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An unexpectedly high rate of revisions and removals in deep brain stimulation surgery: Analysis of multiple databases

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Abstract

Introduction—Deep brain stimulation (DBS) is an established therapy for movement disorders, and is under active investigation for other neurologic and psychiatric indications. While many studies describe outcomes and complications related to stimulation therapies, the majority of these are from large academic centers, and results may differ from those in general neurosurgical practice.

Methods—Using data from both the Centers for Medicare and Medicaid Services (CMS) and the National Surgical Quality Improvement Program (NSQIP), we identified all DBS procedures related to primary placement, revision, or removal of intracranial electrodes. Cases of cortical stimulation and stimulation for epilepsy were excluded.

Results—Over 28,000 cases of DBS electrode placement, revision, and removal were identified during the years 2004–2013. In the Medicare dataset, 15.2% and of these procedures were for intracranial electrode revision or removal, compared to 34.0% in the NSQIP dataset. In NSQIP, significant predictors of revision and removal were decreased age (odds ratio (OR) of 0.96; 95% CI: 0.94, 0.98) and higher ASA classification (OR 2.41; 95% CI: 1.22, 4.75). Up to 48.5% of revisions may have been due to improper targeting or lack of therapeutic effect.

Conclusion—Data from multiple North American databases suggest that intracranial neurostimulation therapies have a rate of revision and removal higher than previously reported, between 15.2 and 34.0%. While there are many limitations to registry-based studies, there is a clear need to better track and understand the true prevalence and nature of such failures as they occur in the wider surgical community.

Keywords

Deep brain stimulation; Quality improvement; Complications; Adverse events; Movement disorders

1. Introduction

Deep brain stimulation (DBS) is an effective surgical treatment for Parkinson's disease (PD) [1,2], essential tremor (ET) [3,4], and dystonia [5], with new indications under active investigation. Several studies from academic centers have documented the rate of electrode

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revision for DBS surgery, with rates ranging from under 2% in the acute phase [6] to 12.4% at 7 years of follow-up [7], and with causes including poor initial placement [8,9], lead migration [8,10], hardware failure [9,11], and infection [12,13]. Yet the rate of revisions in the general neurosurgical community, outside of reported academic series, is unknown.

The Centers for Medicare and Medicaid Services (CMS) Part B has released data publicly on all allowed services since the year 2000. This is a very useful dataset, since Medicare covers an estimated 63% of DBS surgery implants [14]. Also of note, the American College of Surgeons (ACS) began prospectively collecting data on surgical procedures and their complications in 2005 as part of the National Surgical Quality Improvement Program (NSQIP) [15–17]. The NSQIP database uses trained personnel to capture patient and procedural data from over 600 North American hospitals, including centers in Canada and Mexico. Medical and surgical complications are strictly defined, unlike many retrospective studies, and the data entry personnel are frequently audited to ensure accurate additions to the database. Unlike the commonly studied Nationwide Inpatient Sample (NIS) [14,18], NSQIP does not rely on billing statistics for its data acquisition, and is based on the more specific Current Procedure Terminology (CPT) codes to identify surgical procedures, rather than the International Classification of Diseases (ICD-9) codes. As an example, ICD-9 has one code for primary placement or revision of DBS leads (02.93), but there is no way to determine whether a procedure is a primary placement or revision from ICD-9. In contrast, CPT has codes for implantation of the first array both with (61867) and without electrophysiological recording (61863), additional leads with (61864) and without recording (61868), and revision or removal of leads (61880). This allows for a more precise characterization of national practice patterns than the NIS can provide.

Combining the large CMS Part B database and the more precise NSQIP database (which includes expertly curated demographic and complication data) offers a unique view on the current scope of DBS surgeries being carried out in North America, along with the attendant complications in the community at large. Herein, we combine insights from both databases to summarize the current landscape of DBS surgery as it is carried out in North America, the frequency of electrode revisions and removals, and surgical complications.

2. Methods

Records for 2,972,860 surgical procedures from 2005 to 2013 from the NSQIP database were searched for any procedure containing the following CPT codes: 61863, 61864, 61867, 61868, and 61880 (see Table 1 for definitions). These codes could be listed as either the primary CPT code or any of the 20 concurrent CPT codes tracked for each procedure in the database. Epilepsy cases were excluded, since there was no FDA-approved neurostimulation therapy until the last 1.5 months of the 108 months study period (November 14, 2013; the Responsive Neurostimulator of NeuroPace [19]).

Similarly, the number of allowed cases for each CPT code was extracted from the CMS Part B database form 2004–2013 (different CPT codes were used prior to 2004, making it difficult to include older data). The publicly available CMS Part B data has no demographic information, and only includes the number of services.

