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'Simplicity' radiofrequency neurotomy of sacroiliac joint: a real life 1-year follow-up UK data

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Abstract

Background: Sacroiliac joint (SIJ) pain is considered to be the third most common cause of low back pain with the prevalence of 13–25% in all low back pain patients. Its diagnosis and treatment remain a challenge with the poor evidence base for interventional procedures. Patients with SIJ pain experience a low quality of life, worse than some of the chronic health conditions. Simplicity radiofrequency (RF) neurotomy is a novel technique which tackles some of the problems faced by conventional RF neurotomy and may offer better results in managing pain arising from SIJ.

Aim: The purpose of this retrospective review of practice was to look into the effectiveness of Simplicity RF neurotomy in terms of pain relief, quality of health improvement in patients suffering from SIJ pain and complications associated with the procedure.

Methodology: Retrospective review of the patients undergoing Simplicity RF neurotomy at a tertiary hospital (April 2012 to June 2013). Pain scores and responses to SF (Short Form) 12 questionnaire before and at 12 months after treatment were compared using the Wilcoxon signed-rank test.

Results: Out of 26 patients, 16 were considered for analysis. There was statistically significant reduction in both mean pain score (Numerical Rating Scale, NRS from 8.8 pre-intervention to 4.3 post-intervention) and median pain score (NRS from 9 pre-intervention to 5 post-intervention) with a p-value of <0.001 at 12 months. Reduction in the inter-quartile range of pain score was observed from 8–10 to 2.25–6 (p-value of <0.001). Global health as per SF12 scores showed statistically significant improvement, except in some of the psychological subcategories. The procedure-related pain was the only complication noted.

Conclusion: From our data, we can conclude that Simplicity RF neurotomy of lateral branches of S1–S3 along with conventional RF denervation of L5 dorsal ramus may improve pain scores and many components of global health in carefully selected patients.

Keywords

Sacroiliac joint, diagnosis, simplicity, neurotomy, low back pain

Introduction

The sacroiliac joint (SIJ) is a large mechanical joint, which transfers load from axial skeleton to the pelvis. SIJ pain is considered to be the third most common cause of low back pain, following facet joint and discogenic pain, with a prevalence of 13–25% in all low back pain patients.^{1,2} Pain can arise from the joint itself or from surrounding structures, and pain receptors are

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present in the joint capsule and in surrounding ligaments.³

The diagnosis of SIJ pain involves history, examination with stress tests, imaging and diagnostic blocks. None of these have high sensitivity and specificity, and hence, the diagnosis must be made with careful consideration of all findings. The International Association for the Study of Pain (IASP) set diagnostic criteria⁴ in 1993 consisting of pain in the region of the SIJ, with possible radiation to groin, medial buttocks or posterior thigh, reproduction of pain with stress tests, relief of symptoms with intra-articular injection of local anaesthetics, and without pathognomonic radiographic changes. Although several stress tests have been described, their reliability has been questioned.⁵ A pain referral map has been established by Fortin and Group based on injection/arthrography technique.⁶

Once diagnosed, the treatment options vary from intra-articular steroid injection to neurotomy with radiofrequency (RF) ablation of the nerves supplying the SIJ. RF neurotomy of the SIJ is an established treatment for managing SIJ pain as a component of multimodal therapy, however, the evidence is equivocal at best. The anatomy of the SIJ itself is quite variable, and its mesh-like innervation can cause difficulty in performing an effective neurotomy. Cohen⁷ in their comprehensive review showed that the effectiveness of RF denervation for treatment of SIJ pain is inconsistent.

