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Comparison of Bilateral Versus Staged Unilateral Deep Brain Stimulation (DBS) in Parkinson's Disease in patients under 70 years of age

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Abstract

Objective—The most popular surgical method for deep brain stimulation (DBS) in Parkinson's Disease (PD) is simultaneous bilateral DBS. However, some centers conduct a staged unilateral approach advocating that reduced continuous intraoperative time reduces post-operative complications, thus justifying the cost of a second operative session. To test these assumptions, we performed a retrospective analysis of the Truven Health MarketScan® Database.

Methods—Using the MarketScan® Database, we retrospectively analyzed patients that underwent simultaneous bilateral or staged unilateral DBS between 2000 and 2009. The main outcome measures were 90-day post-operative complication rates, number of reprogramming hours one year following procedure, and annualized healthcare cost. The outcome measures were compared between cohorts using multivariate regressions controlling for appropriate covariates.

Results—A total of 713 patients that underwent DBS between 2000 and 2009 met inclusion criteria for the study. Of these patients, 556 underwent simultaneous bilateral DBS and 157 received staged unilateral DBS. No statistically significant differences were found between groups in the rate of infection (simultaneous: 4.3% vs. staged: 7.0%; $p=0.178$), pneumonia (3.1% vs. 5.7%; $p=0.283$), hemorrhage (2.9% vs. 2.5%; $p=0.844$), pulmonary embolism (0.5% vs. 1.3%), and device-related complications (0.5% vs. 0.0%). Patients in the staged cohort had a higher rate of lead revision in 90 days (3.2% vs. 12.7%; $RR=3.07$; $p<.001$). The staged cohort had a higher

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mean (SD) number of reprogramming hours within 1 year of procedure (6.0 ± 5.7 vs. 7.8 ± 8.1 ; $RR=1.17$; $p<0.001$). No significant difference was found between the mean (SD) annualized payments between the cohorts ($\$86,100 \pm \$94,700$ vs. $\$102,100 \pm \$121,500$; $p=0.148$).

Conclusion—Our study did not find a significant difference between 90-day post-operative complication rates or annualized cost between the staged and simultaneous cohorts. Thus, we believe that it is important to consider other factors when deciding between the staged and simultaneous DBS. Such factors include patient convenience and the laterality of symptoms.

Keywords

Complications; Deep Brain Stimulation; Functional Electrical Stimulation; Movement Disorders; Parkinson's Disease

Introduction

Parkinson's Disease (PD) affects an estimated 1 million people in the United States making it the second most common neurodegenerative disorder and a significant source of disability^{1,2}. The motor symptoms of PD, which include tremor, rigidity, and bradykinesia, greatly reduce patients' quality of life through hindering of both physical and social function^{2,3}. Levodopa therapy is the treatment mainstay; however medication-induced motor complications affect the majority of patients in advanced stages of the disease⁴. Bilateral deep brain stimulation (DBS) of both the subthalamic nucleus (STN) and globus pallidus interna (GPi) have been shown to improve motor functioning and quality of life in patients with advanced PD⁵⁻¹⁵. Despite its proven clinical benefits, DBS surgery comes with risks and is associated with peri- and postoperative complications including intracranial hemorrhage, infection, pneumonia, and pulmonary embolism^{16,17}.

The two major timelines for implanting electrodes include simultaneous bilateral DBS (i.e. implanting both electrodes bilaterally in the same operative session) and staged unilateral DBS (i.e. implanting one electrode in the first operative session, and then waiting days, weeks or even months before implanting on the contralateral side). Proponents of the staged approach hypothesize that the reduced continuous intraoperative time leads to reduced complication rates¹⁸. There is a paucity of data on whether the staged approach offers any safety benefit meriting the additional cost of a second trip to the operating room. To our knowledge, there has been no study that directly compares peri- and postoperative complication rates or healthcare costs between staged unilateral and simultaneous bilateral DBS. The goal of this study is to compare complication rates (intracranial hemorrhage, infection, pneumonia, and pulmonary embolism) and healthcare costs between simultaneous bilateral DBS and staged unilateral DBS.

