Parkinsonism and Related Disorders xxx (2016) 1–6

Contents lists available at ScienceDirect

Parkinsonism and Related Disorders

journal homepage: www.elsevier.com/locate/parkreldis

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

John D. Rolston*, Dario J. Englot, Philip A. Starr, Paul S. Larson

Department of Neurological Surgery, University of California, San Francisco, United States

ARTICLE INFO

Article history:
Received 31 July 2016
Received in revised form
7 September 2016
Accepted 12 September 2016

Keywords:
Deep brain stimulation
Quality improvement
Complications
Adverse events
Movement disorders

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.

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 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

* Corresponding author. 505 Parnassus Ave., M779, Department of Neurological Surgery, University of California, San Francisco, CA 94143-0112, United States.
E-mail address: john.rolston@ucsf.edu (J.D. Rolston).

http://dx.doi.org/10.1016/j.parkreldis.2016.09.014
1353-8020/

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

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

Please cite this article in press as: J.D. Rolston, et al., An unexpectedly high rate of revisions and removals in deep brain stimulation surgery: Analysis of multiple databases, Parkinsonism and Related Disorders (2016), http://dx.doi.org/10.1016/j.parkreldis.2016.09.014