PAPER

Deep-brain stimulation: long-term analysis of complications caused by hardware and surgery—experiences from a single centre

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Objective: To determine the surgery-related and hardware-related complications of deep-brain stimulation (DBS) at a single centre.
Methods: 262 consecutive patients (472 electrodes) operated for DBS in our department from February 1996 to March 2003 were retrospectively analysed to document acute adverse events (30 days postoperatively). The data of 180 of these patients were additionally revised to assess long-term complications (352 electrodes, mean follow-up 36.3 (SD 20.8) months).
Results: The frequency of minor intraoperative complications was 4.2% (11/262 patients). Transient (0.2%) or permanent (0.4%) neurological deficits, and in one case asymptomatic intracranial haemorrhage (0.2%), were registered as acute severe adverse events caused by surgery. Among minor acute complications were subcutaneous bleeding along the extension wire (1.2%) and haematoma at the pulse generator implantation site (1.2%). Skin infection caused by the implanted material was registered in 15 of 262 patients (5.7%). The infection rate during the first observation period was 1.5% (4/262 patients) and the late infection rate was 6.1% (11/180 patients). Partial or complete removal of the stimulation system was necessitated in 12 of 262 (4.6%) patients because of skin infection. During the long-term observation period, hardware-related problems were registered in 25 of 180 (13.9%) patients.
Conclusions: Stereotactic implantation of electrodes for DBS, if performed with multiplanar three-dimensional imaging and advanced treatment planning software, is a safe procedure with no mortality and low morbidity. The main causes for the patients' prolonged hospital stay and repeated surgery were wound infections and hardware-related complications.

During the past 10 years, worldwide, a growing number of patients with movement disorders have been treated with deep-brain stimulation (DBS). The most frequent indications were Parkinson's disease, tremor and dystonia. At present, new indications such as obsessive–compulsive disorders (OCD), Gilles-de-la-Tourette syndrome, severe depression or epilepsy are under investigation.[1–5]

DBS is now considered to modulate the functional units of the CNS, serving as a permanent and lifelong treatment. Therefore, a realistic analysis of complications should not be restricted to acute hardware-related and surgery-related adverse events, but should also document problems occurring in the long term. In the literature, a reasonably high number of publications have already dealt with the adverse events associated with DBS. Only a few studies, however, analysed a larger number of patients (n>50),[6–11] and some of this work considered only one possible source for complications, either surgery[6 10] or the implanted hardware.[8 9] In this article, we present a comprehensive analysis of 262 patients of a single centre (Department of Stereotaxy and Functional Neurosurgery, University of Cologne, Cologne, Germany).

CLINICAL MATERIAL AND METHODS

Data assessment

Between February 1996 and March 2003, 262 consecutive patients underwent DBS surgery in the Department of Stereotaxy and Functional Neurosurgery, University of Cologne. For retrospective analysis, the study period was determined to allow a minimum follow-up of 1 year. The patients' data were taken from chart records. In addition, we sent a questionnaire to the patients' homes and, where necessary, completed the information by telephone interviews. Therefore, we were able to register both patients admitted with complications to our department and those treated in other centres.

In addition to common demographic data (age, gender, diagnosis, etc), we registered three factors supposed to increase the risk for wound infections: obesity (body mass index (BMI (weight (kg)/height^2 (m^2)) >25), cigarette smoking and the presence of diabetes mellitus.

Complications related to the implantation of DBS systems were determined for two intervals: (1) perioperative and immediately postoperative (up to 30 days after surgery) and (2) after postoperative day 30 until the actual contact with the patient. The recorded intraoperative details included aborting the procedure, displacement of the frame, dislocation of the electrode, subcutaneous haemorrhage due to tunnelling or the occurrence of new neurological deficits. The use of intraoperative electrophysiology (microelectrode recording (MER) or local field potentials) and of intraoperative functional MRI (fMRI) was also registered.

Adverse events supposedly directly related to surgery were extracranial or intracranial haemorrhage (ICH), and CSF fistula. We defined complaints caused by hardware components, skin erosion, migration or fracture of brain electrodes or extension wires, and seroma as hardware-related complications. Infection was considered to be caused by two factors: surgery and implanted hardware.

