Original Article

Efficacy of cryoneurolysis versus intra-articular steroid in sacroiliac joint pain: A retrospective, case-control study

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ABSTRACT

Background and Aims: Intra-articular steroids provide significant pain relief in sacroiliac joint pain (SIJP), but their action is short-lived. Cryoneurolysis is reported to produce prolonged pain relief in various pain conditions. However, its efficacy has not been evaluated in patients with SIJP. Thus, we compared the efficacy of cryoneurolysis with steroid injections in adult patients with SIJP. **Methods:** This retrospective healthcare records review–based study involved 83 patients with SIJP. Patients were divided into two groups: cases (sacroiliac joint [SIJ] cryoneurolysis, n = 39) and controls (SIJ steroid injection, n = 44). An 11-point numeric pain rating scale (NPRS) was used to assess the pain severity at baseline and immediately, 1, 3 and 6 months post-intervention. A reduction of ≥50% in NPRS score immediately following SIJ cryoneurolysis and steroid injection was considered a successful outcome. The difference between the treatment groups was assessed with a Chi-square test, and $P < 0.05$ was considered statistically significant. **Results:** Both cases and controls showed significantly decreased NPRS scores from baseline to immediately, 1 month, 3 months and 6 months postintervention ($P < 0.001$). However, compared to controls, cases had significantly lower NPRS scores at all time points (all $P < 0.001$). Moreover, a significantly greater proportion of cases had ≥50% decrease in NPRS score from baseline, that is, 1 month (97.44% vs. 75%, $P = 0.004$), 3 months (100% vs. 47.73%, $P < 0.001$) and 6 months (69.23% vs. 27.27%, $P < 0.001$). **Conclusion:** Although both cryoneurolysis and intra-articular steroid injections provide significant pain relief immediately, 1, 3 and 6 months postintervention, cryoneurolysis resulted in significantly greater pain relief.

Keywords: Cryoneurolysis, intra-articular injection, low back pain, radiofrequency ablation, sacroiliac joint, steroids

INTRODUCTION

Low back pain (LBP) is a frequently reported musculoskeletal complaint.[1-3] A recent study suggested that around 60% of patients with LBP have sacroiliac joint pain (SIJP).[4] Patients with SIJP are initially treated conservatively. However, a fraction of patients who do not gain significant relief are usually subjected to sacroiliac joint (SIJ) intra-articular (IA) steroid injections for diagnosis and pain relief.[5] Though both IA and periarticular SIJ steroid injections provide significant immediate and short-term pain relief, they do not differ significantly in terms of the degree of pain relief, and the therapeutic effect is inconsistent and restricted to a limited period.[6,7] Cryoneurolysis, employing

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low temperatures (from −20°C to −100°C) to a target percutaneous peripheral nerve, has demonstrated encouraging short- and long-term outcomes in several chronic pain conditions.[8] A case series involving five patients treated with ultrasound-guided cryoneurolysis for SIJP reported excellent (>50%) pain relief in all the patients at 3- and 6-month follow-ups.[9] However, no extensive studies have reported its efficacy in SIJP.

The efficacy of cryoneurolysis has not been compared with SIJ steroid injections. Thus, this study compared the efficacy of cryoneurolysis with IA steroid injections in patients with SIJP.

METHODS

After obtaining approval from the Institutional Review Board (vide approval number 5/21, September 2021), a retrospective review was undertaken. Patients who had undergone either SIJ cryoneurolysis or SIJ steroid injection between 1 September 2019 and 30 April 2021 were identified, and data were extracted from the electronic healthcare records. Owing to the coronavirus disease 2019 (COVID-19) pandemic, informed consent of the patients was obtained telephonically. The study was carried out by following the principles of the Declaration of Helsinki, 2013.

The study included adult (≥18 years) patients of either gender who had been diagnosed with SIJP (clinically or by provocative tests), with the presence of pain for ≥6 months, a numeric pain rating scale (NPRS) score of ≥5, previous failure to achieve adequate improvement with trials of conservative non-invasive treatments and a positive diagnostic IA SIJ injection of local anaesthetics (1% lignocaine) under fluoroscopy guidance (≥50% pain relief). At the same time, patients with associated anatomical spine abnormalities, infection at the injection site and a history of lumbosacral surgery were excluded.

The healthcare records review identified 83 patients who met the eligibility criteria and had undergone either SIJ cryoneurolysis or SIJ steroid injection. Patients were divided into Group 1 (SIJ cryoneurolysis, number of patients[n]=39) and Group 2 (SIJ steroid injection, $n = 44$). Baseline demographic data included age and gender. Preintervention pain severity was assessed with NPRS scores ranging from 0 (no pain) to 10 (severe pain). NPRS values at 1, 3 and 6 months postintervention were assessed telephonically.

