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Strip-Lesioning Technique in Radiofrequency Ablation for Sacroiliac Joint Pain A Retrospective Chart Review

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Background: Sacroiliac joint pain (SJP) constitutes a substantial proportion of back pain cases, is difficult to diagnose, and requires a range of treatment options based on severity, comorbidities, and available clinical resources.

Objective: We investigated the effectiveness and safety of radiofrequency ablation (RFA) with the Simplicity III (Abbott) strip-lesioning device (SLD) for SJP in a diverse population of patients with chronic pain.

Study Design: Retrospective chart review.

Methods: We collected data from patients who underwent RFA of the lateral branches of S1–S4 in an outpatient setting. Primary outcomes included patient-reported percentage of pain relief, changes in Pain Disability Index (PDI) scores, and daily morphine equivalent dose (MED).

Results: A total of 115 patients were included: 83 women (72.2%) and 32 men (27.8%), with a mean age of 59.5 years. Mean pain relief at 36.1 days (range, 10–84 days) was 64.1% (SD, 24.2%; range, 0%–100%; IQR, 50%–80%); 103 patients (89.6%) reported relief of 50% or more. PDI scores decreased by 2.8 points (SD, 19.4, $P = 0.125$), and MED decreased by 0.7 (SD, 7.2, $P = 0.188$); neither change was statistically significant. No statistically significant associations were found between percentage pain relief and demographic characteristics (age, gender, body mass index), baseline clinical characteristics (PDI, MED, psychological comorbidities), or procedure laterality. Two minor adverse events were recorded.

Limitations: Retrospective design, single center, and inconsistent follow-up intervals.

Conclusions: Our results suggest that RFA with the Simplicity III SLD for SJP is generally a safe and effective intervention for patients in this population overall, though a higher-powered study would be needed to compare subgroups in terms of age, co-morbidities, function, gender, and MED.

Key words: Sacroiliac joint pain; radiofrequency ablation; strip lesioning; interventional pain management

BACKGROUND

Chronic low back pain is the second leading cause of disability worldwide and is associated with high health care expenditures (1). Sacroiliac joint pain (SJP) is estimated to account for approximately 15%–30% of this burden, and affected individuals experience a lower quality of life (2). SJP can arise primarily or secondarily to trauma, surgery, strenuous exercise, pregnancy, ar-

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thritis, or scoliosis. It may also be caused by fracture, spondyloarthropathy, crystal arthropathy, or osseous metastases from cancers such as renal cell carcinoma and prostate cancer (3).

The sacroiliac joint (SIJ) is formed by the articulation of the lateral sacrum and medial ilium and acts as a shock absorber for the spine. The posterior sensory innervation sacroiliac joint complex is mainly supplied by the L5 dorsal ramus and S1–S3 lateral branches, which serve as anatomical targets for SIJ radiofrequency neurotomy (4).

Conservative treatments for SJP include physical therapy, nonsteroidal anti-inflammatory drugs, muscle relaxants, and acetaminophen. Procedural interventions include injections of local anesthetics or glucocorticoids (5). Relief from these treatments may last only hours, days, or weeks. Opioid treatment is common and carries risks including respiratory depression, dependence, constipation, and misuse (6).

SJP often goes undiagnosed because its symptoms may overlap with those of lumbar spine disorders and because sacral innervation and anatomy vary (7). No physical examination finding is pathognomonic, so diagnostic local anesthetic injections are often used (8). Patient-reported pain relief of at least 75% is often used as the threshold to confirm SJP. RFA may be recommended when other nonsurgical treatments have failed or produced suboptimal responses.

RFA, also referred to as radiofrequency denervation, rhizotomy, or neurotomy, uses a high-frequency electrical current generated and applied to nerves through a needle probe with an insulated tip. The resulting temperature (60°C–80°C) creates a lesion that interrupts nociceptive signaling to the central nervous system. Unlike injections of local anesthetics or glucocorticoids, relief from RFA may last months or longer, depending on nerve regeneration (5).

Several RFA techniques are used, each with its own probe type, anatomical approach, benefits, and drawbacks. Classic monopolar RFA approaches individual nerves perpendicularly and has been associated with recurrence (9). Internally cooled RFA may produce relief lasting up to 2 years but requires multiple lesions (10). The strip-lesioning device (SLD) targets multiple nerve fibers through its electrode array and placement parallel to the sacral nerves (11) (Figs. 1–3). It creates 3 monopolar lesions along the sacrum and 2 bipolar lesions in the middle of the probe, ablating a larger area than a monopolar probe and potentially accounting for anatomical variation in nerve distribution.

