Complete removal of vagus nerve stimulator generator and electrodes

Technical note

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Vagus nerve stimulation has become widely used in the palliative treatment of refractory epilepsy. Removal of a vagus nerve stimulator may be desirable or even necessary due to lack of efficacy, intolerable side effects, signs of infection, or failure of the device. Unless the lead or the helical electrodes are defective, only the generator is explanted and the electrodes are usually left behind for fear of damaging nerve or surrounding structures. The authors review their experience with complete removal of the stimulating electrodes and pacemaker-like generator device in 9 consecutive patients, 3 of whom were children.

Using microsurgical techniques, the authors were able to completely remove the stimulator, including electrodes in all patients. All nerves remained morphologically intact. One case of temporary and one of permanent clinically silent ipsilateral vocal cord paresis were observed. (DOI: 10.3171/2009.9.PEDS0810)

KEY WORDS • epilepsy • epilepsy surgery • NeuroCybernetic Prosthesis • vagus nerve stimulation

INTERMITTENT stimulation of the left vagus nerve in the neck has become a possible adjunctive treatment for patients with medically refractory epilepsy.17,18 The NeuroCybernetic Prosthesis System (Cyberonics, Inc.) consists of a pacemaker-like generator, which is placed in an infraclavicular pocket, 2 helical electrodes and a helical anchor tether that are coiled around the left vagus nerve.7,8,11 The device delivers intermittent electrical stimulation to the cervical vagus nerve trunk. The nerve transmits rostral impulses to exert widespread effects on neuron excitability throughout the CNS.1,3,7,12,14

Complete removal of the device including the 3 coils may become necessary in cases of mechanical failure or wound infection. Treatment ineffectiveness or intolerable side effects may also lead to discontinuation of stimulation and make explantation desirable.4,8,10,13,15,19 Whereas in the first 2 situations a medical necessity for complete removal can exist, decision-making in the latter 2 situations reflects patient preferences such as “to become as before” and “to get rid of all foreign material.” As a further argument for complete removal, coils remaining in place after stimulator switch-off or stimulator-only removal may exclude patients from future investigative techniques such as high-field MR imaging.

From the surgical perspective, the generator is easy to remove. Concerns exist, however, regarding the safety of removing the 2 helical electrodes and the tether coiled around the nerve. The vagus nerve and the adjacent anatomical structures (including major blood vessels and nerves) can be encased by fibrosis, making dissection difficult and potentially harmful. In children, manipulation of the vagus nerve during attempted complete removal has been associated with cardiac arrhythmias.16

Although successful removal of the entire VNS system has been reported,4,8,13,15,19 prospective data aimed at minimizing tissue trauma when identifying the nerve and removing the electrodes are missing. We report results and technical nuances of complete NCP system removal based on our experience in a continuous series of patients.

Methods

Since March 2002 complete removal of the device was offered to all patients scheduled for NCP removal. Nine patients underwent complete removal. All 9 were includ-
ed in this series. Fully informed consent to the procedure aimed at complete removal of the system was obtained in all cases. Prior to recommending removal, all patients were evaluated within the comprehensive epilepsy surgery program of Innsbruck Medical University. In 3 cases, the NCP system had been implanted at other institutions. The mean interval between implantation and removal was 39.2 months (range 13–68 months). All patients except the first underwent preoperative and postoperative laryngoscopy as part of their routine evaluation. Data were prospectively entered into a database. Table 1 presents patient characteristics. Operative logs were reviewed retrospectively to identify key steps in electrode removal.

**Surgical Procedure**

After induction of general anesthesia, the patient is positioned supine, the neck is extended, and the head turned slightly to the right. Unipolar cautery is avoided, and bipolar cautery is used only when absolutely necessary. Under antibiotic prophylaxis the infraclavicular scar is opened first, the lead connector pin (or pins, if a dual-receptacle generator was used) is cut off the distal lead, and the generator is removed from its subcutaneous pocket. The cervical incision is reopened without extension, the lead is identified subcutaneously and brought up from the infraclavicular wound. Gentle traction is applied to the lead and it is followed around the anterior sternomastoid border using sharp dissection until all (usually 2) silicone tie-downs are identified.

Thereafter the lead is no longer used for guidance to the nerve. Under the operating microscope, one of the coils around the vagus nerve is directly identified with sharp dissection. Palpation is helpful in identifying the carotid pulse and the coils. This first coil is freed circumferentially, whether it is the anchoring coil or one of the helical electrodes. The vagus nerve remains protected by the coil during this dissection. Once the coil is completely freed, a vessel loop is slung around the nerve at the level of the coil (Fig. 1a). The nerve itself and the other structures within the carotid sheath are not dissected free.

