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ORIGINAL ARTICLE

Efficacy of Sequential Bipolar Radio-Frequency Ablation in Treatment of Chronic Sacroiliac Joint Pain

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ABSTRACT

Background: One of the most common sources of chronic low back pain (LBP) is the Sacroiliac joint (SIJ). The diagnosis and treatment of SIJ as a source of pain represents a true challenge secondary to its complicated anatomy, anatomic variation in its nerve supply and functional biomechanisms of that region. Our aim here is to evaluate the efficacy of sequential bipolar radiofrequency ablation (RFA) in treatment of chronic SIJ pain. **Methods:** A clinical study conducted from June 2021 to February 2022. Selected 25 patients with positive diagnostic SIJ block, underwent RFA of SIJ with 6 months follow-up period. We recorded VAS scores at 1,3 and 6 months post-RFA and considered pain reduction ≥ 50 % in relation to pre-procedural VAS scores clinically significant. Revised Oswestry Disability Index (ODI) recorded pre-procedurals for all patients and at 3- and 6-months post-procedural for assessment of functional outcome. At 6-month post-RFA, the Global Perceived Effect was evaluated.
Results: 84% of patients at 6-months post-RFA obtained ≥ 50% pain relief compared to preprocedural VAS score, and we had statistically significant difference between Pre-procedural VAS and 6 months post-procedural VAS. There was a statistically significant difference between pre-RFA revised ODI and-6 month post-RFA revised ODI. GPE evaluated at 6-month post-RFA where 21(84%) patients had positive responses. **Conclusions:** Sequential bipolar radio-frequency ablation technique is a short-term safe and effective promising treatment alternative for refractory cases of chronic SIJ pain, however larger randomized controlled studies and a longer follow up are recommended in future studies to further support our results.
Key words: The sacroiliac joint; Radio-frequency ablation; The Global Perceived Effect

INTRODUCTION

The sacroiliac joint complex (SIJC) formed of an articular part, which includes the joint capsule, the articular cartilage and the bone, in addition to an extra-articular part, including the posterior sacral ligaments, the tendons and the muscles of the region [1].

The sacroiliac joint (SIJ) has a fibrous capsule and synovial fluid and it is a true joint that is anteriorly innervated by lumbosacral trunks, the gluteal nerves and the obturator nerve, while the posterior sacral network (PSN) formed of the dorsal rami of the S1,S2 and S3 and the dorsal ramus L5 innervate the extra-articular structures of SIJC [2, 3].

Any of the structures of SIJC may cause pain. The Sacroiliac joint can cause pain, that has an estimated incidence of 10–33% diagnosed by at least 75% pain reduction with double intra-articular SIJ blocks, while the pain arising from extra-articular structures of SIJC, its incidence is not known currently [4].

Chronic low back pain (LBP) has many sources and SIJ, representing 15%–30% of all the patients had chronic LBP and that is why SIJ is considered as one of most common sources of it [5,6].

The diagnosis and treatment of SIJ as a source of pain represents a true challenge secondary to its complicated anatomy, the anatomic variation in its nerve supply and the functional biomechanisms of that region. Besides physiotherapy and medical treatment of SIJ pain, many intervention measures as injection of intra-articular steroid, radiofrequency ablation (RFA), prolotherapy, and fusion of SIJ have already been proposed with different efficacies [7].

The success of RFA in treatment of chronic SIJ pain is of conflicting results as it usually depends

on the diagnosis accuracy, anatomical variations in SIJ nerve supply, and the RFA technique used [8]. After RFA, some patients had 100% pain relief. Research suggests that also 75% to 86% of patients received RFA for the SIJ pain may have pain relief [9].

If RFA is effective, the pain relief may last for six months and up to two years. However, other studies reported that ,after RFA for SIJ pain, some patients had pain reduction up to three years [10]. Usually during or after that period, the nerve regenerates, and the complaint may return. RFA could be repeated if the pain return, If SIJ pain relief was achieved after initial RFA. It is reported that, pain reduction in 85% of patients up to ten months after repeated RFA could be achieved. It is worthy to mention that; after RFA of chronic SIJ pain ,some patients did not have any pain reduction [11].

We aim in our study to evaluate the efficacy of sequential bipolar radiofrequency ablation in treatment of chronic SIJ pain.

