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Impact of advancing age on post-operative complications of deep brain stimulation surgery for essential tremor

Terence Verla^a, Andrew Marky^b, Harrison Farber^a, Frank W. Petraglia III^a, John Gallis^c, Yuliya Lokhnygina^c, Beth Parente^a, Patrick Hickey^d, Dennis A. Turner^b, and Shivanand P. Lad^{b,*}

Shivanand P. Lad: nandan.lad@dm.duke.edu

^aDuke University School of Medicine, Durham NC, USA

^bDivision of Neurosurgery, Department of Surgery, Duke University Medical Center, Box 3807, Durham, NC 27710, USA

^cDepartment of Biostatistics and Bioinformatics, Duke University, Durham NC, USA

^dDepartment of Neurology, Duke University Medical Center, Durham, NC, USA

Abstract

Essential tremor (ET) was the original indication for deep brain stimulation (DBS), with USA Food and Drug Administration approval since 1997. Despite the efficacy of DBS, it is associated with surgical complications that cause sub-optimal clinical outcomes. Given that ET is a progressive disease with increase in symptom severity with increasing age, this study evaluated the impact of increasing age on short-term complications following DBS surgery for ET. Thomson-Reuters MarketScan database was utilized (New York, NY, USA). Patients selected were over age 18 and underwent DBS for ET between the years 2000 and 2009. Multivariable logistic regression analysis was used to calculate complication odds ratios (OR) for a 5 year increase in age, after controlling for other covariates. Six hundred sixty-one patients were included in the analysis. The mean (standard deviation) age was 61.9 (14.3) years, with 17% of individuals aged ≥ 75 years. Overall 56.9% of patients were male, and 44.6% had a Charlson Comorbidity Score of ≥ 1. Additionally, 7.1% of patients experienced at least one complication within 90 days, including wound infections (3.0%), pneumonia (2.4%), hemorrhage or hematoma (1.5%), or pulmonary embolism (0.6%). Increasing age was not significantly associated with the overall 90 day complication rates (OR 0.89; 95% confidence interval [CI] 0.77–1.02; $p = 0.102$). The risk of the two most common procedure-related complications, hemorrhage and infection, did not significantly increase with age (hemorrhage: OR 1.02; 95%CI 0.77–1.37; $p = 0.873$; and infection: OR 0.88; 95%CI 0.72–1.07; $p = 0.203$). Our findings suggest that age should not be a primary

*Corresponding author. Tel.: +1 919 681 4986; fax: +1 919 681 1236.

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exclusion factor for determining candidacy for DBS and also suggest a possible expansion of the traditional therapeutic window since postoperative complications remained relatively stable.

Keywords

Age; Deep brain stimulation; Complications; Essential tremor

1. Introduction

Essential tremor (ET) is one of the most common movement disorders in the USA with an estimated prevalence of up to 5%¹⁻³. ET is characterized by postural and action tremor involving the upper extremities and less commonly the lower extremities, head and voice⁴. This causes significant functional disability in affected patients^{5,6}. Due to the adverse effects and time-dependent loss of efficacy, medical management for ET has been associated with sub-optimal outcomes^{4,7,8}. For ET patients with advanced and medically refractory symptoms or with complications to medical therapy, deep brain stimulation (DBS) of the ventral intermediate (VIM) nucleus of the thalamus has been shown to dramatically reduce tremor-associated disability⁹⁻¹¹. The safety, efficacy, adjustability, reversibility of adverse effects and non-destructive nature of DBS has driven its widespread adoption, replacing brain lesioning, with efficacy comparable to thalamotomy^{12,13}. However, as with any surgical intervention, DBS is associated with potential peri and post-operative complications such as infection, hemorrhage/hematoma and pneumonia¹⁴.

The existence of comorbidities such as hypertension and diabetes in elderly patients creates an increased baseline risk of surgical complications following DBS for ET. The increased prevalence of ET in patients over 60 years^{2,9} brings further importance to the impact of advancing age on DBS outcomes. With as many as 15–25% of ET patients being forced into early job retirement¹⁵, there is a need for novel insights into the role of DBS on outcomes in elderly patients seeking surgical management for this exceedingly disabling pathology. Currently, there is a paucity of data addressing this paradigm. Given that the prevalence of ET increases nearly 10-fold with age¹⁻³, together with the aging USA population, we evaluated the step-wise impact of increasing age on short-term complications following DBS surgery. We hypothesized that increasing age would be associated with an increase in post-operative complications.

