Prospective Case Series

Simplicity Radiofrequency Ablation Demonstrates Greater Functional Improvement Than Analgesia: A Prospective Case Series

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Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 05-05-2020
Revised manuscript received: 08-12-2020
Accepted for publication: 08-18-2020

Free full manuscript: www.painphysicianjournal.com

Background: Pain originating from the posterior sacroiliac complex is notoriously difficult to effectively treat due to its complex anatomy and variable innervation. Data on radiofrequency ablation (RFA) is limited. The Abbott Simplicity probe creates 3 monopolar lesions along the medial aspect of the sacroiliac joint and 2 bipolar lesions between the active portions of the probe. This device has been studied previously with improvement of pain-associated disability and pain reduction, but insufficient data is present to determine its utility at this time. Using the most recent literature for the potential innervation of the posterior sacroiliac joint, it is reasonable to explore this novel device and its ability to treat sacroiliac joint pain.

Objectives: Identify the percentage of improved posterior sacroiliac complex pain and improved function in patients who completed posterior sacroiliac complex radiofrequency ablation using the Simplicity probe.

Study Design: Prospective case series.

Setting: A single outpatient pain clinic.

Methods: This prospective case-series occurred at an outpatient pain clinic. Data were analyzed after completion of follow-up appointments. Inclusion criteria included 2 successful lateral branch blocks. Fourteen patients with posterior sacroiliac complex pain were examined and completed sacroiliac ablation with the Simplicity probe. The numeric rating scale and the Modified Oswestry Disability Index were used as outcome measures for pain and function, respectively. The primary outcome measures were improvement in the numeric rating scale score by a reduction of 2.5 points and an improvement in Modified Oswestry Disability Index by 15% based upon previous studies demonstrating these values as the minimal clinical important difference . Patients were followed at a 3 to 6 month interval and 12 month interval (an average of 88 and 352 days, respectively).

Results: In total, 14 patients were examined. At the first follow-up, 29% of patients had analgesia and 38% functionally improved. At the second follow-up, 15% of patients had analgesia and 31% functionally improved.

Limitations: Considering data were collected retrospectively, this study relied on completed charts. Therefore, data points of interest were limited to what was previously documented, which included multiple answers or the absence of numerical data points. In addition, patients were disproportionately female (71.4%). Data were also affected by patients lost to follow-up. Also, this study examined a relatively small number of patients, therefore the results should be carefully considered.

Conclusions: Radiofrequency ablation of the posterior sacroiliac complex with the Simplicity probe resulted in more functional improvement than analgesia. This study provides more data for clinicians to utilize in managing posterior sacroiliac complex pain.

IRB: Protocol number 20170342HU. Not registered in clinical trials.

Key words: Posterior sacroiliac complex, sacroiliac pain, chronic low back pain, radiofrequency denervation, functional improvement, strip lesion, multi-lesion, Simplicity probe.

Pain Physician 2021: 24:E185-E190

Etiologies of chronic low back pain (CLBP) vary widely and can originate from the nerve root, muscle, bone, tendon, facet, or posterior sacroiliac complex (PSIC). The PSIC is the cause of CLBP in 15% to 30% of individuals (1,2). It is notoriously difficult to effectively treat due to its complex anatomy, variable innervation, and difficult clinical diagnosis. Further, pain emanating from the sacroiliac joint (SIJ) area may originate from the overlying ligaments instead of the joint itself. In addition, Maigne et al (3) completed intra-articular sacroiliac blocks on 67 patients suffering from sacroiliac pathology and found only 18.5% as responders, supporting that sacroiliac pain is not limited to the joint itself. Therefore, pain coming from at or about the SIJ may be more correctly referred to as posterior sacroiliac complex pain.

