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Clinical Article

Management of hardware infections following deep brain stimulation

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Summary

Objective. To report our experience on hardware-related infections following deep brain stimulation (DBS).

Methods. The present article presents the retrospective clinical notes review of gained in a two-centre, single-surgeon study experience of 108 consecutive DBS cases between 1996 and 2002. In all patients the minimum follow-up was six months. One hundred and eight patients received an intracerebral electrode implantation and 106 underwent internalization.

Results. In total 178 electrodes were implanted with a mean follow-up of 42.6 months and a cumulative follow-up of 367.7 patient-years. Four patients (3.8%) developed an infection related to the DBS-hardware and all were initially treated with antibiotics. Two patients eventually required additional surgical treatment.

Conclusion. Infections due to DBS-hardware can result in considerable levels of morbidity. In certain cases antibiotic therapy may be adequate. In others, surgical intervention to externalise the electrodes may be necessary. In our experience, there was never a need to remove the electrodes.

Keywords: Deep brain stimulation (DBS); high frequency stimulation (HFS); infection; implants; complications; antibiotics.

Abbreviations

DBS Deep brain stimulation; *HFS* high frequency stimulation; *STN* subthalamic nucleus; *GPi* globus pallidus internus; *Vpm* nucleus ventroposteromedius; *Vpl* nucleus ventroposterolateralis; *Vim* nucleus ventralis intermedius; *Cm* centromedian nucleus; *Spv* substantia periventricularis; *Voi* nucleus ventro-oralis internus; *TS* Tourette syndrome; *PD* Parkinson disease; *ET* Essential tremor; *COPD* chronic obstructive pulmonary disease; *ICH* intracerebral haemorrhage; *MRI* magnetic resonance imaging; *CT* computerized tomography.

Introduction

One of the most distressing hardware-related complications of deep brain stimulation (DBS) is infection of the device. The incidence of infection related to DBS reported in the literature ranges from 1.5 to 22.2% [1–11]. This considerable variation is most probably due to differences in risk factors such as the patient's general medical condition, the surgical method, the duration of the surgery and the use of antibiotics. Infections of DBS hardware cause serious morbidity leading to prolonged hospitalization, long-term use of antibiotics or to the removal of the DBS. There is currently no consensus about the best treatment. Especially the question whether infected implants should always be removed requires special attention because of the not inconsiderable consequences for the patient [12, 13].

Although there have been various reports on the complications of DBS [1, 2, 5–8, 14], little is known about the management of infections. The present study describes our experience with the treatment of DBS device-related infections in four cases out of a consecutive series of 108 patients.

Methods

The present article is the retrospective chart review of experience with DBS in a two-center (University Hospital Maastricht and University

Table 1. *Patient characteristics, number of electrodes and indications for DBS. The values are expressed as means and standard deviations (SD)*

Indication*	Type	N (patients)	N (electrode)	Age at surgery (yr)	Follow-up (mos)	M/F ratio
PD	unilateral pallidal stimulation	26	26	59.0 (8.9)	54.7 (20.1)	20/6
PD	subthalamic stimulation	64	125	60.4 (8.2)	39.0 (20.2)	45/19
ET	thalamus	10	18	66.1 (6.0)	24.3 (22.4)	8/2
Other**	thalamus	6	9	45.3 (4.1)	60.0 (25.1)	6/0
Total		106	178	59.7 (8.9)	42.6 (22.5)	79/27

* *PD* Parkinson disease, *ET* Essential tremor.
** Includes pain (N = 5), Tourette syndrome (N = 2) and Huntington disease (N = 1).

Hospital Ghent), single-surgeon (VVV) study. Between January 1996 and June 2002, 108 consecutive patients underwent DBS surgery for movement disorders and neuropathic pain. From January 1996 until December 1998, 70 patients were operated on in Ghent and between November 1999 and June 2002, 38 patients underwent surgery in Maastricht. The procedures were carried out in stages. In the first session, intracerebral quadripolar electrodes were implanted unilaterally or bilaterally. During the second session, usually one week later, an infraclavicular or abdominal pulsegenerator was placed.

