another reason can be possible behind this delay which is a standardized way of SIJ pain assessment as discussed in the literature. SIJ has deep position and unique shape that lead to difficulty for practitioners for right assessment and distinction from other low back pain issues. There is a likelihood that patients could not be assessed by the consultants rightly for this disease which could be the reason of this delay.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Outcomes</th>
<th>Pre-procedure</th>
<th>Post-procedure</th>
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<tr>
<td></td>
<td></td>
<td>1 Month</td>
<td>P-Value</td>
</tr>
<tr>
<td>CRF</td>
<td>VAS</td>
<td>8.02 ± 1.13</td>
<td>6.2±1.03</td>
</tr>
<tr>
<td></td>
<td>ODI</td>
<td>50.2±10.2</td>
<td></td>
</tr>
<tr>
<td>PRF</td>
<td>VAS</td>
<td>7.98 ± 1.20</td>
<td>7.02± 1.3</td>
</tr>
<tr>
<td></td>
<td>ODI</td>
<td>50.78± 9.98</td>
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</table>

Table II. Comparison between CRF and PRF patients concerning VAS and ODI scores before and after treatment
This was the reason that instigates us to use multiple inclusion criteria to verify the SIJ pain assessment.

Initial average VAS score and ODI scores reflected the intensity of this disease which should be treated timely and appropriately. It has already been discussed that people generally delay the proper treatment of SIJ pain, however, this delay can also be associated with conservative method of treatment. If this is the reason then it means that conservative management is not sufficient in treatment of SIJ pain. Therefore, practitioners uses other options like the conventional radiofrequency and PRF. In these methods the important concern is the angle of the RF. The iliac side is more significant than the sacrum side when it comes to early sacroiliac arthritis, which affects the synovial membrane. As a result, the needle should be aimed at the iliac side and the synovial area should be the goal of the puncture. Anatomically, there are significant individual variations in the angle of the SIJ, as well as the distance between the posterior edge and the midline. As a result, precise placement is quite challenging. Due to its overlapping structure and low density resolution, X-ray fluoroscopy cannot guide the puncture needle into the SIJ; in contrast, the CT has a high density resolution and spatial resolution in the plane with no overlapping interference. It works well for placing and directing the SIJ synovia puncture.

In this trial, sacroiliac pain was treated with the conventional radiofrequency and PRF. The VAS and ODI reduced in both groups. Both groups’ differences from the pretreatment value were appreciably different. Both groups showed a substantial difference from the pretreatment value, proving that both therapies were successful in reducing SIJ pain symptoms. The conventional radiofrequency group had rapid analgesic effects, and improved their quality of life. One month following treatment, the VAS dramatically lowered and the quality of life increased in terms of physical functioning. Up to 6 months following treatment, there was a substantial difference between the two groups, and the pain reduction and disability. On the other side, the effect was gradual and VAS and ODI steadily reduced in the PRF group. This slow reduction can be linked with mechanism of the PRF which does not harm the nerve, however, the reduction of pain may be due to reversible neurons that momentarily block nerve signals from travelling down the nerve conduction pathway. In addition to reducing cytokine release and inhibiting the release of excitatory amino acids in the spinal cord, PRF could also suppress MAPK activation. As a result, the PRF’s analgesic effect was gradual, and its long-term analgesic effect may have something to do with neuromodulation. On the other side, there is an important issue which is associated with the conventional radiofrequency is to damage to the nerves that could result in sensory degeneration, sensory delay, atypical pain, persistent weakness in the lower limbs, and other issues like burning and numbness. PRF is relatively comparable in treatment of local ligament and denervation. Like, there is a literature which showed the acceptable level of efficiency of the PRF in treating shoulder, knee trapezio-metacarpal, and first metatarsophalangeal joints. Overall, it is discussed that the PRF is good and effective in small joints.

CONCLUSION
This study concludes that the existing conventional radiofrequency (CRF) method of treatment can be effectively used in treatment of SIJ with its slight complications. Further research is essential to establish the sustained effectiveness and optimal use of these radiofrequency techniques.

CONFLICT OF INTEREST
The authors declare no conflict of interest.

SOURCE OF FUNDING
There are no sponsors for the research being carried out, it’s a self-sponsored research.

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