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Subthreshold Peripheral Nerve Stimulation with a High Frequency Electric Magnetic Coupled (HF-EMC) Powered Implanted Receiver: A Case Series

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Background: Peripheral nerve stimulation (PNS) is an effective alternative for the management of neuropathic peripheral chronic pain, but the high incidence of adverse events such as lead and battery erosion, migration, lead fracture, disconnection, and infection have limited the widespread use of PNS. Neuromodulation technology that does not include implantable pulse generators (IPGs) but a 4- or 8-contact electrode array with embedded electronics and a small, externally worn rechargeable transmitter reduces the complications related to the implant of an IPG. PNS has traditionally been performed with a tonic stimulation protocol. This case series describes a wireless PNS device at subthreshold frequencies for the treatment of neuropathic pain of peripheral nerve origins.

Case Report: No adverse events were reported, and no complications were encountered during implantation. All patients reported more than 50% pain relief during the one-week trial period, sustained pain relief with various placements and number of electrodes, and an important improvement in quality of life and sleep. Mean VAS scores decreased 78% at one month (n = 11) and remained stable at 6 months with 91% reduction (n = 5) and 76% reduction (n = 1) at 12 months. Mean PGIC at 6 months was 7 of 7.

Conclusion: Percutaneous placement of an externally powered neurostimulation device adjacent to the affected peripheral nerve(s) is an effective, minimally invasive, and reversible method of pain control in patients with neuropathic pain. PNS using subthreshold frequencies effectively controls neuropathic pain from multiple peripheral nerve targets.

Key words: High frequency, peripheral nerve stimulation, peripheral neuropathic pain, externally powered

BACKGROUND

Chronic pain affects more than 90 million Americans and causes direct and indirect costs of over $635 billion annually (1).

Physiotherapy and nonsteroidal anti-inflammatory drugs (NSAIDs) are the first treatments of choice for chronic pain patients. The next step in the treatment ladder is opioids, but these can result in dependence, addiction, abuse, overdose, opioid-induced hyperalgesia, constipation, respiratory or immune dysfunction, hormone imbalance, and death (2). Nerve blocks are effective, but only short-term, and have no predictive value when considering other irreversible therapies such as radiofrequency ablations (3).

Peripheral nerve stimulation (PNS), though considered a more invasive therapy modality, has been demonstrated to be an effective alternative for the management of neuropathic peripheral chronic pain (4).

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A variety of difficulties have limited the widespread use of PNS, including cosmetic concerns, difficulties tunneling to the implantable pulse generator (IPG), and high incidences of adverse events such as lead and battery erosion, migration, lead fracture, disconnection, and infection. New neuromodulation technology does not include IPGs but instead consists of a 4- or 8-contact electrode array with embedded electronics, a receiver, and a small, externally wearable rechargeable transmitter (Fig. 1), which delivers the energy through the skin to power the stimulator lead. Thus, the potential complications related to the implant of an IPG, which can be up to 40% (5,6), are avoided.

PNS has traditionally been performed with a tonic stimulation protocol and there is little evidence related to alternative programming options. This case series includes patients from 6 centers and describes the use of externally powered PNS devices at subthreshold frequencies for the treatment of neuropathic pain of various peripheral nerve origins.

METHODS

Device Description

The Stimwave Technologies Freedom PNS System uses high frequency electromagnetic coupling. The Stimwave device is based on the principle of powering microelectronic devices with radiative electric field coupling through tissues at microwave frequencies (GHz) rather than the more commonly used lower frequencies (100-500 kHz) of the inductive range of frequencies, which is the electromagnetic field approach typical of most implanted medical devices. Microwave-based neurostimulation uses an electrode array with embedded electronics and a receiver that intercepts high-frequency microwave electromagnetic fields, producing an oscillating electric field across the receiver to drive a current flow.

The advantages of using microwave technology over inductive technology include smaller implant sizes, reduced size of external circuitry, and significantly deeper implantable receiver placements. The pulse generator stimulator is no larger than the typical lead body itself, with receiver and nanoelectronics embedded in the electrode array. A pulse generator stimulator of this size can be placed in various lead body types, with multiple numbers of neurostimulators (2, 4, 8, or more) in percutaneous or surgical paddle lead configurations (7).

