Seizure xxx (2013) xxx–xxx

Contents lists available at SciVerse ScienceDirect

Seizure

journal homepage: www.elsevier.com/locate/yseiz

Complications of vagal nerve stimulation for drug-resistant epilepsy A single center longitudinal study of 143 patients

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ARTICLE INFO

Article history:
Received 20 February 2013
Received in revised form 19 June 2013
Accepted 25 June 2013

Keywords:
Vagal nerve stimulation
Complication
Epilepsy

ABSTRACT

Purpose: To longitudinally study surgical and hardware complications to vagal nerve stimulation (VNS) treatment in patients with drug-resistant epilepsy.
Methods: In a longitudinal retrospective study, we analyzed surgical and hardware complications in 143 patients (81 men and 62 women) who between 1994 and 2010 underwent implantation of a VNS-device for drug-resistant epilepsy. The mean follow-up time was 62 ± 46 months and the total number of patient years 738.
Results: 251 procedures were performed on 143 patients. 16.8% of the patients were afflicted by complications related to surgery and 16.8% suffered from hardware malfunctions. Surgical complications were: superficial infection in 3.5%, deep infection needing explantation in 3.5%, vocal cord palsy in 5.6%, which persisted in at least 0.7% for over one year, and other complications in 5.6%. Hardware-related complications were: lead fracture in 11.9% of patients, disconnection in 2.8%, spontaneous turn-off in 1.4% and stimulator malfunction in 1.4%. We noted a tendency to different survival times between the two most commonly used lead models as well as a tendency to increased infection rate with increasing number of stimulator replacements.
Conclusion: In this series we report on surgical and hardware complications from our 16 years of experience with VNS treatment. Infection following insertion of the VNS device and vocal cord palsy due to damage to the vagus nerve are the most serious complications related to the surgery. Avoiding unnecessary reoperations in order to reduce the appearances of these complications are of great importance. It is therefore essential to minimize technical malfunctions that will lead to additional surgery. Further studies are needed to evaluate the possible superiority of the modified leads.
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1. Introduction

The prevalence of epilepsy is 0.5–1%.[1] After adequate antiepileptic drug-therapy, approximately one third still suffer from seizures.[2] Resective surgery, where the cortical location of the onset of the seizures is resected, is one approach to decrease seizure frequency in patients with partial epilepsy. In order for this to be applied, the focus of the onset of the seizures needs to be identified, dispensable and accessible for surgery. In cases when this has proven not possible vagal nerve stimulation (VNS) has emerged as a therapeutic option. The first VNS implantation for the treatment of drug-resistant epilepsy not suitable for resective surgery was conducted in 1988.[3] Over the years, patients with primary generalized epilepsy which has been proven to be drug-resistant have also become candidates for VNS treatment. The positive effect of VNS in reducing seizure frequency has been shown extensively.[4,5] Complications due to surgery and hardware malfunctions have not been evaluated as thoroughly. Vocal cord palsy, transient bradycardia and infection are some of the complications associated with the surgical procedure that have been reported.[6–8] Hardware malfunctions such as lead fracture, disconnection between lead and stimulator, and stimulator malfunction have previously been observed.[6,9,10] VNS has been an integrated tool in the management of drug-resistant epilepsy in the epilepsy surgery program at Umeå University Hospital since 1994. The aim of this study is to describe surgical and hardware complications related both to the implantation and to the treatment course in patients with drug-resistant epilepsy receiving VNS treatment at our department since 1994.

2. Methods

In a longitudinal retrospective study, we identified the patients who between 1994 and 31 December, 2010, underwent implantation of a VNS device (Cyberonics Inc., Houston, TX, USA)

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http://dx.doi.org/10.1016/j.seizure.2013.06.011

Please cite this article in press as: Kahlow H, Olivecrona M. Complications of vagal nerve stimulation for, drug-resistant epilepsy. *Seizure: Eur J Epilepsy* (2013), http://dx.doi.org/10.1016/j.seizure.2013.06.011

for drug-resistant epilepsy at our department and analyzed the occurrence of surgical and hardware complications. The definition of surgical complication used is that of Sokol and Wilson: "A surgical complication is any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped".[11] Infection is a condition that led to an active treatment with antibiotics. Hoarseness that persisted 15 days post surgery is considered vocal cord palsy. Hardware complication is defined as an incident that meant that the device did not work properly.

2.1. Patients

All patients were worked up within the multidisciplinary epilepsy surgery program at the Departments of Neurology, Pediatrics, Neurophysiology, Neuroradiology and Neurosurgery at the Umeå University Hospital, Sweden. They were all diagnosed with drug-resistant epilepsy, either not suitable for resective surgery or failure of the same.

