

Surgical management of adverse events associated with deep brain stimulation: A single-center experience

SAGE Open Medicine
Volume 8: 1–8
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DOI: 10.1177/2050312120913458
journals.sagepub.com/home/smo



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Abstract

Objectives: Deep brain stimulation is widely used to treat movement disorders and selected neuropsychiatric disorders. Despite the fact, the surgical methods vary among centers. In this study, we aimed to evaluate our own surgical complications and how we performed surgical troubleshooting.

Methods: A retrospective chart review was performed to evaluate the clinical data of patients who underwent deep brain stimulation surgery and deep brain stimulation-related procedures at our center between October 2014 and September 2019. We reviewed surgical complications and how surgical troubleshooting was performed, regardless of where the patient underwent the initial surgery.

Results: A total of 92 deep brain stimulation lead implantation and 43 implantable pulse generator replacement procedures were performed. Among the 92 lead implantation procedures, there were two intracranial lead replacement surgeries and one deep brain stimulation lead implantation into the globus pallidus to add to existing deep brain stimulation leads in the bilateral subthalamic nuclei. Wound revision for superficial infection of the implantable pulse generator site was performed in four patients. There was neither intracerebral hemorrhage nor severe hardware infection in our series of procedures. An adaptor (extension cable) replacement was performed due to lead fracture resulting from a head trauma in two cases.

Conclusion: We report our experience of surgical management of adverse events associated with deep brain stimulation therapy with clinical vignettes. Deep brain stimulation surgery is a safe and effective procedure when performed by a trained neurosurgeon. It is important for clinicians to be aware that there are troubles that are potentially manageable with optimal surgical treatment.

Keywords

Deep brain stimulation, adverse events, troubleshooting

Date received: 29 May 2019; accepted: 10 February 2020

Introduction

Deep brain stimulation (DBS) is widely used to treat movement disorders and select neuropsychiatric disorders. A standard surgical procedure has been established, and although there have been improvements in image quality and the quality of implantable devices necessary for surgery, unique complications, such as hardware infections, still exist due to the nature of the therapy.¹ On the other hand, it is well known that the efficacy of DBS can be regained by appropriate troubleshooting.^{1,2}

In this study, we aimed to review adverse events associated with DBS therapy from our center and evaluate how

troubleshooting was surgically performed. We also present cases representing surgically treatable problems associated with DBS surgery including several rare cases.

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Methods

Study design

We retrospectively reviewed the clinical data of patients who underwent surgical procedures associated with DBS therapy at our institution between October 2014 and September 2019, under the approval of our institutional review board. We reviewed clinical outcomes of surgical procedures associated with DBS including initial DBS surgery, replacement of implantable pulse generator (IPG), and troubleshooting cases. In this retrospective analysis, we evaluated surgical complications in our series, but not stimulation-induced side effects. All procedures were evaluated by movement disorder neurologists and performed by a fellowship-trained DBS surgeon (T.M.).

Surgical procedure of DBS implant

As we have reported our detailed surgical procedure elsewhere,^{3,4} here we describe the essential parts of our procedure. High-resolution volumetric magnetic resonance imaging (MRI) was performed before the day of surgery. Anatomical three-dimensional (3D) image construction and stereotactic planning were performed using commercialized software (iPlan Stereotaxy; Brainlab, Germany) prior to surgery. Multiple MRI sequences were automatically fused by the software. The DBS target for each case was identified using MRI, and the DBS lead trajectory was carefully planned so that the DBS lead did not pass through blood vessels, sulci, or ventricles.

If the patient could tolerate an awake lead implantation, a Leksell G frame (Elekta, Sweden) was attached to the patient's head under local anesthesia on the morning of the surgery. The patient was then brought to the computed tomography (CT) scan suite. After CT, the CT image was fused to the MRI images to translate the Cartesian coordinate system on the MRI to the coordinate system of the Leksell G frame.

In the operative suite, DBS leads were implanted under local anesthesia, except for select cases. The patient was in a semi-sitting position with the head fixed to the operating table. A linear skin incision was made, and a burr hole was fashioned along the planned DBS lead trajectory. Using a high-speed drill, a dual floor was made so that the burr hole cover would not protrude out of the skull.^{5,6} After opening the dura, microelectrode recording was performed to map out the target structure. We then implanted a DBS lead and a macrostimulation procedure was performed. In cases of lead replacement, the existing lead was removed following the confirmation of optimal placement of a new DBS lead with macrostimulation. Once threshold levels of stimulation-induced side effects were confirmed, the DBS lead was fixed to the burr hole cover, and the incision was closed. We used saline containing gentamicin during the procedure.