The patients were placed in a prone position with a pillow under the iliac crests. Under aseptic conditions, a 2–5 MHz curvilinear ultrasound probe (M Turbo; FUJIFILM Sonosite, Inc., Bothell, WA, USA) was placed in a longitudinal plane to establish the initial three posterior sacral foramina on the planned intervention side. Subsequently, the probe was shifted laterally to establish the lateral sacral crest (LSC), where the lateral branches of the I, II and III sacral nerves come together to innervate the posterior SIJ [Figure 1]. The planned cryoprobe skin entry point and deeper paraspinal musculature were infiltrated with 1% lidocaine (5 mL), and then a stab incision was made with a blade (size 11). Under ultrasound guidance, a 14Fr cryoprobe (Metrum Cryoflex, Warsaw, Poland) was inserted through the skin and directed through the parasacral muscles until the bone was contacted at LSC just lateral to the S3 foramen. The probe was advanced further in a cranial direction to remain in contact with the bone over the lateral crest to target the lateral branches of S1–S3. The final cryoprobe position was confirmed with fluoroscopy using anteroposterior [Figure 1] and lateral views to ensure that the probe was lateral to the posterior sacral foramina and close to the posterior surface of the sacrum. Before proceeding to cryoneurolysis, sensory stimulation at 50 Hz was applied through the cryoprobe to stimulate the targeted nerves, resulting in paraesthesia concordant with the patients' reported location of pain. Motor stimulation at 2 Hz did not produce muscle contraction in the myotomes innervated by the first three ventral sacral nerve roots. The cryoneurolysis machine was connected to a carbon dioxide (CO_2) cylinder. A 3-min freezing cycle (−78°C for CO_2) and a 1-min defrosting cycle were initiated. Freezing and defrosting were visualised and confirmed under ultrasound. To increase the surface area of neurolysis, the probe was moved to the cephalad or caudad, depending on the probe's position concerning LSC

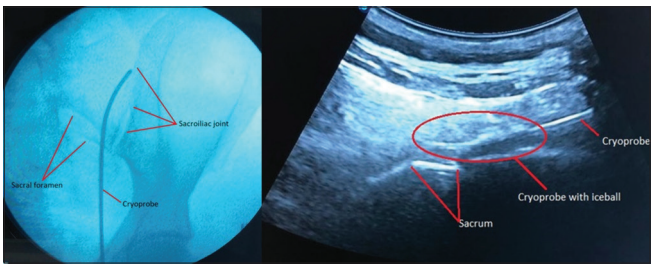

Figure 1: Cryoprobe *in situ* (X-ray [left] and ultrasonography [right]). The cryoprobe is seen between the sacral foramen and the medial joint line on the X-ray image. The cryoprobe with iceball is seen on the ultrasonography image just above the sacral bone

and the probability of freezing the L5 dorsal ramus. A second cycle of freezing and defrosting was then performed. After defrosting, the probe was removed and the skin was covered with adhesive tape. All patients were assessed for the degree of pain relief at the end of the procedure.

All SIJ corticosteroid injections were administered using a posterior approach with a standard single-beam C-arm fluoroscope: Anterior–posterior, contralateral oblique and lateral views guided needle placement. Once the needle tip was believed to be in IA position, 0.5 mL of iohexol (Omnipaque 180; GE Healthcare, Princeton, NJ, USA) was injected. Anterior–posterior images with live fluoroscopy were saved to the picture archiving and communication system. A uniform dose of 1 mL of 2% preservative-free lidocaine hydrochloride combined with 1 mL of triamcinolone acetonide 40 mg/mL was injected. The needle was removed, a sterile dressing was applied, and the patient was transferred to the recovery area for 15 min of monitoring.

The primary outcome measure was proportion of patients with a ≥50% reduction in NPRS score assessed immediately following SIJ cryoneurolysis and IA steroid injection in patients with SIJP. The secondary outcome measure was a ≥50% reduction in NPRS score assessed at 1, 3 and 6 months following SIJ cryoneurolysis and IA steroid injection in patients with SIJP.

The data was analysed with Statistical Package for Social Sciences (SPSS) version 23.0 for Windows (International Business Machines, Armonk, NY, USA). The categorical (gender as well as ≥50% and 100% decrease in NPRS score from baseline) and continuous (age, duration of symptoms and NPRS score) data were represented in frequency (percentages) and mean (standard deviation [SD]). The difference between the treatment groups was assessed with a Chi-square test and independent sample *t*-test for categorical and continuous variables. In both the groups, the change in NPRS score over the study duration was assessed with repeated measures analysis of variance (ANOVA) followed by post hoc analysis with Bonferroni's multiple comparison test. $P < 0.05$ was considered as statistically significant.