2. Methods

2.1. Data source

Data for the study were obtained using the Thomson-Reuters MarketScan database (New York, NY, USA). The MarketScan database contains claims records from employers, health plans, government, and public organizations for over 158 million patients in the USA since 1996. For this study, we used the Commercial Claims and Encounters, the Medicare Supplemental and Coordination of Benefits, and the Medicaid databases within MarketScan. In MarketScan, each patient is assigned a unique, encrypted enrollee identification number that can be used to link patient information across different tables. For this study, all patient data from the years 2000 to 2009 were examined including inpatient admissions, inpatient

services, outpatient services, outpatient pharmaceuticals, and enrollment tables representing all available subsections of the MarketScan database.

2.2. Study sample

Diagnosis (*International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM]) and procedure (CPT) codes were used to identify patients diagnosed with Essential Tremor (ICD-9-CM: 333.1) having undergone DBS (ICD-9-CM: 02.93; CPT-4: 61683, 61687 or 95961) for inclusion in the study. Only patients 18 years and older at the time of the index hospitalization were retained for the analysis.

2.3. Main outcome measures

For purposes of describing the population, patients were divided into 5 year epochs, ranging from <50 up to 90 years of age. Primary outcomes were the overall complication rate and also, specifically, pneumonia, post-operative infection, pulmonary embolism, and intracranial hemorrhage or hematoma within 90 days after surgery.

2.4. Statistical analysis

In statistical models, age was analyzed as a continuous variable. Mortality, lead removal or revision, and generator removal or revisions within 90 days from surgery were summarized but only descriptive statistical analysis was performed. Univariable and multivariable logistic regression models were constructed to evaluate the impact of age on 90 day post-operative complications. Multivariable models were adjusted for Charlson Comorbidity Index (dichotomized as 0 or 1), insurance type (Medicare, Medicaid, or commercial), and sex. Possible nonlinear effect of age was examined by including terms in the models, but tests for nonlinearity were not statistically significant. Statistical significance was defined by $p < 0.05$. All analyses were conducted using SAS 9.3 (SAS Institute, Cary, NC, USA).

3. Results

3.1. Patient cohort

A total of 661 patients met the inclusion criteria and underwent DBS for ET between 2000 and 2009. Demographic characteristics of the cohort are listed in Table 1. The mean (standard deviation) patient age was 61.9 (14.3) years, with 17.1% of individuals aged 75. Overall, 56.9% of patients were male, and 44.6% had a Charlson Comorbidity Score of 1. The majority of the patients had either commercial (43.9%) or Medicare (47.2%) insurance. Figure 1 shows the distribution of ET patients with or without DBS surgery across all the age groups. The majority of patients (119) were 50 years old, with an overall trend towards decreased DBS intervention with advancing age.

Overall, 7.1% of patients experienced at least one complication within 90 days of surgery. The most common complication observed within 90 days was wound infection (3.0%), followed by pneumonia (2.4%), hemorrhage or hematoma (1.5%), and pulmonary embolism (0.6%). Within 90 days, lead replacement or revision was performed for 0.3% of patients and generator removal or revision in 1.1% of patients. Additionally, 2.0% of patients had a length of stay following surgery greater than 1 day and only one (0.2%) patient died within

90 days of DBS. The distribution of 90 day post-operative complications is summarized in Table 2.

3.2. Multivariate analysis

After adjusting for covariates (sex, Charlson score and insurance type), increasing age ranging from <50 to 90 years was not significantly associated with overall 90 day complication rates (odds ratio [OR] 0.89 per 5 year increase; 95% confidence interval [CI] 0.77–1.02; $p = 0.102$). The two most common procedure-related complications, hemorrhage and infection, were not significantly associated with older age (hemorrhage: OR 1.02; 95%CI 0.77–1.37; $p = 0.873$; and infection: OR 0.88; 95%CI 0.72–1.07; $p = 0.203$). Similarly, there was no significant association between pulmonary embolism and age (OR 0.86; 95%CI 0.58–1.29; $p = 0.470$). However, there was a statistically significant correlation between increasing age and the risk of pneumonia (OR 0.77; 95% CI 0.60–0.98; $p = 0.037$). Table 3 shows the complete regression model results.