An IPG was implanted under general anesthesia on the same day as the lead implantation, except for select cases. Additional skin incisions were made over the parietal area, behind the ear, and the subclavian area. It should be noted that we undermined a part of the parietal bone to bury the connector of the intracranial lead and the adaptor. It should also be mentioned that the IPG was implanted in the subfacial layer of the pectoral muscle.

Patients were admitted to the hospital and monitored until removal of the staples or longer. The staples were typically removed sometime between postoperative days 7 and 10. Patients were instructed to start taking showers on postoperative day 2 and use topical gentamicin on the skin incision sites for 7 days. CT scans were obtained on postoperative days 1 and 10 to evaluate adverse events and record stereotactic measurements of the lead position. DBS programming was performed once a month for 6 months following surgery.

Surgical procedure of IPG replacement

A subclavian skin incision on the previous incision site was made, and the connective tissues under the skin were sharply dissected away from the IPG using a #15 blade. Care was taken to avoid cutting the existing extension cable. Once the IPG was taken from the firm capsule, the capsule was dissected away to give the new IPG more room and allow for closure of the incision without tightness. After the IPG was replaced and put back into the pocket, electric impedance was checked and the incision was closed.

Troubleshooting

Surgical interventions as troubleshooting in DBS cases include hardware explantation and replacement, rescue (additional) lead implantation, and wound revision. Indications for hardware explantation are usually severe infection. We performed DBS lead replacement in cases where existing DBS was located in a suboptimal position, fractured, or not effective regardless of lead position. A rescue lead implantation was performed for newly developed or unsolved problems such as troublesome dyskinesia following the initial DBS surgery (Figure 1). Wound revisions were performed for dehiscence or superficial infection before these troubles aggravate seriously.

Results

Patient demographics

A total of 135 new device implantation procedures consisting of 92 cases (67 patients) of DBS lead implantation, 43 cases (29 patients) of IPG replacement, and other surgical cases were included in this study. For lead implantation surgeries, clinical diagnoses included Parkinson's disease (PD; 65 cases and 43 patients), essential tremor (ET; 7 cases and 6

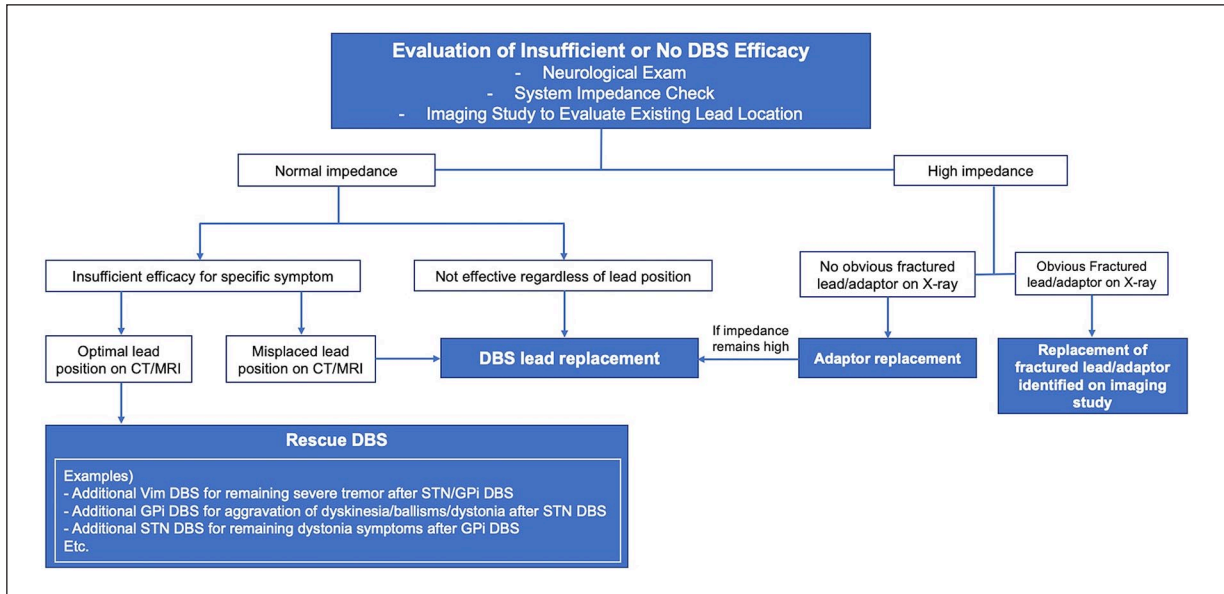


Figure 1. A flowchart summarizing the indications of lead revision and rescue deep brain stimulation.

