Retrospective Study

Peripheral Nerve Stimulation Using High-Frequency Electromagnetic Coupling Technology to Power an Implanted Neurostimulator with a Separate Receiver at the Superior Cluneal Nerve for the Treatment of Chronic Back Pain Due to Neuralgia: A Retrospective Study

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Background: Low back pain is a highly prevalent condition with substantial costs. Superior cluneal neuralgia is present in up to 14% of low back pain cases. This etiology of back pain is often overlooked because the symptoms of superior cluneal neuralgia manifest similarly to those of other conditions, such as radiculopathy and sacroiliac joint pain. Peripheral nerve stimulation (PNS) is an emerging pain management modality used to treat various chronic pain conditions. This retrospective study will examine the outcomes of patients who have back pain caused by neuralgia and are treated with the permanent Freedom® PNS System (Curonix LLC) at the superior cluneal nerve.

Objectives: The primary objective was to examine the responder rate (proportion of patients who experienced greater than 50% relief) and changes in pain scores after the trial procedure. Secondary objectives included changes in pain scores from at least one month after permanent implantation, adverse event occurrences, changes in function and quality of life, and reductions in medication usage.

Setting: This was a retrospective single-site study. All procedures were performed by the same interventional pain physician.

Methods: A retrospective chart review was conducted to assess baseline and follow-up parameters. Inclusion criteria consisted of requirements that patients be 18 years or older and have a confirmed superior cluneal neuralgia diagnosis responsible for their pain presentation. Exclusion criteria included the presence of another active implanted device for pain management. The 11-point verbal rating scale (VRS) was used to assess pain scores.

Results: Twenty-one patients were included in this study. All 21 responded to the trial procedure with a 77% average reduction in VRS scores. At the follow-up (mean = 11 months), 20 patients reported an average 57% reduction in pain scores with the verbal rating scale. The same proportion of patients reported improved function and quality of life. Five patients reported reduced medication usage, including one who stopped taking pain medication altogether. No complications were reported.

Limitations: We were limited to the data available in the patient charts since this was a retrospective study investigating the efficacy and safety of the Freedom® PNS System for patients with refractory chronic back pain.

Conclusion: When used to target the superior cluneal nerve, the Curonix Freedom® PNS System is an effective and safe treatment for neuralgia-caused chronic lower back pain resistant to conservative therapy.

Key words: Peripheral nerve stimulation, chronic pain, superior cluneal neuralgia, low back pain

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Low back pain remains a highly prevalent condition that impacts 90% of people at least once in their lives and is the leading cause of disability globally (1,2). In the United States, low back pain is the primary concern for 3.15% of visits to emergency departments (3). The direct and indirect costs of low back pain are estimated to be between $84.1 billion and $624.8 billion, with lost work productivity being the most significant factor (4). Chronic low back pain or pain that lasts ≥12 weeks, is prevalent in 3.9-20.3% of the US population (4). In addition to causing negative physical effects, chronic low back pain can also reduce cognitive function (5).

Since most cases of low back pain are currently considered nonspecific, more attention may need to be directed toward the superior cluneal nerve as a possible source of pain (6,7). Superior cluneal neuralgia is often an overlooked cause of low back pain because its presentation can be similar to radiculopathy and sacroiliac joint pain (8). It has been estimated that 1.6-14% of low back pain patients suffer from superior cluneal neuralgia, specifically due to the entrapment of the nerve around the iliac crest (6).

Peripheral nerve stimulation (PNS) is a minimally invasive intervention that has been utilized for a variety of chronic pain conditions (9-12). A recent systematic review found that PNS, when used to target the lumbar medial branch nerves, provided modest to moderate pain relief for patients with low back pain (13). PNS that targets the superior cluneal nerve has shown to provide similar or even greater back pain relief when the patient is confirmed to be experiencing neuralgia of the superior cluneal nerve.

The primary objective of this present study was to examine the responder rate and changes in pain scores of 21 back pain patients undergoing a trial procedure with the Freedom® PNS System (Curonix LLC) targeting the superior cluneal nerve. Secondary objectives included changes in pain scores from at least one month after permanent implantation, adverse event occurrences, changes in function and quality of life, and reductions in medication usage.

Methods

This retrospective study received an exemption for review from the institutional review board (IRB).

Patient Selection

This retrospective study included 21 patients who received a permanent Freedom® PNS System at the superior cluneal nerve for treating chronic back pain caused by neuralgia. All patients were required to be at least 18 years old and have a confirmed diagnosis of superior cluneal neuralgia responsible for their pain presentation. Patients reported chronic, intractable back pain. After a successful diagnostic injection and PNS trial, all patients were treated with a permanent Freedom® PNS System and reported at least 50% pain relief before entering the study. A retrospective chart review was conducted to assess the baseline and follow-up parameters.

Patients who had any other implanted neurostimulation devices were excluded.