Abbreviations: BMI, body mass index; DBS, deep-brain stimulation; fMRI, functional MRI; ICH, intracranial haemorrhage; IPG, implantable pulse generator; MER, microelectrode recording; OCD, obsessive–compulsive disorders; STN, subthalamic nucleus

To analyse the effect of the surgeon's experience on complications, we divided our DBS programme into an initial period (February 1996–March 1999) and a late period (April 1999–March 2003). The following items were registered separately for each period: displacement of the frame, intraoperative dislocation of the electrode, damage to hardware components during surgery, neurological deficits, extracranial haemorrhage and CSF fistula.

We also recorded all procedures required to surgically revise, remove or replace hardware components, and to carry out routine changes of the implantable pulse generator (IPG).

Surgical procedure

The method applied for imaging, treatment planning and implantation was published in detail previously.[12] Briefly, in 255 of 262 stereotactic procedures, we fixed the patient's head in a modified Riechert–Mundinger stereotactic aluminium frame. In 7 of 262 patients considered for intraoperative fMRI we used a ceramic version of this frame.[13] All patients underwent stereotactic cranial computed tomography intraoperatively. The MRI was carried out 1–3 days before surgery under non-stereotactic conditions and was integrated into the computed tomography-based three-dimensional stereotactic coordinate system by landmark-based image fusion.[14] From 1996 to 1999, we used ventriculography in addition to computed tomography-based or MR-based targeting in patients treated for tremor or dystonia. In all patients, trajectories were visualised and modified on multiplanar three-dimensional MR images (T1-weighted contrast series and T2-weighted images) to save structures at risk.

The quadrupolar brain electrode model 3389 (Medtronic, Minneapolis, Minnesota, USA) was used for stimulation inside the subthalamic nucleus (STN) or the nucleus ventrocaudalis parvocellularis. In all other targets we introduced the electrode model 3387 (Medtronic). Electrodes were fixed to the cranium at the rim of the 8-mm area of trephination by using a suture; they were additionally stabilised inside the burr hole with methylmethacrylate (Palacos, Merck, Darmstadt, Germany).

In patients scheduled for test stimulation, the brain electrodes were connected to the extension cable (model 7495, Medtronic) and the excess wires were externalised. At the beginning of our DBS programme, we used the tunnelling device model 7495 for the subcutaneous implantation of extension wires. From March 2002, this device was replaced by the less traumatic model 7482. Connectors (brain electrode with extension wire) were positioned behind the ear. The IPG (model 7428, Kinetra; model 7424, Itrell II; and model 7426, Soletra; Medtronic) was implanted either in the upper chest wall or in the abdominal wall.

Follow up

The patients were regularly seen by referring neurologists for adaptation and maintenance of the IPG setting, for documentation of clinical data and for adaptation of specific drugs. In the case of adverse hardware-related or surgery-related adverse events, we advised the patients to preferentially contact our department.

Statistics

To investigate the effect of obesity, diabetes mellitus, smoking, temporary externalisation of electrodes, intraoperative MER or fMRI on the incidence of wound infections, we applied a Cox-regression multivariate analysis using the likelihood ratio and the Wald statistic (prescribed significance level 0.05%). To analyse the effect of the surgeon's experience on complications, we registered specific adverse events as defined in the Data assessment section. The frequency of these events was compared for two time periods by using the χ^2 test (significance level 0.05%).

RESULTS

Demographics

From February 1996 to March 2003, we implanted a total number of 472 brain electrodes in 262 consecutive patients (102 females and 160 males). The patients' ages at the time of surgery ranged from 10 to 82 years (mean age 56.6 (SD 13.1) years). Table 1 lists the diagnoses and anatomical targets of the patients.

The study ended in September 2003 (mean follow-up time 35.3 (SD 21) months). The data of all patients were available for the assessment of early complications. The long-term analysis was based on 180 of 262 patients. The dropouts were 60 patients living abroad (the Middle East or Mediterranean countries), 18 patients who changed their place of living within Germany but had an unregistered address and 4 patients in whom the brain electrodes were removed after test stimulation.

