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Deep brain stimulation hardware-related complications and their management: A single-center retrospective analysis of 65 patients with various dystonic conditions

Michał Sobstyl[a,*], Angelika Stapińska-Syniec[a], Jakub Giziński[a], Tomasz Kmieć[b], Anna Kupryjaniuk[a]

[a] Department of Neurosurgery, Institute of Psychiatry and Neurology, Sobieskiego 9 Street, 02-957 Warsaw, Poland
[b] Department of Neurology, Children's Memorial Health Institute, Aleja Dzieci Polskich 20, 04-730 Warsaw, Poland

1. Introduction

Deep brain stimulation (DBS) is a well-known and commonly used therapeutic approach for patients suffering from disabling dystonic conditions. It is generally used in cases where dystonias control has failed with pharmacotherapy and botulinum toxin injections [1–7]. Numerous studies have shown that patients with hyperkinetic movements including dystonia or epilepsy are at higher risk for the development of DBS hardware-related complications [8–12]. Moreover, rapid discontinuation of DBS therapy may result in the development of serious life-threatening status dystonicus, which can lead to sudden death [13–17].

Attempts should be made to reduce hardware-related complications in patients with implanted DBS hardware for movement disorders [18–36]. Of note, hardware-related infections may be very difficult to manage and require additional hospitalizations. These may lead to a partial or even total removal of the DBS hardware, requiring subsequent reimplantation surgeries [25–30]. An infection may cause a longer loss of DBS's therapeutic efficacy compared with a single hardware malfunction (e.g., breakage or migration), which can be promptly corrected with a single surgery [30–36]. As a consequence, precautions should be considered to better define possible risk factors for the development of hardware-related complications and their appropriate management [18,19,26,37–41].

In the present study, we report our experience of 65 patients with dystonia. We specifically focused on hardware-related DBS complications with their surgical management. Additionally, we highlight several modifications in surgical techniques aimed at lowering the incidence of hardware-related complications. Finally, we analyzed several risk factors due to the development of hardware-related complications, such as the type of dystonia, duration of dystonia, age at diagnosis, and age at DBS surgery.

2. Methods

We performed a retrospective analysis of all hardware-related complications of DBS procedures for patients with dystonia who underwent DBS lead implantations between December 2008 and September 2018 at the Neurosurgical Department, Institute of Psychiatry and Neurology, Warsaw, Poland. We defined a hardware-related complication as any event related to the implanted components of a DBS system requiring a surgical revision. In the present study, 65 patients with DBS electrode implantations and a minimum of 3-month follow-up were included. We reviewed patients' medical records and collected retrospectively acquired data, specifically demographics, dystonia's diagnosis and duration, type of hardware-related complication, and surgical management of a hardware-related complication. The following data regarding a hardware-related complication episode was included: location, time after DBS surgery, surgical management, and culture results. The information about the type of antibiotics used intraoperatively and in case of an infection episode has also been provided. The study was approved by the Institutional Review Board. The board waived the requirement for patient consent due to the retrospective and observational design of the study. The patients with dystonia included were not homogenous based on dystonia etiology, age at onset, and clinical symptoms. Therefore, the patients were included in the following groups: patients with dystonia due to neurodegeneration with brain iron accumulation (NBIA), patients with primary generalized dystonia (PGD) harboring DYT-1 mutation (DYT-1-positive PGD), patients with secondary dystonia, and patients with focal/segmental dystonia involving the neck or trunk musculature.

Adult patients with different types of dystonia were considered eligible for DBS surgery only after repeated failed botulinum toxin injection sessions or ineffective pharmacological trials. Children were found suitable for surgery only after several ineffective pharmacological trials and with referral by an experienced neurologist. All patients and their families were informed about the stereotactic procedures and

* Corresponding author.
E-mail address: msobsty@ipin.edu.pl (M. Sobstyl).

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that DBS is a life-long therapy. All anticoagulation drugs were stopped at least 10 days before the planned surgery. The inclusion criteria comprised negative history of meningitis and cerebral ischemia. The exclusion criteria included suicidal thoughts and active psychiatric diseases. Additionally, we excluded cases with a DBS hardware complication that was managed at our neurosurgical department if the primary initial DBS procedure for dystonia was performed elsewhere.

DBS lead implantations were performed under sedation or general anesthesia with propofol. One or 2 days prior to surgery, we recorded for all patients' distortion-free T2-weighed MR images and T1-weighed 3D volumetric contrast-enhanced images. Our goal was to perform stereotactic trajectory planning and target selection. Special attention was given to distortion-free image acquisition. Specifically, 1.5 T or, more recently, 3.0 T magnet MRI was used for image acquisition (General Electric). In all DBS lead implantations, a stereotactic G frame (Elekta, Instruments, Stockholm, Sweden) was used. Following local/general anesthesia, the head frame was secured to the patient's skull. Then, stereotactic contrast-enhanced, 1.25-mm thick computed tomography (CT) images were obtained. Subsequently, these images were merged with preoperative MRI images using a stereotactic surgical planning software (Brainlab iPlan 3.0 Stereotaxy; Munch, Germany), which allowed to perform adjustments to individual patient's anatomy. During surgery, the patients were placed in the supine position with slight head elevation (approximately 10°–15°). A 14-mm burr hole was drilled at the entry point, according to arc and ring settings provided by the stereotactic trajectory planning. To perform chronic stimulation, DBS electrodes were implanted and secured at the burr hole by a lead-anchoring system. In most patients, the stereotactic target was the globus pallidus pars interna (GPi). Only a subset of patients with NBIA dystonia was implanted bilaterally in the subthalamic nucleus. The subthalamic nucleus target was chosen in 15 patients with NBIA dystonia. In the remaining 50 patients, GPi was implanted.