4 Discussion

ET was the original indication for DBS, with USA Food and Drug Administration approval since 1997. For patients with advanced and medically refractory ET, DBS is an effective therapeutic modality based on randomized controlled studies¹⁶ with the VIM of the thalamus being the preferred target of stimulation. Not only is DBS safe and efficacious, it is very personalized and reversible. Studies have shown that patients undergoing DBS for ET have a robust reduction in tremor symptoms^{9–11}. However, hemorrhagic complication, post-operative infection, pneumonia and death are rare, but often devastating, complications that have been associated with DBS^{14,17}. The exact role of age on adverse events following DBS for ET is poorly defined and is of great relevance given that ET is a progressive disease with increasing symptom severity with age¹⁸. Older patients stand to suffer from post-operative complications due to the existence of multiple comorbidities such as hypertension, decreased cardio-pulmonary function and physical deconditioning due to sub-optimal physiologic reserve. Elderly patients interested in having DBS for disabling tremor symptoms should be informed of the surgical risks and benefits associated with DBS. However, the limited data investigating the association between increasing age and the incidence of peri and post-operative complication makes it very challenging for patients to make informed decisions pre-operatively. In the absence of such data, strict age cut-offs (i.e. >75 years) and the presence of medical comorbidities in elderly patients are often utilized when counseling patients as exclusion criteria for DBS surgery. Given the rapidly expanding elderly population in the USA, it is increasingly essential to have a deeper understanding of the age-associated risks of surgical intervention. The availability of large, secondary administrative databases provides an opportunity to determine mean complication rates in a wide variety of academic and community practices across the USA. In this study we retrospectively examined the Thomson-Reuters MarketScan Database from 2000 to 2009, examining the impact of increasing age on complications associated with DBS surgery for ET. We did not find an association between advanced age and the rates of complications including hemorrhage, infection and pulmonary embolism; however, the number of events in our study was low.

In our study, advancing age had no significant association with hemorrhagic complications within 90 days following surgery. This is in line with several other studies evaluating the impact of age on hemorrhagic complication following DBS for ET¹⁹⁻²³. Binder et al.²⁰ showed that age was not significantly associated with risk of hematoma in a study of 208 patients that underwent implantation of DBS electrodes for movement disorders. However, there are some studies that demonstrate an age-associated increase in incidence of hemorrhagic complications following DBS surgeries^{14,24-26}. Given that the aforementioned studies have been single institutional studies (with the exception of Voges et al.¹⁴), our national level cohort study may reduce the discrepancies in evidence of the role of aging on complications following DBS surgeries. Despite the conflicting evidence in the literature, hemorrhagic complication should be viewed as a multifaceted phenomenon with several pre-operative contributing factors that increase the baseline surgical risk. In order to minimize or avoid intracranial hemorrhage, patients should be thoroughly screened for risk factors such as hypertension, coagulopathy, history of hemorrhage prior to surgery, blood vessel abnormality, medication usage (such as recent antiplatelet usage) and adequate intra-operative and peri-operative blood pressure control.

The occurrence of post-operative infection remains a major surgical impediment, with ramifications for the patient's quality of life and overall healthcare cost. Any implanted device carries a risk of infection and there is a variation in the reported rates of hardware related post-operative infection (4–12.2%)^{17,27-33}. Despite the general incidence of infection, our study showed no association between advancing age and infection. Our findings are similar to a study by Falowski et al.²⁷ evaluating patients who underwent DBS for movement disorder. They showed in a multivariable analysis that age had no effect on complications including infection. Nonetheless, infection remains a debilitating consequence that may compromise the integrity of DBS leads and generators, resulting in surgical debridement, lead revisions and re-operations. Extensive care and attention should therefore be implemented to minimize the incidence of such complications.

In our retrospective series, we found no association between increasing age and the incidence of pulmonary embolism. However, there was an association between advancing age and a lower risk of pneumonia, which contradicts several studies demonstrating that elderly patients are at risk for pulmonary complications^{34,35}. It remains unclear if DBS lead implantation poses any added risk of respiratory or thromboembolic complication to patients. Age is a proxy for comorbidities¹⁹ such as decreased respiratory reserve and activity level, which puts a patient at increased risk for complications. Baseline pre-operative risk factors such as smoking and obesity are confounding variables, which influence the incidence of pneumonia and pulmonary embolism. Nonetheless, preventive measures, such as early ambulation and the use of incentive spirometry should be encouraged in the immediate post-operative period among elderly patients.