Table 1. Summary of surgical cases.

	DBS lead implantation (cases/patients)	Hardware replacement (cases/patients)	Troubleshooting surgery			
			Intracranial lead replacement (cases/patients)	Rescue lead implantation (cases/patients)	Adaptor replacement (cases/patients)	Wound revision (cases/patients)
PD	65/43	43/29	1/1	1/1	3/3	2/2
ET	7/6	–	–	–	–	–
Dystonia	9/8	–	2/1	–	1/1	1/1
Others	11/10	–	–	–	–	2/2
Total	92/67 ^a	43/29	3/2	1/1	4/4	5/5

DBS: deep brain stimulation; PD: Parkinson’s disease; ET: essential tremor.

^aThe total number of DBS lead implantations includes intracranial lead replacement and rescue lead implantation procedures.

patients), dystonia (9 cases and 8 patients), and other movement/neuropsychiatric diseases (11 cases and 10 patients). DBS leads were implanted unilaterally in 80 cases and bilateral simultaneous implantation was performed in 12 cases. Microelectrode recordings were performed in 38 cases. DBS targets included the globus pallidus interna (GPI; 68 cases), subthalamic nucleus (STN; 4 cases), ventral intermediate (Vim) nucleus of the thalamus (15 cases), and centromedian (CM) thalamic nucleus (5 cases).

Surgical troubleshooting was performed as device implant/replacement and management of skin infections. Among 92 DBS lead implantations, we performed a lead replacement in three cases and an additional lead implantation to existing leads in one case. In addition, DBS re-implantation was performed for a patient who previously underwent lead explantation due to severe infection at another institution. A wound revision was performed in three cases following DBS system implantation, one case following IPG replacement, and one

case following adaptor replacement. Two patients had adaptor replacement due to cable fracture after a fall and high electrical impedance. Another patient underwent adaptor replacement to reposition of the IPG from the chest to the abdomen. These demographics are summarized in Table 1.

Adverse events

During the intracranial lead implantation procedure, venous air embolus and seizure were observed during intracranial lead implantation in four cases and one case, respectively. Concerning the relatively high incidence of venous air embolus in our study, we considered that air could likely have been entrapped when the dural and intraosseous veins were exposed, due to the semi-sitting position of the patient during our procedure. A PD patient with comorbid atrial fibrillation felt chest pain and had unstable vital signs during the procedure, but the condition was immediately stabilized.

Table 2. List of adverse events.

Adverse events	N (case)	Percentage ^a
Intraoperative periods		
Venous air emboli	6	4.7
Seizure	1	0.8
Chest pain	1	0.8
Early postoperative periods (within 30 days)		
Transient asymptomatic chronic subdural hematoma	1	0.8
Hematoma in the subclavian pocket following IPG replacement	2	1.6
Aspiration pneumonia	2	1.6
Late postoperative periods (after 30 days)		
Superficial infection	4	3.1
Extension cable fracture	2	1.6

IPG: implantable pulse generator.

^aPercentages are calculated as the rate in all device implantation/replacement surgeries (129 cases including 89 lead implantation procedures and 40 IPG replacements).

Angina was ruled out in the same patient on the basis of electrocardiogram findings.

In early postoperative periods (within 30 days following the procedure), one case had a small chronic subdural hematoma incidentally found on a CT scan performed on postoperative day 10, but the hematoma was asymptomatic and resolved spontaneously. Two patients had postoperative hematoma in the subclavian pocket following IPG replacement, and these patients underwent urgent wound revision. One case had aspiration pneumonia in the early postoperative period.

In the late postoperative period (after 30 days), superficial infection was seen in two cases and wound revision was performed. One PD patient had trauma in the occipital area due to falling and subsequent fracture of the extension cable. Replacement of the adaptor was therefore performed urgently in this case, and this case is presented as representative case 5. These adverse events are summarized in Table 2.