Methods

Data Source

Data for this study was obtained using the Truven Health MarketScan® Database. This database contains information on more than 200 million unique patients since 1995 in the United States. It contains fully integrated patient-level data, including inpatient, outpatient,

drug, and lab information from commercial, Medicare Supplemental, and Medicaid populations. In this study, we examined all patient healthcare utilization between 2000 and 2009 including clinical utilization (inpatient and outpatient), pharmaceutical claims, insurance enrollment and costs representing all subsections of the MarketScan database. In MarketScan each patient is assigned a unique, encrypted enrollee ID that is used to link patient information between tables while allowing all patient information to be de-identified. Because the MarketScan database is de-identified, the Duke University Institutional Review Board deemed our study exempt from review.

Study Sample

International Classification of Diseases (ICD-9) diagnosis and Current Procedural Terminology (CPT-4) procedure codes were used to identify patients for inclusion in the study. To be included in the study, patients had to have a diagnosis of Parkinson's disease (ICD-9 332.0) and have undergone bilateral or staged unilateral DBS (CPT-4: 61863+61864 or 61867+61868). Other inclusion criteria included patient age greater than 18 at the index time of hospitalization. The patients were separated into 2 cohorts: staged unilateral DBS and simultaneous bilateral DBS. Patients in the staged unilateral cohort had unilateral DBS implantation (CPT-4: 61863 or 61867) followed by a second inpatient admission with DBS implantation on the contralateral side (CPT-4: 61863 or 61867) within 360 days. Patients included in the simultaneous bilateral cohort had one inpatient admission with both electrodes implanted in the same operative session (CPT-4: 61863+61864 or 61867+61868). Patients without at least 90 days of follow up after the procedure were eliminated from the sample.

Overall there were 65,101 patients in the database with PD and 1,757 had the diagnosis and procedure codes for DBS implantation listed above. Finally, 713 patients underwent a simultaneous bilateral or staged unilateral procedure. See Figure 1 for an illustrative depiction of patient inclusion/exclusion.

Main Outcome Measures

The main outcome measures for this study were overall postoperative complication rate within 90 days of procedure (including hemorrhage or hematoma, infection, pneumonia, pulmonary embolism, and device-related complications), rate of lead revision (ICD-9: 01.22 or 02.93; CPT: 61880) or generator revision (ICD-9: 86.05 or 86.06; CPT: 61888) within 90 days of procedure, reprogramming hours within 1 year of procedure (CPT: 95978 or 95979), and annualized and standardized submitted healthcare charges. Complication rates were acquired by examining ICD-9 and CPT codes for all hospital admissions within 90 days after DBS surgery. Healthcare costs were recorded beginning on the day of the first DBS procedure and all costs were recorded for the remainder of the patients' follow-up within the database. Each patient's total healthcare costs was then divided by the total number of follow-up days and multiplied by 365 to calculate annualized healthcare costs.

Statistical Analysis

All continuous variables including age, number of reprogramming hours, number of months of follow up, and patient healthcare charges were summarized using means and standard

deviations. Categorical variables including gender, Charlson Comorbidity Index (dichotomized to 0 and 1), insurance type, employment status, postoperative complication rates (including hemorrhage or hematoma, infection, pneumonia, pulmonary embolism, and device-related complications), rate of lead revision, and rate of generator revision were summarized using counts and percentages. A Kaplan-Meier survival curve was used to compare time free from revision between the staged unilateral and simultaneous bilateral cohorts. The rate of postoperative complications (including hemorrhage or hematoma, infection, and pneumonia) between the two cohorts was analyzed using multivariate logistic regression. Pulmonary embolism and device-related complications could not be included in multivariate regression because the number of events was too low between both cohorts. Patient healthcare charges were analyzed between the 2 cohorts using a multivariate linear regression of the log-transformed healthcare charges. Lead revision rates were compared between the groups using a Cox proportional hazard model. A zero-inflated Poisson model was used to analyze annual reprogramming hours between the 2 cohorts. The zero-inflated Poisson model requires the use of 2 different models to fit the data. First, a model is used to analyze “certain zeroes” which includes patients that definitely could not undergo reprogramming. The second model includes all other patients including patients with zero reprogramming hours who could have undergone reprogramming. The “certain zeroes” model used only staged unilateral vs. simultaneous bilateral status as a covariate. All other multivariate models mentioned above were adjusted for age, sex, Charlson Comorbidity Index, and insurance type. Statistical significance was defined by $p < 0.05$. All analyses were conducted using SAS 9.3 (SAS Institute, Cary, NC). The Kaplan-Meier graph was created using Stata 12 (Stata Corp, College Station, Texas, USA).