The SIJ is an auricular-shaped, synovial joint designed to transmit force from the axial skeleton to the appendicular skeleton (1,4). An intricate network of ligaments and muscles provide its stability to withstand coronal forces, although it is frequently injured with axial and rotational forces (1). The innervation of the SIJ is controversial, but imperative when considering diagnostic and therapeutic interventions. Historically, literature suggested the lateral branches of S1-S3 dorsal rami and L5 dorsal ramus supply the posterior aspect of the SIJ (1,5). More recent literature supports that L5 dorsal ramus contribution is variable and inconsistent (6,7). L4 and L5 ventral rami are proposed to innervate the ventral aspect of the SIJ (8). In addition, the nerves providing innervation can vary in depth, number, and location.

Specifically, the lateral branches may run directly on the sacral periosteum or superficial to the sacrum in the layers of the posterior sacroiliac ligament (9). This is supported by Dreyfuss et al's study (9) in which only 36% of cadavers' lateral branches were stained when placing the dye at a single site, single depth near the S1-3 sacral foramina. These findings led to further research which explored multi-site and multi-depth interventions to account for the variable location of nerves deep, superficial, or within the posterior sacroiliac ligament. One study found that a multi-site and multi-depth intervention protocol successfully stained 91% of lateral branches innervating the SIJ (10).

PSIC pain is difficult to successfully diagnose due to variable presentations, poor validity of physical exam findings, and lack of consistent patient-reported analgesia after diagnostic intervention. In addition, PSIC pain may refer to the gluteal region, posterior thigh, or groin (1). To assist with a clinical diagnosis, multiple provocative physical maneuvers can be utilized. However, there is no singular provocative test with dependable validity and reliability (11). Therefore, diagnosis may be achieved by infiltration of the SIJ capsule with anesthetic. However, this strategy used for diagnosis is flawed as the SIJ capsule may not be completely sealed and pain may originate from surrounding structures like the posterior sacroiliac ligament. Therefore, the anesthetic may invade surrounding structures and obscure diagnosis (10,11).

There are conservative and interventional approaches for the treatment of PSIC pain. Conservative treatment includes physical therapy, osteopathic maneuvers, chiropractic manipulation, and oral or topical analgesics. Interventional treatments include intra-articular injections, radiofrequency ablation (RFA), prolotherapy, and surgical fixation. RFA is a common treatment for PSIC pain in those who obtain relief from diagnostic blocks. Types of RFA include unipolar RFA, bipolar RFA, pulsed RF treatment, and cooled RFA – all of which have distinct lesion shapes and relative sizes. This variability may lead to the differences in the analgesic efficacy of each type. Multiple studies found improved pain control after SIJ pain treatment with the Simplicity probe and conventional denervation of the L5 dorsal ramus (12-14). In this paper, we explore the Abbott Simplicity probe which creates 3 monopolar lesions along the posteromedial aspect of the SIJ and 2 bipolar lesions between the active portions of the probe, thereby ablating a large continuous area, a strip lesion, to accommodate the variable anatomy of the SIJ.

Here, we present a prospective case series to further explore the efficacy, as measured by analgesia and improved function, of RFA of the SIJ using the Simplicity probe at S1-S3 and traditional RFA of L5 primary dorsal ramus (PDR).

Methods

Approval for the study was obtained by the Institutional Review Board at UT Health San Antonio (protocol number 20170342HU). This prospective case series occurred at a single outpatient interventional pain clinic. Data were analyzed after completion of follow-up appointments. Inclusion criteria included 2 consecutive L5 dorsal ramus and lateral branches of the dorsal rami of S1-S3 blocks achieving 50% pain relief followed by RFA with the Simplicity probe. Diagnostic blocks were complete as described in Dreyfuss et al (9). Considering there is no singular provocative

physical exam test with dependable validity and reliability, physical exam techniques in this study were provider-dependent (11).