Neurosurgical treatment before DBS was as follows: 12 of 262 patients underwent ablative stereotactic surgery, which was thalamotomy (n = 8; five patients with Parkinson's disease and three patients with tremor), pallidotomy (n = 2, both with Parkinson's disease), combined thalamotomy and pallidotomy (n = 1, patient with dystonia), and anterior capsulotomy (n = 1, patient with OCD). One patient with dystonia received a medication pump for delivery of intrathecal baclofen. Four patients suffering from pain were treated with spinal cord stimulation (n = 2), motor cortex stimulation (n = 1) or stimulation of the Gasserian Ganglion (n = 1).

In all, 11 of 262 patients presented with a BMI >25, in 34 of 262 patients regular cigarette smoking was registered and 4 of 262 patients had diabetes mellitus. One patient had a combination of two factors (BMI>25 and cigarette smoking).

Surgery

In total, we performed 526 operations (initial implantation of the stimulation system, n = 472; additional surgery for complications, n = 27; additional surgery for scheduled replacement of the IPG, n = 27). Antibiotics (fosfomycin 2 g or cefazolin 2 g) were given intravenously for all operations.

In 239 of 262 (91.2%) patients, we introduced the brain electrodes under local anaesthesia. Also, 44 of 239 patients were given additional mild sedation (intravenous diazepam 5–10 mg). General anaesthesia was used during electrode implantation in 23 of 262 (8.8%) procedures (severe dystonia, n = 13; Parkinson's disease, n = 4; OCD, n = 4; myoclonic syndrome, n = 2).

Macrostimulation for electrophysiological confirmation of the calculated target was carried out in all patients. In addition, we carried out MER in 27 of 262 (10.3%) patients and registered local field potentials in 9 of 262 (3.4%) patients. Intraoperative fMRI was carried out in 7 (2.7%) patients after implantation of the first lead by using a 1.5-T machine (Gyroscan, Philips, Best, The Netherlands) located in our operating room.

Stimulation leads were bilaterally implanted in 211 of 262 (80.5%) patients and unilaterally in 51 of 262 (19.5%) patients. Bilateral implantation was staged in 14 of 211 patients. The time from fixation to removal of the stereotactic head ring was, on average, 6–8 h when leads were implanted bilaterally and 4–5 h in unilateral procedures.

Brain electrodes and IPG were placed in one operation in 64 of 262 (24.4%) patients. In 194 of 262 (74.1%) patients, we implanted electrodes and IPG at two different days. In all, 88 of 194 (45.4%) patients with staged IPG implantation underwent test stimulation with the electrodes that were

Table 1 Diagnoses and anatomical targets of 262 consecutive patients treated with deep-brain stimulation

	Targets (no of patients)						
Diagnosis	**STN**	**GPi**	**v.im.**	**VCPC**	**N. acc.**	**CI**	**Total**
Parkinson's disease	164	15	15	—	—	—	194
Dystonia	—	18	—	—	—	—	18
Essential tremor	—	—	15	—	—	—	15
Multiple sclerosis	—	—	11	—	—	—	11
Chronic pain	—	—	—	9	—	1	10
OCD	—	—	—	—	7	—	7
Myocloniforme syndrome	2	—	1	—	—	—	3
Post-traumatic or ischaemic tremor	—	—	2	—	—	—	2
Neuroacanthocytosis	—	1	—	—	—	—	1
Huntington's chorea	—	1	—	—	—	—	1
Total	166	35	44	9	7	1	262

GPi, Gobus pallidus internus; N. acc., Nucleus accumbens; OCD, obsessive–compulsive disorders; STN, subthalamic nucleus; VCPC, ventrocaudalis parvocellularis; v.im., Nuclei ventrointer medii.

externalised for a median time of 8 (range 2–25) days. The brain electrodes were removed in 4 of 88 (4.6%) patients who had no marked improvement in their symptoms (pain, n = 3, post-traumatic movement disorder, n = 1). In patients without externalised brain electrodes but staged IPG implantation (106/194), we intermediately placed the electrodes in a subcutaneous pocket.

Subcutaneous tunnelling was carried out with the device model 7495 in 140 of 258 (54.3%) patients. A less traumatic device (model 7482) was used in 118 of 258 (45.7%) patients . In 92% of the patients we placed the IPG in the upper chest wall and in 8.0% of the patients in the abdominal wall. The IPG model Kinetra was implanted in 51.5%, the model Itrell II in 39.7% and the model Soletra in 8.8% of the patients.

