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Research Article

Randomized, controlled blind study comparing sacroiliac intra-articular steroid injection to radiofrequency denervation for sacroiliac joint pain

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KEYWORDS

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Abstract *Background and objective:* Sacroiliac joint pain is a common cause for chronic axial low back pain, with up to 20% prevalence rate. To date, no effective long-term treatment intervention has been embarked on yet. The aim of our study was to compare steroid block to radiofrequency ablation for SIJ pain conditions.

Methods: A randomized, blind, study was conducted in 30 patients with sacroiliac joint pain. Fifteen patients received radiofrequency denervation of L4–5 primary dorsal rami and S1–3 lateral sacral branch, and 15 patients received steroid under fluoroscopy. Those in the steroid group who did not respond to steroid injections were offered to cross over to get radiofrequency ablation.

Results: At 1-, 3- and 6-months post-intervention, 73%, 60% and 53% of patients, respectively, gained ⩾50% pain relief in the radiofrequency (RF) ablation group. In the steroid group, at one month postintervention follow-up, only 20% gained ⩾50% pain relief, but failed to show any improvement at 3 month and 6 month follow-up.

Conclusions: Radiofrequency ablation at L4 and L5 primary dorsal rami and S1–3 lateral sacral branch may provide effective and longer pain relief compared to the classic intra-articular steroid injection, in properly selected patients with suspected sacroiliac joint pain. Larger studies are called for to confirm our results, and lay out the optimal patient selection and treatment parameters for this poorly comprehended disorder.

1. Introduction

Sacroiliac joint pain remains a major challenge for pain clinicians and it is accounted for up to 20% of patients with low back pain [1,2]. In addition to its prevalence, SIJ pain lacks

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valid clinical/diagnostic tests and no therapeutic modalities for long term improvement have been found yet. Whereas some experts adopt complicated clinical test algorithms as a tool of SIJ pain diagnosis, others advocate intra articular anesthetic block as a sole reliable diagnostic test [3–6].

Treatment of SIJ pain is another dilemma and wide range of therapeutic modalities has been used including pharmacotherapy, chiropractic manipulation, SIJ injection (local anesthetics; steroid or mixture); and surgical fixation [7–12].

Lateral branch radiofrequency (RF) ablation, has gained popularity of recent years [13,14]. There have been many studies, controlled and uncontrolled with promising results [15–17]. However, these studies are distinguished by their wide range of discrepancies including RF technique, standards definitions, and more importantly selection criteria.

Selecting the right patient is crucial for any pain management intervention [18–20].

Due to its prevalence, diverse pain referral zones, and contention over its innervation, SIJ ablation requires strict patient selection approach [21,22].

Nevertheless, pain referral pattern from SIJ bears considerable variability among patients and in uncontrolled studies assessing denervation of SIJ, and various researchers have adopted different radiation maps in the inclusion criteria [23,24].

As lateral branch ablation does not interfere with the afferent supply from the whole SIJ, different parts of the joint have various referral zones. Establishing those referral areas susceptible to benefit from RF ablation would save patients from many unnecessary interventions. Amid this perplexity, we designed our research to compare radiofrequency ablation to intra-articular steroid injection for SIJ pain measured by VAS before and at one, three and six months after intervention.

2. Methodology

This study was approved by Qena School of Medicine Ethical Committee (South Valley University, Qena, Egypt) and has been conducted in Qena university hospital between January 2013 and April 2014. Informed consent was obtained from every patient after explaining the procedures, the potential side effects and possible outcomes.

2.1. Study design

Fig. 1 shows our study flowchart. We designed a prospective, randomized, blind, steroid-controlled study. Eligible patients were randomized into 2 groups using the closed envelope method: Radiofrequency (RF) and steroid (S) group. Blinding of our study was carried out that our patients were not aware of their group assignment. Moreover, clinicians who performed follow-up measurements and data collection were not aware of the study group protocol. However, the pain interventionist who performed the interventions could not be blinded to the procedure but was blind to the rest of the study protocol.