METHODS

This non-randomized prospective clinical study conducted from June 2021 to February 2022, where selected 25 patients with positive single diagnostic SIJ block, underwent RFA of sacroiliac joint. All included patients had more than 18 years when joined this study and they had chronic mechanical LBP not responded to 3 months of conservative management in form of medical treatment and physiotherapy.

Their evaluation included taking detailed history of pain site, duration, intensity, character, aggravating and relieving factors. As part of routine evaluation of patients presenting with LBP ,general examination was done followed by neurological examination, including sites of tenderness , motor power, sensation , reflexes , and straight leg raising (SLR) test for exclusion other causes of LBP as lumbar disc prolapse or spondylolisthesis. All included patients had preprocedural MRI Lumbosacral spine (LSS) to exclude other possible causes of chronic LBP such as degenerative pathology, tumors, infection or fracture spine.

Full laboratory tests were performed including fasting and 2 hours post-prandial blood sugar. renal function tests, coagulation profile and liver function tests.

To make a definite diagnosis of SIJ as a source of pain, unfortunately we have no specific historic features, radiological findings or provocation tests that could do that and that is why the diagnosis of it is a challenge. A diagnostic SIJ block helps to make the diagnosis of intra-articular SIJ pain more accurate. So for diagnosis of intra-articular SI joint pain and selection of our patients we used a combination of the presence of pain that starts usually below L5 dermatomal level and its referral pattern (LBP or buttock pain, which may radiate down the leg) with tenderness over sacroiliac joint along with positive provocative FABER (Patrick's) test .In addition to a positive single diagnostic block (fluoroscopy-guided intra-articular 1-mL local anesthetic lidocaine hydrochloride 1% injection in the SIJ) , which is the standard reference for diagnosis of SIJ pain [12].

A positive response of patients after diagnostic sacroiliac joint injection of a local anesthetic, indicated by more than 80% relief in their pain for a minimum of five hours after the injection. [13].

After the diagnostic block, only those with such positive response were included in our study and proceeded to have sequential bipolar RFA for SIJ pain.

Our patients followed-up at 1,3 and 6 months post- RFA at our outpatient clinics. SIJ pain intensity was recorded at 1, 3- and 6-months post-procedural using Visual analogue Scale (VAS) score of pain and compared to preprocedural recorded VAS for evaluation of pain improvement.

For primary outcome measure:

Pain relief ≥ 50 % is a benchmark for efficacy of radiofrequency ablation of SIJ pain and is considered clinically significant in other studies [14,15]., So we calculated the percentage of pain reduction at 1,3 and 6 months post- RFA using pre-procedural VAS and 1, 3 and 6 months post-procedural VAS records and we considered the pain relief ≥ 50 % in relation to pre-procedural VAS score clinically significant and a successful pain reduction.

For Secondary outcome measure:

A) Revised Oswestry Disability Index (ODI) recorded pre-procedural for our patients and again at 3- and 6-months post-procedural for comparison and assessment of the functional outcome. In review of the literature, for LBP, ODI was found to be the most frequently used outcome questionnaire. It is formed of 10 sections and each of them is scored on a 0–5 scale to evaluate limitations of different daily living activities. To calculate ODI, we divide summed score by the

total possible score, then multiplied by 100 and expressed as a percentage [16].

B) The Global Perceived Effect (GPE) [14] evaluated at 6-month after RFA. A positive GPE is defined as a positive response to the following 3 questions: 1. Since my last visit my pain improved/ stayed the same / worsened 2. After the treatment, my ability to perform daily activities improved/ not improved 3. With the treatment I had I am satisfied/not satisfied and would recommend it to others or not. A negative answer to any of these three questions was considered a negative outcome.

The excluded patients from this study were the patients refused to sign the informed consent, the patients had bleeding tendency, patients with a known cause of low back pain (e.g., lumbar canal stenosis), patients with diabetes Mellitus , concomitant cardiac disease (e.g., history of unstable angina) or with a history of any psychiatric illness in order not to endanger the patient or compromise the clinical outcomes and also the patients had <80% of their LBP relieved after a single diagnostic intra-articular block of SIJ.