All patients received preoperative antibiotics. Ceftriaxone 2 g or clindamicin 600 mg was routinely used, but if a patient was allergic to penicillin, vancomicin 2 g was administered. One dose of this prophylactic antibiotic was administered 30 min to 1 h before incision. Considering that most infections in our series were caused by gram-positive bacteria, starting from November 2014, we routinely administered a single dose of Biofazolin (cefazolin, 2 g). The single dose of 1 g of Biofazolin was administered every 3 h during surgery. Moreover, we routinely introduced starting from December 2014 the self-administered preoperative whole body wash with disposcrub sponge containing 4% solution of chlorhexidine. The self-administered wash was done on the night before surgery or the morning of surgery.

Following the DBS lead implantation, the patients were brought to the emergency unit. One day postsurgery, CT was performed to check the exact location of the implanted lead and to exclude possible hemorrhagic complications. Over the last year, the postoperative CT examination schedule has been modified. Specifically, immediately following a DBS lead implantation with the head frame fixed to the patient's head, noncontrast-enhanced intraprocedural stereotactic CT images were obtained. Our goal was to more promptly assess the exact DBS electrode position and exclude hemorrhagic complications. Postoperative stereotactic CT images and preoperative MR images were merged to localize the implanted lead in a stereotactic space in relation to the midcommissural point and surrounding structures. If no hemorrhagic complication was detected, the implantable pulse generators (IPGs) were placed subcutaneously during the same operative session while the patients were under general anesthesia. In adult patients, IPGs were usually implanted under the clavicle in the chest wall, whereas in children, they were implanted in the abdominal wall.

Statistical analysis included the presentation of data as means with range values. Patients who developed hardware-related complications were investigated for possible contributing factors (e.g., diagnosis, age at surgery, duration and severity of underlying dystonia).

3. Results

Of the 65 patients with dystonic conditions, 30 (46%) were females and 35 (54%) were males. At the time of surgery, 20 (30%) patients were children and 45 (70%) were adults. Of those 65 patients, 63 underwent bilateral procedures and two received unilateral DBS implantation. The clinical diagnoses of the dystonic conditions were as follows: secondary generalized dystonia ($n = 26$), NBIA dystonia ($n = 17$), DYT-1-positive PGD ($n = 11$), focal/segmental/hemidystonia dystonia involving usually the neck and trunk musculature (n = 11). The 20 children were diagnosed with NBIA dystonia ($n = 14$), DYT-1-positive PGD ($n = 4$), and generalized secondary dystonia ($n = 2$). The 45 adult patients were diagnosed with NBIA dystonia ($n = 3$), focal/segmental/hemidystonia dystonia ($n = 11$), DYT-1-positive PGD ($n = 7$), and secondary generalized dystonia ($n = 24$). The 11 patients with focal/segmental dystonia were adults at the time of surgery. They were characterized by cervical dystonia ($n = 5$), segmental dystonia ($n = 3$), and a tremulous form of cervical dystonia ($n = 2$) and hemidystonia ($n = 1$).

Of the 65 patients, 16 (25%) developed hardware-related complications. The most common hardware-related complications were infections (12.3%), followed by lead migration (6%). Additionally, IPG malfunctions, fracture of DBS lead, and skin erosions were equally observed in 4.6% of the patients. Table 1 describes all types of hardware-related complications and their incidence with respect to the number of operated patients and implanted DBS leads during the initial DBS surgery. As explained above, infections were the most common hardware-related complication. Table 2 outlines a detailed analysis of the infection locations and their management. To adequately manage all hardware-related complications, a total of 46 revision surgeries were needed. Among the 46 revision surgeries, 33 were performed to remove or manage hardware problems and 13 to re-implant DBS hardware to maintain the DBS therapy. Table 3 shows all types and numbers of repeated surgeries aimed at correcting separate DBS hardware complications. The mean and average values for year at diagnosis, dystonia duration, patient age at surgery, and follow-up period for four groups of patients with dystonia are presented in Supplementary Material.

Table 1
Types of hardware-related complications and their incidence. These were relative to the number of operated patients and implanted DBS leads in the course of the initial DBS surgery for patients affected by different dystonic conditions.