In RF group, patients received RF ablation of L4–L5 medial branch of primary dorsal rami, and S1 to S3 lateral branch of the dorsal rami under fluoroscopy. In S group, 1 ml of 40 mg/ml of depot methylprednisolone was given in the sacroiliac joint under fluoroscopy. Patients in the steroid group who did not show pain improvement were offered to cross over to RF group and received radiofrequency (data not shown). Those in the RF group who did not experience adequate symptomatic relief, were labeled treatment failure and offered alternative treatment e.g., surgical fusion.

2.2. Outcome measures

We set our primary outcome to be at least 50% decrease in pain intensity measured using VAS before and at 1, 3, and 6 months after intervention. Our secondary outcome was $\geqslant$25% reduction in analgesic consumption. Analgesics consumed were recorded before and after the intervention.

2.3. Enrollment

Patients suffer from low back pain for 6 months or more requiring regular analgesia were eligible for the study according to the following inclusion criteria: (1) Age more than 18 years; (2) American Society of Anesthetists (ASA) physical status was I or II; and (3) Positive diagnostic SIJ block. Our exclusion criteria included the following: (1) patients with MRI evident of symptomatic disk herniation; spondyloarthropathy; facet arthropathy; fractures or tumors; (2) patients with ASA III or more; (3) neurological deficits; (4) coagulopathy; and (5) psychological illness that might compromise an optimal response.

2.4. Diagnostic SIJ block

SIJ block was carried out by inserting spinal needles (20-gauge) at the lower third of the SIJ in 15 degree contralateral oblique C-arm view. Correct placement was confirmed by a sacroiliac joint arthrogram. Then, a 3 ml solution containing 2 ml of Lidocaine 2% and 1 ml bupivacaine 0.5% was administered. After the block, patients were advised to move around and fill up visual analogue scale (VAS) once hourly for 6 h postblock. Positive diagnostic outcome was defined as 75% pain relief for at least 3 h post block [25]. Otherwise the diagnostic SIJ block was considered negative and patient was excluded from the study.

2.5. Radiofrequency ablation

Radiofrequency of L4 and L5 primary dorsal rami lesions was undertaken using 22 gauge cannula (Neurotherm, Washington, MA, USA), with 10 mm active tips inserted parallel to the nerve course till bone was hit at the junction between the transverse process and superior articular processes for L4. However, for L5 we inserted the needle between the ala and the articular process of the sacrum [14,16]. To confirm that the needles are in the right proximity of the target nerve, sensory electro stimulation at 50 Hz, and 0.5 V or less was applied with concordant sensation along the course of target nerve. To ensure that the needles are far enough from the motor fibers, absence of leg contraction in response to motor electro stimulation at 2 Hz up to 2 V was verified before applying RF lesion. Right before applying RF lesion, RF probe was taken out and

