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Peripheral nerve stimulation for the treatment of chronic pain

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Abstract

The aim of this retrospective study is to evaluate the role of the implanted peripheral nerve stimulator in patients with pain in a peripheral nerve distribution. The current study is the largest in the literature that examines the role of the implantable peripheral nerve stimulator in the chronic pain patient. Our patient sample included 38 patients (with 41 nerve stimulators), consisting of 19 males and 19 females with a mean age of 44 years (SD = 11 years). Four groups of etiologic factors were identified; blunt or sharp nerve trauma (14/ 38), iatrogenic injuries from surgery (9/38), inadvertent injection of a nerve (9/38) and post surgery for entrapment or tumour (8/38). Stimulation was attempted in 45 patients, but an initial trial failed in 4. Mean follow-up time from implantation of the stimulator was 31 months (SD = 19 months). Compensation benefit was an issue in 29 cases (76%). Outcome following implantation was assessed based on pain criteria, narcotic usage and return to normal function/ work. Relief from preoperative pain was judged as good (>50% relief) by 23/38 patients (61%). A total of 15 patients reported fair or poor results (39%). Six patients required removal of their stimulators (15%) due to infection or reduction of pain control after an initial good result. A statistically significant decrease in reported pain level was found postoperatively ($p \le 0.05$). Workers' compensation patients have equivalent outcomes to non-compensable patients (p > 0.05). Eighteen of 38 (47%) patients reported a significant improvement in their activity levels following stimulator implant. In conclusion, over 60% of patients had a significant improvement in their pain and lifestyle following implantation of peripheral nerve stimulators. We therefore conclude that peripheral nerve stimulation can be useful in decreasing pain in well selected patients with severe pain in the distribution of a peripheral nerve. © 2005 Elsevier Ltd. All rights reserved.

Keywords: Peripheral Nerve; Pain; Stimulator

1. Introduction

The role of electrical impulses for the treatment of pain has a long history. As early as 400 BC, the *torpedo fish* was used to treat pain with the electric fish placed directly on a painful area of the body. Stimulation-produced analgesia has been used by the Chinese for many centuries, including the use of an electric current applied to acupuncture needles.¹ Electrical stimulation of peripheral nerves using implanted electrodes for treatment of intractable pain has been used over the past 30 years.² Difficulties encountered have included defining the appropriate indications, utilizing approved device technology, and standardizing surgical techniques. Circumferential electrodes treating mononeuropathies have given way to paddle-type electrodes, such as the Resume electrode (Medtronic Inc., Minneapolis, MN, USA).

Chronic pain from trauma to a peripheral nerve can be a challenge for both the pain service and surgeon. Type of surgery depends on the type of insult to the peripheral nerve and may include neurolysis, transposition, nerve grafting, division of the painful nerve proximal to the pain source and resection of the nerve.^{3,4} Implantation of a nerve stimulator is an option for the patient who continues to have pain despite exhausting surgical and medical options. The aim of this study is to review the results of peripheral nerve stimulation at our institution in an attempt to identify the

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patient population that will most benefit from the procedure and to evaluate the overall value of the procedure in light of the relatively high expense of the implanted electrode and generator complex. In addition, we review the results of other large series and compare them to the study presented.

2. Material and methods

2.1. Patient selection and questionnaire

A retrospective review of patient charts and a telephone questionnaire was conducted. The charts of 42 patients were reviewed to confirm the nerve stimulated and the results of the trial stimulation. Only those patients who had permanent implantation of a stimulator were contacted (n = 38). All patients contacted agreed to participate in the phone survey. A questionnaire was devised following consultation with a statistician and the pain management service. The 20-item questionnaire included: assessment of pain preoperatively and postoperatively, using the visual analogue pain scale (VAS);⁵ return to work; improvement in activities of daily living; and use of analgesics.

2.2. Technique

The technique for implantation is performed in two stages. The first procedure involves exposure of the affected nerve proximal to the pathology. The use of a nerve stimulator to confirm the nerve has not been necessary in our experience as the operative exposure usually involves a virgin nerve dissection proximal to the level of the pathologic insult to the nerve. We attempt to leave a layer of mesoneurium over the nerve and to dissect just enough nerve to apply the stimulator device. Two Australian surgeons designed a modified Resume electrode (Medtronic) especially for this indication.⁶ When the electrode is in place, the mesh is loosely wrapped around the nerve and interrupted 4/0 nylon suture is used to attach the electrode to the nerve. A trial lead exits the skin via a stab incision. A representative from Medtronic visits the patient on day 1 to attach a trial generator. The patient is instructed in the use of the generator and can alter voltage and stimulation settings themselves to find the best combination for their pain. Although some authors have an initial trial period of 24-48 hours, we consider this time course too short as the patient is still recovering from a general anaesthetic and may have long-acting local anesthesia wound infiltration with agents such as Marcaine. Our trial period lasts 3-7 days. If the results of early stimulation are not conclusive, we lengthen the trial for up to 7 days.

If the initial trial is successful, the second procedure involves implantation of the battery/generator unit. Tunneling equipment is included in the package from Medtronic and the electrode and battery are connected. Battery placement is discussed with patients preoperatively and is either pectoral, anterior thigh or abdominal wall above the belt line. Discharge is usually day 2 following the second stage procedure and the patient is sent home on prophylactic antibiotics. All authors were involved in the surgical insertion of the stimulators; however the senior author (PB) was the supervisor for all cases.

2.3. Follow-up

All patients were followed up by the senior author (PB) and by the referring pain clinic. The initial visit was 4–6 weeks following surgery and then as necessary. The patient would contact the Medtronic representative for ongoing advice for generator settings. However, follow-up results for this study were reviewed by an independent non-interested assessor. Over an 8-year period, 41 peripheral nerve stimulators were inserted into 38 patients.

2.4. Statistical analysis

Data collected was analysed in Microsoft Excel (Microsoft Inc., Redmond, WA, USA) format for mean and standard deviation. The *t*-test was used for pre- and postoperative analysis.

3. Results

3.1. Demographics

The total number of stimulators followed was 45. A total of four stimulators (8.9%), in four patients failed the initial trial stimulation period and thus were not included in the final analysis. The location of the failed stimulators included: one brachial plexus; one median; one radial; and one common peroneal nerve. There were a total of 41 peripheral nerve stimulators permanently implanted into 38 patients. The mean age of the patients was 44 years (SD = 11) with a range of 25–68 years. There were 19 men and 19 women. The mean duration of symptoms was 58 months (SD = 36) with a range of 6–144 months. The mean follow-up was 31 months (SD = 19) with a range of 9–89 months. Workers compensation and/or litigation was involved for 29 patients (76%).

The peripheral nerve stimulator was placed in the upper extremity in 34 patients and in the lower extremity in seven. Upper extremity stimulators were placed in the following locations: 11 median; 10 ulnar; nine brachial plexus; three radial; and one suprascapular nerve. Lower extremity stimulators were placed in the following locations: two common peroneal; two sural; two posterior tibial; and one sciatic nerve. The minimal number of lower limb stimulators inserted was a reflection on the poor results that our group encountered early on in the series and thus inserting these devices in the lower extremity was discontinued in favor of spinal cord stimulation.

Of the 38 patients who had permanent implantation, four groups of etiologic factors were identified. The most

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