This study has evaluated a nationally selected cohort of patients, reducing the discrepancies and biases that result from selecting patients from single institutions or states. Additionally, as the MarketScan database is comprehensive and inclusive, it more accurately reflects the wide variety of practices across the USA. Despite these strengths, several limitations are present in this study. Firstly, various patient and clinical factors could not be discerned,

including pre-operative symptom severity (such as long-term gait, falls), medication usage and requirement, and neuro-cognitive assessments in the elderly. Additionally, the efficacy of DBS in reducing tremor could not be determined. DBS efficacy may have had an influence on revision rates. The database did not capture pre-operative screening by neurology, neurosurgery and neuropsychology, which could influence outcomes after DBS surgery. Also, as patients and procedures were selected using diagnosis and procedure codes, miscoding may be present. We have attempted to reduce this inaccuracy by using both ICD-9-CM and CPT codes allowing for greater data accuracy. The number of events in the study was low, which may have impacted the statistical power to detect significant associations. Another limitation is that this study is retrospective and non-randomized. As a result, the study is susceptible to the effects of unmeasured confounding variables. In particular, there could be a procedure bias with healthier elderly patients being preferentially selected for DBS intervention. The presence of unmeasured confounders may explain our unexpected finding of a lower risk of pneumonia with advancing age. This was a broad-level study, examining the impact of advancing age on post-operative DBS complications longitudinally and across many different centers. While this is a retrospective review, carrying all of the inherent limitations, it helps identify on a large scale the role of aging on complications following DBS for ET.

5. Conclusion

Among older ET patients, 90 day complication risk and the risk of post-operative hemorrhage or infection remained relatively stable, despite increasing age. Physicians should not underestimate the effect that tremor has on patient's functionality and should be able to identify cases where medications are refractory and surgical intervention may offer improved quality of life. As DBS technology and imaging platforms continue to evolve, refinement of surgical techniques should continue to produce superior clinical outcomes while minimizing surgical complications. Our findings suggest that age should not be a primary exclusion factor for determining candidacy for DBS and support a possible expansion of the traditional therapeutic window. Individual risk assessment should be incorporated in pre-operative counseling of elderly patients.

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Fig. 1.

Distribution of essential tremor patients with (black) and without (grey) deep brain stimulation for essential tremor.

DBS = deep brain stimulation.

Table 1
Baseline demographics of essential tremor patients with essential tremor

	Overall
Patients	661 (100.0)
Age	
Mean (SD)	61.9 (14.3)
Median (Q1, Q3)	63.0 (55.0–72.0)
Age group	
50	119 (18.0)
50 to <55	57 (8.6)
55 to <60	91 (13.8)
60 to <65	97 (14.7)
65 to <70	87 (13.2)
70 to <75	97 (14.7)
75 to <80	76 (11.5)
80 to <85	31 (4.7)
85 to <90	6 (0.9)
Sex	
Male	376 (56.9)
Female	285 (43.1)
Charlson Score	
0	366 (55.4)
1	295 (44.6)
Insurance type	
Commercial	290 (43.9)
Medicaid	59 (8.9)
Medicare	312 (47.2)

Data are presented as number (%) unless otherwise indicated. Q1 = quartile one, Q3 = quartile 3, SD = standard deviation.

Table 2
Outcomes following deep brain stimulation for essential tremor stratified by age

Outcome within 90 days post-operatively	Overall	Age <75 years	Age ≥ 75 years
Total patients, n	661	548	113
No complication or revision	608 (92.0)	503 (91.8)	105 (92.9)
Any complication	47 (7.1)	40 (7.3)	7 (6.2)
Hemorrhagic complication	10 (1.5)	8 (1.5)	2 (1.8)
Infection	20 (3.0)	18 (3.3)	2 (1.8)
Pulmonary embolism	4 (0.6)	4 (0.7)	0 (0.0)
Pneumonia	16 (2.4)	13 (2.4)	3 (2.7)
Lead revision	2 (0.3)	2 (0.4)	0 (0.0)
Generator revision	7 (1.1)	7 (1.3)	0 (0.0)
Mortality	1 (0.2)	0 (0.0)	1 (0.9)
Length of stay following surgery >1 day	13 (2.0)	13 (2.4)	0 (0.0)

Data are presented as number (%) unless otherwise indicated.

Table 3
Effect of 5 year increase in age on post-operative complications within 90 days of deep brain stimulation surgery

Predictor	Outcome	Odds ratio (95% CI)	<i>p</i> value
Age (5 year intervals)	All complications	0.89 (0.77–1.02)	0.102
	Hemorrhagic complications	1.02 (0.77–1.37)	0.873
	Infectious complications	0.88 (0.72–1.07)	0.203
	Pulmonary embolism complications	0.86 (0.58–1.29)	0.470
	Pneumonia complications	0.77 (0.60–0.98)	0.037

CI = confidence interval.