The 61880 CPT code is technically valid for removal of any intracranial stimulation electrode, including those placed for cortical targets (e.g., for motor cortex stimulation for pain [20–22]). Such cortical stimulation placement would be coded with CPT codes 61850 (burr hold for cortical stimulation electrode) and 61860 (craniotomy or craniectomy for cortical stimulation electrode). However, there were so few of these cortical cases (280 out of 28,662 cases across both databases, 0.98%), that we excluded these from analysis. Our analysis focused on subcortical stimulation exclusively.

All statistical analysis was performed with SPSS version 23 (IBM; Armonk, NY, USA). Averages were presented with standard deviation (SD) unless otherwise specified. Means were compared using a Student's *t*-test. Multivariable regression was done with a backward Wald method, an exclusion cut-off of 0.1, and a maximum of 200 iterations. Statistical significance was set to $p < 0.05$.

3. Results

Using the NSQIP database from 2005 to 2013 and the CMS Part B database from 2004 to 2013, we identified 28,370 cases of DBS surgery using the CPT codes identified in Table 1. Cases with solely the insertion, replacement, or removal of a pulse generator (CPT codes in Table 2), were not included.

Using the CPT code 61880, we were able to separate cases that included the revision or removal of neurostimulator electrodes (Tables 3 and 6). Revisions and removals occurred in 15.2% of CMS cases (4289 of 28,179 cases) and 34.0% of NSQIP cases (66 of 194 cases; Table 3). Microelectrode recording occurred in 87.3% (CMS) and 90.4% of cases (NSQIP).

Using the additional data provided in the NSQIP database (which is not available from CMS), procedures were grouped based on the ICD-9 coding of the postoperative diagnosis, which provides data on the surgical indication (Table 4). The most frequent indication for primary surgeries was movement disorder (94.5%), with PD the most commonly treated (63.3%). For revisions, device complications were listed as the primary postoperative diagnosis in 22.7% of cases, and infections in a further 24.2%. Baseline patient demographics are shown in Table 5.

Multivariable regression was used to find significant predictors of revision in the NSQIP cases Both age and ASA (American Society of Anesthesiologists) physical status classification emerged as significant predictors (Table 5). Age was negatively correlated with revision/removal, with an odds ratio (OR) of 0.96 (95% CI: 0.94, 0.98) and ASA class was positively correlated with an OR of 2.41 (95% CI: 1.22, 4.75).

When CPT codes are assigned to cases, there is one code for placement of the first DBS electrode (61863 or 61867), and a separate CPT code for the second DBS electrode, if a second lead is implanted (61864 or 61868). There are also different versions of both codes for performing the surgery with and without microelectrode recording (MER). Using these codes, we were able to extract the number of procedures with these characteristics (unilateral vs. bilateral; with or without MER) in both primary surgeries and revisions (Table 5). Among primary placements, 62.6% (14,966 cases; CMS) to 68.0% (88 cases; NSQIP) were

unilateral, in that they did not code for additional electrode placements. Most placements documented the use of microelectrode recording (87.3%, 20,845 cases, in the CMS database and 90.4%, 117 cases, in the NSQIP database). Unfortunately, there is no way (with these databases) to determine whether revisions or removals were for bilateral or unilateral electrodes.

Pulse generator placement is coded separately in the CPT system (Table 2), but is somewhat imprecise. There are codes for primary placement or revision (CPT codes 61885 and 61886), but also a separate code for revision or removal (CPT 61888). A small number of cases did code for both (2.1%) concurrently. A majority of the revision surgeries (65.2%) did not code for a simultaneous pulse generator revision, while the majority of primary placement cases coded for simultaneous pulse generator placement (96.9%), suggesting that most primary placements were a single surgery with the pulse generator included, rather than a staged surgery. This data was not available in the CMS database, since CPT codes were not grouped by patient.

4. Discussion

While many studies have documented the complications and revision rates of DBS surgeries, most are from high-volume academic centers, and do not necessarily reflect the experience of community neurosurgeons. Using the ACS NSQIP and CMS databases, we identified 28,370 DBS electrode placement and revision cases from 2004 to 2013, spanning a wide range of clinical settings throughout North America.

A high number of DBS cases in these databases were for revision or removal of intracranial electrodes (15.2% in CMS and 34.0% in NSQIP), higher than the upper limits of what has previously been reported (e.g., 12.4% at 7 years follow-up in one study [7]).