RESULTS

The records of 87 patients were assessed, of which 83 were included and divided into Group 1 ($n = 39$) and Group 2 ($n = 44$). At 6 months, data from all 83 patients was analysed [Figure 2]. Both the groups predominantly comprised females; however, there was no significant difference between the groups (Group 1 versus [vs.] Group 2: $n = 25$ vs. 26, $P = 0.640$). Similarly, there was no significant difference between the groups in terms of mean age, duration of painful symptoms and baseline NPRS score (all $P > 0.05$) [Table 1].

Analysis of the groups in terms of number of patients with ≥50% decrease in NPRS score from baseline revealed no significant difference between the groups in the immediate postintervention period ($P = 1.00$). However, at each of the other intervals, a significantly greater proportion of patients in Group 1 had ≥50% decrease in NPRS score from baseline, that is, 1 month ($P = 0.004$), 3 months ($P < 0.001$) and 6 months ($P < 0.001$) [Table 2]. Further evaluation of patients immediately postintervention revealed that six (15.38%) patients in Group 1 and two (4.55%) in Group 2 had complete pain relief, with no significant difference between them ($P = 0.095$). However, none of the patients in Group 2 had complete pain relief at each of the other intervals. On analysis, a significantly greater proportion of patients in Group 1 had complete pain relief at 1 month ($P < 0.001$), 3 months ($P < 0.001$) and 6 months ($P = 0.003$) [Table 2].

Table 1: Comparison of demographic and baseline characteristics

Characteristics	Group 1 (*n*=39)	Group 2 (*n*=44)
Age (years)	52.06 (12.64)	53.50 (10.75)
Gender (male/female)	14/25	18/26
Duration of symptoms, months	8.59 (1.16)	8.27 (1.02)

Data are expressed as mean (standard deviation) or numbers. *n*=number of patients

Table 2: Comparison of pain scores after intervention

Intervals	Group 1 (*n*=39)	Group 2 (*n*=44)	*P*
≥50% decrease in NPRS score from baseline			
Immediately, *n* (%)	39 (100)	44 (100)	1.00
1 month, *n* (%)	38 (97.44)	33 (75)	0.004
3 months, *n* (%)	39 (100)	21 (47.73)	<0.001
6 months, *n* (%)	27 (69.23)	12 (27.27)	<0.001
100% decrease in NPRS score from baseline			
Immediately, *n* (%)	6 (15.38)	2 (4.55)	0.095
1 month, *n* (%)	10 (25.64)	0 (0)	<0.001
3 months, *n* (%)	11 (28.21)	0 (0)	<0.001
6 months, *n* (%)	7 (17.95)	0 (0)	0.003

Data are expressed as numbers (percentages). NPRS=numeric pain rating scale, *n*=number of patients

At 6 months, Group 1 had a significant decrease in mean NPRS score ($P < 0.001$). Post hoc analysis revealed a significant decrease in mean NPRS score between baseline and immediate postintervention, 1 month, 3 months and 6 months (all $P < 0.001$). Moreover, a significant decrease in mean NPRS score was observed between immediate postintervention and 6 months ($P = 0.009$), between 1 month and 6 months ($P = 0.001$) and between 3 months and 6 months ($P < 0.001$). Similarly, Group 2 showed a significant decrease in mean NPRS score at 6 months ($P < 0.001$). Post hoc analysis showed a significant decrease in mean NPRS score between baseline and immediate postintervention, 1 month, 3 months and 6 months ($P < 0.001$). Moreover, a significant reduction in NPRS score was observed between immediate postintervention and 1 month ($P = 0.01$), 3 months and 6 months (both $P < 0.001$), between 1 month and 3 months and 6 months (both $P < 0.001$) and between 3 months and 6 months ($P = 0.003$). Comparison of groups revealed significantly decreased mean NPRS scores among patients in Group 1 at all the intervals, that is, immediately postintervention, 1 month, 3 months and 6 months (all $P < 0.001$) [Table 3].

DISCUSSION

Our study revealed comparable pain relief (≥50% decrease in NPRS score from baseline) in both groups immediately post-intervention, while at 1, 3 and 6 months a greater proportion of patients had ≥50% decrease in NPRS score from baseline in cryoneurolysis group. Evaluation of the secondary outcome measure suggested complete pain relief with both treatments. Moreover, significantly greater proportion of patients receiving cryoneurolysis had complete pain relief at 1, 3 and 6 months.