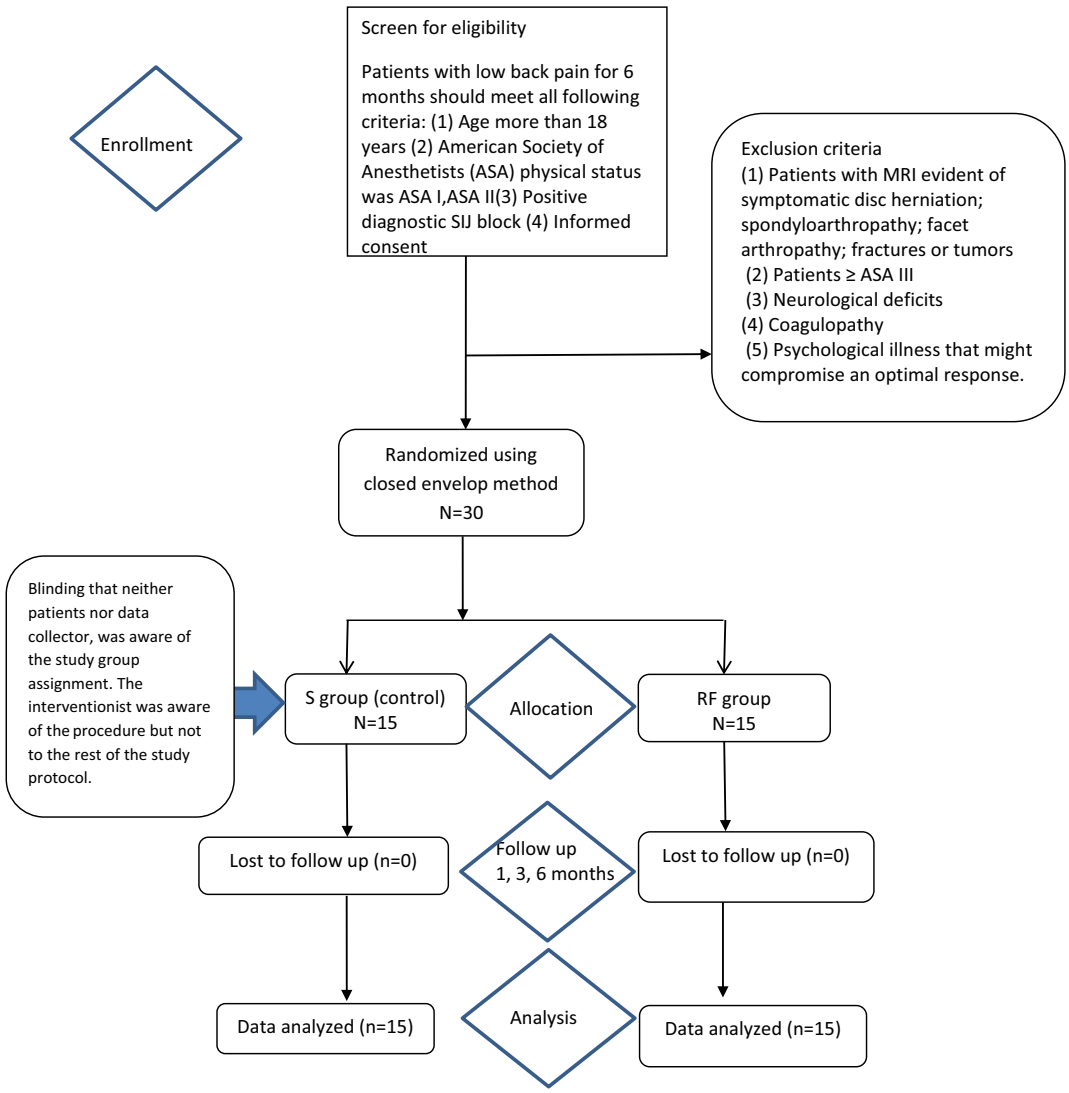

Figure 1 Study flowchart.

0.5 ml Lidocaine 2% was administered through each cannula to decrease thermal pain and reduce the incidence of neuritis. Then, RF probe was reinserted, and a lesion of 90 s and 80 °C was applied using Neurotherm RF generator (Model 1100, USA).

For S1 down to S3 lateral-branch RF, 22-gauge 5 mm active tips (Neurotherm, Washington MA, USA) were inserted perpendicular to the bone between 3 and 5 mm to the lateral border of the foramina. For S1 and S2 we performed 3 thermal lesions and at S3, only two lesions were performed. In the right-sided S1 and S2, the three lesions varied between 1:00, and 5 o'clock positions on the face of a clock; on the left, the sites were between 7, and 11:00. At S3, the two lesions were performed at 1 and 4 on the right side, and 7 and 10 on the left. We applied Sensory stimulation at each level merely for the first needle insertion, eliciting concordant sensation at $\leqslant$0.5 volts.

Before applying RF lesion, 0.5 ml of lidocaine 2% per each sacral level was administered. In order to confirm that anesthetic spread to other foramina did not affect sensory testing, RF probes were inserted and stimulated at adjacent levels before denervation started. Once accurate needles position was confirmed, RF probes were sequentially inserted into the cannula and 90 s 80 °C lesions were performed using Neurotherm RF generator (Model 1100, USA).