Diagnostic SI joint block Technique:

In all patients, fluoroscopy guided injection block of SIJ was performed after skin sterilization and surgical draping in the operation room. All patients received preprocedural prophylactic antibiotics and put in prone position on a radiolucent table, monitored for heart rate, blood pressure and oxygen saturation. To open up the SIJ view, the C-arm intensifier rotated about twenty degrees cephalad; after that a contralateral oblique image was taken until we observed the widest view of the SIJ. Our target selected, which is a point 1-2 cm cephalad of the lower end of the SIJ line. infiltration anesthesia performed using 3 mL of lidocaine hydrochloride 1% to numb the skin and SC tissue, a spinal needle of 22-gauge with a stylet, was targeted to the space of the SIJ joint between the sacrum and the ilium and its entry was recognized by loss of bone resistance when the tip of the needle slipped in. Once inside the joint space for few millimeters, and its position checked by a lateral view image then 0.3- 0.5 mL of IOHEXOL 350 mg I/ml, a contrast medium, injected to outline the joint space, followed by 1 ml of lidocaine hydrochloride 1%. As local anesthetic effect will wear off approximately six hours after the SIJ injection and so we considered this test positive if the patients, after a single diagnostic block, had more than 80% of their pre-procedure pain reduced for a minimum of 5 hours post-procedure. Patients were discharged after 6 hours of hospital observation. All patients had non-steroidal anti-inflammatory drugs (NSAID) for 2-5 days for post-procedure pain **(Figure 1).**

Radio-Frequency Ablation (RFA) technique and device:

The patient preparation was the same as diagnostic block mentioned before, However, the grounding pad was applied to one of patient's leg but not connected to RF machine as the bipolar thermal RF electric current will pass between two RF cannulas tips. 2 mL of Lidocaine hydrochloride 1% was used for skin and subcutaneous infiltrations at all injection sites. 20 G, 10 cm (NeuroTherm, Morgan Automation Ltd., Liss, Hants, UK) RF cannula with 10mm curved active tip was utilized (Figure 2 a). The target of first RF cannula was 1 cm above and medial to the inferior end of the joint line aproximatly parallel to the Carm beam. The second RF cannula was inserted 1 cm above the first one parallel to SIJ line. Then local anesthesia was injected through the needles. After correct placement of the two RF cannulas confirmed, three minutes of bipolar lesioning at 80ºC via the Diros OWL® URF-3AP RF lesion generator, with multisession adapter, Canada. **(Figure 2 b).** The first cannula was removed and reinserted 1 cm above the second one at a 3rd place and again bipolar lesioning was done. Then, the lower 2nd cannula was removed and replaced 1 cm above the other cannula and the process was so on repeated 4-5 times to cover from below S3 to above S1 foramina level creating a 4-5cm strip lesion between 5-6 positions of RF cannulas to interrupt the sensory supply from S1,2,3 roots. Finally, 8 mg dexamethasone and 1ml of lidocaine hydrochloride 1% was injected before needle removal.

To target the dorsal ramus of L5, grounding pad cable connected to the RF machine and the c-arm returned to true A-P view and then tilted caudally 30º. The RF cannula was directed to the junction of the ala of the sacrum with superior articular process of S1 where the dorsal ramus of L5 lies. When the bone was contacted, Lateral C-arm view was requested to assess anterior cannula position. After negative motor stimulation of 2 Hz at 2 V evidenced by no contractions of the leg to avoid thermal injury to the L5 root which has a vital lower limb motor function, unlike the sacral

lateral branch nerves, then continuous RF ablation was started at 80 ° C for 3 minutes. Finally, 8 mg dexamethasone and 1ml of lidocaine hydrochloride 1% was injected before needle removal. The patients were observed and discharged from hospital after 6 hours and NSAID were prescribed for one week. (Figures 2 and 3)

Informed consent and ethics committee approval:

This clinical study was approved by the Research Ethics Committee (REC) of Neurosurgery Department, Faculty of medicine, Benha University in April 2021. Informed consent for the procedure signed by all patients. All procedures involving humans were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments.

STATISTICAL ANALYSIS

The collected data tabulated and analyzed by using SPSS version 26 software. Categorical data expressed as number and percentages meanwhile quantitative data presented as mean ± standard deviation. Analysis of variance (ANOVA) test was used as test of significance in more than two groups, post hoc analysis used to detect significance difference in between groups. P value <0.05 was considered significant.