The purpose of this study was to evaluate pain relief following radiofrequency ablation (RFA) of the S1–S3 sacral lateral branches using the Simplicity III system. The L5 dorsal ramus and S4 lateral branch were not routinely targeted due to insurance coverage limitations. However, the longitudinal lesion geometry of the Simplicity III probe raises the possibility of thermal lesioning extending into the S4 distribution in some patients.

Outcomes besides pain relief included adverse events (AEs), changes in Pain Disability Index (PDI) scores and daily morphine equivalent dose (MED). We also investigated potential associations between RFA outcomes and factors associated with treatment outcomes (12). Psychological comorbidities, including depression and anxiety, may affect pain and the outcomes of pain interventions (13). Obesity may also affect pain and treatment outcomes (14).

METHODS

Western Institutional Review Board's (WIRB's) IRB Affairs Department reviewed the study and determined that it was exempt under 45 CFR § 46.104(d)(4). A waiver of authorization for use and disclosure of protected health information (PHI) was approved on August 20, 2019, under work order #1-1212727-1. Inclusion criteria were age 18–90 years, a diagnosis of SJP, and documented outcomes within 6 months after RFA. Exclusion criteria were other significant pain that might affect SJP reporting, a clinically significant condition that could confound outcomes, and an ongoing health-related legal claim, including workers' compensation claims. Although many patients underwent repeat sacral RFA, only their initial procedures were included in the analysis.

We reviewed data in the eClinicalWorks electronic medical record (EMR) at the Western Reserve Hospital Center for Pain Medicine. We searched for ICD-10 codes M53.3 (sacral pain) or M46.1 (sacroiliitis) and identified 498 charts of patients who underwent outpatient RFA of the lateral branches of S1–S4 between January 1, 2016, and May 5, 2019. All screened patients had received 2 diagnostic injections with at least 75% reported pain relief before RFA, as required by insurance. Most underwent diagnostic sacral lateral branch blocks targeting the S1, S2, and S3 lateral branches before RFA. In a small number of cases, intra-articular sacroiliac joint injections were performed instead. All patients had negative results on a urine drug screen or cheek swab



Fig. 1. Anatomical placement of the strip-lesioning device.

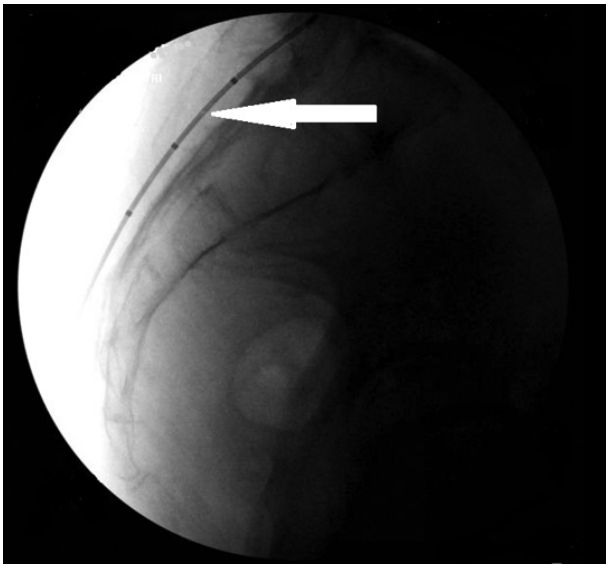


Fig. 2. SLD positioning under fluoroscopy, lateral view.

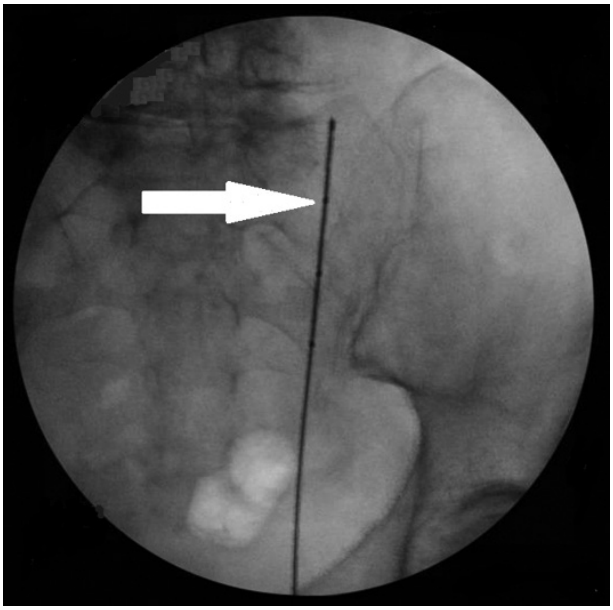


Fig. 3. SLD positioning under fluoroscopy, anteroposterior view.