Hardware-related complications	Number of individual type of hardware complications	Number of patients affected by individual hardware-related complications	Percentage of individual complication in relation to the number of placed DBS implants during initial surgeries	Percentage of individual complications in relation to the number of operated patients
Infections	17 infection episodes	8 patients	13.2%	12.3%
Erosions	6 erosion episodes	3 patients	4.6%	4.6%
DBS lead migration	4 migration	4 patients	3%	6%
DBS lead breakeges	3 breakages	3 patients	2.3%	4.6%
IPG malfunction	3 malfunctions	3 patients	2.3%	4.6%

Table 2
Detailed presentation of an infection's location and management in 65 patients with dystonic conditions.

Component/s s of a DBS system involved by an infection	Number of infections involving DBS hardware	The number of primary (initial) surgery to remove or reposition the implanted hardware	The number of reimplantation surgeyy to maintain DBS tharapy	Total number of surgeries required to manage an infection of individual component/s of DBS system.
IPG	4	4 removals	4 reimplanations	8
IPG and extension cable	4	4 removals	4 reimplantations	8
IPG, extension cable, burr hole cup DBS electrode	4	4 removals	2 subsequent implantations	6
Extension cable, burr hole cup. DBS electrode	1	1 removal	1 reimplanation	2
Extension cable, burr hole cup	2	2 repositioning of the extension cable and skin debridement over the burr hole	–	2
Extensive redness of the skin over the connector (1 case previous infection) and burr hole side 1 case	2	2 Compression, wound debridement, intravenous and oral antibiotics	–	2
Total number of surgeries needed to maintain DBS tharapy	17 infections episodes	17 primary surgeries to remove infected DBS hardware or debridement of wounds	11 reimplantation surgeries	Cumulative number of 28

3.1. Skin complications: infections

Infections were the most common hardware-related complications in our series. They were identified in eight of the 65 patients included in the study (i.e., overall infection rate, 12.3%). Additionally, we observed a 13.2% incidence of infection episodes per initially implanted DBS system. The following three infection sites were reported: the frontal burr hole, the connector side in the postauricular/neck region, and the IPG site located in the chest or abdominal walls. A total of 27 sites of infection were identified during the 17 infection episodes. In our series, we found that seven infection episodes were restricted to one location site and 10 infection episodes were observed in multisite infections. The most common infection site in our patients was the connector side located in the postauricular/neck region (constituting 11 infections sites), followed by the IPG site (ten cases, including five subclavicular and five abdominal locations); only six infection sites were located at the burr hole cup. Of 17 infection episodes, deep infection with purulent drainage was observed in 7 cases. A superficial infection site was observed in 11 cases with the absence of purulent drainage.

The surgical management of hardware-related infections was very problematic (Table 2). To adequately manage these eight patients with hardware infections, a total of 28 surgeries were needed to remove (17 initial surgeries) or reposition the hardware with wound debridement (four surgeries). Additionally, eleven surgeries were needed to replace the previously explanted hardware required to continue the DBS therapy. Among three patients who had all DBS hardware components removed due to a purulent multisite infection, one patient refused further surgery, the second patient was successfully reimplanted, and the third had two removals due to infections episodes and was not further reimplanted.

In 13 infection episodes, the pathogen was *Staphylococcus aureus*. Only in one case, *Acinetobacter baumannii* was detected. In three infection episodes, the pathogenic flora was mixed, containing two pathogens (*Staphylococcus aureus* and *Pseudomonas aeruginosa*). Since a gram-positive bacterium was suspected to be the infective pathogen, intravenous antibiotics were administered intravenously. Usually, cefuroxime or ceftriaxone were given in combination with clindamycin until the results of the sensitivity cultures were obtained. Based on culture and sensitivity results, the antibiotics administered included Biofazolin, cefazolin, clindamycin, syntarpen, ceftriaxone, and doxycycline.

All patients in our cohort who experienced infection episodes were diagnosed with different forms of PGD: NBIA dystonia ($n = 4$), DYT-1-negative PGD ($n = 3$), and severe segmental dystonia of the neck and truncal musculature ($n = 1$). In the present study, the mean time elapsed between the initial surgery and the appearance of infection was 22 months (range, 3–58 months). No infection episodes were observed in the early postoperative period, until 30 days after DBS surgery. We found that five infection episodes (35%) occurred within 6 months, four (28.5%) occurred within 12 months, and the remaining six (35%) occurred after 12 months. Regarding the dystonia operation time in children versus adults, we observed no difference in the incidence of skin infections among the two groups. Large erosion with contaminant infection of the left IPG and the connector site are shown in Video 1 and Video 2, respectively, in a patient with secondary dystonia.

3.2. Skin complications: erosions

We observed six erosions in three patients over the implanted DBS hardware. This type of complication affected 4.6% of the implanted electrodes and 4.6% of the patients. One patient with NBIA dystonia developed four erosion episodes over his implanted hardware. Interestingly, these erosions affected different DBS hardware locations. The most common erosion site in our cohort was the connector side, located in the postauricular area (three erosions), followed by the IPG location (two erosions), and the burr hole cup (one erosion). The mean

Table 3
Types and numbers of repeated surgeries performed to correct DBS hardware complications (i.e., skin complications, such as infections/erosions, or true hardware malfunctions, such as DBS breakages, migration, or IPG malfunction) in a cohort of 65 dystonic patients.