We replaced 27 IPGs because of battery depletion (table 2). Most patients (n = 18) underwent one IPG change within a median time of 36.6 (range 2.6–58.8) months after initial surgery. In five patients the IPG was replaced twice, and in another four patients thrice.

Intraoperative and immediate postoperative complications

Intraoperative problems occurred in 11 of 262 (4.2%) patients. In three of these, the operation had to be finished after implantation of the first brain electrode. Reasons for aborting the procedure were panic attacks, marked brain shift and displacement of the frame. The second, contralateral lead was implanted several days later.

Other intraoperative adverse events were as follows. The lead was damaged during subcutaneous placement in two patients. These leads were immediately exchanged. In three patients, in whom we had used the tunnelling device model 7495, severe subcutaneous bleeding occurred. In three other patients, lead migration along the axis of the intracranial trajectory was noticed on intraoperative stereotactic *x* ray controls and was immediately corrected.

Three patients experienced neurological deficits because of the brain electrode. In one of these patients unilateral moderate motor weakness resolved completely (1/472 electrode sites = 0.2%). Misplacement of the electrode tip beyond the caudal border of the STN in two other patients caused permanent VI cranial nerve palsy, counting for a morbidity rate of 0.4% (2/472 electrode sites).

Subarachnoid haemorrhage was incidentally documented in one patient (1/472 electrode sites = 0.2%) who underwent postoperative CT examination after intraoperative loss of CSF. The bleeding resolved without sequelae. No symptomatic ICH was observed.

Postoperatively, 3 of 262 (1.2%) patients developed haematoma at the IPG implantation site, which had to be surgically removed in one patient. Leakage of the CSF stopped in one patient after drainage of the lumbar CSF. In the second patient (a child with myoclonic syndrome), leakage of the CSF at the site of trephination caused a skin infection, necessitating complete removal of the DBS system. Because the child had not gained immediate improvement from DBS, the parents did not give permission for reimplantation.

Long-term complications

For long-term analysis we had data from 180 of 262 patients (mean actualised follow-up 36.3 months (SD 20.8), range 6–90 months). Hardware-related problems registered in 25 of 180 (13.9%) patients were as follows:

- In 3 of 180 (1.7%) patients treated with STN-DBS for Parkinson's disease, one brain electrode was damaged after a fall. In another patient (0.6%) the cause for fracture

Table 2 Number and diagnosis of patients who underwent replacement of their implantable pulse generator due to battery depletion

	Frequency of IPG replacement			
Diagnosis	**Once**	**Twice**	**Thrice**	**Total**
Parkinson's diease	13	5	4	22
Dystonia	2	—	—	2
OCD	2	—	—	2
Multiple sclerosis	1	—	—	1
Total	18	5	4	27

IPG, implantable pulse generator; OCD, obsessive–compulsive disorders.

of the extension wire was unclear. In all four patients the affected hardware components were surgically replaced.

- Extension wire or extension connectors caused circumscribed discomfort in 12 of 180 (6.7%) patients. Six of these 12 patients needed additional surgery. In 5 of 6 patients (Parkinson's disease, n = 4; dystonia, n = 1) resection of scar tissue led to sustained improvement of the complaints. Another patient asked for complete removal of the system.
- In 5 of 180 (2.8%) patients migration of one brain electrode was noticed and in 1 of 180 patients the extension wire and connector were displaced. All migrated components were surgically repositioned.
- In one patient with skin ulceration at the connector site, we carried out wound debridement and transposed the connector.
- In 2 of 180 (1.1%) patients, sterile seroma at the IPG site was treated by needle aspiration in one patient and necessitated surgical revision in the other patient.

Surgical experience and complications

The rate of complications strongly related to the surgeon's experience was 17.8% (8/45 patients) during the first period of our DBS programme and 6.0% (13/217 patients) during the second period. The difference was significant ($p = 0.008$).

Infection

Skin infection was registered in 15 of 262 (5.7%) patients or after 15 of 526 (2.9%) surgical procedures, respectively. In 4 of 262 patients the onset was within 30 days after surgery (early infection rate 1.5%), and in 11 of 180 patients 1–15 months after initial surgery (late infection rate 6.1%). The mean time interval from initial surgery to registration of the first signs of inflammation was 3.7 (SD 4.1) months.