A small, externally wearable, rechargeable transmitter attached to a transmitting antenna worn in the clothing supplies the energy to power the implanted device wirelessly through the skin. The device uses pulsed electrical current to create an electrical field that acts on nerves to inhibit the transmission of pain signals to the brain. The systems in this report used either 4 or 8 contacts (1.3 mm in diameter with 4 mm spacing) per electrode array, with one or 2 electrode arrays implanted in each patient.

Patients Included

Typically, patients need to be approved by insurance for implantation based on standardized inclusion criteria. This report was compiled from the case reports from 6 centers regarding 11 patients presenting with chronic peripheral neuropathic pain refractory to conventional medical treatment. Patients were chosen by the clinicians based on their clinical presentation and the selection criteria, which included a positive psychological evaluation, physical examination, and a temporary response (> 50%

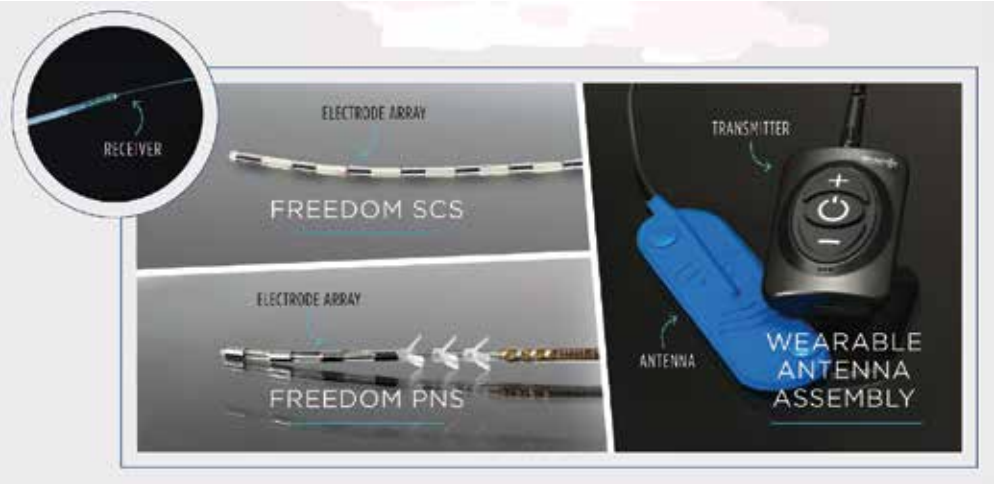

Fig. 1. Freedom SCS/PNS external device.

Abbreviations: MFS, microwave field stimulator; PNS, peripheral nerve stimulation; SCS, spinal cord stimulation

pain relief) to a diagnostic nerve block injection. Eleven patients (6 men and 5 women aged between 53 and 94 years) (Table 1) were implanted with one or multiple wireless neurostimulators (Freedom-4A) at various peripheral nerve targets, depending on the pattern and location of the pain. The peripheral nerves targeted included: superior cluneal nerve (2 patients), superior gluteal nerve (2 patients), genicular nerves (3 patients), suprascapular nerve (2 patients), and tibial nerve (2 patients).

The programming scheme included a frequency of 1.5 kHz with a pulse width of 30 μs at the intensity (mA) preferred by the individual patients. Patients were assessed at 1, 3, 6, and 12 months for pain (using the Visual Analog Scale [VAS] for pain), medication use, and the Patient Global Impression of Change (PGIC) scale (8).

Implant Techniques

Superior cluneal nerve (2 patients): Superior cluneal neuralgia is an underrecognized cause of low-back, buttock, and leg pain. Multiple superior cluneal nerve branches (up to 5) can rise variably from T11 to L5; although they all cross the iliac crest vertically, the most likely entrapment occurs at the most medial branches as they pass through a fibro-osseous tunnel (9). Diagnostic injections at the medial iliac crest approximately 6 to 8 cm from midline can be performed using landmarks, fluoroscopy, or ultrasound (10).

The patients were placed in a prone position, with a sterile prep and drape, 1% lidocaine was applied locally, and a small stab wound was made with a #10 blade at the medial iliac crest. The incision was carried down to the fascia using electrocautary and blunt dissection to a one-cm depth. A 13-gauge Tuohy needle was inserted in the area overlying the superior cluneal nerve on the medial iliac crest. The needle was advanced laterally across the iliac crest one cm inferior to the top of the iliac crest. A 4-contact electrode array was inserted and advanced to the target area (Fig. 2). By placing the stimulator across the top of the iliac crest, we were able to provide stimulation up to 5 superior cluneal nerve branches (11).