Gentle traction on the vessel loop then provides immediate information on the course of the vagus nerve, which is still enclosed in the scar (Fig. 1b). By dissecting in a proximal direction, either another 1 or 2 coils or the 2 leads that run from the anchoring coil toward the generator are identified (Fig. 1c). The leads are cut (Fig. 1d), and the lead forming the caudal strain-relief loop can be removed in retrograde fashion without further caudal dissection. Once all 3 helical coils are identified by dissection, scar tissue is cleared from the point of connection between the coils and the lead. The coils can then be extracted from their connective tissue pockets with the help of a nontoothed forceps. If the sutures emanating from the ends of the coils cannot be completely removed, they are cut and left behind (Fig. 1e). The 3 coils are removed 1 coil at a time. Scissors are not inserted between the nerve and the coils. Excess scar tissue is not trimmed off the nerve (Fig. 1f). The wound is closed in layers after multiple antibiotic rinses.

**Results**

Complete removal of stimulator and electrodes using microsurgical techniques was possible in all patients, as presented in Table 1:

**TABLE 1: Summary of demographic and clinical characteristics of 9 patients**

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>Type of Epilepsy</th>
<th>Duration of Implantation (mos)</th>
<th>Reason for Removal</th>
<th>Complications, Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32, F</td>
<td>lt-sided extratemporal postinflammatory epilepsy</td>
<td>64</td>
<td>no improvement in seizure control</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>13, M</td>
<td>rt-sided postinflammatory TLE</td>
<td>52</td>
<td>no improvement in seizure control</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>36, F</td>
<td>lt-sided multifocal postinflammatory epilepsy</td>
<td>13</td>
<td>no improvement in seizure control, intolerable side effects (unpleasant abdominal feeling, feeling of pressure in throat during stimulation)</td>
<td>transient paresis of recurrent laryngeal nerve</td>
</tr>
<tr>
<td>4</td>
<td>29, M</td>
<td>lt-sided TLE after perinatal MCA infarction</td>
<td>68</td>
<td>no improvement in seizure control</td>
<td>explantation during resection procedure</td>
</tr>
<tr>
<td>5</td>
<td>5, M</td>
<td>cryptogenic generalized epilepsy</td>
<td>27</td>
<td>no improvement in seizure control</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>44, M</td>
<td>rt-sided TLE w/ hippocampal sclerosis</td>
<td>19</td>
<td>no improvement in seizure control</td>
<td>explantation during resective op</td>
</tr>
<tr>
<td>7</td>
<td>38, F</td>
<td>cryptogenic lt-sided TLE</td>
<td>45</td>
<td>no improvement in seizure control, intolerable side effects (feeling of pressure &amp; problems when swallowing)</td>
<td>paresis of recurrent laryngeal nerve, compensated by rt vocal cord, no clinically relevant disturbances</td>
</tr>
<tr>
<td>8</td>
<td>55, F</td>
<td>idiopathic generalized epilepsy</td>
<td>25</td>
<td>no improvement in seizure control</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>13, M</td>
<td>cryptogenic lt-sided frontal lobe epilepsy</td>
<td>40</td>
<td>no improvement in seizure control, stimulation provoked seizures according to parents</td>
<td></td>
</tr>
</tbody>
</table>

* MCA = middle cerebral artery; TLE = temporal lobe epilepsy.
including 3 children. Scarring did not correlate with the time between implantation and removal. In 2 patients the device was removed during the same anesthesia session used for the resective epilepsy procedure. In 1 of these 2 patients, an ipsilateral asymptomatic aneurysm of the middle cerebral artery was clipped during the same session. No proximal or distal identification of the nerve was attempted. All nerves remained morphologically intact. In none of the patients was a new device inserted concomitantly. Mean operative time was about 90 minutes.

The first patient in the series complained about increased postoperative hoarseness due to unilateral vocal cord paresis proven by laryngoscopy. The symptoms subsided completely after 3 months. In a second patient, a clinically silent vocal cord paresis was detected by laryngoscopic examination. Cardiac problems during removal were not observed. No differences between the 6 adults and the 3 children in the series were observed with regard to technical procedure or complications.

**Discussion**

Vagus nerve stimulation is increasingly used as a palliative treatment option in refractory epilepsy. As the number of patients with vagal nerve stimulators increases, the need to occasionally revise or remove these devices will also increase. We here report the successful removal of the entire NCP system in 6 adults and 3 children and describe our technique.

Despite more than 30,000 patients worldwide having an NCP implant, the number of published reports of complete NCP removal remains low. To our knowledge, complete removal of electrodes (with or without removal of the generator) has been described in 26 patients in the English-language literature. Uthmann et al. first reported successful revision operations with unwinding of damaged electrodes from the nerve in 3 patients. Espinosa et al. reported the successful removal of the entire NCP in 7 of 10 patients. In 4 patients new electrodes were placed cephalad to the old electrodes. MacDonald and Couldwell reported removal of the lead in 7 patients in a 2-center study. In 4 patients, the lead was replaced cephalad. Smyth et al. mentioned 2 patients who required revision because of electrode fracture in a large series of 74 children. They also reported that the device was removed in 7 patients without giving further technical details. Rychlicki and colleagues described 2 of 36 children requiring lead and generator replacement due to electrode fracture. Vassilyady and Strawburg reported the case of a boy who required removal of the entire system because of infection. In comments on the paper by MacDonald and Couldwell, Kemeny acknowledged the complete removal of 3 electrodes and Guenot the removal of 1 electrode.