2.2. Surgical procedure

Antibiotics are administered before skin incision. We used cefuroxime (30 mg/kg or 3 g) until the end of 2010 when we changed to cloxacillin (2 g). We use three different approaches, for the placement of the stimulator, depending on the patient. The most commonly used is a transverse incision approximately 3 cm below the collarbone. An incision just behind the anterior axillary line can be used to hide the scar. In one patient, we used a cranio-caudal incision along the course of the bra strap. For the implantation of the electrodes we used, in the very first patients, an incision along the sternocleidomastoid muscle. We soon changed to a partial collar incision. With blunt and sharp dissection the carotid sheath is entered. The nerve is identified and prepared for approximately 4–5 cm. A vessel loop is run beneath the nerve and used to hold the nerve while the electrode and anchor helices are being applied around the nerve. The electrode is secured with one anchor to the fascia of the medial muscles. The stimulator is tested and connected to the electrode followed by another test to verify that the system is functioning properly. The stimulator is usually not anchored to the fascia of the pectoral muscle. Stimulator replacements are done under local or general anesthesia and with prophylactic antibiotics. Leads are replaced under general anesthesia and with antibiotics.

2.3. Follow up

If no complications occurred the patient revisited the hospital two weeks post surgery for initiation of the stimulation. This was accomplished in three days by either the senior author or by a single epilepsy nurse. The adjustment to our standard parameter setting of 1.25 mA was reached in a great majority of the patients. Patients were evaluated at our clinic for outcome and the occurrence of complications every three months the first year, followed by yearly assessments. Medical charts from local hospitals were collected from the time in which the patients received treatment.

2.4. Statistics

Continuous variables are reported as means ± standard deviations. The median and range are also presented. Chi-squared is used for the comparison of proportions. A Kaplan–Meier plot was used to illustrate and analyze difference in lead survival time. A p-value of <0.05 is considered to be statistically significant. The statistical software used is JMP 9.0.0 (SAS Institute Inc.)

2.5. Complication frequency

Complication frequency is reported as percentage in relation to number of relevant procedures (npr) as well as the proportion of patients that suffered from complication (npts). Calculation basis npr or npts is shown after the percentage figure. The relevant procedures chosen for the different complications are presented in Table 3.

2.6. Ethics

The study was approved by the Regional Ethical Review Board Umea, dnr 2011-214-31.

3. Results

We identified 143 patients who had had a VNS device implanted between 1994 and 2010. Previous resective epilepsy surgery had been done in 27 of these patients. Patient characteristics are shown in Table 1.

The median follow-up time was 55 months (1–193) and the mean follow-up time was 62 ± 46 months. This corresponds to a total treatment time of 738 years. 110 patients were still receiving stimulation on 31 December 2010. Table 2 shows a summary of the 251 surgical procedures performed. The mean time to stimulator replacement was 58 ± 20.2 months and the median time 62 months (0.25–98). For the stimulators that were replaced before end of power the mean time to replacement was 66 ± 9.8 months and for the stimulators that were replaced because of end of power 62 ± 13.5 months. We used a skin incision below the collarbone in the midclavicular line in 79 patients and an incision in the anterior axillary line in 63. The system was implanted on the left side in all cases but two. Previous lymphoma on the left side of the neck was the reason in one patient. The other presumably had extensive tissue adhesions around the left vagus nerve as a result of infection during earlier left VNS treatment. We noted 28 surgical (11.2% npr) and 25 hardware (10.4% npr) complications in 40 patients (28% npts). 24 patients (16.8% npts) were afflicted by complications related to surgery and 24 patients (16.8% npts) suffered from hardware malfunctions. The total number of individual patients who experienced any complication leading to a surgical intervention was 25 (17.5% npts).

Table 3 summarizes all the complications.

Table 1
Patient characteristics.[a]

	Mean age, SD, at implantation, years	Median age (range) at implantation, years	PG	P	Unclear classification of seizures	Total
Men	25.4 ± 15.4	22.9 (2.2–64.2)	25	56	0	81
Women	30.7 ± 15.6	31.7 (4.1–72.7)	15	46	1	62
Adults	35.8 ± 11.9	34 (18.1–72.7)	30	67	1	98
Children	10.1 ± 4.3	9.4 (2.2–17.8)	10	35	0	45
Total	27.7 ± 15.7	27.8 (2.2–72.7)	40	102	1	143

[a] P, partial onset seizures; PG, primary generalized seizures.

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