Two patients (2 electrodes) without pain relief during trial stimulation underwent removal of the electrodes. In total 106 patients (178 electrodes) underwent internalization and implantation of the pulsegenerator and these patients were included in the study (Table 1).

Data collection and follow-up

Medical records of all patients were reviewed and demographic data were collected including age, sex, diagnosis and the presence of comorbidity. Details of the surgical sessions were documented, including the length of the procedure, the use of antibiotics, and the time to internalization. All post-operative infections related to DBS hardware were recorded. Data were collected on the infection including the type, localisation, chemistry, microbiology and treatment. In all patients a minimum follow-up of 6 months was obtained with a range of 6 to 83 months.

Surgical procedure

In all but two Tourette Syndrome (TS) patients, the entire stereotactic procedure was performed under local anaesthesia with 1% lidocaine (with epinephrine 1:100 000). Both patients with TS underwent surgery with sedation (one patient with propofol and the other patient with remiphentanyl/lorazepam). The Leksell G stereotactic frame was used for patients operated on at the University Hospital of Ghent, and stereotactic co-ordinates were determined on CT-images. For the patients operated on at the University Hospital Maastricht the CRW-stereotactic frame was used, and stereotactic co-ordinates were determined on fused CT/MRI-images. The target was defined in relation to the anterior and posterior commissures. The angles of approach were chosen in order to avoid the lateral ventricle. In 38 patients semi-micro-electrode recordings were performed. A monopolar test electrode with a naked tip of 2 mm (Radionics, Model 3101-2) was introduced for macro-stimulation 6 mm above target and test stimulation was performed in all awake patients. The stimulus intensity was increased to obtain the desired response or note side-effects. Test stimulations were continued in 2 mm steps until 4 mm beneath target. When a good effect was found in the absence of side-effects, the test electrode was replaced by the final quadripolar electrode (Medtronic Models 3387; n = 53, and 3389; n = 125), which was fixed in the burr hole with acrylic cement (Antibiotic Simplex; Howmedica, Ireland), and connected to an externalized extension cable. In the sedated TS patients, sedation was tapered so that the patients were able to communicate, and side-effects could be examined. In all patients, fluoroscopy was used to evaluate the position of the quadripolar electrode, before its fixation, with respect to the position of the test electrode. In patients with bilateral implantation (n = 72) the same procedure was performed on the contralateral side.

After this first operation, the patients were tested with externalised electrodes, connected to a screener (Medtronic Model 3625). In all patients, a postoperative MRI-scan was performed to evaluate the position of the electrodes and to detect asymptomatic bleeding. Once agreement was reached between the neurologist, neurosurgeon, nursing staff and the patient about the beneficial effects of stimulation, a second operation was performed after one week to implant the pulsegenerator infraclavicularly or abdominally (Medtronic Models 7424/Itrel II; n = 21, 7425/Itrell III; n = 99, 7428/Kinetra; n = 29). The duration of the trial stimulation before internalization for patients with pain (n = 5) was 4 weeks and with TS (n = 2) two weeks.

Antibiotic prophylaxis

Prophylactic antibiotics were given to patients in both sessions. Patients who underwent surgery in Ghent received 1.0/0.2 gram amoxicillin/clavulanic acid pre-operatively and infusion of the same dose was repeated every 6 hours for a period of 24 hours (in total 4.8 grams). Patients operated on in Maastricht received 2 gram of cefazolin one hour pre-operatively, and subsequently 1 gram every 4 hours (2×) followed by 1 gram every 6 hours (2×). In total 6 grams of cefazolin was given throughout a period of 24 hours. Patients with penicillin or cephalosporin allergies received vancomycin. The present antibiotic prophylaxis was in accordance with the local hospital infection prevention programme. Both antibiotics are broad-spectrum and largely effective against sensitive Gram-positive and Gram-negative bacteria. In addition, the cement which was used for fixation of the intracerebral electrode (Antibiotic Simplex; Howmedica, Ireland) contains erythromycin and colistin.