Representative cases

Case 1: lead misplacement. The patient initially underwent bilateral simultaneous STN DBS at the age of 43 years for PD. His history was complicated with a lead replacement surgery due to lead misplacement on the left, but his PD symptoms on the right side of the body and severe dyskinesia were not resolved with the surgery. He was referred to our department for troubleshooting at the age of 50. A CT scan revealed the misplaced lead position of the left DBS lead, and the left DBS was considered ineffective following thorough evaluation. Therefore, he underwent replacement of the existing left DBS lead with a new GPi DBS lead (Figure 2). Following surgery, his on/off motor fluctuation and dyskinesia improved.

Case 2: rescue DBS for severe dyskinesia. The patient was a 75-year-old woman who underwent bilateral STN DBS for PD at age 67. The surgery was performed uneventfully, and the patient initially felt benefit from the DBS therapy. However, the patient gradually developed PD symptoms, especially dyskinesia that could not be suppressed either by medication or by STN stimulation that impaired her quality of life. Following careful discussion, we performed a rescue DBS lead implantation in the right GPi, as dyskinesia was worse on the left side of the body. Another burr hole was fashioned in addition to existing burr holes for the current STN DBS, and a DBS lead was placed in the GPi (Figure 3). In this case, we did not explant the existing right STN lead, as preoperative evaluation showed some clinical benefit of the stimulation. The existing IPG (Activa SC; Medtronic, USA) was replaced with a dual-channel IPG (Activa PC; Medtronic). Following surgery, her dyskinesia was resolved.

Case 3: delayed-onset epilepsy and loss of benefit due to ventral lead migration. A 40-year-old dystonia-1 (DYT-1)-positive dystonia patient, who had undergone bilateral GPi DBS at another institution, was brought to the emergency department at our institution for generalized tonic-clonic seizure. The seizure subsided immediately with administration of intravenous diazepam. The patient had no past medical history of epilepsy prior to the visit.

He had gradually developed dystonia symptoms since his childhood, and initially underwent DBS surgery at age 26. His dystonia symptoms were dramatically improved, but once had to have the left DBS system removed at age 35 due to severe infection following an IPG replacement. Although he underwent revision of the left DBS, his condition did not return to the same status as when underwent the first DBS surgery.

A CT scan at our clinic revealed that his bilateral DBS leads migrated ventrally. We attributed his severe axial symptoms to the movement of the DBS leads. The left electrodes had completely migrated into the mesial temporal lobe, which we considered to be the cause of the seizure. He, therefore, underwent revision of the bilateral DBS leads in a staged fashion, and his dystonia symptoms improved (Figure 4).

Case 4: superficial wound infection. A 62-year-old PD patient underwent a right DBS system implantation uneventfully. Four months later, he noticed inflammation of the left subclavian incisional site. He was then prescribed topical gentamicin. However, symptoms progressed and redness and superficial hemorrhage developed. He came to our neurosurgical department 5 months later and underwent an urgent wound revision.

Case 5: lead fracture. A 71-year-old woman underwent a left-sided unilateral GPi DBS for PD at our institution and was discharged uneventfully. She fell in her home 2 months