2.6. Sample size

A pre-determined sample size was chosen by using a power analysis based on our main (primary) outcome measure. In a previous study sustained pain relief after steroid block was 0.35 [16]. Thus a sample size of 15 in each group was decided to achieve a statistical power of 80% at a two sided significance level of 0.05.

2.7. Statistics

Analysis of variance was used for intergroup comparisons. Unpaired *t*-test was carried out for comparisons between groups. Percentage and number of patients were used to report

Table 1 Patient characteristics.

	S (n = 15)	RF (n = 15)
Sex		
Male (n = 12)	7 (46.6%)	5 (33.3%)
Female (18)	8 (53.3%)	10 (66, 6%)
Age (SD, range)	51.8 (13.1; 31–74)	51.9 (13.6; 27–75)
Weight in Kilograms (SD, Range)	74 (12.3; 67–82)	72 (13.4; 66–80)
Height in centimeters (SD, range)	168 (1.3; 163–175)	169 (1.6; 164–173)
Baseline VAS (SD, range) median (interquartile range)	6.4 (1.8; 3.5–10) 6 (5.5–7)	6.2 (1.8; 3–8) 6 (5–8)
Failed back surgery syndrome (n = 9)[a]	4 (26.6%)	5 (33. 3%)

Continuous data quoted as the mean (standard deviation, range), and median and (interquartile range, 25–75%), categorical data as number and percentage.
[a] includes 5 patients with spinal fusion and 4 post-laminectomy.

Table 2 Percentage of patients with primary outcome (at least 50% decrease in pain intensity measured using VAS) at follow-up visits.

Follow-up visits	S group (n = 15)	RF group (n = 15) (%)
At one month	20%	73[a]
At 3 months	none	60[a]
At 6 months	none	53[a]

* $P < 0.05$ as compared to steroid group.

categorical data, and Fisher exact test was used for the distribution of categorical variables. Statistical significance was accepted for P less than 0.05.

3. Results

No complications happened and no patient dropped out of the study.

3.1. Demographics

Patient characteristics including age, weight, height, male/female ratio and baseline VAS scores, and the number of patients with failed back syndrome were not significantly different ($P > 0.05$) between steroid and RF groups, Table 1.

3.2. Primary outcome

Table 2 shows percentage of patients with primary outcome. In the RF group, 73%, 60% and 55% of patients, gained ⩾50% pain relief at 1, 3 and 6 months respectively. In the S group, at one month postintervention, only three patients (20%) gained ⩾50% pain relief, but failed to show any improvement at 3 or 6 months. Twelve patients in the S group crossed over to receive radiofrequency ablation; at 1-month, one patient at 3 months (data not shown).

3.3. VAS scores follow-up

Fig. 2 shows that RF group had statistically significantly less VAS mean scores than the steroid group ((1.9 ± 1.7; range 0–9) vs. (6.4 ± 1.8, 3.2–9.5), at one month and (2.3 ± 2.4; range 0–6) vs. (6.2 ± 2.3, 3–10) at 3 months respectively,

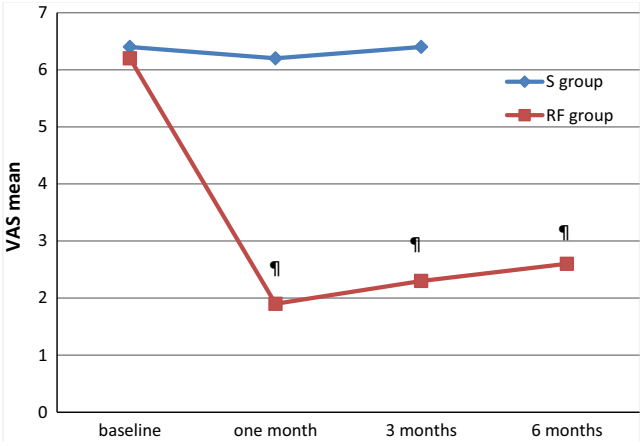

Figure 2 VAS scores: Baseline and follow-up at 1, 3, 6 months.
¶ $P < 0.001$ as compared to steroid group.

Table 3 VAS scores: Baseline and follow-up at 1, 3, 6 months.