RESULTS

According to our study inclusion criteria ,25 patients who had positive single SIJ block were enrolled and underwent RFA for sacroiliac joint pain, where 14 of them (56%) were males and 11(44%) were females and they were aged between 23-64 years (mean age ±SD = 45.36 ± 10.7 years). The mean duration ±SD for the bipolar RFA was 47 ± 6 minutes.

For primary outcome measure:

We did assessment of pain relief, where VAS scores for pain intensity recorded at 1,3 and 6 months after RFA and were compared to pre-RFA and summarized in Table 1.

Table (1) states that there was statistically significant difference between the VAS at different time measurements, post hoc analysis revealed that there was statistically significant difference between Pre-procedural and 1 month, 3 months and 6 months post-procedural. There was statistically non-significant difference between 1-month post-procedural and 3 months and 6 months post-procedural and, we found statistically non-significant difference between 3-months post-procedural and 6 months post-procedural.

We found that the patients obtained ≥ 50% pain relief were 23(92%) patients ,22(88%) patients and 21(84%) patients at 1-, 3- and 6-months post-RFA respectively.

For secondary outcome measures:

A) We did an assessment of the functional outcome where revised ODI scores at 3 and 6 months post-RFA scored and compared to pre-RFA score and summarized in Table 2.

Table (2) states that there was statistically significant difference between the revised ODI at different time measurements, post hoc analysis revealed that there was statistically significant difference between pre-RFA and 3 -and-6 months post-RFA, and there was statistically non-significant difference between 3-months post-RFA and 6 months post-RFA.

B) GPE was evaluated 6-month post-RFA, where 21(84%) (Confidence Interval (CI) of 63.9 - 95.5) patients had positive GPE responses.

Post-procedural complications:

most of the patients had temporary worsening of their pain lasting about one-week post-RFA due to the procedure itself and/or temporary neuritis. The temporary neuritis may be attenuated by the 8 mg dexamethasone injected before needle removal. Three patients had transient buttock paresthesia that resolved one week later. However, no serious complications were reported by our patients.

Table (1): shows pre-RFA VAS score and its changes at 1,3 and 6 months post-RFA

Evaluation time	Study group (25)		p-value	P1 (Pre-operative)	P2 (1mo. post)	P3 (3mos. post)
	Mean	±SD				
Pre-RFA	7.48	1.19	<0.001**			
1 mo. post-RFA	3.08	0.91		<0.001**		
3 mos. post-RFA	3.36	0.91		<0.001**	0.54	
6 mos. post-RFA	3.60	1.04		<0.001**	0.15	0.99

*VAS: visual Analogue Scale * RFA: Radio-frequency Ablation

* P-value <0.05 was considered significant.

Table (2): shows pre-RFA revised ODI score and its changes at 3 and 6 months post-RFA

Evaluation time of revised ODI score	**Study group (25)**		**p-value**	**P1 Pre-RFA**	**P2 3 mos. post-RFA**
	Mean	±SD			
Pre-RFA	15.96	3.22	<0.001**		
3 mos. post-RFA	13.60	2.47		<0.001**	
6 mos. post-RFA	13.56	1.61		0.02*	0.99

*ODI: Oswestry Disability Index * RFA: Radio-Frequency Ablation

* P-value <0.05 was considered significant.

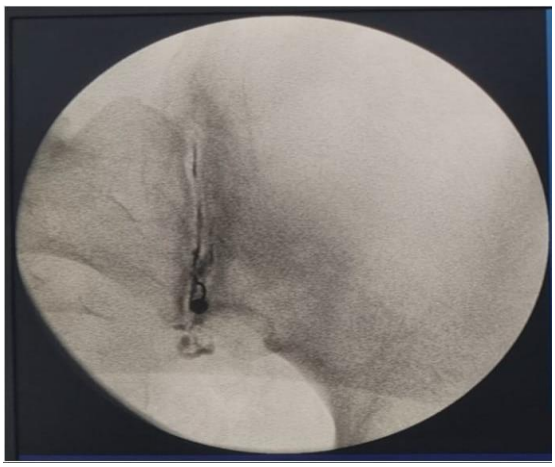


Fig 1: shows left oblique fluoroscopy view of diagnostic Rt. sacroiliac joint injection of contrast medium (IOHEXOL 350 mg I/ml) outlining the sacroiliac joint line.