Knowledge of SIJ innervation is essential to performing RF neurotomy procedures. There has been a debate about the nerve supply, but as per cadaveric and stimulation studies, the posterior part of the joint is supplied by the dorsal rami of S1-S3 with a contribution from the L5 dorsal ramus,⁷⁻¹⁰ though some literature claims additional contribution from the L4 ramus. Nerve supply to the ventral aspect of the joint is less well-defined though the ventral rami of L4-S2 are most commonly cited, which are not amenable to RF treatment. Posterior lateral branches have variable course among patients, and nerves run at different depths, some close to the bone and some embedded in soft tissue. This suggests that RF denervation treatment, as a single plane lesion cannot ablate sensory nerves.⁸⁻¹²

RF neurotomy techniques include conventional RF denervation, where individual nerves are individually ablated, bipolar RF denervation, and cooled RF denervation. Simplicity RF neurotomy is a newer technique, which causes 'strip' lesions by placing a Simplicity probe via a single insertion site and performing a uniform lesioning of the lateral branches of the S1-3 dorsal rami, leading to a higher probability of ablating the sensory nerve fibres supplying the SIJ.

At our hospital, we have been performing Simplicity RF neurotomy for SIJ pain. The purpose of this retrospective review of practice was to look into the

effectiveness of this intervention in terms of pain relief, quality of health improvement in these patients and complications associated with the procedure.

Methodology

Institutional approval was obtained for the conduct of review of our practice. A retrospective review of the patients undergoing Simplicity RF neurotomy at a tertiary care hospital between April 2012 and June 2013 was performed. In all, 26 patients underwent Simplicity RF denervation for chronic SIJ pain. We collected Numerical Rating Scale pain scores (NRS, with 0 for 'no pain' and 10 for 'worst possible pain') and SF (Short Form) 12 data before the procedure, at 6 months and at 12 months follow-up. Patients were reviewed in outpatient pain clinics and filled in the outcome questionnaires. Before undergoing RF neurotomy, all of the patients underwent clinical screening and therapeutic SIJ injection to confirm the diagnosis. Clinical diagnosis of SIJ pain was made based on IASP criteria. Patients with pain for more than 6 months and who had tried pharmacotherapy (with or without opioids) were initially offered therapeutic SIJ injections. Patients consenting for the procedure underwent a therapeutic SIJ injection as a day case procedure under fluoroscopic guidance. The intra-articular injection was performed with 2 mL of 0.25% bupivacaine and 40 mg of methylprednisolone. Pain scores in the form of NRS were collected pre-procedure and post-procedure. Patients were seen in follow-up clinic after the procedure. Pain relief of more than 50% on NRS for a period of at least 6 months was considered as a positive result. Patients in whom pain returned after 6 months were considered for Simplicity RF neurotomy following informed consent.

Procedure (Simplicity RF neurotomy)

This involves the Neurotherm Simplicity III probe, which is an ergonomically designed curved probe, with three independent active electrodes, creating a combination of monopolar and bipolar lesions in a pre-programmed heated sequence (80° for 60 seconds, total duration for the sequence 5 minutes). Under the biplanar fluoroscopic guidance, using aseptic technique and good practice standards for performing RF denervation, the probe is positioned with a single entry point, curve of the probe following the curvature of the posterior surface of the sacrum. Correct placement of the probe is confirmed by anterior-posterior (Figure 1) and lateral view (Figure 2) on fluoroscopy and by motor (2 Hz) stimulation. Once confirmed, RF ablation is performed in a sequential manner, leading to strip lesion. The lesion is larger and more uniform

Figure 1. Simplicity probe in situ (anterio-posterior view).

Figure 2. Simplicity probe in situ (lateral view).

compared to conventional RF denervation. All patients underwent a combination of Simplicity RF neurotomy of S1-3 and conventional L5 dorsal ramus RF neurotomy (80° for 60 seconds) in order to ablate the posterior sensory supply to the SIJ.

All 26 procedures were performed by a single operator to avoid any bias, and the patients were discharged as per the hospital ambulatory care policy.

Statistical analysis

Pain score was presented as a mean, median and interquartile range (IQR). Responses to the other Likert scale items in the questionnaire were presented as a count with percentage or illustrated as pie charts or stacked bar graphs, as appropriate. Pain scores and responses to SF12 questionnaire before and after treatment were compared using the Wilcoxon signed-rank test. A *p*-value less than 0.05 were considered statistically significant. All statistical analyses were conducted using the PASW 18.0 (SPSS Inc, Chicago, IL).

