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Peripheral Nerve Stimulation With High-Frequency Electromagnetic Coupling at the Sural and Posterior Tibial Nerves for the Treatment of Complex Regional Pain Syndrome in Lower Extremities: Case Report

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Background: Complex regional pain syndrome (CRPS) type 1 is a debilitating condition that is notoriously difficult to treat due to its various manifestations. Peripheral nerve stimulation (PNS) is generally recommended when a patient's symptoms are refractory to conservative measures, as CRPS often is. We present one case of CRPS with intractable lower extremity pain managed effectively with PNS.

Case Report: A 32-year-old man developed CRPS after a work-related accident that resulted in multiple injuries, including a crushed pelvis, injured left lower extremity, and a fractured face and skull. After pelvic and hip reconstruction, the patient was left with numbness, tingling, and pain in the left foot affecting functional activities and sleep. Previous therapies, including nerve blocks, physical therapy, narcotics, opioids, anticonvulsants, antidepressants, and nonsteroidal anti-inflammatory drugs, did not alleviate symptoms. The placement of a PNS device, however, led to significant improvement.

Results: Pain scores at baseline compared to 12-month follow-up decreased from 6/10 to 2/10 at rest and from 8/10 to 4/10 with activity. Average hours of sleep per night increased from 4 to 8 hours (an improvement of 100%). Antidepressants have been discontinued and opioids reduced to an as-needed basis (once every few days). The patient reports decreased sensitivity to cold, reduced swelling, and improved color changes in the foot. In addition, the patient has been able to increase activity, such as walking, standing, and wearing closed-toed shoes, from 20 minutes to now 4 hours at a time with pain levels maintained at a 4/10.

Conclusions: Subthreshold PNS utilizing high-frequency electromagnetic coupling at the posterior tibial and sural nerves successfully relieved the patient's chronic, debilitating pain in the lower extremity as a result of CRPS.

Key words: Peripheral nerve stimulation, chronic pain, posterior tibial, sural, CRPS, lower extremity, foot

BACKGROUND

Complex regional pain syndrome (CRPS) is a pain condition affecting one or more extremities with sensory, autonomic, motor, and trophic abnormalities (1). The condition is usually associated with a traumatic event, although it has also been reported to occur spontane-

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ously. The nature of this condition is still unclear, but may be neuropathic or inflammatory.

CRPS can present with a wide array of manifestations, and the diagnosis is mainly clinical. Given the variety of symptoms, standardization of treatment is challenging. Although several therapies have been reported to show promise, there is currently no agreement on the best way to manage CRPS (2).

Patients typically receive multiple pharmacologic agents with varying results as a conservative measure. Among these are oral corticosteroids, antidepressants, and antiepileptics. A 2013 Cochrane review (2,3) determined that oral steroids do not substantially lessen pain in CRPS patients based on 3 trials compared to a placebo. Anticonvulsants and antidepressants, such as gabapentin and amitriptyline, have demonstrated a reduction in pain symptoms (1). However, a Cochrane study (2) found strong evidence that gabapentin users experienced a range of side effects more frequently than a placebo, which may make it difficult for patients to continue taking the medication.

Given its crippling nature, aggressive treatment at onset is typically recommended to prevent progression. Early-stage CRPS is more amenable to conventional therapy, highlighting the urgency of prompt care. Furthermore, patients with severe pain are less active during the day, often leading to physical and psychological comorbidities.

This case report will discuss a patient diagnosed with CRPS of the lower extremity due to trauma and effectively managed with peripheral nerve stimulation (PNS).

CASE PRESENTATION

A 32-year-old man developed CRPS type 1 after a work-related accident that resulted in multiple injuries, including a crushed pelvis, an injured left lower extremity, and a fractured face and skull. After pelvic and hip reconstruction, numbness, tingling, and pain persisted in the left foot, along with sensitivity to cold, swelling, and temperature changes in the affected limb.

Average pain is rated at 6/10 without and 8/10 with activity. The patient experiences difficulty standing, walking, and wearing closed-toe shoes for more than 20 minutes consecutively. The pain interfered with sleep, which averaged 4 hours per night, and decreased quality of life. After presenting at our clinic, the patient was diagnosed with CRPS. Previous therapies include nerve blocks, physical therapy, narcotics, opioids, anticonvulsants, antidepressants, and nonsteroidal anti-inflammatory drugs (NSAIDs). Medication intake at baseline was gabapentin 800 mg tid, tramadol 50 mg bid, and bupropion 150 mg prn.

