Percutaneous trial of stimulation for patient selection for implantable stimulating devices

DONALD L. ERICKSON, M.D.
Department of Neurosurgery, University of Minnesota Hospitals, Minneapolis, Minnesota

The author describes a flexible electrode which can be inserted percutaneously for a period of several days in candidates for an implantable electrical stimulating device for pain relief. This allows the patient a trial of stimulation which closely mimics that of the intended implantable system. If this trial does not give adequate pain relief in a variety of situations, the patient is not considered to be a suitable candidate for an implantable device. The trial of stimulation in no way obviates the need for careful scrutiny of the social and psychological factors accompanying chronic pain problems.

KEY WORDS  •  flexible electrode  •  peripheral nerve  •  spinal cord  •  pain

THE psychological and sociological problems that are associated with chronic pain present almost insurmountable obstacle to accurate patient selection for operative pain-relieving procedures. Some patients will fail regardless of what is done surgically. Other patients will respond positively for a brief duration, again regardless of the procedure performed. The introduction of implantable electrical stimulating devices for chronic pain relief has in no way alleviated this selection problem.

In an attempt to improve our patient selection from a social and psychological standpoint, all patients are screened during a 2-week period of behavioral modification training. This includes drug detoxification, increase in physical activity, and psychological counseling. Only after a patient has made adequate progress in that setting do we consider him a candidate for a surgically implantable stimulating system. It is then necessary to test the patient for his response to the intended stimulating device to ascertain whether or not stimulation will give adequate pain relief. Techniques for direct nerve or spinal cord stimulation have been previously employed but have had the shortcoming of being very brief in duration and not therefore, allowing the patient to establish the effectiveness under a variety of activities.1,2

We have employed a flexible electrode which can be inserted percutaneously adjacent to the spinal cord or peripheral nerve and left in place for several days during which time the patient uses a stimulating system which closely mimics the implantable device. The patient is therefore able to be fully active during the testing period and is better able to determine whether the stimulation is effective for pain relief during normal activities. We have used this system over the past year in 58
Percutaneous trial for implantable stimulating devices

patients and believed it is a useful procedure for patient selection. The remainder of this communication will be devoted to describing the technique and presenting our results with its use.

Materials and Methods

Equipment

The components of the percutaneous device* are shown in Fig. 1. The stimulating electrode is composed of a hollow stainless steel coil coated with Silastic. The total length is 18 in. and the bare stimulating tip is ½ in. in length. The diameter of the electrode is 0.040 in. and a flexible stainless steel stylet of 0.006 in. is provided with it to add rigidity during insertion. This system fits through a thin-walled 17-gauge spinal needle. A carbon rubber transcutaneous-type electrode is used on the skin surface as an indifferent electrode. A stimulating current is produced by a pocket-sized device; this generates a constant voltage with a maximum output of 17 V and a biphasic wave form similar to that produced by the implantable device, which uses the radiofrequency transmitter system. The device has internal controls for voltage and pulse width and external controls for voltage and frequency. The patient is therefore able to adjust the voltage level and change the frequency while the internal controls are adjusted by the physician to control pulse width and the limits of voltage. The system has been tested in animals and there is no evidence of central nervous system injury by the maximum available current.†

Technique

This electrode can be placed adjacent to the spinal cord for stimulation of the anterior or posterior columns or adjacent to a major peripheral nerve to achieve peripheral nerve stimulation.

Spinal Cord Stimulation. Depending on the level of the spinal cord that one wishes to stimulate, the spinal puncture is performed either at the C-2 or upper lumbar levels. It is desirable to stimulate at approximately the level at which the stimulating device would be ultimately implanted. A spinal puncture is performed with a 17-gauge thin-walled Touhy spinal needle.† This needle, because of its side outlet, gives somewhat better control of the electrode direction as it is inserted through the needle. Additional control is achieved by bending the stylet that accompanies the electrode so that the electrode tip will have a simple curve that can then be manipulated into the desired location. Once the spinal puncture is accomplished, the needle stylet is removed and the electrode with its stylet is introduced. Under fluoroscopic control, the electrode is manipulated to the desired area of the spinal cord. Occasionally, the electrode tip seems to be impeded because of a fold in the arachnoid. At times, it may be possible to manipulate the electrode to bypass such barriers but at other times, it proves impossible to go beyond a certain level, either cephalad from a lumbar puncture or caudally from the C-2 puncture. In the cervical area flexion or extension of the neck may change these arachnoid folds and enhance electrode positioning. This, of course, is impossible in

*The flexible electrode percutaneous stimulating device is manufactured by Medtronics, 3055 Old Highway 8, Minneapolis, Minnesota 55418.