Results

Patient Cohort

A total of 713 patients that underwent DBS between 2000 and 2009 met inclusion criteria for the study. Of these patients, 556 underwent simultaneous bilateral DBS and 157 underwent staged unilateral DBS. The demographic characteristics of the patient cohorts are outlined in Table 1. The mean (SD) age of patients was 61.1 ± 9.9 years (simultaneous: 60.6 ± 9.8 years vs. staged: 62.9 ± 10.1 years) with 243 (34.1 %) patients greater than 65 years old (simultaneous: 174 (31.3%) vs. staged: 69 (43.9%)). Of the cohort, 207 (29.0%) patients were female (simultaneous: 170 (30.6%) vs. staged: 37 (23.6%)). Patients with a Charlson Comorbidity Index of greater than or equal to 1 totaled 289 (40.5%) (simultaneous: 219 (39.4%) vs. staged 70 (44.6%)).

Postoperative Outcomes

The 90-day postoperative complication rates for both the simultaneous bilateral and staged unilateral groups are shown in Table 2. The most common postoperative complication for both groups was infection (simultaneous: 4.3% vs. staged: 7.0%) followed by pneumonia (simultaneous: 3.1% vs. staged: 5.7%), hemorrhage (simultaneous: 2.9% vs. staged: 2.5%), and pulmonary embolism (simultaneous: 0.5% vs. staged: 1.3%). The rate of device-related complications within 90 days in the simultaneous group was 3 (0.5%) compared to 0 (0.0%) in the staged group. Within 90 days, 18 (3.2%) patients in the simultaneous group had lead

revision compared to 20 (12.7%) in the staged group and the rate of generator revision in the simultaneous group was 17 (3.1%) patients compared to 6 (3.8%) patients in the staged group. The mean (SD) number of days to lead revision was $270.5.9 \pm 360.6$ for the simultaneous group vs. 99.4 ± 145.3 for the staged group. Figure 2 is a Kaplan-Meier Survival curve demonstrating the percent of patients free of lead revision versus time for each of the two groups. Within one year, the mean (SD) reprogramming hours was 6.0 ± 5.7 for the simultaneous group vs. 7.8 ± 8.1 for the staged group. The mean (SD) total annualized payment to provider for the simultaneous group was $\$86,100 \pm \$94,700$ (inpatient payments: $\$46,100 \pm \$67,000$ and outpatient payments: $\$38,600 \pm \$48,200$ and outpatient payments:) compared to $\$102,100 \pm \$121,500$ (inpatient payments: $\$56,000 \pm \$67,600$ and outpatient payments: $\$44,400 \pm \$60,600$) for the staged group.

Table 3 summarizes the outcomes of multivariate regression analysis performed between the two groups adjusting for the covariates age, sex, Charlson Comorbidity Index, and insurance type. Logistic regression analysis of 90-day postoperative complication rates showed no statistically significant difference in the rate of infection, pneumonia, or hemorrhage between the simultaneous and staged groups. Multivariate regression could not be performed to compare the rates of pulmonary embolism or device related complications between the 2 groups due to low number of occurrences of these adverse events. Linear regression showed no significant difference in the natural logarithm of total payment between both groups (difference: 0.13; 95% CI -0.05, 0.30; $p = 0.485$). Zero-inflated Poisson regression showed that reprogramming hours within 1 year was 1.17 (95% CI 1.09, 1.25; $p < 0.001$) times higher in the staged group, among patients who are not certain zeroes. Cox proportional hazard model concluded that patients in the staged group had a significantly increased hazard of undergoing revision (HR=3.07; 95% CI 1.81, 5.19; $p < 0.001$).