Due to minimal improvement with other therapies, the decision was made after a diagnostic injection to offer a peripheral nerve stimulator trial targeting the left posterior tibial and sural nerves. The procedure was performed using ultrasound and fluoroscopic guidance (Fig. 1). Two 4-contact electrode arrays were placed and secured sterilely, and the patient was sent home for the trial period. The patient wore the external transmitter on the left calf. Preferred stimulation settings were discovered at 1,499 kHz and 0.5-0.9 mA. After the trial, the patient reported almost 70% relief. The trial electrode arrays were subsequently removed in the office without complications, and the patient decided to proceed with the permanent implant.

Device Description

The Freedom® PNS System (Curonix LLC, Pompano Beach, FL) uses high-frequency electromagnetic coupling technology to power the implanted neurostimulator (Fig. 2). Each stimulator is comprised an electrode array with 4 or 8 contacts and the electrode array is connected to a separate implanted receiver. A small, external rechargeable transmitter supplies the energy and data to the implanted neurostimulator through the skin. The device uses pulsed electric current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain.

Permanent Implant Procedure Methods

The patient was placed in the prone position on the operating table. The left leg below the knee was prepped and draped in the usual sterile manner using a chlorhexidine and alcohol prep solution. The sural nerve at the lateral ankle was located by ultrasound. The electrode array was placed on the skin, with the distal electrode placed at the sural nerve near the lateral malleolus with the remainder of the electrode array running vertically cephalad up the posterior calf. The needle entry point and pathway were planned using palpation and fluoroscopy (Fig. 1). The skin and deeper tissues were anesthetized using a mixture of 1% lidocaine and 0.25% bupivacaine with 1:100,000 epinephrine. A first incision was made, and the 13-G introducer needle was passed through the incision and advanced subcutaneously in the fascial plane to the sural nerve target under ultrasound guidance. The electrode

array was inserted through the cannula and advanced to the sural nerve at the left lateral ankle.

A second electrode array was placed at the posterior tibial nerve on the left medial ankle, which was located with ultrasound. The electrode array was again laid on the skin, with the distal electrode at the posterior tibial nerve on the left medial ankle near the malleolus and the remainder of the electrode array running cephalad up the posterior calf. A second needle entry point and pathway were planned. The skin and deeper tissues were anesthetized, and an incision was made. A 13-G introducer needle was again passed through the stab incision and subcutaneous tissues toward the posterior tibial nerve target. The needle was advanced subcutaneously in the fascial plane, and subsequently, the electrode array was inserted through the cannula and placed at the posterior tibial nerve.

The steering stylets were removed, and separate receivers were connected to the electrode arrays. A receiver pocket was created using a second incision, and the neurostimulators were tunneled beneath the skin from the first incisions to the receiver pocket. A knot was tied to permanently connect the separate receivers and electrode arrays. The neurostimulators were coiled, and the coils were sutured to the fascia and secured within the pocket. The receiver pocket was closed with subcutaneous and subcuticular sutures, then covered with Tegaderm.

RESULTS

Immediately following the permanent procedure, the patient reported dramatically improved pain scores decreasing from 6/10 to 2/10 at rest and 8/10 to 4/10 with activity. This has remained consistent 12 months after the permanent implant. Average hours of sleep per night increased from 4 to 8 hours (an improvement of 100%). The patient no longer experiences severe sensitivity to cold, swelling, or color changes in the foot. Medication intake has reduced significantly with the patient no longer taking bupropion and using tramadol only when needed (once every few days). In addition, the patient has been able to increase activity, such as walking, standing, and wearing closed-toe shoes, from 20 minutes at a time preoperatively to now 4 hours at a time, with pain levels maintained at a 4/10. No complications were reported.

DISCUSSION

With an incidence of roughly 5.4 to 26.2 per 100,000 person-years, CRPS is a chronic neurologic disorder often brought on by severe injury (4). Although many CRPS patients report experiencing trauma before the onset of symptoms, cases are also known to occur spontaneously. Since the specific cause of CRPS is unknown, the focus of treatment is pain management, which enables patients to engage in more physical therapy and improve daily function (1). The patient, in this case, complained of pain resulting in difficulty standing, walking, and wearing closed-toe shoes, despite utilizing several treatment modalities, including nerve blocks, physical therapy, opioids, anticonvulsants, antidepressants, and NSAIDs. Both sleep and daily activities were limited by pain.

