A Prospective Analysis of Peripheral Nerve Stimulation for Lower Extremity Nerve Pain

T. Jay Kleeman, MD; Christopher P. Chiodo, MD; Peter W.-C. Lam, MD;
Gail B. Levin, RN; and Lew C. Schon, MD

From the Department of Orthopaedic Surgery,
The Union Memorial Hospital,
Baltimore, Maryland
(e-mail: elaineb@helix.com)

Abstract

We prospectively studied 23 patients managed with peripheral nerve stimulation (PNS) for intractable lower extremity nerve pain secondary to various injury mechanisms. Visual analog scales were used to assess pain [0 points (pain free) to 10 points (worst pain imaginable)] and dysfunction [0 points (dysfunction despite the pain) to 10 points (wheelchair- or bed-bound)] before and after PNS implantation. Duration of pre-PNS symptoms averaged 53 months. Follow-up averaged 16 months. Average pain and dysfunction levels improved significantly ($p \leq 0.001$ and 0.02, respectively). The 11 complications (2 minor wire complications, 3 infections, 6 hardware problems) resolved after device modification or removal and replacement. Twenty patients reported they would undergo PNS implantation again, 19 stated the stimulator was worthwhile (4 were unsure), and 15 reported overall beneficial partial pain/dysfunction relief. Overall improvement averaged 41%. We concluded that this procedure improves symptoms and function in patients with intractable lower extremity nerve pain.

1. Introduction

Chronic intractable lower extremity nerve pain that is not responsive to conventional methods of treatment can pose a difficult management problem. The physical, psychological, social, and economic consequences of long-term pain can be considerable.

There are many different causes of chronic neurogenic pain. For cases that fail to respond to nonoperative and conventional operative methods, other surgical options exist, including revision neurolysis, transection with or without translocation, containment procedures (such as centrocentral anastomoses), barrier procedures (such as vein wrapping), and peripheral nerve stimulation (PNS) or spinal cord stimulation (SCS) [6].

The use of PNS has been described for the management of chronic intractable neurogenic pain in the upper extremity [2-5,8,10]; however, reports on its use in the lower extremity are sparse. The current report is a prospective review of the preliminary results of a consecutive series of patients with intractable, lower extremity nerve pain treated with PNS.

2. Materials and Methods

We prospectively reviewed 23 consecutive patients with intractable, lower extremity nerve pain. The 14 women and 9 men had an average age of 39 years (range, 17 to 73 years). Primary and contributory secondary mechanisms of nerve insult included: crush injury (9 patients), stretch/traction injury (8 patients), surgical transection (5 patients), compression (2 patients), repetitive trauma (2 patients), and idiopathic (1 patient).

The average duration of symptoms before PNS was 53.6 months (range, 8 to 173 months). Of the 23 patients, 21 had previous surgery on the affected foot [average number of previous surgeries, 2.7 (range, 0 to 6 surgeries] and 15 had at least one previous surgery for management of the neurogenic pain.

All of the patients in this study had failed nonoperative management, which included medical management, such as tricyclic antidepressants (e.g., Elavil)

or antiepileptic drugs (e.g., Klonopin), physical therapy, and desensitization techniques. Three of the patients had undergone attempted SCS without success. In the remaining patients, as a matter of protocol, the alternative option of SCS was discussed but subsequently deferred by the patient and/or physican.

The indications for PNS include patients with chronic peripheral neuralgia for whom the following procedures have failed: 1) nonoperative management protocol; 2) nerve release(s) with or without a containment procedure (i.e. vein, fat, or muscle graft); 3) transection and transposition of nerve with burial into muscle or bone; 4) other conventional surgical techniques (these patients are being considered for either a main nerve trunk transection or limb amputation); 5) spinal cord stimulator, or 6) nerve grafting and reanastomoses.

Previous infection or wound complications are not contraindications to PNS. However, active infection or ulceration at the electrode or generator site is a contraindication to PNS because the stimulator is an implantable device. Patients who have other implanted electrical devices, such as pacemakers, defibrillators, or spinal cord stimulators, should not have PNS if there is the possibility of electrical interference between these and the PNS device. Surgical procedures for patients with PNS devices should avoid unipolar cautery to prevent damage to the signal generator; bipolar cautery is safe to use. External electrical devices involving electromagnetic fields or microwaves are potentially hazardous if used injudiciously with PNS. Magnetic fields such as those generated by magnetic resonance imaging (MRI) machines, antitheft devices, and some heavy machinery can disrupt PNS. Thus, operating heavy machinery may be dangerous because sudden pain may occur if PNS is switched off inadvertently. MRI is contraindicated for patients with PNS devices because the device is implanted and contains metal.

3. Surgical Technique

Although a detailed outline of the surgical technique cannot be described here, it should be noted that PNS is performed with an intraoperative wake-up test to ensure optimal coverage of the patient's pain by the neurostimulator. Once final placement position is determined, the lead is secured to the epineurium, and the pulse generator is inserted proximally.

4. Postoperative Protocol

Postoperatively, the patient's leg is splinted for 2 weeks, followed by progressive range-of-motion exercises and weightbearing as tolerated. The electrical signal of the PNS device is adjusted at each follow-up visit until optimal pain control is achieved.

A standardized assessment protocol is used for every patient at each office visit. A 10-point visual analogue scale is used for evaluating pain and dysfunction. On the pain scale, 0 represents no pain and 10 represents the worst pain imaginable. On the dysfunction scale, 0 represents unrestricted function despite the pain, and 10 represents patients who are wheelchair-bound or bed-bound. A subjective satisfaction scale is used: satisfied, satisfied with some reservation and unsatisfied. Work status is documented as working at the same level as that before the nerve injury, working lighter duties, or not working. Finally, the presence of sleep disturbance due to pain is noted.