The needle and the steering stylet were removed, and the receiver was coupled with the electrode array. A surgical pocket was created approximately 8 cm cephalad in the lumber region of L3-4. The stimulator was sutured to the fascia using 2-0 silk, then tunneled to the secondary surgical pocket and knotted at the proximal end. A receiver pocket and a receiver coil were created. The stimulator was secured into the fascia of the pocket and the skin was closed.

Gluteal nerve (2 patients): There are several important nerves in the gluteal region, including the superior gluteal nerve, which passes through the sciatic notch and lies between the piriformis and gluteus medius muscles (12). Patients with superior gluteal nerve entrapment will present with deep buttocks pain, potentially radiating down the leg. Diagnostic injections are usually done under fluoroscopy, though ultrasound is being proposed as a tool as well (13).

The patients were placed prone on the table, with a sterile prep and drape. Fluoroscopy was used to locate the sciatic foramen and greater trochanter. Needle entry points and lead pathways were planned and marked

Table 1. Basic Demographics and Characteristics (n = 11).

#	Diagnosis	Age (y)	Location	VAS Pre-PNS	VAS One Mo Post-PNS
001	Peripheral nerve damage (mononeuritis)	54	Tibial	100	20
002	CRPS	79	Tibial	100	10
003	Sacroilitis and superior cluneal neuralgia	70	Superior and medial cluneal	90	30
004	DX chronic pain	69	Superior and inferior cluneal	100	30
005	Chronic pain following TKA	73	Knee – superior medial genicular	80	30
006	Chronic pain following TKA	74	Genicular	80	0
007	Neuralgia of the nervus saphenus	53	Condylus lateralis femoris	80	20
008	Chronic shoulder pain following right glenohumeral osteoarthritis	94	Suprascapular	70	0
009	Suprascapular neuropathy	84	Suprascapular	80	32
010	Neuralgia of the superior gluteal and sciatic nerves	62	Gluteal	80	24
011	Neuropathy of the LFCN and superior gluteal nerves	76	Lateral femoral cutaneous and superior gluteal nerves	80	16

Fig. 2. Placement at the superior cluneal nerve.

on the skin. The first needle entry point lateral to the posterior superior iliac spine (PSIS) was injected with local anesthetic and a 13-gauge PNS catheter-over-needle introducer was inserted and advanced under fluoroscopic guidance until reaching the greater sciatic foramen where the sciatic nerve passes. An 8-contact wireless stimulator was introduced through the catheter and advanced to the sciatic nerve's exit point at the foramen. The steering stylet and the needle were removed. After the receiver was coupled to the electrode array, intraoperative testing was performed confirming capture. The second needle entry point was then injected with local anesthetic and the PNS introducer needle was inserted about 4 inches lateral to the previous electrode array and advanced under fluoroscopic guidance lateral to the sciatic foramen between the piriformis and gluteus medius muscles and medial to the greater trochanter. A 4-contact electrode array was then inserted through the needle and advanced to target the branches of the superior gluteal nerve (Fig. 3). The steering stylet and needle were removed, and after the receiver was coupled to the electrode array, intraoperative testing confirmed capture. A single anchor stitch with 2-0 silk was placed deep into the fascia, then secured around the stimulator at the channel marker bands. A one-inch receiver pocket was created proximal to the second marker (cut) band on each stimulator. The stimulators were tunneled beneath the skin from the needle entry points to the receiver pocket. A knot was tied in each stimulator tail, and the tip of the tail, after the knot, was secured by passing anchor stitches through deep fascia and then through the lead tail itself to create a coil. Intraoperative testing of each lead was again performed with good coverage of the painful areas. The receiver pocket was closed in layers.

Genicular nerve (2 patients): There are 10 nerves that innervate the anterior knee capsule (14). However, in general, knee pain is usually addressed at the superior-lateral, superior-medial, and inferior-medial regions (15). Diagnostic injections can be done under fluoroscopy or ultrasound.