Time	S group (n = 15)	RF group (n = 15)
Baseline		
Mean (SD, Range)	6.4 (1.8, 3.2–9.5)	6.2 (1.7, 3.5–8.6)
Median (interquartile range)	6 (5–6.5)	6 (5–7.5)
One month		
Mean (SD, Range)	6.2 (2.3, 3–10)	1.9 (1.7, 0–9)[a,b]
Median (interquartile range)	7 (5–8)	3 (1–4)
Three months		[a,b]
Mean (SD, Range)	6.4 (1.8, 3.2–9.5)	2.3 (2.4, 0–6)
Median (interquartile range)	6 (5–6.5)	1.3 (1–4)
Six months		[a,b]
Mean (SD, Range)	None	2.6 (2.1, 0–6)
Median (interquartile range)		2.3 (1.4–2.4)

[a] $P < 0.05$ as compared to steroid group.
[b] $P < 0.05$ as compared with same group baseline.

Table 4 Percentage of patients with secondary outcome (⩾25% reduction in analgesic consumption) at follow-up visits.

Time	S group (n = 15)	RF group (n = 15) (%)
One month	16.2%	73.3[a]
Three months	0	60[a]
Six months	0	33.2[a]

[a] $P < 0.05$ as compared to steroid group. Confidence interval (95% CI).

$P < 0.001$). At 6 months, VAS mean in the RF group was 2.6 ± 2.1 and the range was 0–6 and no patients remained in the S group at 6 months.

Within-group analysis, in Table 3, shows that patients who received radiofrequency intervention reported significantly lower VAS mean scores at 1, 3 and 6 months post-intervention compared to baseline scores ($P < 0.001$). In contrast, the 1-month VAS scores of patients who had steroid treatment were unchanged from baseline ($P > 0.9$). No more within group analysis was done because of insufficient patient number remaining in the steroid group at 3 and 6-month time points.

3.4. Secondary outcome

Table 4 shows the percentage of patients who experienced 25% reduction in their analgesic medications. In the steroid group it was 16.2% at one month follow-up. In the radiofrequency group, the percentage of patients who showed decrease in their analgesic intake was 73.3% (n = 11), 60% (n = 9) and 33.3% (n = 5) at 1, 3 and 6 months, respectively.

4. Discussion

Our study reveals that radiofrequency ablation of L4–5 medial branch of dorsal rami and S1_S3 lateral branches of dorsal rami might ensure substantial pain relief and decrease analgesic need in patients suffering from chronic painful sacroiliac.

At 1-, 3- and 6-months post-RF intervention, 73%, 60% and 53% of patients, respectively, gained ⩾50% pain relief.

This high incidence of pain relief was in accordance with other studies that showed above average pain relief (⩾50%) [26,27] and could be attributed to applying tight inclusion criteria as well as the RF ablation technique as we created a continuous lesion in a wide area of tissue lateral to the S1–3 foramina used, rather than ablation of individual nerves. The logic behind this approach is based on a cadaveric research revealing a complex network of nerve fibers anastomosing with multiple primary dorsal rami around each neural foramen [14].

Moreover, other studies using similar technique, showed higher success rates than we obtained in ours; however, these studies were open-label studies which tend to result in higher outcome rate than in controlled studies [28]. This point needs to be pursued in subsequent randomized trials, to detect the role if there is any of RF lesion size in pain relief outcome.

Although individual nerve branch site was demonstrated to differ according to the level, all nerves pass through a definite tissue volume just between the lateral rim of the foramen and SIJ. By inserting RF probes around the foramen (multiple sites), this definite tissue mass could be heated to neurolytic temperature, and consequently occlude nociceptive signals to the primary posterior ramus. Single RF application will potentially miss some afferent fibers to the sacroiliac joint resulting in poor or failed outcome [13,17].

Indeed, we designed our study to cross our patients over to receive RF ablation at their 1-month follow-up, based on pilot study data that showed the chances of someone gaining long-term SIJ pain relief after steroid injection, if none was experienced at 1-month postintervention, to be exceedingly low [29]. Moreover, our chief inclusion criterion of ⩾75% decrease of pain with diagnostic SI joint block has higher threshold than that employed in other prior studies [14,16].