Discussion

Parkinson's disease is a significant cause of disability and diminished quality of life throughout the world. Because of its safety, efficacy, reversibility, and personalization, bilateral DBS of the GPi or STN has become the most prominent surgical treatment for medically refractory Parkinson's disease. Despite its widespread use, there is still debate over the best surgical methods. Our results show that the more common surgical approach is simultaneous bilateral DBS; however some physicians advocate for staged unilateral DBS, arguing that it decreases peri- and postoperative complications. Both methods have been proven to be efficacious for reducing the motor symptoms of Parkinson's disease. In one of the only studies directly comparing simultaneous bilateral and staged unilateral DBS, Tanei and colleagues retrospectively reviewed 22 patients. Both the simultaneous bilateral and staged unilateral groups had a significant improvement in Unified Parkinson's Disease Rating Scale scores with no significant difference in percent improvement between the groups. The incidence of stimulation-related adverse effects including neuropsychiatric symptoms, gait impairment, speech impairment, and eyelid-opening apraxia was higher in the bilateral simultaneous group (42%) than the unilateral staged group (20%); however, this difference was not statistically significant. This study reports that there were no incidences of intracranial hemorrhage or device-related complications¹⁹; however they do not report on

other complications such as infection, pneumonia, and pulmonary embolism as does our study.

Both the simultaneous bilateral and staged unilateral methods have advantages. The simultaneous bilateral approach offers patient convenience and presumed healthcare cost saving due to only one operative procedure for lead implantation. The presumed disadvantage of simultaneous bilateral DBS is increased peri- and post-operative complication rates due to increased intraoperative time. The advantages of unilateral staged DBS include decreased continuous intraoperative time leading to a presumed decreased risk of peri- and postoperative complications. The disadvantages of staged unilateral DBS include a delay in time to therapeutic efficacy, two hospital stays, and two frame placements for the patient. Given the decreased continuous intraoperative time, many groups have elected to use unilateral staged DBS in elderly patients, especially those over the age of 70¹⁸. The trend of more elderly patients undergoing the staged unilateral procedure was validated in our cohort, as 43.9% of patients in the staged unilateral group vs. only 31.3% of patients in the simultaneous bilateral group were greater than 65 years of age (p-value=0.003 comparing groups >65-yo vs. <65-yo). It is intuitive that elderly patients would be at higher risk for peri- and postoperative complications due to increased number of comorbidities, decreased cardio-pulmonary reserve, and physical deconditioning. However on the contrary, a recent study by our group shows no statistically significant association between increasing age and overall complication risk of DBS surgery for PD, including postoperative hemorrhage, pneumonia, pulmonary embolism, and infection¹⁶.

At this point, it is unclear whether staged unilateral or simultaneous bilateral DBS is superior, as few studies have directly compared the peri- and postoperative complication rates and healthcare costs between simultaneous bilateral and staged unilateral DBS. In this study we retrospectively review a large, nationwide cohort of patients that underwent simultaneous bilateral or staged unilateral DBS and compare complications, healthcare costs, and revision rates.

In our study, we found no statistically significant difference in hemorrhagic complication, pneumonia, or infection rates between the spontaneous bilateral and staged unilateral groups. In a previous study, Odekerken *et al.* found that the target of DBS (STN or GPi) had no effect on the rate of surgical adverse events in patients¹². Thus, we can assume the number of patients in each group that received STN and GPi DBS should not impact peri- and post-operative complication rate. Although a potentially devastating postoperative complication, hemorrhage is rare with rates reported previously between 0.4-5.1%^{6,12,14-17,20-27}. The rate of hemorrhagic complication found in our study (simultaneous: 2.9% vs. staged: 2.5%) corroborates these previous results. Similarly, the combined rate of pneumonia and infectious complications in our study (simultaneous: 7.4% vs. staged: 12.7%) is similar to that of the existing literature which ranged from 1.0-11.6%^{5,6,14-17,20-28}.