The patients were positioned in the supine position. After a sterile prep and drape, local anesthetic was given by raising a skin wheal going down to the hub of a 27-gauge 1.25-inch needle. The introducer needle was advanced parallel to the diaphysis of the right superiomedial femur to the diaphysis and condyle junction. A 4-contact electrode array was inserted into the introducer and advanced until the tip was visible at the site of the superior medial genicular nerve by fluoroscopy. The steering stylet was removed and replaced with the receiver to couple with the electrode array. A second stimulator was similarly positioned, this time parallel to the diaphysis of the right inferiomedial tibia at the diaphysis and condyle junction, stimulating the inferior medial genicular nerve (infrapatellar saphenous nerve) (Fig. 4). Introducers were retracted and the position confirmed with intraoperative testing. A pocket for the receivers was made distal to the insertion location of the stimulator. The tunneler passed subcutaneously, directed from the receiver pocket toward the initial incisions for the stimulator. The tails of the stimulators threaded through the tunneling tool from the entry port to the receiver pocket. The receiver element was coiled and then placed in the receiver pocket. The receiver coil was secured to the fascia with a 3-0 nylon suture and the pocket was closed in layers.

Condylus lateralis femoris of the left knee (genicular nerves) (one patient): The permanent implant was performed under light sedation, with local anesthesia and in the supine position. The entry point of the 2 stimulators was laterally above the knee, and the electrode arrays were placed at the condylus lateralis femoris (Fig. 5) and then mated with the receiver. The approach was made from the lateral to the poplietus nerve as in a distal ischial block. The stimulators were then fixed with a conventional anchor on the muscle fascia and tunneled to a subcutaneous pocket, as described above.

Suprascapular nerve (2 patients): The suprascapular nerve is a branch of the brachial plexus that passes posteriorly through the suprascapular notch, traveling caudad underneath the supraspinatus muscle and then passing through the spinoglenoid notch to innervate the infraspinatus muscle. The supraspinatus nerve is a

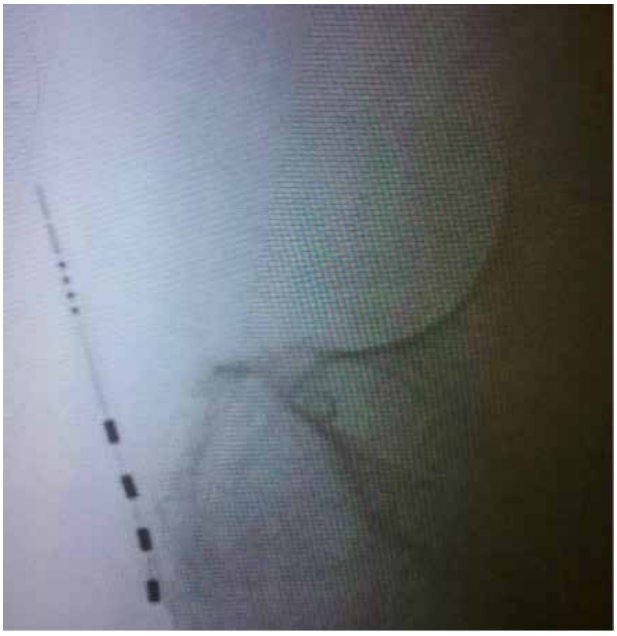

Fig. 3. Placement at the superior gluteal nerve.

major innervator of the shoulder, providing sensation to the shoulder capsule and the glenohumeral joint (16).

The implant procedure was done in the prone position under light sedation, with local anesthesia. Under fluoroscopy, the suprascapular notch was identified at the lateral one-third of the scapula, and an 8-cm Touhy needle was advanced to the suprascapular nerve after the track was infiltrated with local anesthetic. Once the electrode array was placed, the introducer and steering stylet were removed and the position was verified with fluoroscopy (Fig. 6). The receiver was unpackaged and threaded into the inner lumen of the stimulator body to couple with the electrode array. A receiver pocket 2 cm long was made about 12 cm distal from the entry point and a Touhy needle was utilized to tunnel the receiver the full length of the track to the subcutaneous pocket. The distal portion of the receiver was coiled, sutured to itself to eliminate any sharp ends, and then sutured to the fascia. Multilayer wound closure was done after copious irrigation. Steri-Strips™ were applied and Tegaderm was placed over the incisions. The placement was verified with renewed testing at settings similar to those found effective during the trial period.