Statistical analysis

Data that approximated normal distribution were analysed using the two tailed two-sample *t* test. Analysis of non-parametric data was performed using Friedman's test, for *k*-related comparisons, and Wilcoxon signed rank test, for two related comparisons. The Kaplan-Meier survival method was used to determine infection-free survival. The level of significance was accepted at $p < 0.05$.

Results

In total 178 electrodes were implanted over a period of 6 years in 106 patients (79 men, 27 women) (Table 1). The mean age of the total population at the time of surgery was 59.7 years with a range of 40 to 82 years. The diagnoses included Parkinson disease (PD) (n = 90), Essential tremor (ET) (n = 10), and other disorders (Tourette Syndrome; n = 2, de-afferentiation pain; n = 5, and Huntington disease; n = 1). The targeted nuclei were the subthalamic nucleus (STN), and globus pallidus internus (GPi) for PD, thalamus (nucleus venteroposteromedius (Vpm)/nucleus ventroposterolateralis (Vpl) for pain, nucleus ventralis intermedius (Vim) for ET, and centromedian nucleus (CM)/substantia periventricularis (Spv)/ventro-oralis internus (Voi) for TS) [15]. Six patients had undergone previous ablative stereotactic procedures.

In 34 patients an electrode was implanted unilaterally in the GPi (n = 26), STN (n = 3) and thalamus (n = 5) and 72 patients underwent bilateral surgery at the level of the STN (n = 61) and thalamus (n = 11). The duration of the trial period lasted in all cases one week except for 7 patients (2 weeks for TS and 4 weeks for pain). All patients received antibiotics pre- and postoperatively (cefazolin; n = 37, amoxicillin/clavulonic acid; n = 67, vancomycin; n = 2) according to the protocol.

The follow-up duration of the 106 patients ranged from 6 to 83 months with a mean of 42.6 ± 22.5 months. In total six PD patients died during follow-up. Four PD patients (1 with bilateral STN and 3 with unilateral GPi stimulation) died due to unrelated carcinoma of the liver pulmonary embolism following hip surgery, acute myocardial infarction and COPD. One patient (bilateral STN) had a subcortical haemorrhage with a discrete hemiparesis post-operatively and died because of septic cholecystitis during hospitalization. One with bilateral STN stimulation committed suicide. Fourteen patients who had previously undergone unilateral GPi stimulation with unsatisfactory results long-term [16] underwent bilateral STN stimulation in another centre. Eighty-six patients continued to use their DBS. The cumulative follow-up period was 367.7 patient-years in this group studied.

Infections

Four PD patients (3 men, 1 woman), two operated on in Ghent (patients 1 and 2) and two in Maastricht (patients 3 and 4), developed infections related to the DBS hardware (Table 2). No risk factors for infection could be determined involving these patients. They were included in the selection for unilateral pallidal stimulation (patient 1) and bilateral stimulation of the STN (patients 2, 3, and 4) because of severe motor fluctuations which present in advanced PD. Their medication included only levo-dopa and dopamine-agonists. The duration of the first sessions from the first skin incision to skin closure ranged from 5 hours and 48 min to 8 hours and 10 min. The patients underwent internalization and implantation of the pulsegenerator (Medtronic Models 7424/Itrel II; n = 1; for patient 1, 7425/Itrell III; n = 4 for patient 2 and 4, 7428/Kinetra; n = 1 for patient 3) in the left hypogastric region (patient 3) or infraclavicularly (patients 1, 2 and 4). The duration of the second sessions ranged from 50 min to 1 hour 25 min.

The first patient presented with localized oedema and erythema around the infraclavicular (left side) implanted pulsegenerator, 92 days following internalization. The body temperature was normal and infection parameters of the blood (C-reactive protein (CRP), sedimentation (BSE) and white blood cell count (WBC) were slightly increased. The patient showed no signs of septicaemia or meningismus. After hospitalization, the collection along the hardware was punctured and *Staph. aureus* was isolated. The patient received antibiotic therapy (flucloxacillin) for 10 days intravenously (inpatient stay) and one week orally (outpatient). The infection totally resolved in this patient without any surgical intervention and he has been followed-up for 30 months after the infection.