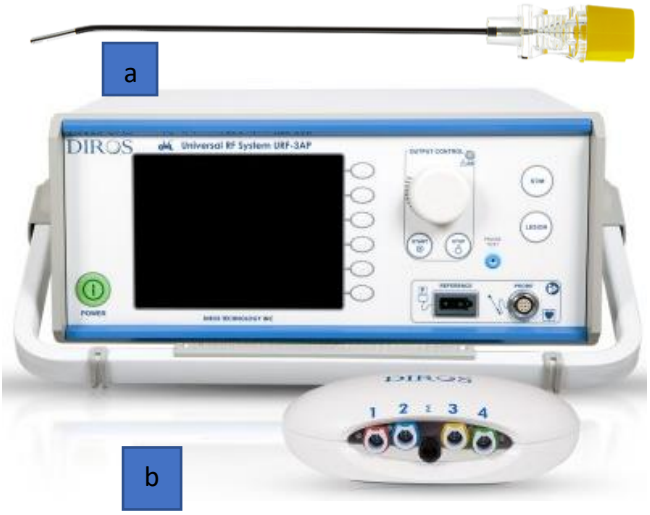


Fig 2: a) RF cannula 20G,10cm with 10mm curved active tip, b) The Diros OWL® URF-3AP RF lesion generator, with Multisession adapter for 4 cannulas.

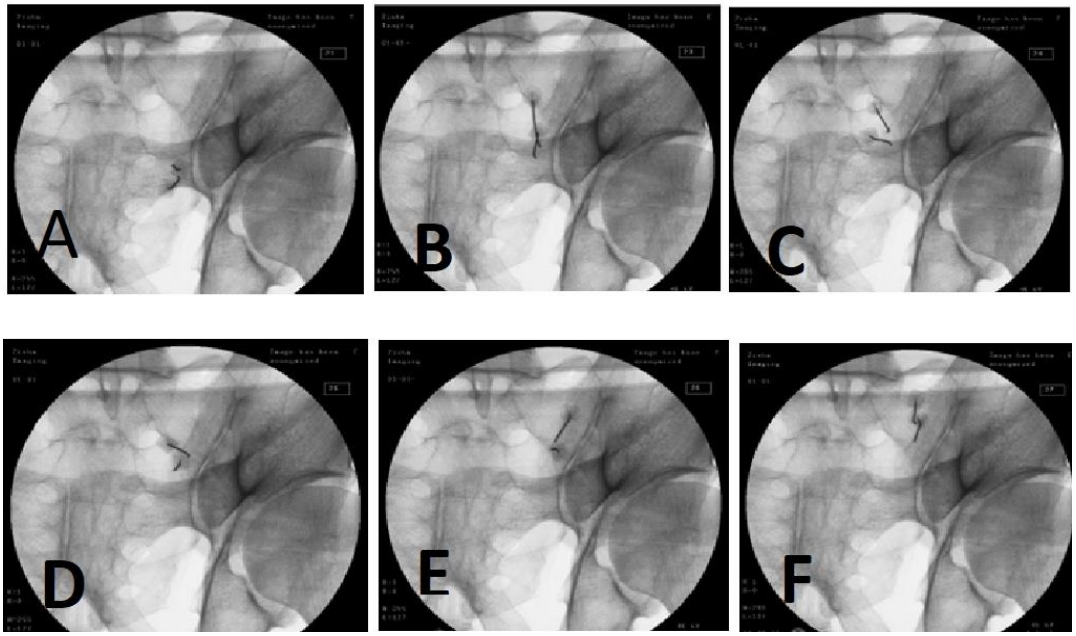
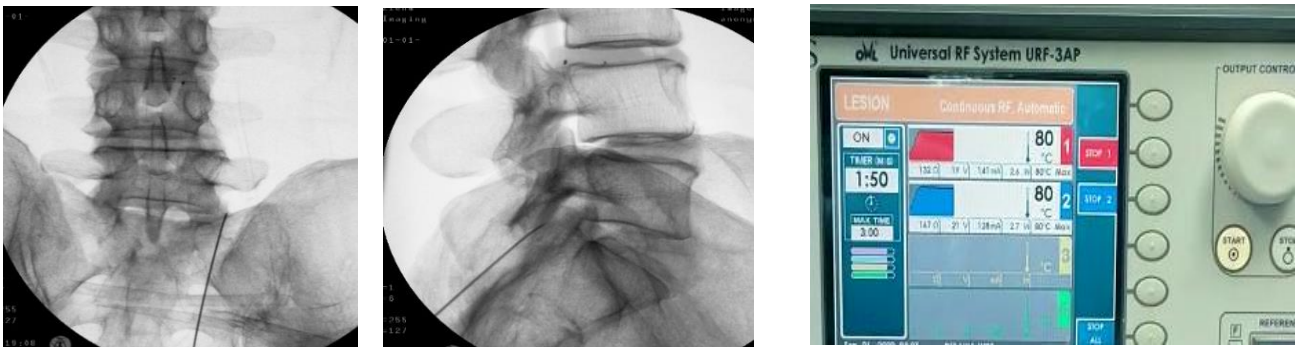