Immediate pain relief after cryoneurolysis is attributed to axonal degeneration with local necrosis, severe disruption of myelin lamellae, as well as oedema of mitochondria, microfilaments and microtubules.[10] Moreover, it reliably inhibits the transmission of afferent and efferent signals for several weeks or months as the axon regrows slowly, allowing complete nerve regeneration and functional recovery.[10,11] On the other hand, steroids inhibit phospholipase A2, leading to decreased synthesis of the pain-promoting derivatives of the cyclooxygenase and lipoxygenase pathways, thus reducing inflammatory pain.[12] Therefore, based

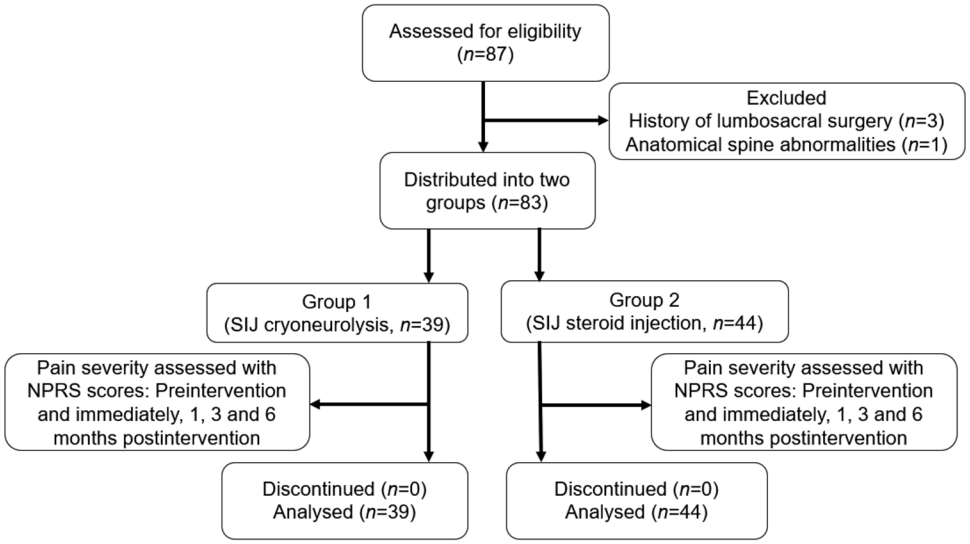

Figure 2: Study flowchart. NPRS = numeric pain rating scale, SIJ = sacroiliac joint, n=number of patients

Table 3: Comparison of NPRS scores at each interval

Intervals	Group 1 (*n*=39)	Group 2 (*n*=44)	Mean difference (95% CI)	*P*
Baseline	7.31 (1.06)	7.09 (1.24)	0.22 (−0.29, 0.72)	0.396
Immediately	1.21 (0.77)	2.05 (0.99)	−0.84 (−1.23, −0.45)	<0.001
1 month	1.15 (1.04)	2.75 (1.18)	−1.59 (−2.09, −1.11)	<0.001
3 months	1.33 (1.08)	3.93 (1.48)	−2.59 (−3.17, −2.02)	<0.001
6 months	1.77 (1.65)	5.11 (2.13)	−2.49 (−3.50, −1.49)	<0.001
P	<0.001	<0.001		

Data is expressed as mean (standard deviation) or numbers. NPRS=numeric pain rating scale, CI=confidence interval, n=number of patients

on direct action, cryoneurolysis is expected to have significantly greater immediate pain relief.

Youssef and Meleka reported that 96.6% of patients with SIJP experienced immediate, complete relief with computed tomography-guided steroid injections. However, 1–3 months later, 60% of patients returned to the baseline pain score.[13] In another study, Nacey *et al*.[6] reported that 64% of patients had ≥75% pain relief immediately after fluoroscopically guided SIJ steroid injections, which reduced to 22% one week postintervention. In a randomised controlled trial (RCT), Kim *et al*.[14] reported that 27.2% of patients with SIJP experienced ≥50% pain relief 6 months after IA steroid injections. Similarly, we found that 100%, 75%, 47.73% and 27.27% of patients experienced ≥50% decrease in mean NPRS score immediately, 1, 3 and 6months post-steroid injections, respectively.

The study's limitations include its retrospective study design, inclusion of patients without spine surgery, absence of randomisations and blinding, and small sample size. Further RCTs with large sample sizes are required to compare cryoneurolysis with IA steroid injection.

CONCLUSION

There was significant pain relief with both cryoneurolysis and IA steroid injections immediately, 1, 3 and 6 months post-intervention. However, a significantly greater proportion of patients receiving cryoneurolysis had a ≥50% decrease in mean NPRS score from baseline at 1, 3 and 6 months post-intervention. At similar intervals, a significantly greater proportion of patients receiving cryoneurolysis had complete pain relief.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author).

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Nil.

Conflicts of interest

There are no conflicts of interest.

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