for illicit drug use. To improve accuracy and reduce bias, 2 team members reviewed the charts independently. A supervisor (DA) reconciled discrepancies and missing data with the reviewers. After screening, 383 charts were excluded, leaving 115 for analysis. The reasons for exclusion included missing documentation of pain relief as a percentage (232), loss to follow-up (87), incomplete documentation (45), concurrent procedures for lumbar pain (19).

The procedures were performed in a procedure room under anteroposterior and lateral fluoroscopy. Patients were positioned prone with continuous hemodynamic monitoring and intravenous sedation. After a needle was inserted to confirm the electrode path and deliver anesthetic along the lesion track, the Simplicity III SLD (Abbott, Austin, TX, USA) was advanced toward the S1–S4 lateral branches, medial to the SIJ and ventral to the ilium. Contact with the sacrum was maintained along a cephalad and slightly lateral path until the sacral ala prevented further advancement. Position was confirmed by changing the caudal–cephalad tilt of the C-arm. Lesioning was performed at 80°C for 60 seconds. Four physicians performed and documented all RFAs using the same methods and equipment.

Percentage pain relief was chosen as the primary endpoint because it was the measure used to document change attributable to RFA. The numeric pain rating scale (NPRS) is used at the center for other painful conditions or global pain and was therefore not used to assess SJP alone (15). When patient-reported relief was documented as a range (eg, 50%–60%), the midpoint (eg, 55%) was used.

Because this was a retrospective study, follow-up intervals varied considerably; we therefore report their means and ranges.

Adverse events (AEs) documented in routine post-procedure telephone calls and office visit notes were

classified according to the Common Terminology Criteria for Adverse Events (CTCAE) (16).

Function was assessed with the Pain Disability Index (PDI), a patient-reported measure with 7 domains: family and home responsibilities, recreation, social activity, occupation, sexual behavior, self-care, and life-support activities. Each domain is rated from 0 to 10, yielding a total score of 0–70; higher scores indicate greater disability (17).

Because patients received opioids of varying potency and dose, morphine equivalent dose daily (MED) was calculated using the Ohio Automated Rx Reporting System (OARRS) method (18). Body mass index (BMI) was calculated automatically by eClinicalWorks from office visit measurements as weight in pounds divided by height in inches squared, multiplied by 703 (19).

Data were summarized as mean (SD) for normally distributed variables, median (IQR) for nonnormally distributed variables, and n (%) for categorical variables. Full summary statistics are provided to show the data distributions. Spearman rank correlation assessed associations among nonnormally distributed measures. The Wilcoxon signed-rank test assessed paired differences between time points or compared pain relief with a hypothesized value. The Wilcoxon rank-sum or Kruskal–Wallis test assessed differences in pain relief across demographic and clinical categories. The chi-square test of independence, or Fisher exact test when expected cell counts were less than 5, assessed associations between categorical variables. Analyses were conducted in Stata/BE version 18.0 (StataCorp LLC, College Station, TX), with a significance threshold of $\alpha = 0.05$. Retrospective data may be biased or inconsistently recorded, limitations that statistical analysis cannot eliminate. Sensitivity analysis, test assumptions and multiplicity were not assessed.

RESULTS

Unless otherwise stated, analyses included 115 patients.

Demographics: The initial EMR search identified 498 patients with SJP who had undergone RFA at least once. After screening, 115 patients were included. Of these, 83 (72.2%) were women and 32 (27.8%) were men; mean age was 59.5 years (range, 28–86 years). Demographic characteristics are presented in Table 1.

Baseline clinical characteristics: Mean BMI was 33.9 kg/m² (range, 19–58 kg/m²), and mean MED (milligram morphine equivalent daily) was 17.6 (range, 0–135). For psychological comorbidities, we divided the cohort into three categories: (1) 40 patients (34.8%) without depression or anxiety, (2) 40 (34.8%) with depression or anxiety, and (3) 35 (30.4%) with both of these conditions and/or bipolar disorder. Mean baseline PDI score was 39.3 of 70 (n = 108; range, 9–64). Procedures were bilateral in 64 patients (55.7%), left-sided in 20 (17.4%), and right-sided in 31 (27.0%). Clinical characteristics are presented in Table 2.