Patient 2 presented, 29 days postoperatively, with wound dehiscence of the right infraclavicular incision,

Table 2. *Characteristics of the patients who developed infections of the DBS-hardware and received treatment*

Patient	Age at surgery	Sex	Disease	Surgery	Infection (days after surgery)	Treatment
1	54	m	PD	Unil. Gpi	92	antibiotic
2	47	m	PD	Bilat. STN	29	antibiotic/surgery*
3	64	m	PD	Bilat. STN	37	antibiotic
4	50	f	PD	Bilat. STN	69	antibiotic/surgery**

* Surgery involved externalisation of the electrode.
** Surgery involved the removal of the pulsegenerator and extension cables, followed by graciloplasty.

erythema and pus. His general practitioner had prescribed oral antibiotic therapy (flucloxacillin) for two weeks but this was unsuccessful. Microbiological culture taken of the wound demonstrated *Staph. aureus.* The other wounds showed no signs of inflammation. The patient had a subfebrile body temperature without signs of septicaemia or meningismus and blood examination revealed increased infection parameters. The patient underwent removal of the right extension cable/pulsegenerator and debridement of the wound under general anaesthesia. Post-operatively, flucloxacillin was given intraveneously. On subsequent days the wounds showed adequate healing. The patient was discharged from the hospital under instruction to take oral antibiotics for another 14 days and to attend weekly consultations. Two months later a new extension cable and pulsegenerator were implanted on the right side. The infection resolved completely and he has been followed-up for 18 months after the infection.

Thirty-seven days following internalization, patient 3 presented with a localized oedema and erythema around the abdominal implant and the cables at the level of the neck on the left side. His body temperature was subfebrile and blood examination revealed increased CRP, ESR and WBC. The patient was hospitalized and *Staph. aureus* was isolated from the fluid obtained by puncture along the hardware. After treatment for 14 days intravenously (as an in-patient stay) and 14 days orally (outpatient) with flucloxacillin and rifampicin, the infection totally resolved making surgical intervention unnecessary. The patient has been followed-up for 13 months after the infection.

Patient 4 presented on the 69th day postoperatively with a 2 mm- wound dehiscence and serous exudate on the left side of the head without erythema, oedema or pus. The microbiological culture taken from the wound was negative. Subsequently, after debridement and treatment with local antibiotics (gentamycin) the wound was closed and the patient was discharged. Four weeks later she returned because of a purulent discharge from the same wound and another wound dehiscence in the neck on the right side. Blood examination revealed increased infection parameters. The patient had a subfebrile body temperature without septicaemia or meningismus. *Staph. aureus* was isolated and the patient was treated (inpatient) for 14 days intravenously with antibiotics (flucloxacillin/rifampicin). After 14 days of intravenous antibiotic therapy, there was still obvious inflammation as well as considerable purulent discharge from the wounds. She underwent removal of the right extension cable/pulsegenerator and debridement of the wounds. A drain was left in the neck wound on the right side and gentamycin beads [17] were placed in the left wound on the cranium. Post-operatively, flucloxacillin (i.v.) was administered and on the sixth day the gentamycin beads and the drain were removed. The wounds appeared to heal adequately. The patient was discharged from the hospital on oral antibiotics (flucloxacillin) for another