†Touhy needle made by Becton-Dickinson, Rutherford, New Jersey 07070.
the thoracolumbar area. If anterior stimulation in the cervical area is desired, the neck is placed in mild hyperextension which then stretches the anterior portion of the dura and arachnoid, and makes a smoother dural-arachnoid surface for electrode passage. A more flexed position is used if dorsal column stimulation is desired in the cervical area.

Once the desired electrode position has been achieved, the spinal needle is removed and a purse-string suture is placed in the skin around the electrode exit. Before we used this suture, several patients had rather profuse cerebrospinal fluid leakage at the electrode site. The electrode is then firmly taped in place to prevent inadvertent dislodgement. It is possible for spinal fluid to pass the coils in the bare stimulating tip and leak through the hollow electrode, and we recommend plugging the distal catheter with bone wax while it is still sterile. At this point, we obtain a permanent x-ray film to document the electrode position (Fig. 2).

The indifferent electrode is then taped to the skin and the negative pole of the transmitter is connected to the stimulating electrode while the positive pole is connected to the indifferent electrode. Internal controls are then adjusted until the desired stimulation is achieved and the patient is instructed in the use of the external controls. In the case of dorsal column stimulation, the end point is determined by the production of paresthesias in the area of pain. When anterior cord stimulation is desired, one must observe muscle twitching or record evoked cortical potentials to ascertain that the system is functioning. When the anterior cord at the C-2 level is stimulated, occasionally paresthesias are produced before motor activity. In all trials of anterior cord stimulation, the transmitter is readjusted to stimulate at a subliminal level.

The patient is then encouraged to be as active as possible over the 2 or 3 days of the trial of stimulation in order to ascertain the effectiveness of the system during a variety of activities. We instruct the patient to try the stimulation in several different ways. We prefer that he perform activities that produce pain with the stimulator off, and then activate the stimulator to determine how effective it is in relieving pain and also how much stimulation time is required to alleviate the pain. We also attempt to determine if pain relief lasts beyond the period of stimulation. We do not ask for a report of percentage of pain relief, but use only complete or nearly complete pain relief as a determination of a successful trial of stimulation.

**Peripheral Nerve Stimulation.** Percutaneous peripheral nerve stimulation can be instituted even more easily with this system. It is not necessary to use x-ray control. At the bedside, the skin over the target nerve is prepared and draped, and a 17-gauge thin-walled spinal needle is inserted until paresthesias are produced in the target nerve. We do not use disposable needles for this purpose because they tend to be excessively sharp and could injure the target nerve. When paresthesias are produced, the needle stylet is removed and a rigid stimulating electrode is inserted. This is connected to the negative pole of the stimulating device, and once again an indifferent electrode is placed on the skin. If adequate paresthesias are produced in the distribution of a target nerve, the rigid electrode is removed and the flexible electrode is inserted. If it is in proper position, the flexible electrode will follow the peripheral nerve along the surrounding areolar tissue. This allows placement of at least several centimeters of electrode beyond the needle tip. The needle is then removed, the electrode taped in place, the equipment adjusted, and the patient instructed as above in the use of...
Percutaneous trial for implantable stimulating devices

the transmitter and the type of physical activity to be performed.

Results

Dorsal Column Stimulation

Sixteen patients underwent percutaneous dorsal column stimulation and 10 of these patients indicated satisfactory pain relief during the trial. Seven patients ultimately underwent implantation of the dorsal column stimulator. All of them initially had excellent pain relief with their stimulators, but over the follow-up period of 8 to 12 months, only one of them has continued to have satisfactory pain relief and this is not complete pain relief. One patient, who did not obtain pain relief with a percutaneous trial, nevertheless requested that we implant a dorsal column stimulator because of his desperate situation, and this implant did not provide even immediate postoperative pain control. We have subsequently discontinued implantation of dorsal column stimulators.