In our series of 9 patients, extending previous skin scars proved unnecessary. Extensive deep dissection also did not seem necessary when the goal was to remove and not replace the lead. Although identification of a nerve first in unscarred tissue and then within the scar is a time-honored principle of peripheral nerve surgery, this strategy may expose the vagus nerve and the neighboring anatomical structures to unnecessary risk. In the first patients in the series, the strain-relief loops of the lead were followed within the scarred carotid sheath in a cranial and caudal direction to identify the vagus nerve. This was also recommended by other authors. After observing vocal cord paresis in 2 patients, we changed the dissection strategy, adopting a direct approach with the nerve encircled by the coils as the target and performing minimal circumferential dissection of the nerve, which was still protected by the coils. We never had any difficulty identifying the nerve. During circumferential dissection the coils protected the nerve and, by dissecting close to their surface, damage to the surrounding neurovascular structures was avoided.

Various techniques have been described for removing the helical coils. Espinosa and coworkers freed the nerve from scar tissue first, then inserted tenotomy scissors beneath the electrodes and nerve and mobilized the coils by prying open the scissor blades. MacDonald and Couldwell described a technique that consisted of cutting the helix loops along the axis of the nerve using microsurgical straight scissors, followed by dissection of the sili-{fig 1. Microsurgical steps of VNS removal (photographs artistically enhanced for clarity). a: A vessel loop is slung around the vagus nerve (indicated by x) at the level of the first identified coil. b: Gentle traction on the vessel loop provides information on the course of the vagus nerve, still enclosed within the scar. The caudal strain-relief loop of the lead (interrupted line) is not dissected free. c: By dissecting in either a proximal or distal direction, all coils and the 2 leads that run from the anchoring coil to the generator are identified (outline of the most proximal and the most distal coil loop enhanced for clarity; other coils identified by stars). d: Cutting the cables (short arrow) entering the anchoring coil. Note that no tension is applied to the nerve, identified by the vessel loop. The nerve is stabilized by holding the connector between cable and distal coil (long arrow). e: The loops of the anchoring coil are extracted from their connective tissue pockets with the help of nontoothed forceps (forceps not shown, direction of traction shown by the large arrow). The sutures emanating from the tip of the coils (arrowhead) are cut (short arrow) and left behind if they prevent complete extraction of the coils. f: The vagus nerve after removal of the coils. Excess scar tissue is not trimmed off the nerve when reimplantation is not intended.}
cone fragments and lifting the platinum contacts from the nerve. Piecemeal removal of the helical coils has also been suggested by other authors.\textsuperscript{5,7,13} In our experience, neither insertion of a scissor blade between scarred perineurium and coils nor piecemeal removal has been necessary. Much as a shunt catheter can be easily removed once the connective tissue membrane covering the implant surface has been opened, so too can the coils be extracted from their scarred pocket once freed from connective tissue near their insertion point.

Removal of the entire device is not without risks. Vocal cord paralysis was noted in 2 adult patients early in this series. Only in 1 patient did this damage manifest itself in the form of new postoperative hoarseness. The patient recovered completely within a few weeks. In the second patient, vocal cord paresis was compensated by the contralateral vocal cord and was detected during routine postoperative laryngoscopy. Since the introduction of the above-described changes in dissection strategy, no further problems regarding the recurrent laryngeal nerve have been observed.

Vocal cord paresis may remain undetected unless laryngoscopy is performed in all patients. Damage from surgical manipulation of nerve fibers (neurapraxia) of the recurrent laryngeal nerve running within the vagus nerve must be suspected as the main cause of this complication. Traction on the nerve was suspected by Kalkanis et al.\textsuperscript{6} in a patient with vocal cord paresis who manipulated his generator in the subcutaneous pocket. Vassilyady and Strawsburg\textsuperscript{19} reported a temporary left-sided vocal cord paralysis occurring 3 weeks after explantation of the whole device. Their patient, vocal cord paresis was noted in 2 adult patients early in this series. Only in 1 patient did this damage manifest itself in the form of new postoperative hoarseness. The patient recovered completely within a few weeks. In the second patient, vocal cord paresis was compensated by the contralateral vocal cord and was detected during routine postoperative laryngoscopy. Since the introduction of the above-described changes in dissection strategy, no further problems regarding the recurrent laryngeal nerve have been observed.

Because of the risks associated with complete removal of the device, available evidence indicates that only a minority of patients may be candidates for this procedure. Pros and cons must be discussed carefully with all persons involved. One also should be prepared to abandon the removal of the wires intraoperatively when it appears that none of the techniques described are going to work instead of irreversibly damaging the nerve.

In conclusion, as long as we are unable to preoperatively identify those patients who will benefit from implantation of a vagus nerve stimulator,\textsuperscript{5} full reversibility of the procedure is highly desirable from the perspective of the patient and the referring physician. In our experience, complete removal of the system is feasible in adult and pediatric patients without undue morbidity when using the described microneurosurgical techniques.

**Disclosure**

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

**References**