Fig. 3: shows left oblique fluoroscopy views of right Sacroiliac joint, explaining the steps of sequential bipolar RF ablation for right sacroiliac joint pain in one of our patients A) The insertion of 1st cannula at about 1 cm above and medial to the inferior end of the SI joint line with the 2nd cannula insertion at about 1 cm above it and parallel to the joint B) The lower RF cannula was removed and reinserted 1 cm above the other one. C), D) and E) are views revealing the sequential same steps where the cannulas located medial to SIJ and lateral to sacral foramina. F) the final position of the cannula above S1 foramen.



(a) (b) (c)

Fig. 4: shows (a) A-P and (b) Lateral fluoroscopy views of targeting right L5 dorsal ramus of the same patient (c) the Diros OWL® URF-3AP RF lesion generator, with multisession adapter, Canada, showing the setup parameters we used during SIJ RFA of S1-S3 lateral branches and L5 dorsal ramus.

DISCUSSION

The SIJ is a true joint that is anteriorly innervated by lumbosacral trunks, the gluteal nerves and the obturator nerve, while the posterior sacral network (PSN) formed of the dorsal rami of the S1, S2 and S3 and the dorsal ramus L5 innervate the extra-articular structures of SIJC [2, 3]. SIJ pain is a challenge that affects about 15% to 25% of the patients presenting with chronic LBP, and currently, we have no effective long-term standard treatment [17].

The diagnosis and treatment of SIJ as a source of pain represents a true challenge secondary to its complicated anatomy, the anatomic variation in its

nerve supply and the functional biomechanisms of that region [7].

Apart from the challenges that arise from the diagnosis of pain of SIJ by history taking, examination, and radiological findings, For the diagnosis and better selection of patients, for sacral lateral branch -RFA(SLBRFA), the intra-articular joint block was used as the reference standard in vast majority of studies [18]. However, currently the incidence of pain arising from the extra-articular structures is unknown. For a more accurate and specific diagnosis, double blocks were proposed [19]. However, for SLBRFA more than 50% of the cases were selected after single positive diagnostic SIJ block.

In the current study, for diagnosis and selection of cases, positive single diagnostic SIJ block using 1 ml of lidocaine hydrochloride 1% was required (the positive response was indicated by more than 80% pain relief, compared to the initial pain and lasted for at least five hours after the injection).

Besides physiotherapy and medical treatment of SIJ pain, many intervention measures as injection of intra-articular steroid, radiofrequency ablation (RFA), prolotherapy, and fusion of SIJ already proposed with different efficacies [7].

For refractory cases of Sacroiliac joint pain, RFA is a promising treatment [6]. The principle of disrupting sensory nerve supply to spine structures emerged from > 30 years of using RFA for treating the pain of the facet joint. [20] There are many RFA technologies used to create a strip lesion, including conventional monopolar and bipolar RFA, cooled RFA, and a multielectrode probe using both conventional bipolar and monopolar technology [21]. The two most frequently used techniques for lesioning of the Sacral lateral branches (SLBs) are the peri foraminal lesioning, where the probes placed at multiple clock face locations of the posterior sacral foramina, and strip lesioning, where bipolar or monopolar lesions made in a linear pattern lateral to the sacral foramina and medial to the SIJ.