Type of hardware-related complication	Primary surgery for removal of hardware or wound debridement	Secondary surgery consisting of reimplanation	Total number of surgeries required for maintenance of continuous DBS
17 infection episodes	13 surgeries were done to remove the hardware and 2 surgeries with excessive debridement of the wound and repositioning of hardware 2 plastic surgeries for wound debridement	11 replacement surgeries	28 surgeries were needed to maintain the DBS stimulation due to infection episodes
6 erosion episodes	4 surgeries for wound debriment and plastic 2 surgeries reqiured IPG removal	2 replacement of previously removed IPG	8 surgeries were needed to maintain the DBS stimulation
4 lead migration	4 surgeries to replace the migrated DBS lead	-	4 surgeries were needed
3 lead breakage	3 surgeries to replace the broken DBS lead	-	3 surgeries were needed
3 IPG malfunction	3 surgeries with IPG replacement	–	3 surgeries were needed
Total number of revisions	33 surgeries were needed to remove or manage hardware problems.	13 surgeries were needed to reimplant DBS hardware	Total number of 46 surgeries

time between the initial surgery and the development of an erosion episode was 28 months (range, 6–71 months). All patients who developed erosions were affected by PGD. Specifically, two patients were diagnosed with DYT-1-negative PGD, and one patient who developed four erosion episodes was affected by NBIA dystonia. All six erosion episodes were managed by revision surgeries. To adequately manage these three patients, a total of eight surgeries were required to remove and replace the previously explanted hardware and maintain continuous DBS therapy.

All skin erosions required revision surgeries including one wound debridement and relocation of the skin flap (erosion located over the burr hole cup), three musculocutaneous flaps (erosions located in the postauricular area), and two IPG removals with subsequent reimplantations. All revisions caused by skin erosions were uneventful. Erosion over the right IPG is shown in Video 3. The unusual erosion in the parietal region causing extrusion of the connector with the distal part of the DBS lead is shown in Video 4.

3.3. Lead migration

A total of four migrated DBS electrodes occurred in four patients. This type of complication affected 3% of the implanted electrodes and 6% of the patients. All patients who experienced a DBS lead migration were diagnosed with PGD (three with NBIA dystonia and one with DYT-1-negative PGD). The mean time elapsed between the initial surgery and the appearance of this hardware-related complication was 12 months (range, 1–34 months). One patient's minor trauma represented the lead migration's cause. In three patients, the causes for lead migration were unknown. Surgical repositioning of migrated leads was responsible for both motor and functional benefits. No recurrent cases of DBS lead migrations were observed.

3.4. Lead breakage

A total of three breakages of extracranial portions of the DBS electrodes took place in three patients. This type of complication affected 2.3% of the implanted electrodes and 4.6% of the patients. The three patients' diagnoses were as follows: DYT-1-positive PGD (n = 1), DYT-1-negative PGD (n = 1), and NBIA dystonia (n = 1). During the preoperative period, the three patients suffered from severe dystonia affecting the craniocervical musculature. After the stereotactic replacement of the broken lead, the patients achieved both motor and functional benefits. The mean time between the initial surgery and the appearance of this hardware-related complication was 57 months (range, 27–82 months). A lead breakage caused rapid reappearance of dystonia. Standard radiological examinations allowed identifying the exact side of the DBS lead breakage. Specifically, we identified one breakage near the connector and two breakages near the burr hole cup. As described in earlier reports, the stereotactic placement of a new DBS lead resulted in the disappearance of hemidystonic symptoms for the three patients. During the follow-up period, we did not observe the development of either surgery-related complications or erosions related to the exchange of broken DBS leads.

3.5. IPG malfunction

IPG malfunction represented the fourth most common hardware-related complication in our cohort of patients. This type of complication affected 2.3% of the implanted DBS systems and 4.6% of the patients. All patients who experienced IPG malfunction had a diagnosis of PGD (two patients were diagnosed with NBIA dystonia and one patient with secondary generalized dystonia). The mean time elapsed between the initial surgery and the appearance of this hardware-related complication was 7.3 months (range, 4–10 months). IPG malfunction presented with unexpected switching off. As a consequence, the patients suffered from an acute clinical aggravation of the dystonic symptoms. All patients underwent exchange of the malfunctioning IPG without neurological sequels.

4. Discussion

Hardware-related complications may inadequately affect the postoperative course of patients with implanted DBS hardware. Additionally, they may impair the maintenance of a continuous DBS therapy, which is mandatory in patients with dystonia [1–5,12,37–39]. Hardware-related complications are affected by the surgical team's experience. Additionally, the occurrence of hardware-related complications is associated with the patient's suffering and may pose a significant economic burden. Such issues strongly support the need, in the future, to minimize the incidence of hardware-related complications in DBS-treated patients.