Fig. 1. Fluoroscopic image of placement at the posterior tibial and sural nerves.

Fig. 2. Freedom PNS Systems.

For decades, PNS has been utilized to treat neuropathic pain (5). Wall and Sweet published the first account of pain alleviation with peripheral electrical stimulation in 1967 (6). The gate control theory is the most popular explanation for the mechanism behind PNS. When less aggressive treatment options fail to help the patient, as in the case presented here, PNS is typically considered (6).

Most existing research on neurostimulation and CRPS has examined CRPS in the upper limb and utilized devices designed and approved for spinal cord stimulation (SCS), including placement of sizeable implantable pulse generators (IPGs). Research by Frederico et al (7) documents 14 patients with painful upper limb CRPS who had not responded to conservative treatment. This study examined the effectiveness of implanting an electrode under ultrasound guidance to stimulate the brachial plexus using a traditional SCS system, including an internal IPG.

Although the results indicated a long-term benefit in treating upper extremity CRPS, intrusive procedures with traditional SCS systems requiring sizeable internal battery placement discouraged patients from pursuing this treatment. Additionally, the risks of infection, hemorrhage, pneumothorax, and lead migration (7) outweigh the advantages of this approach.

A new generation of devices has recently been developed specifically for PNS placement that enables wireless impulse transmission from external power sources to implanted electrodes with receivers and does not require internal battery placement (8). Compared to procedures using earlier SCS-based systems, the implant is substantially less traumatic with a lower risk of complication. In a study by Wiederholz et al (9), 7 patients were implanted with a PNS system placed at the brachial plexus, showing considerable improvement without factors that previously deterred patients from pursuing permanent implantation.

Similarly, the Freedom PNS System was used in this case on the sural and posterior tibial nerves, and the patient reported a significant decrease in pain. The effectiveness of PNS therapy in controlling chronic pain over the long term is not well supported by research (8). However, in this case, results have persisted 12 months postimplant.

CONCLUSIONS

Prior research documenting results of PNS therapy for CRPS has consisted predominantly of upper extremity CRPS patients utilizing traditional SCS systems placed at a peripheral nerve. These studies show a notable reduction in pain and increased risk of complications related to the invasive placement of sizeable batteries. Newer devices explicitly designed for PNS have been shown to provide the same benefit, with less traumatic placement procedures and a potentially lower risk of complication. In this case, the PNS system was placed at the posterior tibial and sural nerves to provide subthreshold PNS, successfully treating a patient suffering from chronic, debilitating pain in the lower extremity as a result of CRPS.

REFERENCES

1. Abd-Elsayed A (ed). *Pain: A Review Guide*. First Edition. Springer, Switzerland, 2019.
2. O'Connell NE, Wand BM, McAuley J, Marston L, Moseley GL. Interventions for treating pain and disability in adults with complex regional pain syndrome - an overview of systematic reviews. *Cochrane Database Syst Rev* 2013; 2013:CD009416.
3. Dey S, Guthmiller KB, Varacallo M. Complex regional pain syndrome. In: *StatPearls* [Internet]. StatPearls Publishing, Treasure Island, FL, 2022. www.ncbi.nlm.nih.gov/books/NBK430719/
4. Petersen PB, Mikkelsen KL, Lauritzen JB, Krogsgaard MR. Risk factors for post-treatment complex regional pain syndrome (CRPS): An analysis of 647 cases of CRPS from the Danish Patient Compensation Association. *Pain Pract* 2018; 18:341-349.
5. Chmiela M, Hendrickson M, Hale J, et al. Direct peripheral nerve stimulation for the treatment of complex regional pain syndrome: A 30-year review. *Neuromodulation* 2021; 24:971-982.
6. Wall PD, Sweet WH. Temporary abolition of pain in man. *Science* 1967; 155:108-109.
7. Frederico TN, da Silva Freitas T. Peripheral nerve stimulation of the brachial plexus for chronic refractory CRPS pain of the upper limb: Description of a new technique and case series. *Pain Med* 2020; 21(suppl 1):S18-S26.
8. Nayak R, Banik RK. Current innovations in peripheral nerve stimulation. *Pain Res Treat* 2018; 2018:9091216.
9. Wiederholz M, Beacham TJ, Satija P, Sanapati M, Vanquathem NE. Brachial plexus nerve stimulation with a high-frequency electromagnetic coupled (HF-EMC) powered implanted receiver to treat complex regional pain syndrome: A case series. *Pain Medicine Case Reports* 2021; 5:337-341.