5. Results

Prospective follow-up was available for all patients. Average length of follow-up after PNS was 16 months (range, 12 to 20 months). Pain scores improved an average of 2.6 points (7.7 points preoperatively to 5.1 points at latest follow-up), a statistically significant difference ($p \leq 0.001$). Dysfunction scores improved an average of 0.8 points (5.6 points preoperatively to 4.8 points at latest follow-up), also a statistically significant difference ($p \leq 0.02$). Work status did not change significantly: 17 patients did not change their work status, two patients changed from not working to working full time in construction/ physical labor jobs, and four patients improved from light to moderate duty.

Postoperatively, 11/23 patients (48%) developed complications requiring revision: 2 had minor wire complications (resolved without sequelae after minor revisions), 3 developed infection (all doing well after revision), and 6 developed hardware problems (requiring major revision, including revision of the leads).

Despite, the high complication rate, the overall patient satisfaction rate was encouraging. Of the 23 patients, 20 reported that they would undergo PNS implantation again (with its accompanying hospitalization, discomfort, and expense) to achieve the same results; 19 stated that they thought the stimulator was worthwhile (4 were unsure); and 15 reported overall beneficial partial pain/dysfunction relief. Average overall improvement was 41%. There were also improvements reported in hours of sleep per night, hours of uninterrupted sleep, and average walking distance. Sixteen of the 23 patients were involved in Workman's Compensation.

6. Discussion

The idea for using nerve stimulation in the treatment of chronic intractable lower extremity nerve pain is based on the theory of pain mediation. Stimulation of large myelinated A-beta touch and pressure fibers sends nonpainful touch signals to the brain and is theorized to

prevent perception of pain by interfering with pain signal transmission.

There are several pain phenomena that should be understood. Nociceptive neuralgia refers to nerve pain from mechanical or tactile nerve irritation and ectopic neuralgia refers to nerve pain from a spontaneous abnormal nerve discharge without mechanical stimulation. Although the nociceptive type may respond to nerve transection and/or translocation, the ectopic form usually will not.

Another important pain phenomenon is deafferentation, which refers to pain in the distribution of a nerve that has been transected. Disruption of afferent sensory input from the transected nerve may result in hypersensitivity from adjacent sensory nerves. At times, these adjacent nerves may carry pain signals from the zone of deafferentation, even in the absence of light-touch sensation. This particular deafferentation sequela is termed by some as anesthesia dolorosa. The deafferentation phenomenon is theorized to occur at the spinal cord level where the transected nerve pain signals are augmented, causing hypersensitivity [11]. We have found that PNS is often effective for deafferentation pain and anesthesia dolorosa.

The surgical alternatives to nerve stimulation include transection and burial. One of the complications of this procedure is the development of deafferentation pain that has been described earlier. We have found this technique to be helpful only for cases of nociceptive neuralgia. Vein wrapping may be used in revision nerve release cases when there is evidence of adhesive neuralgia. However, the nerve must be intact, and the patient must have had at least partial temporary improvement in symptoms after the previous procedure.

Transcutaneous electronic nerve stimulation, which provides neurostimulation through the skin, has been found to be effective as an adjuvant form of pain management. It has the benefits of being noninvasive, portable, and adjustable, however, many patients will not receive benefits or will have inadequate pain control. The primary disadvantage of TENS is that it is bulky and cumbersome and precludes swimming and bathing with pain control. Although the success of TENS does not correlate well with future PNS success, patients who have increased pain with TENS are worrisome candidates for PNS.

SCS provides neurostimulation by direct lead application to the spinal cord and may be effective in relieving limb pain [7,9]. Although it is an invasive procedure, trial stimulation is performed percutaneously, usually with only local anesthesia. The zone of stimulation tends to be broader than TENS or PNS. If lead placement adequately covers the pain, a surgical procedure is then warranted to insert the pulse generator. Disadvantages of the SCS include the variable acceptance by patients of the need for a spinal procedure to control limb pain. In addition, the broad coverage at times introduces abnormal sensations to normal, nonpainful zones, which may be a limiting factor in the patient's ability to increase the stimulation to the painful zones. Finally, lead positional change or migration with flexion and extension of the spine can occur and may require limits in the patient's function to avoid fluctuations in stimulation intensity.

Peripheral nerve stimulation, unlike TENS and SCS, is directly applied to the affected nerve or nerves and has been used successfully to control upper extremity nerve pain. The literature reports improvement of pain symptoms in the upper extremity as ranging from 53% to 84% [1-6,8,10]. Hassenbusch et al [3] reported on 30 patients, who underwent PNS, 12 of which were for lower extremity nerve pain. In this subgroup, all had stimulation of a single nerve (7, posterior tibial nerve; 5, common peroneal nerve). Of the 12 patients, only 2 had good results, both of whom had stimulation of the posterior tibial nerve. The lack of success in this study may have represented problems with inclusion criteria or technical factors.

Patients with chronic nerve pain due to intrinsic nerve compromise who have not responded to other surgical techniques should be considered for PNS. Although in our series, PNS did not provide complete relief of symptoms in any patient, all experienced some improvement in the pain level and reported an improvement in quality of life and psychological well-being. Of the 23, 20 (87%) stated they would undergo the procedure again. Although average improvement was a modest 41%, it should be noted that these patients had incapacitating symptoms that failed to improve or that worsened after multiple surgical and nonsurgical interventions. We believe that some of the higher success rate in the current series, compared with that in other studies, may be attributed to the use of a wake-up test, to technical improvements in the device, and to the surgical technique used. Although the early results of PNS are encouraging, additional follow-up is required to assess the long-term results for the management of intractable lower extremity nerve pain.

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