Results

In all, 26 patients underwent Simplicity RF denervation during the period of April 2012 to June 2013. A total of 10 patients were lost to follow-up, and we were able to include 16 patients for our analysis. Baseline data for 16 patients are presented in Table 1.

We had 9 female and 7 male patients, with a mean age of 45.4 ± 20 years. All were on analgesic medications, including antineuropathic agents; some were also taking weak opioids such as codeine or tramadol. All the patients had unilateral SIJ pain except one who had bilateral pain but had Simplicity RF denervation to only the left side during the period.

None of the patients had any RF treatment to the SIJ before. There were no complications noted from patients, other than post-procedure pain. The maximum duration of pain relief these patients had after therapeutic SIJ injections was 7 months. The average duration of pain patients had before Simplicity RF neurotomy was 2.6 years, ranging from 11 months to 5 years.

There was statistically significant reduction in mean pain score from 8.8/10 (SD-1.1) before Simplicity RF neurotomy to 4.3/10 (SD-2.5) post-procedure with a *p*-value of <0.001 at 12 months (Table 2 and Figure 3). Similar findings were found in Median pain scores, which showed reduction from 9/10 (SD-1.1) before intervention to 5/10 (SD-2.5) post intervention with *p*-value of <0.001 at 12 months (Table 2 and Figure 3). Reduction in the IQR of pain score was observed from the range of 8–10 to 2.25–6, with the *p*-value of <0.001 (Table 2 and Figure 3). Analgesic effect was maintained for at least 1 year in patients who had pain relief at 6 months. General health (Table 3, Figure 4), health limiting various activities (Table 4, Figure 5), bodily pain (Table 5, Figure 6) and health affecting routine activities (Table 6, Figure 7) components of SF12 showed statistically significant improvement. Although there was an improvement in general health and psychological components (Table 7, Figure 8) of SF12 post-procedure, this was not demonstrated in all subcategories.

Discussion

SIJ pain accounts for 13–25% of all low back pain.^{1,2} Cher et al.¹³ in their population study have demonstrated that quality of life is markedly impaired in patients with SIJ pain, worse than many chronic health conditions. Despite this, the condition is not easily diagnosed and remains a challenge to manage. Various diagnostic tools including IASP guidelines have been used with variable success. As with all chronic pain conditions SIJ pain benefits from prompt diagnosis and a biopsychosocial approach to management.

Table 1. Baseline data of 16 patients with Numerical Rating Scale [NRS].

Patient	Age (years)	Sex	Site	Duration of pain	NRS (pre-procedure)	NRS (6 months)	NRS (12 months)
1	63	M	Right	11 months	8	10	9
2	48	M	Right	3 years	10	5	6
3	36	F	Left	1.5 years	9	6	6
4	49	F	Right	4 years	8	5	6
5	62	F	Left	2 years	10	4	2
6	59	M	Right	3 years	9	4	0
7	66	F	Left	1.5 years	9	5	6
8	42	F	Left	2 years	10	1	1
9	48	M	Right	4 years	10	5	4
10	50	F	Left	1.5 years	10	2	0
11	39	F	Right	3.5 years	8	3	3
12	36	M	Right	2 years	7	4	5
13	44	M	Left	3 years	8	4	4
14	33	M	Right	5 years	9	5	6
15	48	F	Left	3 years	8	5	5
16	59	F	Bilateral	2 years	7	4	5

Table 2. Pain Scores before procedure and at 12 months on NRS (Numerical Rating Scale).

	Before			After			<i>p</i>
	Mean	Median	IQR	Mean	Median	IQR	
Pain Score	8	9	8–10	4.3	5	2.25–6	0.001

IQR: inter-quartile range.

Figure 3. Pain score on NRS.

Interventional procedures play an important part in multimodal approach in the management of the patient with SIJ pain. RF denervation is an established treatment option but lacks a good evidence base in the management of SIJ pain. Some of the methods used for performing SIJ neurotomy include conventional RF denervation, bipolar RF denervation, cooled RF

denervation. Cohen et al.¹⁴ demonstrated that in a 28-patient group (randomised placebo-controlled), cooled RF denervation was effective in providing pain relief for up to 6 months. A prospective study by Burnham and Yasui¹⁵ showed bipolar RF denervation provided good pain relief and improved patient satisfaction at up to 12 months.