Post-operative diagnosis data were only available in the NSQIP database, and not in the CMS dataset. While this is a small population, it nevertheless offers some insight into the characteristics of patients undergoing revision. For example, nearly half of revisions and removals (31 out of 66 NSQIP cases; 47%) were for hardware complications or infection. An additional 2 cases were for brain tumors and 1 for breast cancer, which presumably necessitated removing the hardware for separate oncological treatments. These tumor, hardware failure, and infection cases together account for 51.5% of revision cases. The remaining cases were likely required for malpositioned electrodes or lack of clinical effect, as these are the only other indications for electrode revision or removal. This is consistent with prior studies of failed DBS therapy, where suboptimally placed electrodes accounted for 46% of revisions referred to two centers [23]. Revision of malpositioned electrodes offers a considerable chance for improvement, with one study showing a 24.4% improvement in UPDRS scores for revised PD patients, a 60.4% Tremor Rating Scale improvement in ET patients, and a 75% improvement in the Unified Dystonia Rating Scale for dystonia patients [24].

Significant predictors of revision (using the NSQIP data) were age and ASA physical status classification. ASA classification reflects worse functional status preoperatively, which

likely predisposes the patient to other complications. Age, on the other hand, appeared to have a protective effect. While the mechanism is unknown, this might reflect the reluctance to revise an electrode in older patients, or possibly that older patients have less time for hardware failures or complications to accrue before other medical problems preclude them from additional neurostimulation therapy.

There are many reasons that the estimates of revision rates from CMS and NSQIP are higher than previous reports. Reporting bias likely plays some role [25], but there are also important to differences in follow-up when examining CMS and NSQIP databases as compared to clinical trials or case series. The CMS and NSQIP databases capture revisions at the time of their performance, and in that sense are not related to the “follow-up” of a particular patient. That is, they capture all the primary and revision surgeries that occur in one year. On the other hand, most reported case series and trials follow a single patient after primary placement, and only record a revision if it happens within a defined follow-up period (for example, 6 months, 1 year, etc.). The CMS and NSQIP data will therefore capture revisions occurring at any time in a patient’s treatment, which could be years or decades after the first placement. Traditional case series and trials will not.

Another likely cause of the higher rates in CMS and NSQIP is the heterogeneous population of hospitals participating in these databases. Prior studies using the Nationwide Inpatient Sample found a beneficial association between surgical volume and outcome [14,26], so it is possible that by including many low-volume surgical centers in the above analysis, we observe an increased rate of revisions and removals that high-volume centers do not encounter—and these are the centers that typically publish their surgical experiences. Such volume-outcome relationships have been observed in nearly all areas of neurosurgery [27], and could be explored as a possible contributor to DBS revisions.

Why are the rates of revision and removal different between the CMS and NSQIP databases? While both rates are higher than expected, the NSQIP database shows that over one-third of cases (34.0%) are for revisions and removals, compared to the 15.2% in the CMS database. One source of differentiation between the two databases is the patient population. NSQIP includes both private and public insurers, unlike the single-payer Medicare database. This entails different socioeconomic backgrounds and potential baseline health statuses, and also means the two databases almost certainly have different age distributions. With the exception of end-stage renal disease, Medicare becomes available to those over the age of 65, while the average age of the NSQIP DBS cohort was 61.1 ± 13.7 years (Table 5). As noted in the Results section, there was a significant trend for patients undergoing electrode revision to be younger (average age 57.1 ± 15.3 years). It is possible, therefore, that the difference between the two databases reflects the younger age of the NSQIP patients, and their increased likelihood for getting revisions and removals as compared to the older Medicare patients.

The true proportion of DBS surgeries for revision or explanation is unknown, but possibly between the two estimates herein: 15.2% for CMS and 34.0% for NSQIP. Ideally, companies providing DBS hardware would provide their data to a disinterested third party for detailed analysis of the frequency of electrode revisions and removals. Even then, though, pure

hardware removal surgeries might escape documentation by device manufacturers, leading to continued underestimates. National and international databases of neurostimulation surgeries, like CMS or NSQIP, remain the best alternative until these additional data are available.

4.1. Limitations

There are many limitations to this study. First, the NSQIP and CMS databases are a limited sampling of cases. The number of cases reported here, 28,370 is a subsample of the over 100,000 DBS implants that have reportedly been performed worldwide [28]. Other large databases like the NIS do not track procedures in enough detail to differentiate primary electrode placement vs. revision, since they are based on ICD-9 procedure codes rather than CPT codes. Newer registries, like the National Neurosurgery Quality and Outcomes Database (N2QOD), do not yet have modules tracking neurostimulation surgeries specifically, but might in the future.