Pain relief: Mean reported pain relief was 64.1% (SD, 24.2%; range, 0%–100%; IQR, 50%–80%). Relief was at least 75% in 52 patients (45.2%), 50%–74% in 51 (44.3%), 25%–49% in 4 (3.5%), and 0%–24% in 8 (7.0%) (Fig. 4). Thus, 103 patients (89.6%) reported relief of 50% or more.

Sixty-seven patients (58.3%) underwent repeat RFA; outcomes of those procedures are not reported here.

Follow-up time: The mean interval between the procedure and the report of percentage pain relief was 36.1 days (range, 10–84 days) (Fig. 5). The mean interval between baseline measurement of PDI and MED and follow-up was 94.9 days (range, 23–288 days).

Mean PDI score decreased from 39.3 at baseline to 36.5 at follow-up, a change of -2.8 (SD: 19.4, $P = 0.125$). Mean MED decreased from 17.8 to 17.1, a change of –0.7 (SD, 7.2, $P = 0.188$). Neither change was statistically significant (Fig. 6).

Correlations: Percentage pain relief was not significantly associated with gender ($P = 0.099$), procedure laterality ($P = 0.730$), or comorbid anxiety or depression ($P = 0.714$). No statistically significant association was found between percentage pain relief and postprocedure PDI ($P = 0.252$), baseline BMI ($P = 0.848$), or postprocedure MED ($P = 0.575$). Correlations were reported between age and BMI ($P = 0.016$), age and PDI ($P = 0.003$), and BMI and PDI ($P = 0.032$), though no effect estimates were calculated.

Adverse events: No major adverse events were reported. The two adverse events occurred in separate patients (1.7%), who reported increased leg pain after the procedure and were treated with ice and oral medications (CTCAE grade 2).

DISCUSSION

Given the prevalence of SJP, pain specialists need a range of treatments to meet individual patients' needs. These include conservative treatments, such as physical therapy and nonsteroidal anti-inflammatory drugs;

injections and RFA; and joint fusion. Recent guidelines generally place RFA after injections and before fusion in treatment algorithms (20). RFA may be an option for patients whose first-line treatments have failed and who cannot undergo fusion. RFA is minimally invasive and targets the anatomical source of pain without systemic drug exposure. A review of 37 studies found that sacral RFA generally produced 40%–60% pain relief at 12 months, improved function, and had a low reported rate of adverse events (21).

The same review found substantial heterogeneity in anatomical targets, techniques, study designs, follow-up intervals, outcome measures, and sample sizes. All included studies examined lesioning of S1–S3, whereas S4 and the L5 dorsal ramus were targeted less consistently. Approaches included monopolar, bipolar, strip-lesioning, and cooled RFA. Probe temperatures and lesioning durations also varied. Most studies used the numeric rating scale (NRS), but fewer assessed functional or psychological outcomes. Few randomized controlled trials had more than 20 participants; the largest included 27 (21).

These differences make comparisons across studies difficult, particularly for strip lesioning, for which sample sizes have been small. The review found 8 strip-lesioning studies meeting its inclusion criteria; the largest was a retrospective review of 64 patients (9).

The Centers for Medicare & Medicaid Services local coverage determination cited here does not cover sacral RFA for SJP (22). The authors quote an earlier version of that determination below:

The literature shows a positive trend for SIJ RFA pain improvement and most subject matter experts on our panel support this as a treatment option. While meta-analysis that have been done in attempt to reconcile the small sample size, extremely high heterogeneity in these studies is problematic.

Our cohort was relatively large (n = 115) and underwent a consistent procedure with the SLD. Mean reported pain relief was 64.1% at a mean of 36.1 days after RFA, consistent with other retrospective studies (24-26). At least 50% relief was reported by 103 patients (89.6%), compared with reported rates of 41%–64% at 1 month in other studies (5).

Although disability scores and daily morphine equivalent dose decreased at follow-up, neither change was statistically significant. Clinical significance was not consistently documented. The available data may not capture all effects of RFA because patients with chronic pain often have more than one painful condition and may find it difficult to distinguish relief of SJP from changes in other symptoms.

Table 1. Patient demographic characteristics at baseline.

Age (mean)	Gender	
59.5 (range: 28-86)	Women 83 (72.2%)	Men 32 (27.8%)

Table 2. Patient clinical characteristics at baseline and procedure laterality.