In our cohort of patients with dystonia, the most common hardware-related complication was infection (affecting 12.3% of the operated patients). Similar to previous reports, our results confirm the observation that infections are the most common hardware-related complications in the DBS population [2,12,18,25–27]. As described in a literature overview, earlier clinical studies show that infection rates may range between 1.1% and 15.2% [25–31,42–45]. Such variability can be due to many nonprocedural and nonsurgical factors such as duration and severity of movement disorders' symptoms, patients' age at surgery, comorbidities (e.g., hypertension and diabetes mellitus), poor hygienic habits, and low cultural background [25,26,29]. Surgical factors significantly affecting the incidence of a hardware infection include a surgical technique in one stage (i.e., implantation of the entire DBS system in one surgery session) versus a staged surgery (i.e., implantation of the DBS leads first with subsequent at second stage implantation of connection cables and IPGs), duration of surgery, number of staff in the operation theater, and use and duration of postoperative antibiotic

treatment [26,27,29,30,44,45]. Additionally, both the inclusion criteria for an infection episode and the computation methods may differ [29]. Specifically, some authors calculate the infection rate based on the number of patients, while others calculate it based on the number of DBS implants [29]. Some authors group only infections that require surgical revisions, while others include superficial skin infections as well, which can be effectively treated with antibiotics alone [26–30]. Moreover, the follow-up duration influences the incidence of infection rates due to the inclusion of patients who undergo IPG replacement as a consequence of their discharged battery. Important factors to reduce infection rates are both early detection and proper management of erosions over implanted DBS hardware. Infections can be revealed during the early 30 postoperative days, generally due to intraoperative bacterial contamination. Additionally, they can develop months or even years after DBS surgery as a result of an infected preexisting erosion [29,30]. These observations should lead the treating physicians to inspect the DBS hardware during scheduled follow-up visits. Furthermore, parents and adults should be alerted to checking the skin for signs of erosion. [38,39]. These precautions may greatly lower the incidence of hardware-related infections.

We observed 17 infection episodes in eight patients. A total of three patients suffered from one infection episode, while the remaining five had ≥ 2 hardware-related infection episodes. This observation is in line with the current literature, indicating that the majority of patients affected by one infection suffer from additional ones [29,30,44].

We observed that the most common infection site in our patients was the connector site placed in the postauricular–retrosigmoid area. All infections encountered at this location were observed at least 5 months later, suggesting that their development may be related to preexisting skin erosions. The subcutaneous layer in the retromastoid region is extremely thin and very prone to erode. Changing the connector's position to the high parietal region by creating a bone groove to harbor the connector may prevent its slippage to the postauricular–retromastoid area (Fig. 1 and Fig. 2). This maneuver may greatly reduce the erosions and subsequent infections of implanted DBS hardware. The second most common infection site in our cohort was the IPG site. This can be related to malnutrition due to excessive hyperkinetic dystonic movements, especially in children affected by NBIA dystonia. To reduce the mobility of the implanted IPGs, we tried to place them far away from the skin incision by firmly suturing them to either the pectoralis or the abdominal fascia.

The burr hole cup was the least affected infection site in our patients. Such observation is very interesting because some authors highlight that this site is most commonly affected by infection episodes in their patients [29,30]. We believe that an explanation for this discordance is the patient's age and associated indication for DBS surgery. Specifically, patients with Parkinson's disease (PD) or essential tremor (ET) are usually much older at the time of surgery than those with dystonia. Elder patients with PD and ET have thinner and less supplied with blood skin in the frontal regions than the younger patients with dystonia [25]. Other authors reported equal rates of infection regardless of the indication for DBS surgery [44]. The high infection rates reported by some authors may be due to straight rather than curvilinear skin incisions made over the burr hole cup. In our cohort, an isolated skin infection over the burr hole was observed in one patient. In four additional patients, the burr hole skin infection site had multisite infections (e.g., connector and IPG locations). Such findings suggest that the burr hole cup infection resulted from spreading of the infection starting from a connector site with a purulent drainage. Additional studies also found a very low rate of infection at the burr hole cup and at the connector site [25,27]. Such differences in incidence of infection locations may primarily be attributable to the surgical technique itself (a two-stage procedure vs. the simultaneous implantation of the DBS leads). Other reports evaluating additional factors in infected and noninfected patients (i.e., age, sex, length of surgery, coexisting hypertension, presence of diabetes, tobacco use, artery coronary disease) did not have a significant impact on the development of infections [27,30,45].

To manage these 17 infection episodes in the eight patients, 17 primary surgeries were performed to remove the infected DBS hardware. Similar to other neurosurgeons, we tried to protect the intracranial components of the implanted DBS leads whenever possible. Specifically, we were mindful of the fact that the abrupt loss of continuous DBS therapy may lead to a rapid aggravation of dystonia [1,13–17,38,39]. Partial hardware removal was performed with nine surgeries, while total DBS system removal was performed with four surgeries. As mentioned above, we tried to maintain a DBS lead for usage subsequently to infection's healing. Therefore, we gave preference to the strategy of incision and wound debridement versus initial removal. Compared with other reports, the percentage of total DBS system removal in our study was lower (four total DBS system removals) [20,21,24,27,29,30,44,45].