Device Description

The Freedom® PNS System (Curonix LLC, Pompano Beach, FL) uses high-frequency electromagnetic coupling (HF-EMC) technology. It includes an implanted electrode array (with 4 or 8 contacts), a separate implanted receiver, an external transmitter assembly, and a wearable accessory. The Freedom PNS System is comprised of a 2-component implant that the physician connects during the procedure (Fig. 1). The physician is also required to create a pocket (14).

Permanent Implant Surgical Technique

Informed consent was obtained from all patients, who were taken to the operating room and appropriately placed in a prone position on the table. The implant site was cleaned and covered with sterile drapes. The needle entry point and pathway were planned using palpation and fluoroscopy. The skin and deeper tissues were anesthetized using a local anesthetic. The initial introducer path was also infiltrated with a local anesthetic. The first incision was made with an 11-blade scalpel, and the 13-gauge introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the superior cluneal nerve under imaging guidance, using small amounts of local anesthetic. A 4-contact electrode array with tines was inserted through the cannula and advanced to the superior cluneal nerve. By way of the same technique, 16 patients received a secondary electrode array on the opposite side. Four patients had the electrode array positioned on the left side, and one patient received an electrode array on the right side (Fig. 2).

Receiver pockets were created using blunt dissection through a second incision. The steering stylets were removed from the previously implanted electrode arrays and separate receivers were connected to the

electrode arrays. The electrode arrays and receivers were tunneled beneath the skin from the first incision to the second incision receiver pocket. A knot was tied to permanently secure the connected separate receivers and electrode arrays. The receivers were coiled into small diameter coils and 2 nonabsorbable sutures were used to permanently form the receiver coils. The edges of the receiver coils were tucked underneath the coils to avoid protruding edges. Using a nonabsorbable suture, the receiver coils were sutured to the fascia in 2 locations ensuring they were flat in the pocket. The receiver pocket was closed with deep and superficial absorbable sutures.

Programming Protocol.

Patients were programmed at sub-threshold levels with a frequency of 1,499 Hz (n = 16) or 1,000 Hz (n = 5) and a pulse width of 60 μs (n = 16) or 100 μs (n = 5) at variable intensities (mA). The transmitter assembly was carried in a wearable on each patient's lower back.

Demographics

Data were collected for 21 patients. All patients were diagnosed with peripheral neuralgia that caused chronic lower back pain. Mean pain scores at the baseline were recorded as 8.7 ± 1.2 on the VRS (Fig. 3). Sixteen patients (76%) received 2 neurostimulators bilaterally. Four patients received a neurostimulator on the left side (19%), and one received a system on the right side. The mean age was 70 ± 14 years; 12 patients (58%) were women, and 9 (48%) were men. The mean patient height was 68 inches, and their mean weight was 198 pounds (Table 1). Nineteen out of 21 patients were taking pain medication before starting treatment with the Freedom PNS System.

Data Analysis

The primary analysis utilized the verbal rating scale (VRS) to assess the responder rate. Secondary analysis included pain reductions with the VRS, an 11-point scale ranging from 0 (no pain) to 10 (extreme pain). Patients filled out the VRS before treatment with the Freedom® PNS System and after a trial period. A long-term follow-up was collected to assess current percentiles of pain relief, function, quality of life, and medication usage.

Adverse events (AEs) were reported descriptively and classified as serious or nonserious AEs and related or unrelated AEs.

The data were collected from electronic medical records and case report forms and entered into an Excel spreadsheet. Statistical analysis was performed using descriptive statistics and paired t-tests for comparing pre- and post-procedure pain scores. The *P*-value was considered significant if ≤ 0.05.