Skin infection was circumscribed in 12 patients (extension wire/connector site, n = 7; burr hole site, n = 5) and affected a larger skin area in three patients. In no patient had infection extended intracranially. Systemic antibiotics were given as the preferred treatment in 5 of 15 patients. Drugs stopped the inflammation in three of them, and we had to remove the entire stimulation system in the remaining two. All other patients underwent immediate surgery for wound debridement and removal either of parts (n = 3) or of the entire system (n = 7). In all cases treated with surgery for skin infection bacterial cultures yielded skin flora.

Multivariate Cox regression analysis did not show a statistically significant correlation between the variables MER, fMRI, externalisation of the electrode, diabetes mellitus, BMI, smoking and the occurrence of system infection.

DISCUSSION

In the retrospective analysis presented here, we documented adverse events associated with DBS surgery for two time intervals: perioperative and immediately postoperative (up to 30 days after surgery), and after postoperative day 30. For the first interval we had the data of all 262 patients, who were treated in our department with DBS surgery until March 2003. For the long-term analysis, 60 patients admitted from other countries and 18 patients living in Germany could not be contacted. DBS is performed in only a few specialised centres worldwide. Therefore, in case of an adverse event, we recommended that our patients contact our department. Because we had no request from the patients referred to as dropouts, we assume that a marked bias owing to these non-evaluated patients is unlikely in our long-term results.

We documented minor adverse events in 5.0% of the patients intraoperatively, which necessitated aborting the procedure in 1.9% of the cases. Aborted procedures were also reported in the literature, with a frequency ranging from 0.9% to 4.9% per patient (average 2.4%).[7 9 11] In our experience, the most serious intraoperative event was extracranial subcutaneous venous bleeding (n = 1). All other events did not directly endanger the patient's health but impaired the patient's condition because of the prolonged stay in hospital or the need for repeated head fixation.

In our study, the total rate of acute adverse events caused by DBS surgery was 2.7% per patient. The 30-day mortality rate was 0. Both the frequency of ICH (0.4% per patient or 0.2% per implanted electrode) and the rate of permanent morbidity (0.4% per patient) were comparably low. When publications containing the data of more than 50 patients were considered (table 3), the frequency of ICH was much higher, with an average of 3.0% (range 1.2–3.6%) per patient or 1.8% (range 0.6–2.2%) per implanted electrode.[6–11] Also, the morbidity rates were higher than those in the current study, ranging from 1.3% to 6% (average 3.6%).[7–10]

Regular postoperative CT or MRI examinations were not prescribed in our protocol. As a consequence, we were not able to determine the real incidence of ICH. In the literature, however, studies with postoperative MRI examinations reported a rate of intracranial bleedings, ranging from 1.2% to 3.6% per patient,[9–11] which was almost comparable to the incidence given for studies without postoperative imaging (range 1.5–3.3% per patient).[6–8]

The only ICH in our series was asymptomatic and was registered incidentally. Because this patient had a marked loss of the CSF owing to MER on the first implantation side, subsequent brain shift and deviation of the individual anatomy from the initial treatment plan may have been caused by this event. Even though speculative, we attribute our low rate of symptomatic ICH to both the use of highly developed treatment planning software in combination with three-dimensional CT-based or MR-based multiplanar imaging and the restricted application of MER.

Unilateral misplacement of the electrode tip beyond the caudal border of the STN caused permanent irritation of the 6th cranial nerve function in two of our patients. These two events took place at the beginning of our DBS programme. Also, other adverse events supposedly related to the surgeon's experience, such as displacement of the frame, intraoperative dislocation of electrodes, damage of hardware components, extracranial haemorrhage and CSF fistula, were statistically significant and more frequently observed within the first 3 years of our DBS programme, indicating a learning curve.