A minimal clinical important difference (MCID) of the numeric rating scale (NRS) for pain and the Modified Oswestry Disability Index (MODI) were used as outcome measures. The MCID was utilized to measure meaningfulness of intervention. The MCIDs used were based upon prior studies which validated a 2.5-point NRS change and a 15% MODI reduction as clinically meaningful improvement in the treatment of SIJ pain (15,16). The NRS is a pain rating scale of zero to 10; zero indicating no pain and 10 indicating greatest amount of pain. The MODI measures disability related to low back pain. The MODI is a questionnaire completed by patients; the higher the score indicates increased disability (scored 0 to 100, 100 indicating maximal disability). Patients were followed up at a 3 to 6 month and 12-month interval (an average of 88 and 352 days, respectively). Outcome measures were completed on the day of procedure and at each follow-up appointment.

Statistics reported are descriptive statistics. No further statistical tests were utilized in the absence of a comparator group.

Procedure Details

After informed consent was obtained, the patient was placed prone in the fluoroscopy suite. Skin was prepped and draped in sterile technique. Anatomic landmarks were identified by palpation and fluoroscopy. The procedure was performed under fluoroscopic guidance.

The superior articular process of S1 and sacral ala junction was identified. Local anesthetic was injected subcutaneously for skin infiltration. A 20 gauge, 10 cm SMK needle with a 10 mm active tip was inserted and advanced to this junction. Needle placement at the junction of the superior articular process of S1 and the sacral ala was confirmed by anterior posterior and lateral views. Motor stimulation at 3V and 2 Hz and sensory stimulation at 1V and 50 Hz confirmed needle placement by ensuring no distal motor response or inappropriate sensation. After a 1 mL of 2% lidocaine injection, one cycle of ablation at 80 degrees Celsius for 90 seconds was performed followed by 1 mL of 0.5% bupivacaine. The needle was removed and puncture sites were dressed.

Next, the S1-S4 foramen and inferior border of the sacrum were identified. A 25 gauge, 3.5 inch spinal needle was inserted at the inferior aspect of the sacrum to anesthetize the tissue prior to placement of the probe, and local anesthetic was injected subcutaneously for skin infiltration. The needle was advanced while in constant contact with the dorsal aspect of the sacrum. At the inferior border of the sacrum, 5 mL of a 30 mL solution of a mixture of 15 mL 0.5% bupivacaine and 15 mL 2% lidocaine was injected. Then, the needle was advanced to the lateral S4 border where an additional 5 mL of the same solution was injected. This process was repeated at S3, S2, and S1. The 25-gauge needle was removed.

Then the Simplicity probe was inserted along the same tract along the lateral sacral foramen borders to the superior aspect of the sacral crest at its mid-point. After optimal position of the probe was confirmed in lateral and anterior posterior views (see Figs. 1 and 2), the probe was activated to create 2 bipolar lesions and 3 monopolar lesions at 80 degrees Celsius for 90 seconds as per Simplicity probe protocol. The probe was removed, and the skin was bandaged.

Analysis

According to the MCID, a 2.5-point decrease in the NRS and a 15% decrease in the MODI were considered meaningful. Patients were determined to be respond-

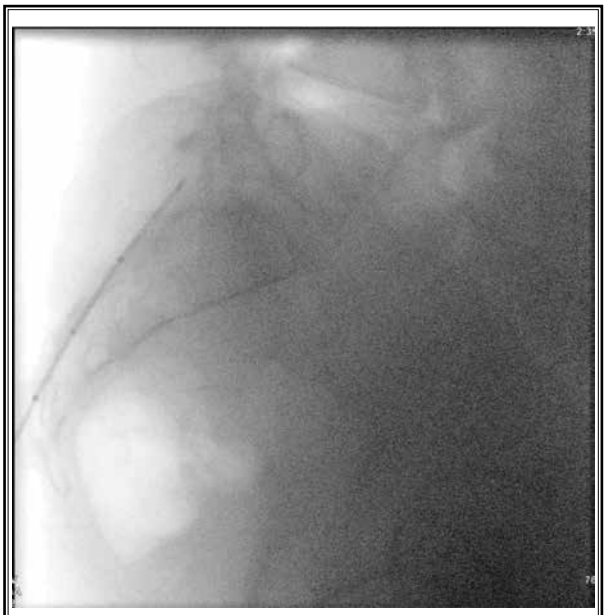

Fig. 1. *Lateral fluoroscopic view of the sacrum with placement of Simplicity probe on posterior border.*

