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NEW SACRAL NEUROMODULATION LEAD FOR PERCUTANEOUS IMPLANTATION USING LOCAL ANESTHESIA: DESCRIPTION AND FIRST EXPERIENCE

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ABSTRACT

Purpose: In functional urology today chronic stimulation of the sacral nerves has become one of the most accepted methods of stimulation treatment. Many studies have described the advantage of test stimulation prior to implanting the definitive system to enable effective patient selection. We studied a method aimed at improving lead anchoring by developing a self-blocking electrode with a simple placement procedure, in the process creating a 2-stage approach to full percutaneous implantation that allows a long screening period during the first temporary stimulation stage.

Materials and Methods: A new tined lead was specifically designed to allow minimally invasive percutaneous lead placement requiring no incision and no additional fascial anchoring. From September 2001 to November 2002, 15 consecutive patients (3 males and 12 females) 27 to 70 years old (mean age 49) underwent this procedure and were prospectively evaluated. No PNE test was performed.

Results: Following the first stage screening phase 12 patients were implanted with the implantable pulse generator (IPG), while 3 who did not respond positively to test stimulation (neurogenic voiding dysfunction, urge incontinence and neurogenic urge incontinence in 1 each) did not undergo IPG implantation and had the tined lead removed under local anesthesia. We did not observe any lead displacement during the screening period (average 38.8 days) or during followup of IPG implanted cases (average 11 months, range 5 to 19).

Conclusions: Our results show that the new tined anchoring system is a reliable way to allow truly minimally invasive placement of the chronic lead.

KEY WORDS: prostheses and implants, bladder, incontinence, transcutaneous electric nerve stimulation

In the field of functional urology today chronic stimulation of the sacral nerves has become one of the most accepted methods of stimulation treatment. Many studies have described the advantage of prior test stimulation, often described as the PNE test, to allow the selection of suitable patients. This approach was seen to be less reliable when some patients proved to have unsuccessful PNE testing but still responded well to therapy and experienced sustained clinical benefit after permanent implant placement. At this point the search for alternatives to test stimulation and, thus, alternatives to patient selection began.

The new concept presented in this study centers on the development of a minimally invasive approach for percutaneous positioning of the definitive quadripolar lead into the foramen without surgically opening the layers above the sacral foramen, which has been the case to date. After experience with percutaneous lead implant with fascial fixation[1–3] we studied a method to improve lead anchoring by developing a self-blocking tined lead electrode and a simple placement system, namely a sacral percutaneous implant introducer kit. The particularity of this technique is that it represents a 2-stage approach to fully percutaneous implantation, which allows a long screening period during the first temporary stimulation stage. We started on September 2001 with a pilot study. We now present the first experience using the new apparatus for introduction and tined lead in 15 patients.

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MATERIALS AND METHODS

A new tined lead was expressly designed to allow minimally invasive percutaneous placement requiring no incision and no additional fascial anchoring. The tined lead is a quadripolar in-line lead containing 4 cylindrical electrodes of equal length that are spaced equidistantly. An anchoring mechanism proximal to the electrodes forms an integral part of the lead body and comprises 4 tine elements with each tine element consisting of 4 flexible, pliant tines. The system was studied to be implanted in and engage subcutaneous tissue, particularly muscle tissue, to inhibit axial movements of the lead body and consequent dislodgment of the stimulation electrodes (fig. 1).

The apparatus consists of a directional guide wire, a metal dilator with a concentric plastic sheath and a dilator locking mechanism (fig. 2). The sheath is slightly tapered at the distal end to allow smooth transition to the dilator. The dilator is made of stainless steel tubing tapered at the distal end for smooth insertion. The directional guide is made of stainless steel wire rounded at each end. It has depth markings etched into the surface along the distal end.

Technique. The patient is placed prone. Using local anesthesia a foramen needle is inserted in the S3 foramina, which is then stimulated to ensure the correct sensory and motor