Skin infection may, in general, be caused by both DBS surgery and implanted hardware components. In total, we registered skin infections in 15 of 262 (5.7%) patients, which necessitated partial or complete removal of the stimulation system in 12 of 262 (4.6%) patients. Our own data are in line with infection rates given in the literature, ranging from 1.2% to 15.2%.[6–11] Although factors that prolong operation time, such as MER or intraoperative MRI, and factors that impair wound healing, such as obesity, smoking and diabetes mellitus, have been previously suggested to increase the rate of infection, this was not found in our study. Also, the frequency of skin infections seems not to follow a learning curve. The results published by Oh *et al*[9] and Lyons *et al*[11] confirm this observation. These investigators displayed the registered complications per observation year and did not find a regular distribution pattern. Also, the fact that in our experience and in that of others bacterial samples taken from the infection site yielded skin flora shows that the implantation of foreign material in itself has an inherent risk for infection.[8]

During the long-term follow-up, hardware-related complications were documented in 25 of 180 (12.8%) patients.

Table 3 Demographic data and complications rates taken from the literature

	Beric *et al*[7]	Kondziolka *et al*[8]*	Oh *et al*[9]	Umemura *et al*[10]	Limousin *et al*[6]*	Lyons *et al*[11]	This study
No of patients	86	66	79	109	111	80	262/180
No of electrodes	149	66	124	179	135	155	472/325
No of surgeries	NG	100	NG	NG	NG	160	526
Follow-up time	3.5 years†	29 months‡	33 months§	20 months§	12 months†	5 years†	35.3 months§
Aborted procedures	3.5%	—	0.9%	—	0.9%	4.9% [2.5%]	1.9% [1.0%]
Mortality	—	—	—	1.8%	—	—	—
Morbidity	6%	NG	1.3%	4.6%	—	—	0.4%
SURGERY							
ICH	3.3%	1.5%	3.6% (2.3%)	3.6% (2.2%)	2.7% (2.2%)	1.2% (0.6%)	0.4% (0.2%)
Extracranial haemorrhage	—	—	—	—	1.8%	—	2.4%
Venous infarction	—	—	—	0.9% (0.6%)	—	—	—
Seizure	2.3%	—	—	0.9%		1.2% [0.6%]	—
CSF fistula	—	—	1.3%	0.9% (0.6%)	—	—	0.8% (0.4%)
INFECTION							
Total	1.2%	10.6%	15.2%	3.7% [2.2%]	1.8%	6.2% [3.8%]	8.3% [2.9%]
Hardware removed	—	6.0%	13.9%	3.7%	1.8%	6.2% [3.8%]	6.7% [2.3%]
HARDWARE							
Lead fracture	—	15.2%	5.1%	—	—	2.5% (1.3%)	1.7%
Lead migration	3.5% (2.0%)	1.5%	5.1%	—	—	6.3% (3.2%)	2.8% (1.5%)
Extension wire**	3.5%	—	—	—	—	2.5%	1.1%
IPG malfunction	1.2%	1.5%	3.8%	—	—	13.8%	—
Local discomfort	1.2%	—	—	—	—	Some patients	6.7%*
Others††							1.7%*

ICH, intracranial haemorrhage; IPG, implantable pulse generator; NG, not given. Only studies which explicitly addressed complications and had analysed more than 50 patients were taken into consideration.
Frequencies are given as %/patient, (%/electrode) or [%/no of operations].
*Thalamic targets only.
†Time period.
‡Average.
§Mean values.
**Summarising malfunction, migration or break.
††Summarising minor events such as skin ulceration or seroma.

Other study groups reported hardware-related complication rates ranging from 10.5% to 27% per patient,[7–9 11] or 4.6% to 34.0% per operation.[8 10 11] Although in our analysis hardware-related problems required surgical revision in 8.9% of the patients, most of them were minor complications. With increasing experience we can avoid some of these problems. Skin ulceration, for instance, was not observed after introduction of low-profile connectors, and migration of the extension wire was successfully hindered by fixation of the connectors to the periosteum.

In summary, according to the literature, DBS surgery, even when performed in specialised centres, has on average a morbidity rate of 3.7%, which is mainly caused by ICH.[7–10]. The use of highly developed treatment planning software together with multiplanar three-dimensional imaging or the restricted application of intraoperative electrophysiology may minimise the risk for bleeding, consequently lowering the incidence of permanent morbidity considerably. To date, however, prospective studies to investigate this hypothesis have not been carried out. During the long-term observation period, two factors, skin infection and hardware-related complications, were mainly responsible for the patient's discomfort and additional costs.

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