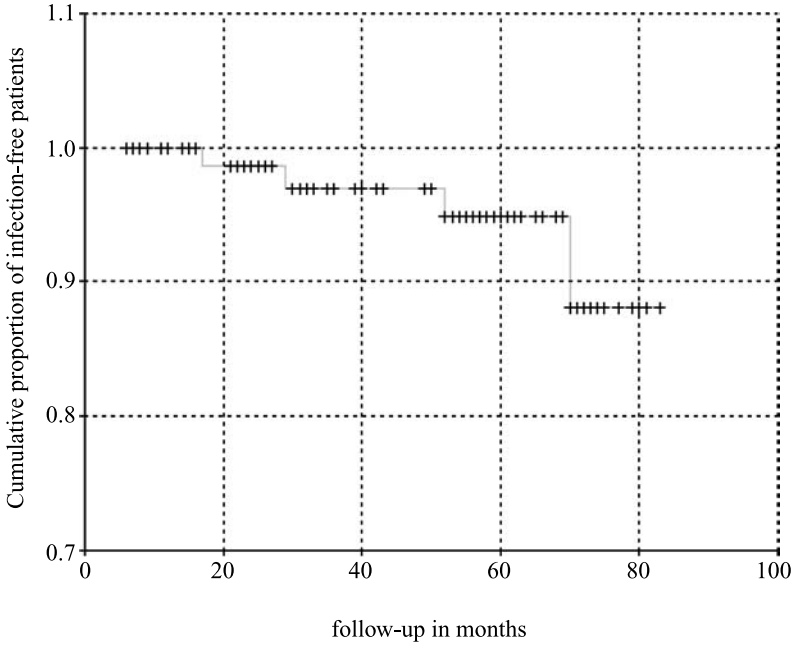

Fig. 1. Infection-free survival plot (Kaplan-Meier) of 106 DBS patients. Each ¬ (step) demonstrates the patient with hardware-related infection. Patients with infections are displayed in relation to the cumulative proportion of infection-free patients during follow-up

14 days. Every week the wounds were inspected at the consultation. During the consultation two months later an erosion and dehiscence of the left cranial wound was seen. The skin had become very thin resulting in impaired wound healing with bone exposure. Subsequently, a two stage procedure was performed. In the first stage a surgical debridement of the wound was performed, followed by microsurgical free-tissue transfer in order to stimulate vascularization and consequently enhance the local concentrations of i.v. administered antibiotics. After graciloplasty, the vessels of the m. gracilis were anastomosed end to end to the a. and v. temporalis superficialis. The wound erosion resolved and healing proceeded normally. One month later, a new extension cable and pulsegenerator were implanted on the right side. The infection totally resolved. After 6 months the expected muscular hypotrophy of the graciloplasty resulted in a cosmetically normal appearance. The patient has been followed-up for 19 months.

Figure 1 demonstrates the infection-free survival plot of 106 patients treated with DBS. There was no significant association ($p > 0.05$) of infections with unilateral or bilateral surgery or duration of surgery.

Discussion

DBS has almost completely replaced ablative surgery for pain and movement disorders. This surgical intervention is noncurative in nature and involves ''blind'' targeting of brain structures. The beneficial effects of DBS in selected cases of pain and movement disorders are clear and its advantages compared to ablative surgery are well known. On the other hand, DBS is accompanied by a new set of side effects and complications, which may occur any time from surgery to several years postoperatively. Recently, several groups have reported on their experience with DBS and associated complications [1, 2, 5–8, 14]. When attention is paid to the infection rates in these reports, a considerable variation can be noticed. Benabid *et al.* [10] reported an infection rate of 1.5% (10 patients in a series of 300) whereas Obeso *et al.* [9] described a rate of 22.2% (8 patients in a series of 36) (Table 3). All these studies focus mainly on the incidence without discussing the treatment. As the main objective of DBS is to improve the quality of life, it is essential for caregivers to be aware of the management of related complications.

Risk factors

For (neuro)surgical procedures in general, it is well known that smoking, excessive alcohol consumption, systemic illness and the use of certain drugs as well as an inadequate scalp thickness may increase the risk of infection [18–21]. A study of 464 surgical patients showed the risk of an infection increased with the time spent in the operating theatre [22]. Also the number of surgeons involved seems to have a negative influence factor [23].

When reports specifically dealing with DBS-related infections were considered, no significant association was found between the above mentioned risk factors and infections. This might be due to the small sample size. In the present study, the infection rate was 3.8%. There was no significant association between risk factors, nor with unilateral or bilateral surgery or duration of surgery. Patients who had undergone previous ablative surgery were not at greater risk of infection.