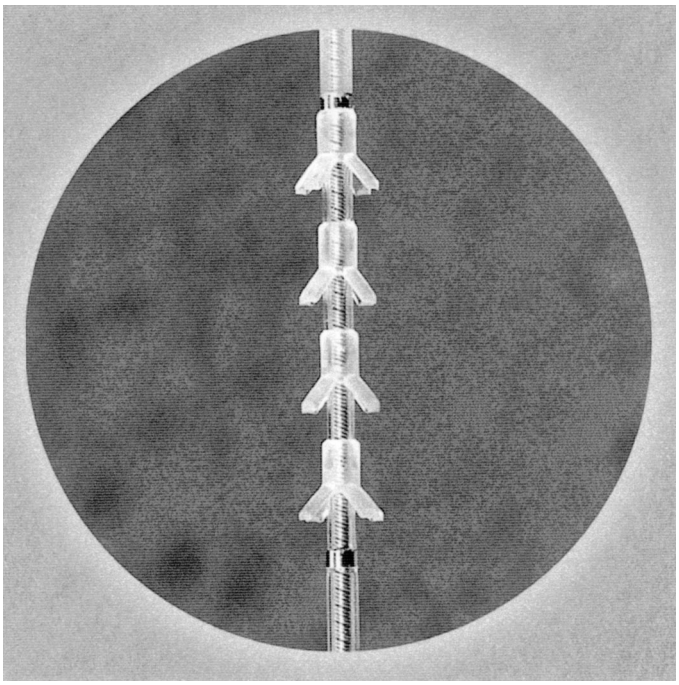

FIG. 1. Tines

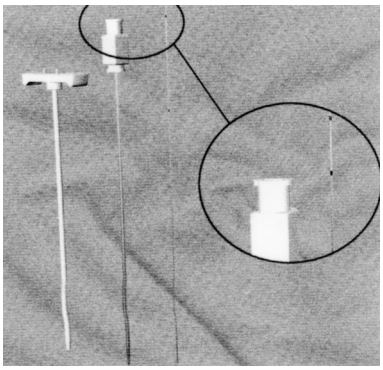

FIG. 2. Introducer kit

response. The inner stylet of the needle is removed and replaced with the directional guide. The foramen needle is removed, and the dilator and introducer sheath are placed over the directional guide and advanced into the foramen. The directional guide and dilator are removed, leaving the introducer sheath in place. The lead is passed through the introducer sheath until the proximal electrode enters the foramen (fig. 3). Electrodes 0 to 3 are tested while the patient is observed for responses. Simultaneous fluoroscopy is essential to place correctly and confirm the position of the tined lead in relation to optimal patient sensory responses.

With the lead held in place the introducer sheath is retracted until the visual marker band on the lead is aligned with the introducer sheath handle. Under fluoroscopic guidance it is essential to confirm that the radiopaque marker band at the tip of the sheath is proximal to electrode 3 and adjacent to the radiopaque marker band on the lead. Electrodes 0 to 3 are again tested to confirm the previously observed response. The rest of the procedure is the same as that of the 2-stage technique, as described by Janknegt et al.[4] The lead and percutaneous extension are connected at the site of future neurostimulator in the buttock.

From September 2001 to November 2002, 15 consecutive patients (3 males and 12 females) 27 to 70 years old (mean age 49) underwent tined lead implantation under local anesthesia with ropivacaine and were prospectively evaluated. A PNE test was not performed. Indications were idiopathic overactive bladder in 3 patients, neurogenic overactive bladder in 2 (D8 to D12 incomplete lesions), idiopathic complete urinary retention in 5, complete retention with a peripheral incomplete lesion in 3 and urgency frequency syndrome in 2.

Average time to complete the procedure was 45 minutes (range 25 to 60). Fluoroscopy was used in all cases during implantation with an average exposure time of 1 minute. X-ray examination with the patient standing and bending was done the day after implantation and at the last followup to assess lead stability.

Explantation. The patient is placed prone. An incision is made at the level of the connection with the percutaneous extension. At this point it is possible to locate the connection and cut it. By making an incision at the site of percutaneous lead access and locating the lead it is possible to expose it with care taken not to cut it. By inserting an 8Fr plastic dilator it is possible to dilate the tissue around the lead, allowing lead removal through the fascia with gentle traction.

RESULTS

Following the first stage screening phase 12 patients were implanted with the implantable pulse generator (IPG) while 3 who did not respond positively to test stimulation (neurogenic voiding dysfunction, urge incontinence and neurogenic urge incontinence in 1 each) did not undergo IPG implantation and had the tined lead removed under local anesthesia. We did not observe any lead displacement during the screening period (average 38.8 days) or during followup of IPG implanted cases (average 11 months, range 5 to 19).

The positive clinical results achieved during the screening period were maintained in all 12 patients who underwent second stage implantation. Continence was fully restored in 2 patients with nonneurogenic urge incontinence. Daily incontinence episodes decreased from 4 to 1 in 1 patient with neurogenic urge incontinence and the mean number of incontinence episodes decreased from 3.7 to 0.3. Spontaneous voiding was regained in the 7 patients with voiding disturbance. Residual volume decreased from 334 to 85 ml and the number of catheterizations decreased from 3.1 to 0.7. Frequency