Posterior tibial nerve (2 patients): The tibial nerve (often called the "posterior tibial nerve" as it approaches the ankle) travels deep to the flexor retinaculum in the tarsal tunnel. It divides into the medial plantar, the

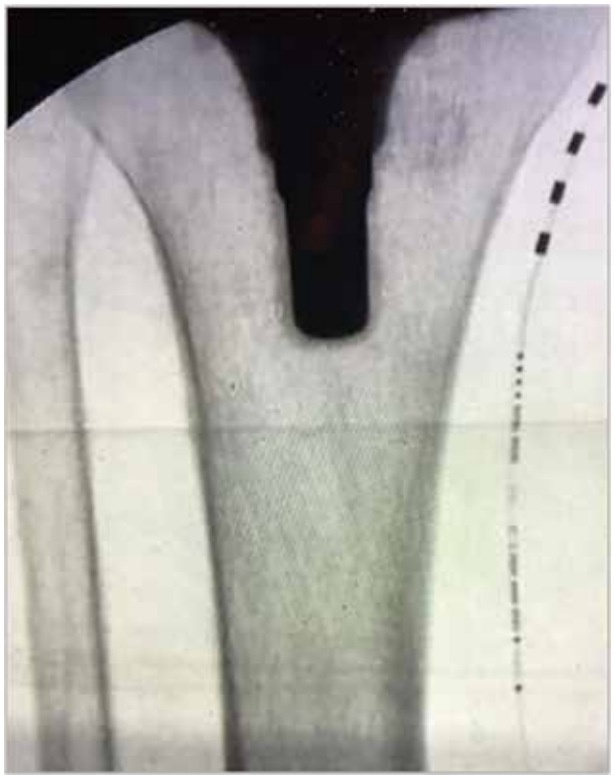

Fig. 4. Placement at the inferior medial genicular nerve.

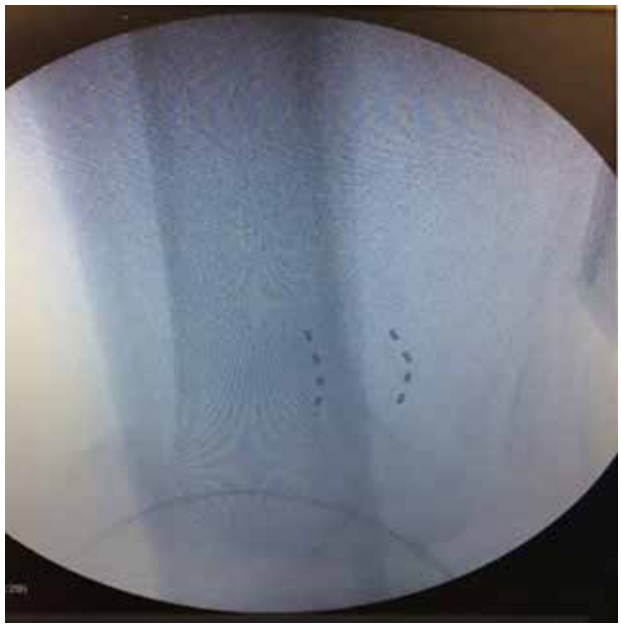

Fig. 5. Placement at the condylus lateralis femoris of the left knee.

lateral planter, and the medial calcaneal nerves, which provide most of the sensation in the medial arch and plantar foot.

In one patient, following a 2-week successful percutaneous trial, a permanent PNS system with 4 contacts was implanted at the right tibial nerve. The device was introduced caudally to cranially at one-third distance from the medial malleolus, between the malleolus and Achilles tendon (Fig. 7), using landmark guidance. After the introducer and steering stylet were removed, the receiver was then coupled with the electrode array and tested on the table. The stimulator was tunneled to a small subcutaneous pocket, where the proximal end of the stimulator was coiled and secured with a 2-0 silk suture, and then anchored with sutures in 2 places - at the introduction site and at the coil. The pocket was then closed in layers. In the other patient, a PNS system was placed 0.5 cm superficial to the tibial nerve between the medial malleolus and the Achilles tendon, using landmark guidance, and tunneled to a subcutaneous pocket as describe above, tied at the proximal end, and secured to the fascia using 2-0 silk. Deep layers were closed using 2-0 Vicryl in an interrupted fashion. Superficial layers were closed using 2-0 Vicryl suture in an interrupted fashion. The patient is wearing the antenna on the calf using a compression calf sleeve.

