The Effects Of Radiofrequency Neurotomy On Patients With Sacroiliac Joint Pain: Results from a sham, controlled, randomized trial.

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Background

Chronic low back pain is a debilitating and costly disease that can cause severe disability and mental impairment. Approximately 20% of all low back pain cases are attributed to the sacroiliac joint (SIJ) 1. The SIJ is the largest axial joint in the body and is prone to trauma and degeneration over a period of time leading to pain and discomfort.

Radiofrequency neurotomy (RFN) is an established therapy aimed to provide lasting back pain relief for SIJ pain. RFN involves applying a local electrical current to the nerves that produces lesions that disrupt pain signals. Traditional RFN for SIJ pain involves multiple injections that create individual lesions to the lateral branches of the L5 and S 1,2,3,4 nerve roots. Recently, an advanced RFN therapy, using the Simplicity III system, facilitates the creation of the 5 lesions through a single entry point, avoiding the need for multiple injections.

Although RFN has been used for over 30 years and resulted in numerous publications, there have been only a few publications that evaluated RFN in patients suffering from SIJ pain2-4. Moreover, there have been no published randomized, controlled trials that evaluated RFN using Simplicity III for SIJ pain. The purpose of this study was to provide evidence that that RFN using Simplicity III is safe and effective for reduction of SIJ pain.

Methods

The study was a single-center, prospective, double-blinded, randomized, sham-controlled trial evaluating the Simplicity III device for patients suffering from SIJ pain for more than six months duration. Enrolled patients, who consented to participate in the study, were randomized (1:1) to either a sham (no lesions performed) or an active group (lesions performed). Blinding was maintained by having identical surgical procedures with only the active group receiving the lesions. Both the patient and the clinical operator (chief investigator VM) were blinded to the procedure. Outcomes were recorded at baseline, 3 months and 6 months. At 3 months post-randomization, patients in the sham group with a pain intensity score of more than 4 on the numeric rating scale were given the option of crossing over to receive active treatment.

- Outcomes measurements collected at all visits were:
- Numeric Rating Scale (NRS),
- Hospital and Depression scale (HADS),
- Adverse Events

The primary endpoint was improvement of the NRS at 3 months and was analyzed using an ANOVA model with Tukey's post-hoc test for pairwise comparisons.

Study Design

T0
- Patient screened and assessed for eligibility in the pain clinic according to history and clinical examination. Patient information sheet given and details of trial explained.

T1
- Patient receives two sets of diagnostic intra-articular injections. If they achieve a positive response to the first diagnostic block, then they will be invited to participate after giving informed, written consent.

T2
- Patient randomized to receive active or sham tretment 1:1.

T3
- Measurements observed at 3 months followint randomization
- Primary outcomes recorded in the two groups
- Secondary outcomes recorded in the two groups

T4
- Measurements observed at 6 months followint randomization
- Secondary outcomes recorded in the two groups
- End of study

Table 1: Study Design. 30 patients were enrolled with 17 patients randomized to either sham (n=6) or treatment (n=11). 4 out of the 6 patients in the sham group crossed-over to the active group after the 3 month visit for a total of 15 patients at 6 months receiving active treatment.

Reason Patient Did Not Continue	Number of Patients (N=13)
Failed Diagnostic Block	5
Lost to Follow-Up	3
Did not have SIJ Pain	1
Not Suitable for Injections	1
Voluntarily Withdrew	1
Withdrawn (No Reason)	2

Table 2: Reason for discontinuation. 30 patients were enrolled after which 13 patients did not continue on to the randomization phase. Five patients did not get pain relief from the two diagnostic blocks and were deemed ineligible for the study. Three patients were lost to follow up and 2 patients were withdrawn with no reason given. Remaining 3 patients did not continue due to not having SIJ pain, not being suitable for injections and voluntarily withdrawing.

Study Design

Patient Characteristics	N	Mean
Age		
Active	11	56.6
Sham	6	62.5
Gender		
Males	1	—
Females	16	—

Table 3. Patient characteristics. No statistical differences were found in age between the active and sham group. Out of 17 randomized patients, 16 were females and 1 was a male.

Results

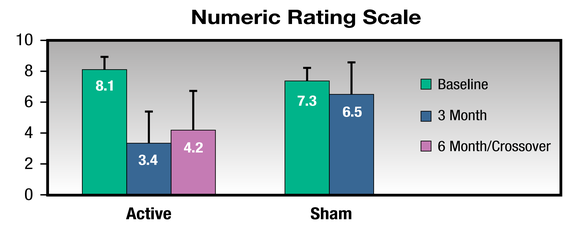

Figure 1: NRS scores for active (n=11) and sham (n=6) group. ANOVA model shows significant decrease from baseline for the active group at 3 and 6 months ($p<0.001$) but not sham group at 3 months ($p>0.01$). Moreover, independent t-test shows significant difference at 3 months between active and sham group ($p<0.001$).

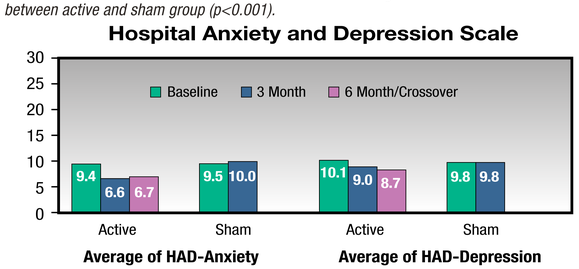

Figure 2: Hospital Anxiety and Depression Scale for active (n=11) and sham (n=6) group. No significant differences were found between active vs. sham group at 3 months or change from baseline scores at 3 and 6 months . However, for the anxiety measure, patients, on average, in the active group went from borderline abnormal anxiety (8-10) to normal levels of anxiety (0-7). On the other hand, patients, on average, in the sham group went from borderline abnormal anxiety to high levels of anxiety (11-21).

Results

Event	Active	Sham
Pain on Site	3	0
Pain extended to all over back	0	1
Asthma Diagnosis	0	1
Developed Rheumatoid Arthritis	0	1
Flare up around site	1	0
Developed L5-S1 disc prolapse on the same side	1	0
TOTAL	**5**	**3**

Table 4: Safety Analysis. No differences were found in AE rates between active and sham group. None of these events were classified as a Serious Adverse Event (SAE).

Summary and Conclusions

- Results show that at 3 months, patients with RFN using Simplicity III reported better pain relief compared to a sham treatment (NRS score 3.5 vs. 6.5; $p<0.001$, respectively).
- The HADS scale demonstrated, for the treatment group, a clinically meaningful decrease in anxiety levels at 3 months compared to baseline.
- No Serious Adverse Events (SAE's) were reported during the course of the study.
- Although preliminary, these results show that up to 6 months, RFN using the Simplicity III device is an efficacious therapy to treat sacroiliac joint pain.
- Long term safety and efficacy results are needed to properly conclude the Simplicity III device's effectiveness in treating sacroiliac joint pain

References

1. Rupert et al. Evaluation of Sacroiliac Joint Interventions: A Systematic Appraisal of the Literature. Pain Physician 2009; 12:399-418
2. Starr B. Radiofrequency Lesioning of the SI joint with the Simplicity III Probe. A Case Series. Reg Anesth Pain Med 2009; MCC:28
3. Vivek Mehta. SACROILIAC JOINT RADIOFREQUENCY DENERVATION Using The Neurotherm® Simplicity III System. A Case Series
4. Cohen et al. Randomized Placebo-controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain. Anesthesiology 2008; 109:279 – 88

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