Varied results for RF denervation can be attributed to a variety of factors. These may include poor patient selection as a result of the inaccurate diagnosis, varied anatomy in patients (variable depths and pathways of nerves, and the additional contribution of supply from L4) and diversity of techniques used.

The diagnosis of SIJ pain remains an enigma, with no clinical sign having a high specificity. SIJ pain presents clinically without any demonstrable lesion, but may present as generalised buttock pain that may radiates to superior medial, inferior to the posterior superior iliac spine in the lateral quadrant of a thigh with some radiation to the greater trochanter, upper lateral thigh and groin, rarely affecting below the knee. The bedside clinical tests to detect SIJ dysfunction include the Faber Patrick test, Gaenslens test, Yeomans test, SI shear test (POSH- post shear test) and Gillets test; however, neither these nor any other interventional tests are considered definitive diagnostic tools. Map of

Table 3. Effect on general health.

	Before		After		p
	No of Patients Reporting	%	No of Patients reporting	%	
General health					.001
Poor	6	37.5%	1	6.3%	
Fair	5	31.3%	2	12.5%	
Good	5	31.3%	5	31.3%	
Very good	0	0%	7	43.8%	
Excellent	0	0%	1	6.3%

Figure 4. Effect on general health.**Table 4.** Health limiting various activities.

	Before		After		p
	No. of patients reporting	%	No. of patients reporting	%	
How long has your health limited you following activities					
1. Vigorous activities					.002
Limited >3 months	15	93.8%	3	18.8%	
Limited <3 months	1	6.3%	11	68.8%	
Not limited at all			2	12.5%	
2. Moderate activities					.005
Limited >3 months	14	87.5%	4	25.0%	
Limited <3 months	2	12.5%	10	62.5%	
Not limited at all	0	0%	2	12.5%	
3. Climbing hill and flight of stairs					.002
Limited >3 months	13	81.3%	1	6.3%	
Limited <3 months	3	18.8%	11	68.8%	

(Continued)

Table 4. (Continued)

	Before		After		p
	No. of patients reporting	%	No. of patients reporting	%	
Not limited at all	0	0%	4	25.0%	
4. Bending, lifting, stopping					.003
Limited >3 months	12	75.0%	1	6.3%	
Limited <3 months	3	18.8%	10	62.5%	
Not limited at all	1	6.3%	5	31.3%	
5. Walking one block					.007
Limited >3 months	9	56.3%	1	6.3%	
Limited <3 months	2	12.5%	4	25.0%	
Not limited at all	5	31.3%	11	68.8%	
6. Eating, dressing, bathing or using toilet					.257
Limited >3 months	2	12.5%	1	6.3%	
Limited <3 months	2	12.5%	1	6.3%	
Not limited at all	12	75.0%	14	87.5%

Figure 5. Health limiting various activities.

Table 5. Bodily pain in last 4 weeks.

	Before		After		p
	No. of patients reporting	%	No. of patients reporting	%	
Bodily pain in last 4 weeks					.003
None	0	0%	2	12.5%	
Very mild	0	0%	1	6.3%	
Mild	1	6.3%	6	37.5%	
Moderate	3	18.8%	5	31.3%	
Severe	8	50.0%	2	12.5%	
Very severe	4	25.0%	0	0%

Figure 6. Effect on bodily pain.**Table 6.** Health affecting routine activities.

	Before		After		p
	No of patients reporting	%	No of patients reporting	%	
Does your health keep you from working at a job, doing work at house					.012
YES, >3 MONTHS	5	31.3%	10	62.5%	
YES, <3 MONTHS	2	12.5%	4	25.0%	
NO	9	56.3%	2	12.5%	
Unable to do certain kind of work like house work, school work					.003
YES, >3 MONTHS	2	12.5%	9	56.3%	
YES, <3 MONTHS	2	12.5%	6	37.5%	
NO	12	75.0%	1	6.3%

Figure 7. Health affecting routine activities.