As mentioned above, one of the main factors that may greatly influence the incidence of DBS hardware infections is postoperative antibiotic schedule. Different authors use various treatment algorithms with respect to perioperative antibiotic and postoperative antibiotic strategy [24,27,29,30,44,45]. Most authors use single preoperative dose of an antibiotic, while others authors continue oral administration

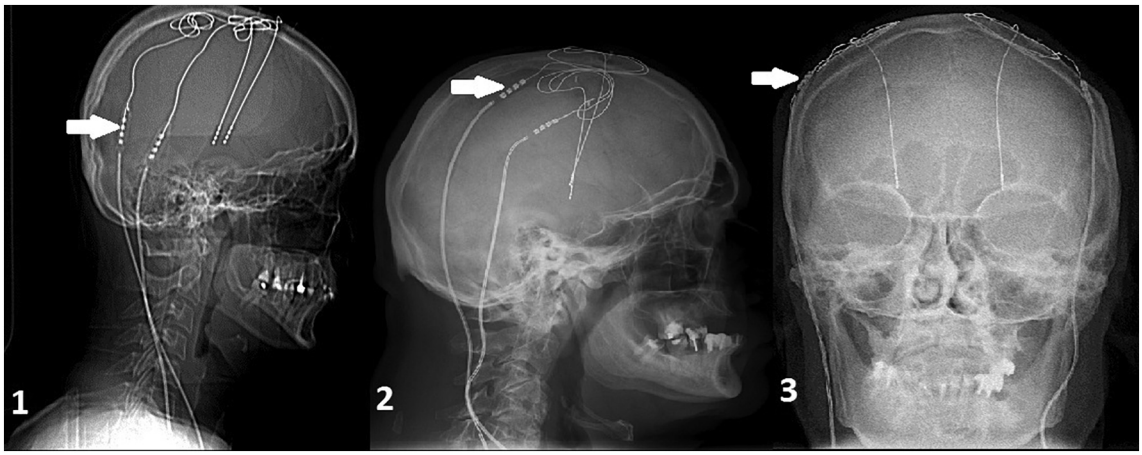

Fig. 1. Lateral X–ray of implanted electrodes. Connectors were placed and partially slipped bilaterally in the lower parieto-occipital regions. A white arrow indicates the slipped down connector. This circumstance may contribute to the development of skin erosions with subsequent infections as well as a higher incidence of breakages of the extracranial portion of a DBS lead (image 1). A white arrow marks the lateral X–ray of the connectors placed in the high parietal region (image 2). The white arrow indicates in the anteroposterior X–ray the placement of a connector in the high parietal region (image 3).

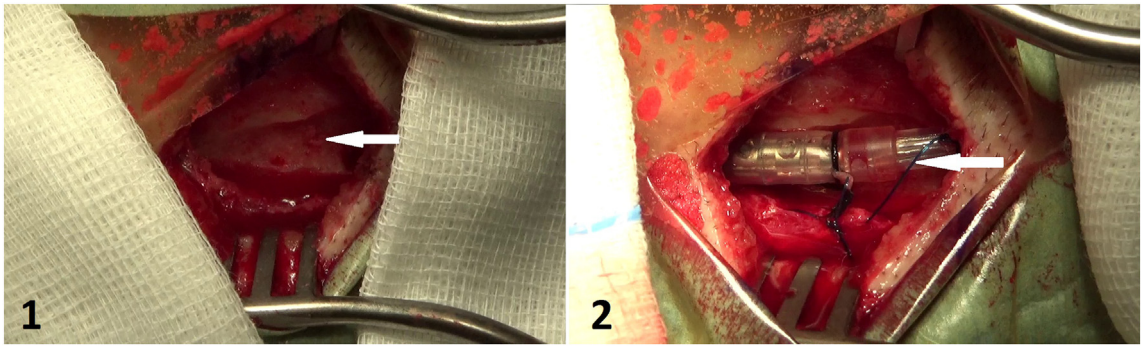

Fig. 2. The bone groove marked by the white arrow was drilled to place the connector in the high parietal region (image 1). The connector was placed in the bone groove. The white arrow indicates the placement of the anchoring suture. The latter is located around the proximal part of the connection wire, just below the connector, which prevents the connector itself from lowering (image 2).

of antibiotics even up to 7 days [29,46]. Fenoy et al. advocate that oral antibiotics should be continued in all patients for 7 days after DBS surgery as prophylactic therapy beside the preoperative single dose of cefazolin or vancomicin (if a patient has penicillin allergy) [46]. Another author used additional doses every 3 h perioperatively beside 2 g of Cefalotin prior to surgery. In cases of allergy to penicillin, most authors used vancomycin, clindamycin, or cloxacilin [29,46] As a standard cefazolin was routinely used by most authors usually 30 min to 1 h prior to incision [29,30]. If a patient was allergic to penicillin, most authors used vancomicin [27,29]. In a series of 246 consecutive DBS surgeries in 169 advanced PD patients, Kim et al. showed that infection after DBS surgery was associated with a short period of prophylactic antibiotic therapy and postoperative stay in the intensive care unit [43].