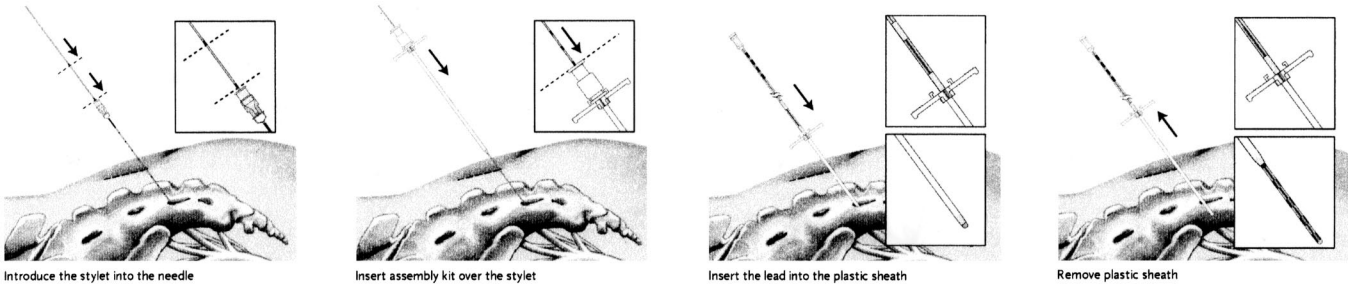

FIG. 3

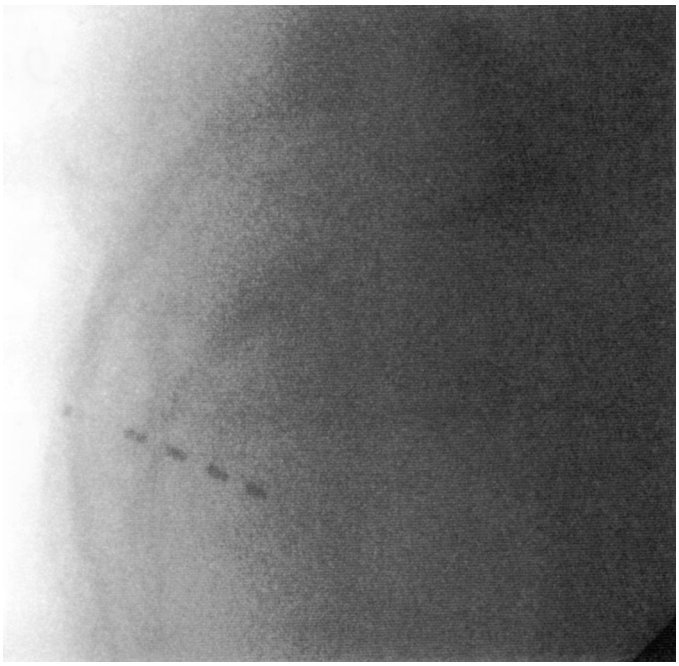

FIG. 4. Tined lead x-ray

was normalized in the 2 patients with urgency frequency and the number of daily voids decreased from 17.5 to 7.5.

DISCUSSION

To date a positive response to the PNE test has been the only predictive factor for the long-term efficacy of sacral nerve stimulation therapy.[5] However, reported success of the PNE test varies to a great degree from 40% to 100%.[6–8] Published studies shown that in up to 40% of patients who experience improvement in symptoms during PNE test stimulation with a temporary lead this improvement is not carried through after neurostimulator implantation.[9] In our study 12 of the 15 patients (80%) who underwent tined lead implant without PNE testing reported a positive outcome during the screening phase, which was maintained at an average followup of 11 months, resulting in a higher success rate than that currently reported in the literature.

The development of the new tined lead allows fully percutaneous implantation of the quadripolar permanent lead and offers the possibility of a longer and more reliable screening period than that possible with the PNE test. The advantage of permanent lead placement vs PNE for patient screening are that the permanent tined lead is less prone to migration, if the results of screening are positive, the lead is already in the precise place where positive results were obtained, and there is a decrease in false-positive and false-negative results after screening, resulting in more appropriate selection of patients who can benefit from sacral neuromodulation.

CONCLUSIONS

Our results show that the new tined anchoring system is a reliable way to allow truly minimally invasive placement of the chronic lead. It has a number of benefits. 1) A 2-stage, fully percutaneous approach is feasible with local anesthesia. It eliminates the need for the PNE test. It is more rapid than the traditional implantation procedure and it may decrease adverse events associated with the surgical procedure required to implant the lead. 2) The use of local anesthesia means that the implanting physician can use the patient conscious sensory response to stimuli as an aid in accurately placing the stimulation lead. 3) The tined lead allows a truly percutaneous approach with no skin incision or fascial anchoring. 4) Lead explantation is simple, rapid and safe. 5) The screening phase performed with a permanent tined lead is a more reliable patient selection method than PNE, which could improve long-term outcomes.

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