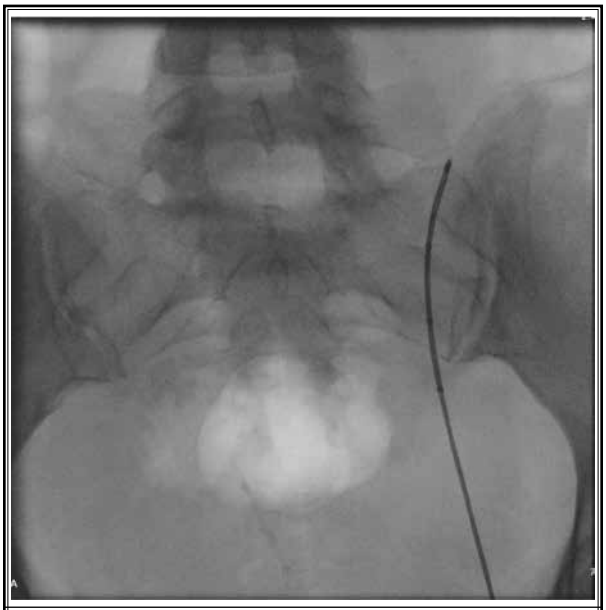

Fig. 2. *AP fluoroscopic view of the sacrum with placement of Simplicity probe between sacral foramina and sacroiliac joint.*

ers if their NRS decreased by 2.5 points or their MODI decreased by 15% at each follow-up visit.

Results

In total, 14 patients were included, aged 30 to 73, with lower back pain attributed to PSIS pain as diagnosed at least 50% relief with 2 consecutive lateral branch block procedures. There were 10 women and 4 men with mean body mass index (BMI) of 32.7. Seven patients had a history of prior opioid use for pain. Analysis was completed based on available data. At the first follow-up, 29% (95% CI, 8% – 58%) of patients obtained analgesia by achieving a greater than or equal to 2.5-point decrease in their NRS and 38% (95% CI, 2% – 45%) functionally improved as demonstrated by a 15% decrease in their MODI. At the second follow-up, 15% (95% CI, 14% – 68%) of patients had analgesia and 31% (95% CI, 9% – 61%) functionally improved. Table 1 demonstrates the outcome of each patient at each time point. Table 2 categorically demonstrates if the patient obtained clinically significant improvement as measured by the NRS and MODI outcome measures.

Adverse Outcomes

One mechanical fall occurred immediately following the procedure. There was no injury as a result of the fall. There were no other noted complications.

Discussion

The PSIC pain syndrome has remained a difficult diagnosis to treat. The difficulty may originate in the highly debated innervation of the SIJ as discussed above. Interventional pain procedures have attempted to address PSIC pain through multiple RFA techniques which result in various lesion morphology. In this study, we specifically explore the Abbott Simplicity probe use in RFA of the PSIC. The Abbott Simplicity probe creates a strip lesion to address the multi-site and multi-depth innervation of the PSIC. The goal of this study is to identify the percentage of improved PSIC pain and the percentage of improved function in patients who completed PSIC RFA using the Simplicity probe.

This study found 29% of patients had meaningful clinical improvement in analgesia at 3 to 6 months and 15% of patients had meaningful clinical improvement at 12 months after the procedure. The nominal improvement seen in the 12-month follow-up may be expected in the setting of nerve regeneration over time (17).