Beside prophylactic antibiotics, some authors advocate self-administered alcohol-based whole body wash on the night before DBS surgery or the morning of surgery for the prevention of surgical site infections [47]. Halpern et al. have found that using self-administered wash in a consecutive sample of 172 patients with movement disorders who underwent DBS surgery contributed to complete reduction of DBS-related infections. In a group of 48 patients with the self-administered body wash, there were no infections. In contrary, in the remaining patients without self-administered body wash, the infection rate was 6.47%, affecting 11 cases with an infection. In conclusion, these authors state that the incorporation of the self-administered antiseptic wash is warranted to be introduced as a standard antiseptic protocol for patients undergoing DBS surgery [47]. We have shown that changing the antibiotics form third-generation cephalosporin to first-generation cephalosporin with administration of alcohol-based whole body wash contributed greatly to reduce the infection rates in our series. In cases of an infection with purulent drainage, some authors advocate the so-called DBS leads-sparing hardware removal [27]. Dlouhy et al. propose the technique of usage of antibacterial-impregnated catheter coverage of DBS leads, which facilitates preservation after hardware infection [48]. In seven of eight patients with pus and deep tissue infection around the hardware at either frontal, parietal, or chest incisions, the DBS leads could be saved without the need for removal.Dlouhy et al. concluded that this technique improves the preservation of the DBS leads, is inexpensive, and confers no additional risks to patients. Moreover, the need for DBS leads reimplantation is avoided.

In addition to skin infections over the implanted hardware, we observed six episodes of skin erosion in three patients. All six surgeries for skin erosions were uneventful, similar to the two additional IPG implantations. Because the commercially available connectors used are still bulky, we began to create a groove in the outer layer of the parietal bone to place the connector. We then sutured it over with fascia (Fig. 2). Such surgical technique may reduce both skin (e.g., erosions and subsequent infections of slipped connectors into the post-auricular–retromastoid area) and hardware complication rates related to the breakage of DBS electrode's extracranial portions. We believe that placing the IPG deep over the pectoralis fascia, rather than subcutaneously, reduces the erosion and infection rates. To minimize skin complications at the IPG site, we suggest creating pockets to harbor the IPG far away from the straight skin incision. Moreover, suturing and immobilizing the IPG at the pectoralis or abdominal fascia allows aligning the IPG to the fascia's surface. This, in turn, reduces flipping or the development of edgy protrusions that can evoke wound dehiscence or skin erosion [25,30,33,41]. As stated above, simple immobilization of the connector higher in the parietal region may result in lower frequency of lead breakage. In addition to cosmetic benefits, such localization of the connector may also reduce DBS lead-related hardware complications.

As mentioned above, in the present study, skin complications (i.e., erosions and infections) affected 15% of all operated patients. Moreover, some patients were troubled by repeated erosions and infections. Among the 33 hardware-related episodes, 23 were related to skin complications due to the implanted DBS hardware. On the contrary, the true hardware-related complications like migration (n = 4), breakages (n = 3), and IPG malfunctions (n = 3) were much easier to manage. In particular, usually one repeated exchange surgery was required to adequately solve the individual's DBS problem. As previously mentioned, skin complications pose a much more complex problem. Specifically, they were associated with many repeated hospitalizations associated with DBS hardware removals and reimplantations. On the contrary, 10 hardware-related problems required only 10 repeated surgeries. In line with previous reports, our results showed that hardware-related skin complications are common and much harder to manage than true hardware damage or malfunction [2,10,12,25,27,29,30,33].

Additionally, we found that the incidence and prevalence of hardware-related complications among patients with dystonia is similar to those of other studies [12]. The overall incidence of all hardware-related complications in patients with dystonia is estimated to be 26% versus 14% in patients with PD [9,12,18,22,23,31,35,40,41,43]. This difference among hardware-related complications highlights a strong association between the indication of DBS and the incidence of hardware problems [12]. Especially, lead breakages and migrations seem to prevail in patients with dystonia versus patients with PD or ET [9,12]. Additionally, the high prevalence of children and adolescents among patients with dystonia may contribute to a higher incidence of hardware-related complications especially affecting the skin [17,38,39].