Table 3. *Overview of infection rates in publications on deep brain stimulation*

Research group*	Publication year	Number of stimulated patients	Journal	Infection rate**
Benabid *et al.* [3]	1998	197	Movement Disorders	1.5%
Kumar *et al.* [10]	1997	68	Neurosurgery	5.9%
Levy *et al.* [13]	1987	114	Neurosurgery	16.3%
Limousin *et al.* [14]	1999	110	J Neurology Neurosurgery Psychiatry	1.8%
Lyons *et al.* [15]	2001	206	Neurology	2.5%
Obeso *et al.* [18]	1998	36	Movement Disorders	22.2%
Oh *et al.* [19]	2002	79	Neurosurgery	8.8%
Pahwa *et al.* [20]	2001	50	Neurology	6.9%
Pollak *et al.* [21]	2002	300	Movement Disorders	3.3%
Present study	2003	106		3.8%

* The references are listed in the bibliography.

** Infection rates refer to the percentage of patients who developed DBS hardware-related infection within the study group.

Treatment

Most of the reports on the management of infected implants, in common neurosurgical practice, deal with CSF shunt infections. In general, these authors conclude that the shunt should be removed. An infected CSF shunt is considered to be a medical emergency because of its intracerebral location. Hence, the question arises is an infected DBS-device just as much an indication for urgent treatment because of its intracerebrally located electrodes.

With the present study, we have shown that antibiotic therapy can be an effective treatment for localized infections related to DBS hardware. If conservative treatment failed, debridement and surgical removal of the affected lead(s) and pulsegenerator followed by antibiotic therapy was sufficient to treat the infection. In all cases, the electrodes and in case of bilateral pulsegenerators (Itrell 2 or 3), the contralateral lead and pulsegenerator remained in situ and did not cause subsequent morbidity. We believe that antibiotics-containing cement which is used to fix the electrode can form an active barrier against the spread of bacteria [24]. These data suggest that in the case of localized extracranial infections with a stable physical condition, a) treatment with antibiotics should be started immediately, b) if conservative treatment fails, debridement of the wounds should follow and infected hardware should be removed with, whenever possible, preservation of the intracerebral electrodes.

Conclusion

There is a considerable variation in published DBS-related infection rates. The sample sizes are in general too small to detect significant associations with risk factors, and no guidelines are available for the treatment. The removal of the intracerebral electrodes in a successful DBS means a serious handicap in the further treatment of the underlying disease. We believe that our results may encourage physicians/surgeons to consider conservative treatment as the treatment of first choice in the case of extracranial infections. When this fails, removal of the infected material is indicated. Removing the electrodes is, however, not absolutely necessary.

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Comments

This article is a retrospective case note review of 108 deep brain stimulator implantation cases with special attention to the infections and their management. As they currently state, the incidence of infection in the literature ranges from 1.5 to 22% and there is no consensus about the treatment when such an event occurs. The authors observed 4 infections in their series. They give a very detailed history of these cases.

As the use of implanted neurostimulators increases worldwide infection, the common concern with these operations, is going to be a major factor in morbidity and cost.

In view of the small number of infected cases in this study no risk factors were identified. Nevertheless it is of interest that previous ablative surgery was not a significant factor. The management strategy put forward by the authors, namely prophylactic antibiotics at implantation and in infected cases initial antibiotic therapy followed by removal of only the infected component of the system, is sensible and appears to work.

A. A. Kemeny

The paper by Temel *et al*. entitled ''Management of hardware infections following deep brain stimulation'' deals with the important problem of the specific complication related to the implantation of hardware in functional neurosurgery, and particularly in deep brain stimulation. This complication, which does not appear in the ablative surgery, is one of the points of debate about the current acceptability of this method as a reference method. The authors honestly report their 4 cases of infections, involving hardware in a series of 108 patients. They tend to conclude that although those complications are bothersome, they can be dealt in 2 cases out of 4 without removing the hardware, and in two cases by removing part of the hardware but not the electrodes. They provide an extensive description of their cases, along with a description of their methods.

This paper is interesing to provide additional data in the current debate about the pros and cons of DBS.

A. Benabid

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