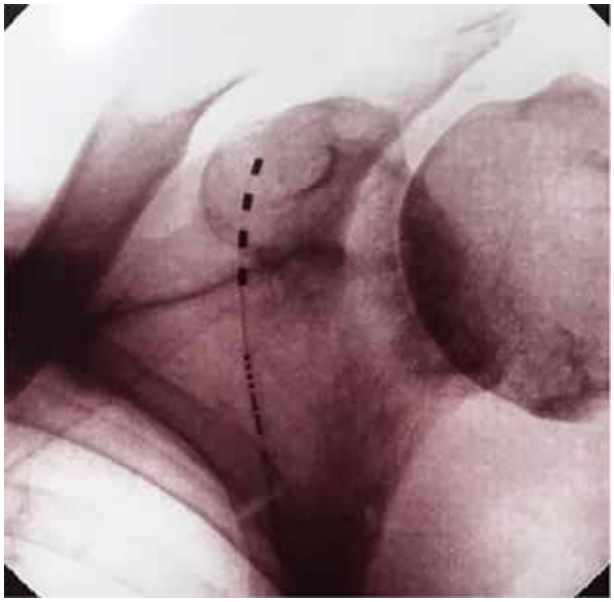

Fig. 6. Placement at the suprascapular nerve.

Data Analysis

Data were recorded at baseline and throughout the follow-up. VAS data were reported as raw scores, means, and percent change from baseline. Additionally, medication use and the PGIC score, which consists of 7 points: 1 = "No change (or condition has got worse)," 2 = "Almost the same, hardly any change at all," 3 = "A little better, but no noticeable change," 4 = "Somewhat better, but the change has not made any real difference," 5 = "Moderately better, and a slight but noticeable change," 6 = "Better, and a definite improvement that has made a real and worthwhile difference," 7 = "A great deal better, and a considerable improvement that has made all the difference" were registered.

RESULTS

There were no adverse events (AEs) reported. No complications were encountered at the nerve targets. All patients reported more than 50% pain relief during the one-week trial period, after which they received a permanent device. All patients reported sustained pain relief with various placements and number of electrodes. The mean VAS score decreased 77% at one month (n = 11) and remained stable at 6 months with 86% reduction (n = 11) (evaluation is ongoing) (Fig. 8). The median PGIC score at 6 months was 7 of 7 ("A great deal better"). One patient stopped all pain medication while the other patients reduced medication by at least 50%. There was an important improvement in quality of life and sleep reported by all patients.

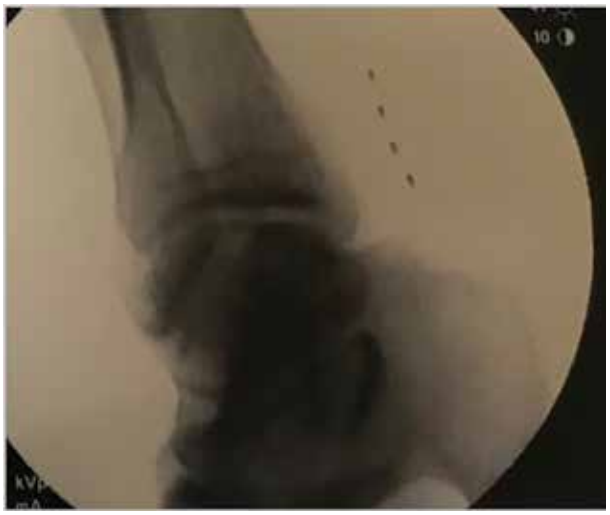

Fig. 7. Placement at the tibial nerve.