Another limitation is the lack of demographic data and diagnostic data in the CMS database. The NSQIP database has much of this information, allowing us to analyze certain predictors of revision surgery, though the NSQIP dataset is unfortunately smaller than that of the CMS. Furthermore, there is only a single postoperative diagnosis tracked in the NSQIP database. Therefore, it is unknown to what extent a postoperative diagnosis of PD also involved hardware failure and vice versa. For example, if a patient's primary diagnosis was listed as hardware infection, there is no way to know what the initial indication for DBS surgery was, whether PD, ET, or some other condition.

CPT codes themselves present a limitation in the amount of information they contain. For instance, there is no diagnostic information in the code, and only procedural information. That is, a CPT code can say a DBS electrode was placed, but not the indication. Databases that combine ICD codes with CPT codes hold the most promise in ameliorating this concern, and the NSQIP dataset does this to some degree (though, as noted above, NSQIP only logs a single diagnostic code). A further limitation is the inability to differentiate electrode removal from revision, since a single code is used for both. This lack of clarity also poorly accounts for the difference in work between the two procedures.

5. Conclusion

Of 28,370 tracked DBS procedures, 15.2% (CMS) and 34.0% (NSQIP) were undertaken for electrode revision or removal. This rate of revision and explantation in the North American surgical community deserves further study. The true prevalence of such revision surgeries should be documented, and the indications understood, in order to best serve these patient populations.

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Table 1

CPT codes for neurostimulation electrode implantation, revision, and removal.

CPT code	Description
61863	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61867	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; first array
61868	Twist drill, burr hole, craniotomy, or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (eg, thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of intraoperative microelectrode recording; each additional array (List separately in addition to primary procedure)
61880	Revision or removal of intracranial neurostimulator electrodes

Table 2

CPT codes for neurostimulator pulse generator placement, revision, and removal.

CPT code	Description
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver

Table 3

Rates of DBS procedures across the Medicare Part B database, 2004–2013, and the ACS NSQIP database, 2005–2013.

Procedure	Medicare part B (%)	NSQIP (%)	All (%)
Stereotactic implant of subcortical electrode, without MER			
First array	3045 (10.8)	12 (6.2)	3057 (10.8)
Second array	1162 (4.1)[a]	3 (1.5)[a]	1165 (4.1)[a]
Stereotactic implant of subcortical electrode, with MER			
First array	20845 (74.0)	113 (58.2)	20958 (73.9)
Second array	7762 (27.5)[a]	37 (19.1)[a]	7799 (27.5)[a]
Revision or removal of intracranial stimulator electrodes	4289 (15.2)	66 (34.0)	4355 (15.4)
Total	***28179***	***194***	***28370***

[a]Because second array placements are not primary procedures, they are not included in the total number of procedures (i.e., one cannot bill only for a second array without a first array). Percentages are based off the total number of procedures excluding second arrays.

Table 4

Principal diagnoses of primary and revision surgeries in NSQIP database (based on ICD-9 codes).

Principal diagnosis	Primary (n = 128)	Revision or removal (n = 66)	All (n = 194)
Movement disorders	**121 (94.5)**	**24 (36.4)**	**145 (74.7)**
Parkinson's	81 (63.3)	16 (24.2)	97 (50.0)
Essential tremor	31 (24.2)	2 (3.0)	33 (17.0)
Dystonia	7 (5.5)	2 (3.0)	9 (4.6)
Abnormal involuntary movements	2 (1.6)	3 (4.5)	5 (2.6)
Undefined movement disorder		1 (1.5)	1 (0.5)
Other neurologic/psychiatric disorders	**5 (3.9)**	**3 (4.5)**	**8 (4.1)**
Depression	2 (1.6)		2 (1.0)
Atypical facial pain	1 (0.8)	1 (1.5)	2 (1.0)
Trigeminal neuralgia		1 (1.5)	1 (0.5)
Complex regional pain		1 (1.5)	1 (0.5)
Tourette's	1 (0.8)		1 (0.5)
Multiple sclerosis	1 (0.8)		1 (0.5)
Device complication	**0**	**15 (22.7)**	**15 (7.7)**
Malfunction of device		12 (18.2)	12 (6.2)
Other device complication		3 (4.5)	3 (1.5)
Infection or wound complication	**0**	**16 (24.2)**	**16 (8.2)**
Infection of device		13 (19.7)	13 (6.7)
Open scalp wound		1 (1.5)	1 (0.5)
Wound dehiscence		1 (1.5)	1 (0.5)
Other postoperative infection		1 (1.5)	1 (0.5)
Other	**1 (0.8)**	**8 (12.1)**	**9 (4.6)**
Adjustment of brain "neuropacemaker"		3 (4.5)	3 (1.5)
Brain tumor		2 (3.0)	2 (1.0)
Blindness		1 (1.5)	1 (0.5)
Cranial nerve injury		1 (1.5)	1 (0.5)
Breast cancer		1 (1.5)	1 (0.5)
Meningitis/arachnoiditis	1 (0.8)		1 (0.5)

Table 5

Patient demographics for surgeries in NSQIP database (N = 194). Variables significantly associated with revision are shown in bold.