Function was improved in 31% of patients one year after denervation. Thereby, this study showed more positive effects as measured by function than by analgesia. Similarly, Reddy et al (12), a retrospective observational study, examined 16 patients who underwent denervation by the Abbott Simplicity probe and found improved general health as demonstrated by the Short Form-12 (SF-12) . Reddy et al (12) was similar to our study in the number of patients examined and provided a similar outcome although measured by different tools. Bellini and Barbieri (13), a prospective observational study, examined 60 patients who completed denervation by the Abbott Simplicity probe and also found improved function as demonstrated by the Oswestry Disability Index. Like Bellini and Barbieri (13), our study also measured function and concluded with a similar outcome of improved function. Bayer et al (18) examined 121 patients and compared monolesion RFA technique to strip lesion RFA technique via the Simplicity probe and found superior pain relief and pain-related disability of those treated with the Simplicity probe. Contrary to Bayer et al (18), our study did not find superior pain relief. Each of the aforementioned studies demonstrated improved function of those treated with the Abbott Simplicity probe, which is congruent with our findings.

This study has multiple limitations. Because data were collected retrospectively, this study relied on

Table 1. *Outcome at each time point.*

Patient	Age	Gender	BMI	Opioid Use (Yes/ No)	Pre-Procedure NRS	Post-Procedure NRS	Day of Procedure MODI	3-6 month f/u NRS	3-6 month f/u MODI	12 month f/u NRS	12 month f/u MODI
1	54	Female	45	Yes	6	5	56	*	*	*	*
2	51	Female	35	Yes	6	**	56	8	48	5 to 9	34
3	40	Female	27	No	9	0	30	0	4	0 to 2	0
4	67	Female	24	Yes	6	0	60	0	44	6 to 8	50
5	30	Female	34	No	6	0	54	8	26	8 to 10	94
6	56	Female	35	No	5	0	52	6	46	**	60
7	52	Female	33	Yes	3	1	44	*	*	*	*
8	49	Male	28	No	9	5	38	6	74	7	74
9	53	Female	34	Yes	8	0	48	4 to 7	56	5	48
10	73	Male	43	Yes	9	2	**	7	52	9	54
11	60	Male	36	No	6	1	66	8	48	9	52
12	60	Female	26	Yes	6	0	36	7	46	9	62
13	30	Female	34	No	6	0	54	8	26	8 to 10	94
14	49	Male	28	No	9	5	76	7	74	7	74

*indicates patient lost to follow-up. ** indicates a numerical answer was not documented. Body Mass Index (BMI). Numeric Rating Scale (NRS). Modified Oswestry Disability Index (MODI). Follow-up (f/u).

Table 2. *Minimal clinical important difference improvement.*

Patient	2.5 PT NRS Improvement at 3-6 month f/u compared to Pre- Procedure (Yes/No)	2.5 PT NRS Improvement at 12 month f/u compared to Pre-Procedure (Yes/No)	15% Improvement on MODI at 3-6 month f/u compared to Pre-Procedure MODI (Yes/No)	15% Improvement on MODI at 12 month f/u compared to Pre-procedure MODI (Yes/No)
1	*	*	*	*
2	No	No	No	Yes
3	Yes	Yes	Yes	Yes
4	Yes	No	Yes	Yes
5	No	No	Yes	No
6	No	**	No	No
7	*	*	*	*
8	Yes	No	No	No
9	Yes	Yes	No	No
10	No	No	*	*
11	No	No	Yes	Yes
12	No	No	No	No
13	No	No	Yes	No
14	No	No	No	No

*indicates patient lost to follow-up. ** indicates a numerical answer was not documented. Numeric Rating Scale (NRS). Modified Oswestry Disability Index (MODI). Follow-up (f/u).

completed charts. Therefore, data points of interest were limited to what was previously documented, which included multiple answers or the absence of numerical data points. In addition, the majority of the patients were disproportionately female (71.4%). Data were also affected by patients lost to follow-up.

Also, this study examined a relatively small number of patients; therefore, the results should be carefully considered.

Conclusion

In conclusion, this prospective case series sought to provide additional research on the treatment of lower back pain attributed to the PSIC. There is limited data on successful treatment of the PSIC which may be due to its complex anatomic innervation and difficult diagnosis. The purpose of this research was to examine if the Simplicity probe, designed to provide a broad surface area of ablation, provided meaningful analgesia and improvement in disability. Interestingly, this study revealed more functional improvement than analgesia.

This study provides more data for clinicians to utilize in managing PSIC pain.

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