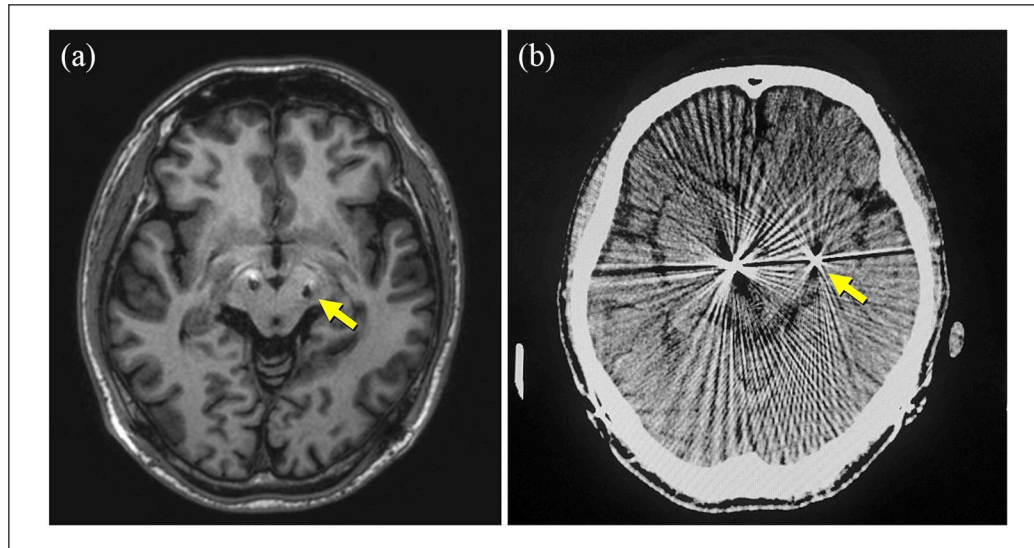


Figure 2. An axial MRI image showing the misplaced deep brain stimulation (DBS) lead tip on the left side of the brain: (a) It is located posterolaterally to the ideal location (arrow); (b) the left DBS lead was repositioned to the globus pallidus interna (GPi).

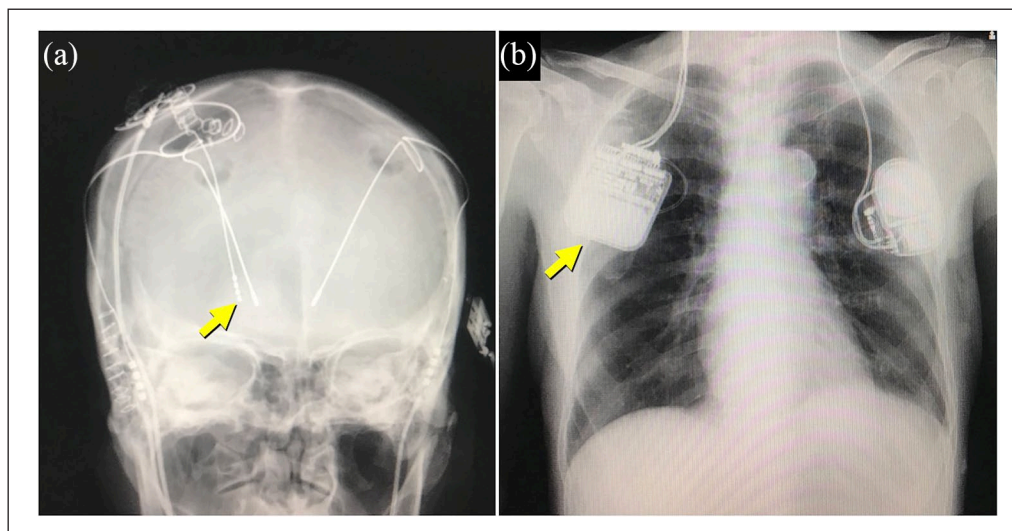


Figure 3. X-ray films showing an additional deep brain stimulation (DBS) lead in the globus pallidus interna (GPi) (a) and the replaced dual-channel implantable pulse generator (b).

following surgery and suffered head trauma at the site of the extension cable behind her ear. She then felt sudden loss of benefit of DBS, as her on/off motor fluctuations became aggravated. The impedance was extraordinarily high at all contacts, and an x-ray revealed that the cable was fractured. Therefore, she underwent urgent replacement of the extension cable, which restored the benefits of the DBS (Figure 5).

Discussion

Life-threatening complications associated with DBS surgery are most commonly intracranial hemorrhage and severe

hardware infection. Incidence of intracranial hemorrhage and severe hardware infection is reported to be 0.6%–3.3%^{7–14} and 0%–15%,^{1,9,13–19} respectively. Most hemorrhagic complications are avoidable with careful stereotactic planning to avoid blood vessels using high-resolution MRI to visualize structures.²⁰ Concerning the prevention of postoperative infection, topical use of antibiotics (e.g. neomycin, polymyxin, and vancomycin) has been recommended by several groups.^{21–23} Another important adverse event is a lead misplacement, which can be recovered with an optimal replacement surgery, as presented in this study and the literature.^{1,24} It should, however, be noted that a recent study of a large national registry including over 28,000