Because the incidence of pulmonary embolism and device-related complications was so low in both cohorts, multivariate regression analysis could not be performed to test for a statistically significant difference between the two groups. By examining the rates of

pulmonary embolism (simultaneous: 0.5% vs. staged: 1.3%) and device-related complications (simultaneous: 0.5% vs. staged: 0.0%) alone, one can intuit that there is not an appreciable difference in the rates of these complications between the cohorts. The rates of pulmonary embolism in our study were also within the previously reported range of 0.0-1.8%^{6,16,23,25,27}.

To our knowledge there have been no prior studies comparing the healthcare costs between simultaneous bilateral and staged unilateral DBS. Even so, it has been a generalized assumption that staged unilateral DBS would result in higher cost due to an additional hospital admission and an additional operation. Our study demonstrates the opposite; there was no significant difference between the annualized healthcare cost between the simultaneous bilateral and staged unilateral groups (simultaneous: \$86,100±\$94,700 vs. staged: \$102,100±\$121,500). The annualized cost found in our study is similar to those found in prior studies. Recently, Stroupe and colleagues estimated that the total healthcare cost in the first year after DBS was approximately \$90,000²⁹.

The results of our study do not support many of the popular assumptions regarding simultaneous bilateral and staged unilateral DBS. Unilateral staged DBS does not reduce the rate of peri- and postoperative complications when compared to simultaneous bilateral DBS despite the reduced duration of continuous intraoperative times using this technique. On the other hand, staged unilateral DBS did not result in a significant overall increase in healthcare cost despite the need for two separate operative procedures. Thus, we suggest that operative risk and healthcare costs should not be the primary factors considered when deciding between simultaneous bilateral or staged unilateral DBS for patients with PD. One factor to consider is whether the patient has predominantly unilateral symptoms. In such a patient, it may be appropriate to begin with a unilateral DBS implant on the side contralateral to the symptoms. Unilateral DBS has been shown to be effective in treating the motor symptoms of PD, especially in patients with predominately unilateral symptoms³⁰⁻³⁵. In these select patients, their symptoms may be treated with a less invasive and shorter duration unilateral procedure. However, a significant proportion of patients that undergo unilateral DBS do not achieve satisfactory relief of their symptoms and must undergo DBS implantation on the contralateral side (a staged unilateral procedure). Previous literature shows that this occurs for 17-30% of patients^{19,32,33}. Thus, it may be appropriate to choose a patient with predominantly unilateral symptoms for unilateral DBS with the plan of converting to staged unilateral DBS if the patient does not receive adequate benefit from the unilateral procedure.

Lead revision in DBS for PD is needed at times due to a multitude of factors including loss of efficacy, infection, device malfunction, and lead fracture/migration. In a retrospective review of 326 patients, Falowski and colleagues showed a 5.2% rate of DBS lead revision for PD patients with 1.0% of revisions due to device-related complications (device malfunction or lead fracture). The investigators found the most common reason for lead revision was loss of efficacy³⁶. In our study, we found that patients that underwent staged unilateral DBS were 3 times more likely to undergo lead revision than those that underwent simultaneous bilateral DBS. Also, Figure 2 shows the duration to revision for the simultaneous bilateral DBS group is prolonged compared to the staged unilateral group. This may suggest that patients that undergo staged unilateral DBS are more likely to experience

loss of efficacy. Unfortunately, using the MarketScan database, the indication for lead revision was unable to be determined. Thus, we have no evidence of why patients undergoing staged DBS were more likely to require revision. Similarly, there was a statistically significant difference in number of hours of reprogramming within 1 year after surgery. The staged unilateral group received 1.17 times more reprogramming hours than the simultaneous bilateral group. The increased number of reprogramming hours in the unilateral group is likely the result of undergoing an additional mapping session. Bilateral simultaneous DBS patients undergo a single mapping session, whereas patients must undergo two separate mapping sessions for staged unilateral DBS, one after each electrode is implanted. The increased number of reprogramming hours may also reflect a reduced efficacy of DBS in the staged unilateral group. Unfortunately, in our retrospective study we were not able to evaluate the efficacy of DBS to validate these conjectures.