Patient characteristic	Primary placement (%)	Revision (%)	Total (%)	Univariate odds ratio (95% CI)	Multivariate odds ratio (95% CI)[b]
Gender					
Male	79 (61.7)	38 (57.6)	117 (60.3)	1 [reference]	
Female	49 (38.3)	28 (42.4)	77 (39.7)	1.2 (0.6, 2.2)	
Age (years ± SD)	**63.7 ± 12.2**	**57.1 ± 15.3**	**61.1 ± 13.7**	***p* = 0.003**[a]	**0.96 (0.94, 0.98**[a]
Height (inches ± SD)	67.0 ± 4.3	67.5 ± 4.0	67.1 ± 4.2	*p* = 0.429	
Weight (lbs. ± SD)	180.9 ± 44.0	186.0 ± 51.3	182.7 ± 46.5	*p* = 0.494	
ASA Classification	**2.6 ± 0.5**	**2.7 ± 0.5**	**2.6 ± 0.5**	***p* = 0.061**	**2.41 (1.22, 4.75)**[a]
Race					
White	119 (93.0)	60 (90.9)	179 (92.3)	1 [reference]	
Black or African American	0	3 (4.5)	3 (1.5)	n/a	
Asian or Pacific islander	2 (1.6)	0	1 (1.0)	n/a	
Unknown	7 (5.5)	3 (4.5)	10 (5.2)	0.9 (0.2, 3.4)	
Hispanic ethnicity					
No	121 (94.5)	63 (95.5)	184 (94.8)	1 [reference]	
Yes	4 (3.1)	1 (1.5)	5 (2.6)	0.5 (0.05, 4.4)	
Unknown	3 (2.3)	2 (3.0)	5 (2.6)	1.3 (0.2, 7.9)	
Diabetes					
No	115 (89.8)	57 (86.4)	172 (88.7)	1 [reference]	
Yes	12 (9.4)	9 (13.6)	21 (10.8)	1.5 (0.6, 3.8)	
Dyspnea					
No	121 (94.5)	65 (98.5)	186 (95.9)	1 [reference]	
Yes	7 (5.5)	1 (1.5)	8 (4.1)	0.3 (0.03, 2.2)	
Hypertension requiring medication					
No	79 (61.7)	43 (65.2)	122 (62.9)	1 [reference]	
Yes	49 (38.3)	23 (34.8)	72 (37.1)	0.9 (0.5, 1.6)	
Tobacco use					
No	116 (90.6)	62 (93.9)	178 (91.8)	1 [reference]	
Yes	12 (9.4)	4 (6.1)	16 (8.2)	0.6 (0.2, 2.0)	

[a] Indicates a statistically significant difference.

[b] Using the backward Wald method. Only variables with significant associations of $p < 0.1$ were included in the model.

Table 6

Surgical characteristics for primary and revision surgeries in NSQIP database.

Surgical characteristic	Primary placement	Revision/removal	All
	Number (%)	Number (%)	Number (%)
Unilateral vs. bilateral placement			
Unilateral	88 (68.8)	[a]	88 (45.4)[a]
Bilateral	40 (31.3)		40 (20.6)[a]
Microelectrode recording used			
No	11 (8.6)	[a]	11 (5.7)[a]
Yes	117 (91.4)		117 (60.3)[a]
Battery placement/replacement/removal in same surgery[b]			
No	2 (1.6)	43 (65.2)	45 (23.2)
Placement or revision (CPT 61885 or 61886)	124 (96.9)	8 (12.1)	132 (68.0)
Removal or revision (CPT 61888)	0	13 (19.7)	13 (6.7)
Dual coded[c]	2 (1.6)	2 (3.0)	4 (2.1)
Any complication			
No	118 (92.2)	59 (89.4)	177 (91.2)
Yes	10 (7.8)	7 (10.6)	17 (8.8)

[a]There is no explicit code for unilateral vs. bilateral revision/removal of electrodes, nor for the utilization of microelectrode recording for revision. Therefore, none of the cases marked as revisions/removals could be categorized.

[b]There is one CPT code for revision/removal of pulse generators (61888) and two for primary placement or revision (61885 and 61886).

[c]These cases listed both the 61888 CPT code for revision/removal and either 61885 or 61886 for placement/revision.