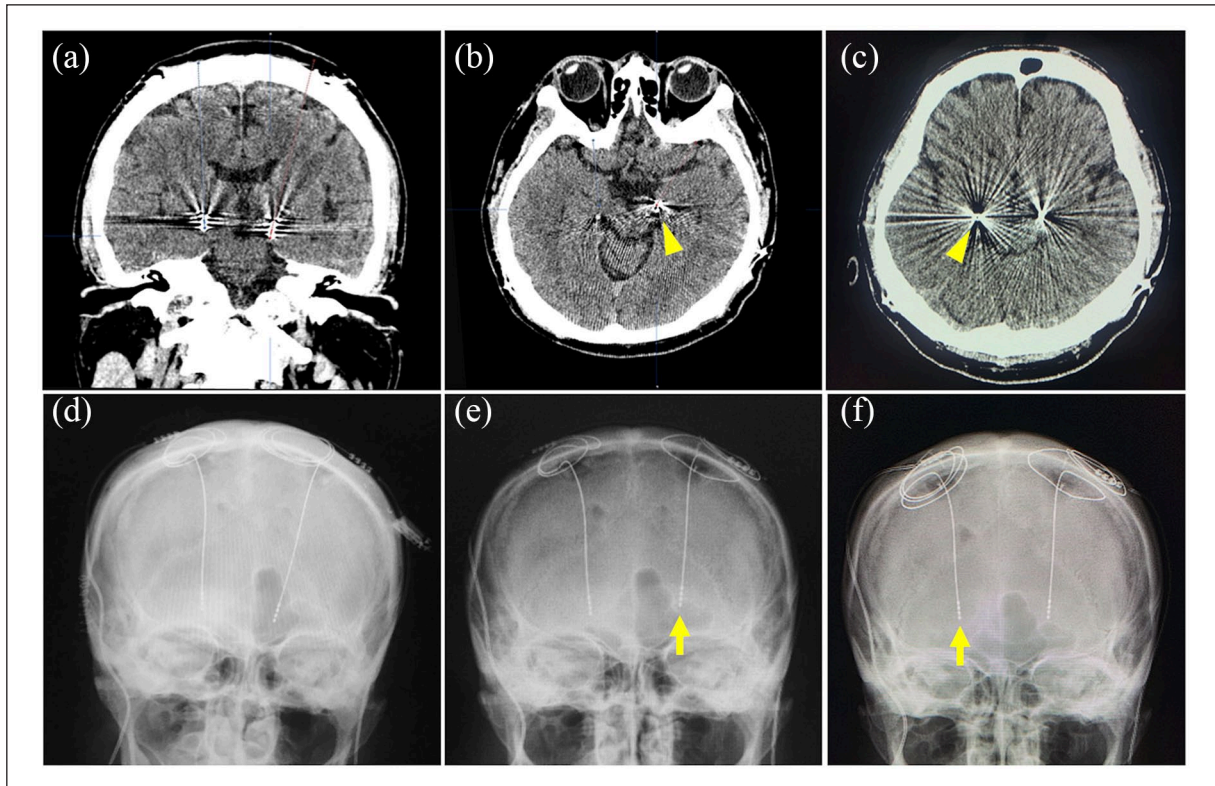


Figure 4. A ventrally migrated deep brain stimulation (DBS) lead is shown on the coronal (a) and axial (b, c) CT images and a skull x-ray (d). Two preoperative axial CT images (b, c) show the tips of the left and right DBS leads, respectively. The left and right leads were replaced with a new lead in a staged fashion (e, f).