This potentially high inclusion threshold might have participated in our high positive outcome rate. Thus, attention must be sought when inferring these results to cases wherein less strict inclusion criteria are employed. In a prevalence research carried out in 43 patients with low back pain below L5–S1, Schwarzer et al. showed that 30% obtained ⩾75% pain relief following sacroiliac joint block [22]. However, as the aim of our study was to detect the therapeutic benefit, if any, of this interventional technique, the use of rigorous inclusion criteria was pursued to minimize the proportion of false-positive cases, hence increasing the validity of the trial. Once the efficacy of the intervention is established, subsequent studies can be carried out with less strict inclusion criteria.

Although we designed strict inclusion criteria, still a considerable number of patients did not show any significant improvement in each of the studied groups. The high false-positive proportion associated with single diagnostic sacroiliac joint blocks [28], and the fact that the L4 through S3 primary dorsal rami might not represent all the nerve supply to the sacroiliac joint could be possible explanation. Applying double confirmative diagnostic sacroiliac joint blocks using 2 dissimilar local anesthetics may have improved the outcome and decreased the failure up.

Prognostic blocking of lateral divisions might exclude those with pain felt in the sacroiliac joint but not supplied by posterior rami branches [30].

There were a couple of researches where SIJ block was combined with lateral branch block to screen out patients eligible for radiofrequency, and they showed that 89% patients experienced more than 50% VAS reduction that lasted for 9 months [13–17].

A disappointing outcome of our study is the extended radiofrequency lesion size we applied, and did not in fact lead to substantial longer pain free duration. The duration of pain relief is apparently influenced by nerve regeneration which takes place between 6 months and one year [31,32]. Future studies are needed to address whether innovations in the RF technique (e.g. using bipolar rather than unipolar mode), or in the inclusion requirements e.g. pain referral tendencies and/or repeated RF ablations can influence duration of pain relief or success rate for that matter.

One critique that might stand against this research is our RF lesions that targeted five levels to obtain successful outcome carry the risk of extensive tissue damage. However, sacroiliac joint nerve supply is a matter of great controversy. On the one hand, some researchers have detected nerve feeders to the superior part of the SIJ from as far as L4 [1,33]. On the other hand, other experts have failed to verify these findings

[34]. Nerve branches originating from the L4 and L5 dorsal rami may not only supply the sacroiliac joint but they innervate para-spinal muscles and ligaments, the L4–5 and L5–S1 facet joint as well [31]. Whether a less extensive RF lesion would result in better or worse outcome is a valid point that should be investigated in future well controlled studies.

It is worth mentioning that although diagnostic SIJ block was mandatory for inclusion in this study, it has low specificity [28,29]. Nevertheless, uncontrolled blocks of the sacroiliac joint have high false-positive rate [24,30].

There are many limitations in our study. First, in spite of the fact that our power analysis aimed at detection of statistically significant differences between the studied groups, was attested by positive outcome, the limited sample size in this research had the potential to produce several variables that might influence the outcome including functional ability/disability, the type of back surgery, and patients with legal issues [15,31]. Recruiting patients in large multi-center pilot study is warranted to verify our outcomes, and it should be properly powered to be able to detect these variables. Moreover, the small sample size studied in our research raises a concern regarding how safe this extensive RF lesion was. Fifteen patients in each group are not enough to pin out small albeit potentially risky neurological damage, that could be further cofounded by extensive RF lesion used.

A second limitation is that we did not analyze the cross over data. Radiofrequency after steroid block was not the focus of our study.

In conclusion radiofrequency ablation at L4 and L5 primary dorsal rami and S1–3 lateral sacral branch may provide effective and longer pain relief compared to the classic intra-articular steroid injection, in properly screened patients with painful sacroiliac joint pain. Larger studies are called for to confirm our results, and lay out the optimal patient selection and treatment parameters for this poorly comprehended disorder.

Conflict of interest

There is no conflict of interest to declare.

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