Our series included, at the time of surgery, 20 children and 45 adult patients with different dystonic conditions. Of the 16 patients affected by hardware-related complications, six were children and ten were adults at the time of surgery. This means that 30% of the operated patients aged < 18 years developed hardware-related complications in subsequent months, as opposed to 22% of adult patients with dystonia. Also, among the 33 hardware-related complication episodes, 16

occurred in children. These numbers suggest that patients with dystonia have greater chance of being affected by a hardware-related complication. Interestingly, to correct the 16/33 hardware compilations in children, 20 revision surgeries were performed. Such finding demonstrates that infections and erosions were more frequently found in children and required additional implantation surgeries postinfection healing. Among the six children affected by hardware-related complications, five were diagnosed with NBIA dystonia and one with DYT1-positive PGD. In the group of NBIA patients with dystonia, we observed that DBS hardware removal was performed following infections ($n = 4$) and erosions ($n = 2$). Revision surgeries were either replacements postinfection healing (n = 4) or replacement surgeries postwound healing due to primary erosions (n = 2). One patient developed on one side a massive infection of all components of the DBS system and refused the reimplantation procedure following a successful wound healing. Additionally, two surgeries in patients with NBIA were performed due to small wound dehiscence, which required plastic surgery. Overall, patients with NBIA dystonia required surgeries for hardware removal (partial or total, $n = 7$), replacement surgeries ($n = 6$), and wound debridement (n = 2).

Since all infections described in the present study appeared after 30 days from surgery, we believe that in children, most infections resulted from contaminated preexisting erosions. To reduce future problematic skin complications, it is necessary to increase the awareness of parents or legal guardians of children harboring DBS hardware by prompting them to perform frequent inspections of the skin. The other types of hardware-related complications (e.g., DBS lead migration or breakage) were also more commonly seen in children than in adult patients with dystonia. Such types of hardware-related complications can be explained by the severe hyperkinetic movements of children referred for DBS surgery. An additional explanation is the postoperative response of bilateral continuous stimulation, which is well expressed in DYT-1-positive PGD and in segmental dystonia of adult patients [2–7]. Based on the dystonia's etiology, we can conclude that adult patients with DYT-1-positive PGD had the lowest incidence of hardware-related complications, contrary to children with NBIA dystonia who experienced the highest incidence of hardware complications [2–7,38,39]. It is well known that the response to bilateral GPi in DYT-1-positive PGD is not usually fast. However, it increases with the stimulation period, potentially contributing to reduce hardware-related complications. This observation is in line with other reports showing that treated DYT-1-positive PGD patients had a relatively lower incidence of all complications, including hardware-related complications [2,4,5,7,8,37].

Interestingly, hardware-related complications in patients with cervical dystonia or dystonia affecting the cervico–thoracic musculature were not observed. Some authors suggested that hyperkinetic axial dystonic movements lead an increased incidence of hardware breakages and lead migration [9,12]. We could not support this observation because our 10 patients with cervical or truncal dystonia were not troubled by breakages or migration of DBS lead, except for one patient, who developed one infection and two erosion episodes.

Several limitations can be identified in the present study. First, it was a retrospective analysis of hardware-related DBS complications for different dystonic conditions. Second, patients who were treated at our center from remote areas were subsequently managed nearer to their locations, contributing to the loss of some patients to follow-up. Additionally, IPG replacement as DBS surgery became more available at other institutions, closer to the permanent residence of our patients. These circumstances contributed greatly to the dropout of patients from our follow-up. We attempted to contact the patients or their parents or caregivers. As a consequence, we became aware of four deaths related to dystonia progression. The patients who passed away harbored the following diagnosis: NBIA dystonia ($n = 2$) and secondary dystonia (n = 2). Among the contacted patients with NBIA dystonia, most required constant assistance. After DBS surgery, the patients with DYT-1-positive PGD and segmental dystonia affecting the cranio–cervical–thoracic musculature remained healthy, in contrast to patients with NBIA dystonia and secondary generalized dystonia. Our heterogeneous group of patients enabled us to recognize the most vulnerable group of patients with dystonia to development of hardware-related complications. Pediatric patients referred for DBS surgery as well patients with secondary generalized dystonia should be informed about their possible increased risk of hardware-related complications. We believe that in many of these patients, subsequent infections developed from preexisting erosions, which may have been overlooked by children and their parents. Patient information and teaching is needed to reduce skin complications due to implanted DBS hardware, especially in children with dystonia. We believe that all hardware-related complications should be collected and registered in a prospective, homogeneous, and unbiased way. DBS hardware manufacturers should undertake the attempt to optimize the dimensions of the DBS hardware itself. This is especially true for implantation in the pediatric population. The latter constitutes still a large number of patients with dystonia referred for DBS surgery. In the future, information sessions for patients, parents, and legal guardians may greatly lower problematic skin complications related to implanted DBS hardware.

5. Conclusion

The present study included 65 patients with different dystonic conditions. The overall rate of all hardware-related complications affected 25% of the operated patients. Skin complications (infections and erosions) were the most commonly observed complications. They required a higher number of repeated surgeries compared with true hardware malfunctions (e.g., lead breakage, migration, or IPG failure). The most vulnerable population of patients troubled by hardware complications were children with NBIA dystonia, as opposed to adult patients with DYT-1-positive PGD or dystonia affecting the cervical and truncal musculature. The simple maneuver of suturing (immobilizing) the connector within the bone groove in the high parietal region can reduce not only erosion and infection rates but also possible breakages or migrations of a DBS lead.

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