DISCUSSION

Recent advances in neurostimulation include subthreshold stimulation, externally powered stimulation, and closed loop stimulation. While efficacy has been shown for spinal cord stimulation (SCS), little is known of the effects of these novel therapies for PNS. This is most probably due to the fact that, until a short time ago and as reported by Slavin (17) in "Technical aspects of peripheral nerve stimulation: Hardware and complications," PNS has been performed with devices designed for SCS. According to the author, this might be the reason for the high complication rate due to the differences in the anatomy for which the devices have been designed and the anatomy of the sites where PNS is used. Schwedt (18) reported that 60% of the patients treated with occipital nerve stimulation (ONS) required lead revision within one year, one patient required generator revision, and surgical revisions were common. Slavin (19) also mentions in a technical note that migration and suboptimal positioning of PNS electrodes are one of the most commonly observed complications of the PNS approach. PNS has been in use for over 50 years to treat patients suffering from chronic pain, but devices that are normally used for PNS are not conceived for this application and this has led to an unnecessary number of device complications and the limited adoption of this therapy (20). Finally, Eldabe (21) reported in his complication rate review that ONS and peripheral nerve field stimulation (PNFS) complication rates were between 0% and 100% considering lead migration (0%-100%), lead fractures (0%-5%), and site infection (1%-6%), stressing the fact that there was no adequate hardware for PNS at the time of the review. With the new HF-EMC stimulation technology, these complication rates are reduced, since percutaneous placement of a wireless stimulation device adjacent to affected peripheral nerve(s) is a minimally invasive and a reversible method of pain control in patients with neuropathic pain refractory to conventional medical management. This enables a more adequate study of the parameters and effects of PNS.

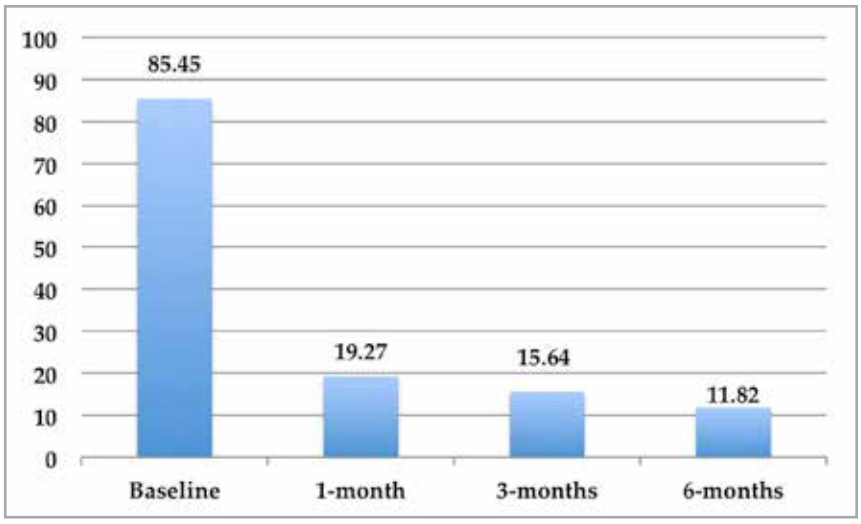

Fig. 8. VAS scores.

Abbreviation: VAS, Visual Analog Scale

In this case series, PNS using 1.5 kHz frequency was found to effectively control neuropathic pain from multiple peripheral nerve targets at subthreshold amplitude levels without causing paresthesia. PNS does not only offer a treatment for previously difficult-to-treat pain patterns, but it also provides a treatment modality for many previously underrecognized pathologies such as the superior cluneal nerve entrapment, which may be the cause of as much as 14% of the back and leg pain syndromes (22).

Taking into account the good results observed in this case series, the system should also be considered for cases of intercostal neuralgia, ilioinguinal neuralgia, posterior tibial and sural pain, craniofacial pain, and for radial/ulnar placement for neuropathic pain due to traumatic injury to the forearm. Further studies including these conditions should demonstrate the feasibility of this approach.

Limitations

This was not a prospective study and it did not include standardized inclusion/exclusion criteria or a follow-up scheme applying to all 6 centers and patients. Pain response assessed with the VAS and the PGIC scores were the only variables routinely assessed in the centers that provided data for this case series. Though pain response is useful, functionality is a more reliable measure of efficacy in some indications such as low-back and shoulder pain syndromes, and it should be assessed in future prospective studies.

CONCLUSION

Percutaneous placement of an externally powered neurostimulation device adjacent to the affected peripheral nerve(s) is a minimally invasive and reversible method of pain control in patients with neuropathic pain refractory to conventional medical management and enables neurostimulation in cases in which it would have been virtually impossible to implant a conventional system with an IPG. PNS using a subthreshold frequency was found to effectively control neuropathic pain from multiple peripheral nerve targets at subthreshold amplitude levels.

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