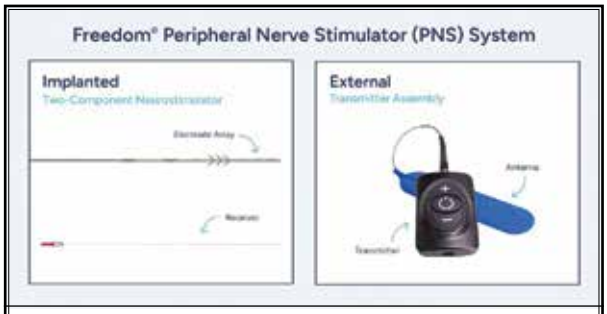

Fig. 1. *Freedom® PNS System.*

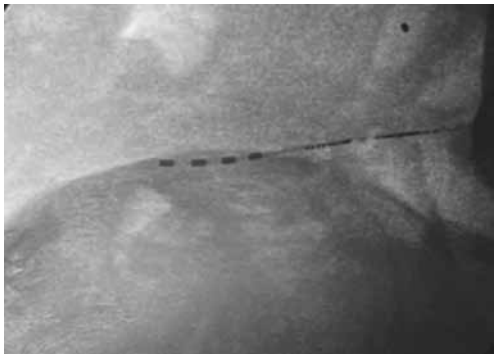

Fig. 2. *X-ray of device positioning at the superior cluneal nerve.*

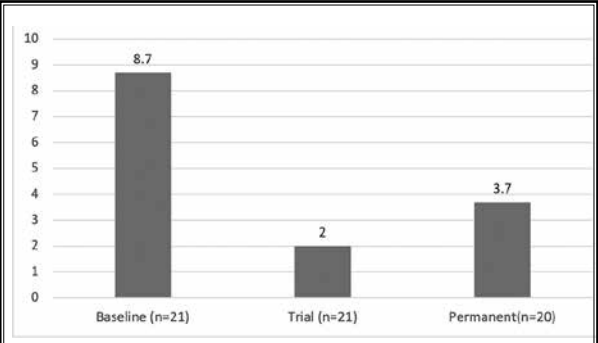

Fig. 3. *Mean verbal rating scale (VRS) pain scores.*

Results

Primary Outcome Responder Rate

At the end of the trial period, 21/21 (100%) patients reported more than 50% pain relief, with mean

Table 1. *Demographics*.

Research Number	Age at Implant	Gender	Height (inches)	Weight (pounds)	Duration Of Therapy (mos)
1	54	F	68	220	17.8
2	73	M	75	255	0.9
3	83	F	58	97	15.0
4	83	M	71	200	12.3
5	52	M	77.5	230	19.6
6	77	M	71	217	15.0
7	89	M	68	240	10.6
8	67	F	65	213	8.8
9	75	M	70	184	18.7
10	50	F	70	245	2.9
11	50	F	66	280	15.1
12	91	M	75	221	1.7
13	77	F	65	175	8.1
14	76	F	69	223	7.0
15	38	F	66	167	17.0
16	78	M	67	228	7.6
17	79	M	64	145	19.4
18	86	F	68	160	0.9
19	75	F	60	182	11.0
20	69	F	68	130	10.4
21	57	F	71	142	14.3

pain scores reducing from 8.7 ± 1.3 to 2 ± 1.4 (77%; $P < 0.001$).

Long-Term Follow-Up

All 21 patients had a permanent implant for at least one month, with an average follow-up period of 11 months. One patient stopped using the device because the wearable interfered with her stoma, even though she was reporting significant pain relief. Fifteen out of the remaining 20 patients (75%) experienced at least a 50% improvement in pain at the last assessment. The average VRS score decreased to 3.7 ± 3.1 (57%; $P < 0.001$) (Fig. 3). Fifteen out of 20 patients reported drastically improved functionality and quality of life. Five patients out of 19 (26%) reduced their medication intake, with one abandoning pain medication completely (5%). No complications were reported.

Discussion

Results on PNS used specifically for back pain caused by superior cluneal neuralgia have been previously reported in other publications (15-18). Our results largely align with these findings, with the average pain improvement greater than 50%. Vu et al (15) used a temporary PNS system and reported the patient had an 80% improvement in pain at the end of the treatment period, with reduced medication usage and no complications. At the 2-month follow-up, the improvement in pain was 60%. The other 3 studies utilized the Freedom® PNS System (16-18). Chauhan et al (16) reported 100% relief of symptoms after the trial procedure. At 6 months post-implantation, the patient experienced greater than 80% improvement in pain and function, with no AEs. The patient in the study conducted by Song et al (17) reported a significant improvement in pain during the trial and at one week post-implantation, with no procedural complications. Abd-Elsayed (18) reported on 2 patients, one of whom experienced 100% pain relief one month post-implantation and another who reported 90% pain relief after the trial. No complications occurred for either patient. This study confirms what has been reported in previous publications on PNS treatments applied at the cluneal nerve.

The permanent Freedom® PNS System has also been used successfully for several other types of pain. Fruh et al (19) targeted the infrapatellar saphenous

nerve for treating post-surgical knee pain. Pollina et al (20) stimulated the posterior tibial nerve for treating foot pain caused by idiopathic, diabetic, and alcoholic neuropathy. Lastly, Abd-Elsayed and Moghim (21) targeted multiple different nerves depending on the chronic pain condition being treated. The genicular nerve was stimulated for knee pain, the superior cluneal nerve for low back pain, the posterior tibial and/or sural nerve for ankle pain, the middle cluneal nerve for sacroiliac joint pain, the radial and ulnar nerves for hand pain, and the right common peroneal nerve for foot pain. Abd-Elsayed and Moghim's study also provided evidence for the system's long-term (24-month) efficacy (22).

The externally powered design of the Freedom® PNS System comes with several advantages. Risks associated with both battery implantation and replacement can be avoided (18). Additionally, the external transmitter assembly fits discreetly in a purposefully designed wearable and can be placed so that it does not interfere with movement.

Percutaneous implantation has replaced the previous open surgical technique, mitigating many risks for complications. Additionally, cylindrical electrode arrays specifically designed for PNS have been created, eliminating the need for cuff and paddle leads (23).

Limitations

Since our study design was retrospective, we were limited to the data available in the medical records.

Conclusion

Applying permanent PNS at the superior cluneal nerve using the Curonix Freedom PNS System is an effective, safe therapy for treating chronic lower back pain that is caused by neuralgia and resistant to conservative therapy.

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