Our study analyzed a large, nationwide cohort of patients reducing biases and discrepancies that can result from differences in practice at different institutions and geographical locations. Despite its strengths, our study has weaknesses that must be acknowledged. First, the study is retrospective and nonrandomized allowing for confounding variables to affect the outcomes. For example, the study is susceptible to selection bias where more elderly patients with higher surgical risks could have been selected for staged unilateral DBS. This could have resulted in increased complication rates in the staged unilateral cohort. Our analysis of the MarketScan database, did not allow us to evaluate cognitive complications following DBS implantation. This is an important limitation of the study as some surgeons advocate that elderly patients should undergo staged procedures to reduce cognitive complications. Also, given that the average of the patient population in this study was 61 years, these findings may not be generalizable to elderly patients greater than 70 years of age. In our review of the MarketScan database, there were also multiple clinical factors that we were not able to discern: Unified Parkinson's Disease Rating Scale, symptom severity, medication usage, neuro-cognitive assessments, the type of symptom leading the patient to undergo surgery, and the efficacy of DBS. Importantly, the efficacy of DBS may affect revision rates as mentioned above. Because patients were selected using diagnosis and procedure codes, miscoding may be present. In an attempt to reduce the effects of miscoding both ICD-9 and CPT codes were used.

Conclusion

Our study offers valuable insights into the risks and benefits of simultaneous bilateral and unilateral staged DBS. Our findings are especially relevant because it is unlikely that a randomized controlled trial will be conducted in the near future to compare simultaneous bilateral vs. staged unilateral DBS. In patients with medically refractory PD who are considering surgery, bilateral or staged DBS approaches have similar overall postoperative complication rates and associated healthcare costs. Thus, we believe that it is important to consider other factors when deciding between staged and simultaneous DBS, such as patient convenience and the laterality of symptoms.

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Figure 1.

Figure 2.

Table 1

Patient Demographics

Total, no.	713	556	157
Age mean (SD)	61.1 (9.9)	60.6 (9.8)	62.9 (10.1)
Age Group, no. (%)			
18-34	7 (1.0)	6 (1.1)	1 (0.6)
35-44	29 (4.1)	23 (4.1)	6 (3.8)
45-54	134 (18.8)	105 (18.9)	29 (18.5)
55-64	300 (42.1)	248 (44.6)	52 (33.1)
65+	243 (34.1)	174 (31.3)	69 (43.9)
Female, no. (%)	207 (29.0)	170 (30.6)	37 (23.6)
Charlson Score, no. (%)			
0	424 (59.5)	337 (60.6)	87 (55.4)
1+	289 (40.5)	219 (39.4)	70 (44.6)
Insurance Type, no. (%)			
Commercial	398 (55.8)	322 (57.9)	76 (48.4)
Government	315 (44.2)	234 (42.1)	81 (51.6)

Table 2
90 Day postoperative complication rates

	Overall	Simultaneous	Staged
Hemorrhage, no. (%)	20 (2.8)	16 (2.9)	4 (2.5)
Infection, no. (%)	35 (4.9)	24 (4.3)	11 (7.0)
PE, no. (%)	5 (0.7)	3 (0.5)	2 (1.3)
Pneumonia, no. (%)	26 (3.6)	17 (3.1)	9 (5.7)
Device Complication, no. (%)	3 (0.4)	3 (0.5)	0 (0.0)
Lead revision, no. (%)	38 (5.3)	18 (3.2)	20 (12.7)
Generator revision, no. (%)	23 (3.2)	17 (3.1)	6 (3.8)

Table 3
Results of Multivariate regression analyses on postoperative complication rates, lead revision, and reprogramming hours

	Type of Regression	Risk Ratio (95% CI)	p-value
Hemorrhage within 90 days	Logistic	0.89 (0.29, 2.74)	0.844
Infection within 90 days	Logistic	1.67 (0.79, 3.52)	0.178
Pneumonia within 90 days	Logistic	1.60 (0.68, 3.75)	0.283
Reprogramming Hours within One Year	Zero-inflated Poisson	1.17 (1.09, 1.25)	<.001
Reprogramming Hours within One Year	Zero-inflated Poisson (Certain Zeros)	0.51 (0.28, 0.94)	0.03
Revision	Cox PHM	3.07 (1.81, 5.19)	<.001