Table 7. Statements about general health and psychological health.

	Before		After		p
	No of patients reporting	%	No of patients reporting	%	
Following statements					
1. I am somewhat ill					.035
Definitely true	8	50.0%	2	12.5%	
Mostly true	1	6.3%	2	12.5%	
Not sure	2	12.5%	4	25.0%	
Mostly false	4	25.0%	7	43.8%	
Definitely false	1	6.3%	1	6.3%	
2. I am as healthy as anybody I know					.046
Definitely true	1	6.3%	2	12.5%	
Mostly true	4	25.0%	6	37.5%	
Not sure	3	18.8%	5	31.3%	
Mostly false	1	6.3%	1	6.3%	
Definitely false	7	43.8%	2	12.5%	

Table 7. (Continued)

	Before		After		p
	No of patients reporting	%	No of patients reporting	%	
3. My health is excellent					.019
Definitely true	3	18.8%	5	31.3%	
Mostly true	4	25.0%	4	25.0%	
Not sure	2	12.5%	6	37.5%	
Mostly false	2	12.5%	0	0%	
Definitely false	5	31.3%	1	6.3%	
4. I have been feeling bad lately					.010
Definitely true	5	31.3%	4	25.0%	
Mostly true	4	25.0%	0	0%	
Not sure	5	31.3%	4	25.0%	
Mostly false	1	6.3%	5	31.3%	
Definitely false	1	6.3%	3	18.8%

Figure 8. Statements about general health and psychological health.

medicine (UK) recommends the use of diagnostic SIJ injections with local anaesthetic under fluoroscopy for diagnosis, along with clinical history and examination

findings. Diagnosis is based on a pattern of findings, as no one SIJ clinical sign is validated. The large variation in reliability is reported, with signs and tests that may

be positive in 20% of asymptomatic patients. In a systematic review, Rupert et al.¹⁶ reported a prevalence of SIJ pain between 10% and 38% with a false positive rate ranging between 20% and 54% for uncontrolled single blocks. They further recommended a limited evidence (level II-III) for RF neurotomy for SIJ.

The Simplicity probe provides a range of advantages and tackles some of the above problems. Insertion and accurate placement of the probe is easy (single entry point, single probe and it is placed in between the SIJ and foramina) and the procedure time can be significantly less than conventional RF denervation techniques. It provides a strip lesion, wider compared with conventional RF needles, with good sensory nerve ablation.

From our data of 16 patients, we have demonstrated that Simplicity RF denervation of dorsal rami S1-S3 using the Neurotherm Simplicity III probe along with conventional RF denervation of L5 dorsal ramus can be very effective in reducing pain scores and improving many of the components of the quality of general health, measured by NRS and SF12. In all, 75% of our patients demonstrated at least a three-point drop in pain scores. There was a global improvement in the majority of components of biopsychosocial health though this was not demonstrated on all of the psychosocial components. The effect has been shown to last for at least 12 months. The procedure was also shown to be safe, as none of our patients reported any complications apart from immediate procedure-related pain.

However, these data need to be evaluated as a proof of concept work due to the methodological limitations. This is real life data in a busy secondary care clinical setting and not a randomised placebo-controlled trial. The diagnosis of SIJ pain ideally should be a double block intra-articular local anaesthetic injection without any steroid. We had 10 patients who were lost to follow-up, reflecting the limitations of a clinical setting. We measured only NRS and SF12 scores, but we have not recorded other measures such as the change in medication intake which might be useful in ascertaining health economic benefits of the procedure.

Conclusion

From our experience and the data, we conclude that Simplicity RF neurotomy of lateral branches of S1-S3 by creating a 'strip lesion' using a combination of monopolar and bipolar pre-programmed heating sequence, together with conventional RF denervation of the L5 dorsal ramus can be effective in improving pain scores and many components global health in carefully selected patients for up to 12 months. This proof of concept work investigates the effect of SIJ denervation in a real life setting, and the data provide a positive signal that should be investigated in a research environment.

Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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