BMI (mean)	MED (mean)	Psychological disorders	PDI* (mean)	Laterality
33.9 kg/m^2 (range: 19-58)	17.6 (range: 0-135)	None 40 (34.8%)	39.3/70 (range 9-64)	Right 31 (26.9%)
		Depression or anxiety 40 (34.8%)		Left 20 (17.4%)
		Depression and anxiety or bipolar disorder 35 (30.4%)		Bilateral 64 (55.7%)

*PDI data were available for 108 patients.

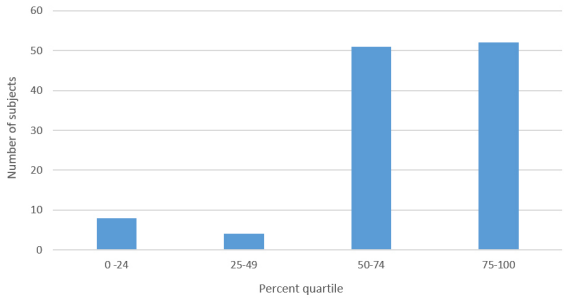


Fig. 4. Percentage pain relief.

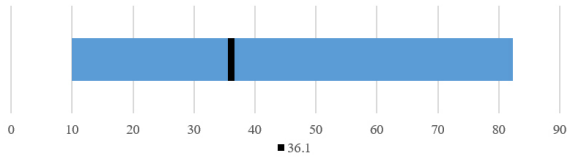


Fig. 5. Time from procedure to follow-up in days.

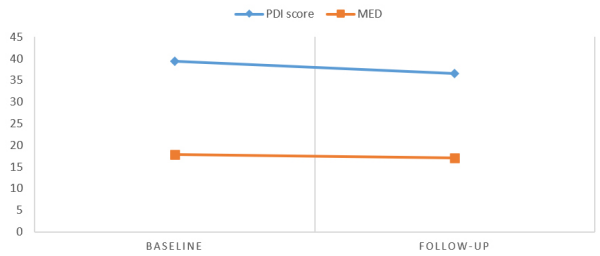


Fig. 6. Changes in mean PDI and MED from baseline to follow-up.

In this cohort of patients who underwent a uniform strip-lesioning procedure with the Simplicity III SLD, we examined disability and potential associations between pain relief and opioid use, disability, age, and gender. These factors may affect treatment outcomes (12–14). We found no statistically significant association between pain relief and the assessed demographic or clinical variables, including laterality, BMI, psychological conditions, and disability scores.

This finding may reflect the difficulty of assessing a single procedure in patients with multiple pain complaints or centralized pain. This finding may reflect the difficulty of assessing a single procedure in patients with multiple pain complaints or centralized pain. Because the study was retrospective and limited to existing documentation, potential associations should be investigated in prospective studies with more precise outcome assessment.

The retrospective design had several limitations. Pain and disability outcomes were limited to information routinely documented in the EMR. Follow-up intervals varied, and consistent data at 3, 6, and 12 months were unavailable. Patients were not uniformly trained to report pain outcomes, which may have increased variability in their responses.

A further limitation is the lack of consistent 6-month follow-up, when relief of more than 50% is often used to guide repeat procedures. The absence of these data reflects incomplete clinical documentation rather than an observed lack of sustained improvement. Other studies of this technique have reported relief at 6 months; the authors expect that comparable results might have been observed here with more complete documentation (2,23,24).

CONCLUSION

Radiofrequency denervation of the sacral nerves with the strip-lesioning technique appears safe and effective among patients with varying comorbidities, functional levels, and daily morphine equivalent doses. Many patients opted to repeat the procedure. Furthermore, the relatively large sample size and consistent technique of this study contribute to the breadth of the existing literature.

Declarations

i. The Western Reserve Hospital Research Committee approved the study protocol. Western Institutional Review Board's (WIRB) determined this study to be "exempt under 45 CFR § 46.104(d)(4) because this is a retrospective chart review in which the only identifier used is the account number and that number will be stripped and removed from the data."

ii. Consent for publication: The authors state that informed consent for publication was not required because this retrospective study reported deidentified data.

iii. Availability of data and material: The data supporting this study are available upon reasonable request from the corresponding author.

iv. Competing interests: The authors declare no competing interests.

v. Funding: No outside funding was required for this study.

vi. Code availability: Not applicable.

Authors' Contributions

J. Sable performed some procedures and contributed to protocol design. N. Capaldo collected data and contributed to the introduction. M. Narouze and T. Souza collected data and contributed the figures and tables to the final manuscript. Syed Ali, MD, Dmitri Souza, MD, PhD and Samer Narouze, MD also performed procedures but did not contribute as authors.

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