In treating SIJ pain, the different success rates reported for RFA may result from different utilized techniques and/or due to possible anatomic variation of sensory supply to SIJ. Yin et al [22], in a cadaveric study reported that the anatomic sites of the LSBs are of great variation and within each segment, the location, number and path of the LSBs to innervate the SIJ were not the same.

In review of the literature, we found not only different techniques and technologies used, but also different sensory nerve branches were targeted. In the majority of the studies, RFA targets the S1, S2 and S3 SLBs and the L5 dorsal ramus. Less frequently, the studies included also the medial branch of L4 and the articular portion of SIJ [23].

Regarding the role of steroid intra-articular injection versus pulsed radiofrequency (PRF) in treating refractory cases of chronic SIJ pain, Dutta et al., [13] stated that, the patients received intra-articular depo methylprednisolone only had short-term pain reduction, only 20% of their patients had ≥ 50% pain relief and functional improvement at 3- and 6-months after injection, On the other hand, their PRF group (maximum temperature of 42°C) targeted the L4 medial branch , L5 dorsal ramus and S1-3 LSBs had significant pain reduction and functional improvement. At the 6-month post-procedure (86.7%) of patients obtained at least 50% pain relief and functional improvement.

Vallejo et al., [24] reported that, twenty-two patients were treated for refractory sacroiliac joint pain using PRF of LSBs of L4-S2 where 16 patients of them (72.7%) had more than 50% pain relief that lasted > 6 months. In addition, their quality-of-life scores improved significantly.

The higher success rate of Dutta et al., with PRF when compared to results of Vallejo et al., partly could be explained by that, they performed PRF for 3 minutes at 3 sites for S1 and S2 and 2 sites for L4, L5 and S3, unlike Vallejo et al., who performed PRF two lesions at each level from L4 to S2 for a shorter duration of 2 minutes.

In our study we did strip lesion targeted S1-S3 sacral lateral branches in linear fashion using 2 adjacent needles which are sequentially placed for 5-6 positions lateral to sacral foramina and medial to sacroiliac joint, as well as created lesion of L5 dorsal ramus, instead of performing 9 monopolar RFA lesions superior, lateral and inferior to S1,2,3 foramina which are small and difficult to adjust needles without several trials and additional radiation exposure. Our technique is essentially a modification of Ferrante et al., [25] technique who used 2 bipolar electrodes, in a repetitive way for ablation along the sacroiliac joint line for 90 seconds at 90°C. Where 36.4% of their patients had a 50% pain relief, lasted for > 6 months. The superiority of our results compared to Ferrante et al, may be explained by longer time during bipolar

ablation (3 minutes) at 80°C, in addition to, L5 ramus ablation which is an important sensory supply of SIJ.

Cohen SP. et al., [26] used conventional RF lesions at 80°C for 90-seconds for L4 medial branch, the dorsal ramus of L5 and LSBs of S1, S2 and S3 in their 9 patients who had intractable SIJ pain, where eight of them (88.88%) had at least 50% pain reduction, lasted more than 9 months.

The cooled RF denervation is also used for SIJ pain. Ho et al., [27] reported that in treatment of SIJ pain, Cooled RF denervation, for 150 seconds at 60°C at the S1- S3 sacral foramina lateral aspect, showed long-term efficacy as fifteen out of twenty patients (75%) had a significant pain relief and positive GPE in 16 (80%) patients at two years follow up. Kapural et al., [28] reported that 50% of their 26 cases with refractory SIJ pain who underwent cooled RF at 60°C for 150 seconds of SLBs and L5 dorsal ramus, had ≥50% reduction of VAS at 3–4 months follow-up.

The main limitation of this study is lack of a placebo-control group. However, establishing a control group with sham electrodes raises an ethical problem for not offering patients a true therapeutic option and exposing them to hazards of radiation and injections. A second limitation is the relatively small number of patients enrolled with short-term follow up, which leaves unresolved questions regarding efficacy of the technique on the long-term.

CONCLUSION AND RECOMMENDATION

Sequential bipolar RFA technique is a short-term safe and effective promising treatment alternative for refractory cases of chronic SIJ pain, however larger randomized controlled studies and a longer follow up for 12 to 24 months to assess the long-term efficacy of the technique are recommended in future studies to further support our results for this poorly understood disorder.

Conflict of Interest: None.

Financial Disclosure: None.

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