Anterior Column Stimulation

Ten patients have undergone a percutaneous trial of anterior spinal cord stimulation. Five of these patients reported satisfactory pain relief during the trial of stimulation. An anterior spinal cord stimulator has been implanted in three patients. Of these, one received no pain relief after the implant and we could not obtain an evoked cortical potential in this patient at a subliminal stimulation level. The two other patients were receiving good pain relief at 3 and 6 months, respectively.

Percutaneous Peripheral Nerve Stimulation

Thirty-two patients have undergone a trial of percutaneous peripheral nerve stimulation. Fifteen of these patients had adequate pain relief during the trial and 13 of them ultimately underwent implantation of a peripheral nerve stimulator. Nine of these patients have continued to receive satisfactory pain relief during the follow-up period of 6 to 16 months.

Complications

No complications have been encountered in percutaneous spinal cord stimulation. In one patient, the insulation of the stimulating electrode became frayed, presumably on the sharp edge of the spinal needle. This frayed edge of the insulation became entangled with the dura and arachnoid and required considerable traction to withdraw it. Although it did not cause any damage, there was considerable pain to the patient during the extraction of the electrode. As was mentioned in the section on technique, several patients developed profuse spinal fluid leaks from around the electrode but this has been eliminated by use of the purse-string suture. One of these patients returned to the hospital 2 days after discharge with signs and symptoms of bacterial meningitis. Although this was not confirmed by culture, the spinal fluid cell count was compatible with meningitis and antibiotic treatment was successfully instituted. Several patients have had sufficient spinal headaches while the electrode was in place to prevent full range of activities during the trial of stimulation. We have had no cases of neurological deficit related to use of these electrodes.

Discussion

The use of flexible percutaneous stimulating electrodes affords us the opportunity of producing, in a preoperative trial, a situation that mimics quite closely the stimulation produced by surgically implanted devices. We believe this system affords advantages over previous selection techniques where the results of transcutaneous stimulation were used to estimate the effectiveness of implantable stimulating systems or where only brief trials of percutaneous stimulation were used. We have certainly found that the correlation between transcutaneous stimulation and percutaneous stimulation is not sufficiently accurate. Some patients have responded poorly to transcutaneous stimulation and yet very positively to percutaneous stimulation. The reverse is occasionally encountered as well. Brief-duration percutaneous stimulation can also be deceptive because it does not allow the patient to perform the usual range of activities during the trial.

Our results with implantation of sciatic nerve stimulators would suggest that percutaneous stimulation is a good predictor of success. It does not, however, seem to be a satisfactory predictor of success for implanta-
tion of dorsal column stimulators. It may predict certain failure if the patient does not get pain relief during the trial stimulation. Our results with anterior spinal cord stimulation are too recent to make any judgment regarding its usefulness in that area. Our limited experience does suggest that the stimulation produced by the percutaneous electrode is essentially the same as that produced by an implantable stimulating system.

Several simple precautions may avoid problems. We recommend that patients undergoing subarachnoid stimulation be placed on broad-spectrum antibiotics prior to and during the trial of stimulation. If spinal fluid leak develops during the trial, we recommend discontinuation. During electrode placement, if it becomes necessary to withdraw the electrode for repositioning, one must do this very slowly to avoid fraying the insulation on the tip of the spinal needle. We do not recommend attempting to withdraw the flexible electrode back through the spinal needle when doing peripheral nerve placement, and for that reason we use the rigid electrode for the initial stimulation before inserting the flexible electrode.

Chronic pain is an extremely complicated problem and we do not pretend to imply that a positive response to percutaneous stimulation will necessarily predict a patient's success if other social and psychological criteria are not also strictly adhered to.

References

3. Medtronic (Unpublished data)

Address reprint requests to: Donald L. Erickson, M.D., Department of Neurosurgery, University of Minnesota Hospitals, Minneapolis, Minnesota 55455.