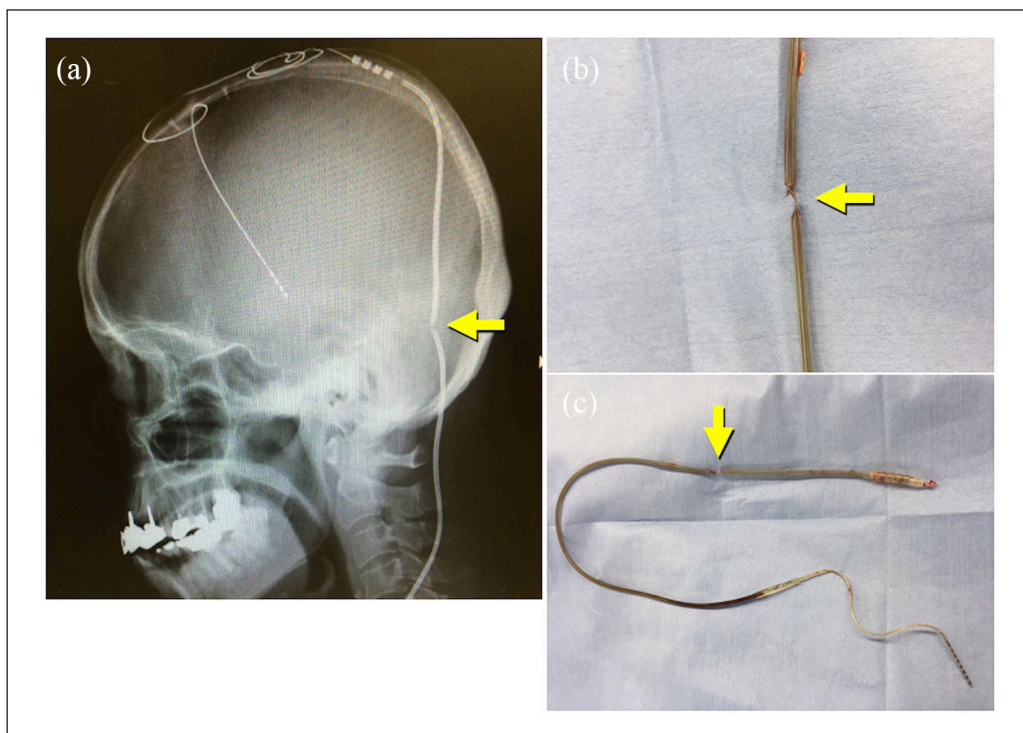


Figure 5. Fractured lead shown on the skull x-ray (a) and intraoperative pictures (b, c).

cases revealed that the incidence of revisions and removals of DBS electrodes was greater than 15%, which the authors considered might be due to improper targeting or lack of therapeutic effect.²⁵ In addition, a recent study showed that complication rates could be reduced with sophistication of surgical techniques.^{6,14} These reports may have addressed the importance of the subspecialty training prior to opening a DBS practice.

Among various adverse events associated with DBS therapy, surgically treatable problems include lead misplacement, surgical site infection, and lead/cable fracture. In our series, we performed two cases of DBS lead replacement and one additional DBS lead implantation. These cases illustrate the importance of evaluating the efficacy of the existing DBS lead. If the existing DBS lead is judged as ineffective, the lead should be replaced. Adding another DBS lead may also be useful in cases where the existing DBS system partially but not sufficiently addresses the problems.^{26,27} As described above, dyskinesia or ballistic movements resulting from STN DBS that are effective for other symptoms may be addressed by an additional GPi DBS.²⁸ In PD cases with remaining severe tremor following initial DBS surgery targeting STN or GPi, adding a ventralis intermedius (VIM) lead may be an option.²⁷ Besides, rescue STN DBS may be an option for remaining severe dystonia symptoms following initial GPi DBS for dystonia.²⁷

We presented a case of ventral lead migration, which illustrates the importance of follow-up imaging studies. It has been reported that dystonia patients with axial symptoms were susceptible to ventral lead migration.^{6,29} Ventrally migrated DBS leads may become dislodged into the amygdala, which may result in mood changes³⁰ and epilepsy, as described in our case. Clinicians should be cautious when unexpected mood changes and/or epilepsy arise in a long-term follow-up patient following GPi DBS.

In cases where continued DBS therapy was effective, sudden explantation of the DBS system may result in DBS withdrawal syndrome.³¹ To avoid this situation, it is important to provide urgent intervention to minimize the severity of each complication. Therefore, superficial skin infection should be treated immediately to avoid development of severe hardware infection, and lead/cable fracture should also be immediately normalized to minimize the period of DBS withdrawal.

The incidence of adverse events in our series was acceptable. Although we report acceptably low incidence of complications and successful troubleshooting methods, our study included a relatively small case volume, and all procedures were performed by a single surgeon. We would prefer to collect data from multiple centers to obtain a universal incidence of complications associated with DBS therapy. However, it is important for clinicians to share clinical knowledge from a single-center experience, as our case series included unique cases.

Conclusion

We report our 5-year experience of surgical management of adverse events associated with DBS therapy using clinical vignettes including several rare cases. DBS surgery is a safe and effective procedure when performed by a trained neurosurgeon. It is important for clinicians to be aware that there are troubles that are potentially manageable with optimal surgical treatment.

Author's note

Kazumichi Yamada is now affiliated with Department of Neurosurgery, School of Medicine, Kumamoto University, Kumamoto, Japan.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

Ethical approval for this study was obtained from Fukuoka University—Medical Ethics Review Board (IRB approval no. 2018M102).

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This study was partly supported by the Japan Society for the Promotion of Science (JSPS) Grant-in-Aid for Scientific Research (C) 18K08956, and JSPS Fujita Memorial Fund for Medical Research.

Informed consent

Informed consent was not sought because this is a retrospective study and the process was waived by Fukuoka University—Medical Ethics Review Board.

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