# Short-Term and Long-Term Safety of Deep Brain Stimulation In the Treatment of Movement Disorders

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## ABSTRACT

**OBJECTIVE:** To assess the long term safety of deep brain stimulation (DBS) in a large population of patients with a variety of movement disorders. **METHODS:** All patients treated with DBS at the Baylor College of Medicine Parkinson's Disease Center and Movement Disorders Clinic from 1995-2005 were assessed for intraoperative, perioperative, and long term adverse events (AEs). **RESULTS:** A total of 319 patients underwent DBS implantation at our center, 182 of whom suffered from medically-refractory PD; the other patients had essential tremor, dystonia, and other hyperkinetic movement disorders. Intraoperative AEs were rare; perioperative AEs included headache in 48 patients, confusion in 16, and hallucinations in 9. The most serious intraoperative /perioperative AEs occurred in 4 patients with an isolated seizure, 2 patients with intracerebral hemorrhage, 2 patients with intraventricular hemorrhage, and 1 patient with a large subdural hematoma. Long term complications of DBS surgery included dysarthria, worsening gait, cognitive decline, and infection. Revisions were completed in 25 (7.8%) patients for several reasons: loss of effect, lack of efficacy, infection, lead fracture, and lead migration. Hardware related complications included 12 lead fractures and 10 lead migrations. **CONCLUSIONS:** In our ten-year experience, DBS has proven to be safe for the treatment of medically-refractory movement disorders.

## INTRODUCTION

Deep brain stimulation (DBS) was first introduced in 1987 by Benabid et al. targeting the VIM nucleus of the thalamus to treat Parkinson's disease (PD). Since that time, DBS has largely replaced ablative procedures for the treatment of hyperkinetic movement disorders. The dramatic shift in the surgical management of movement disorders has brought with it concerns regarding the safety of DBS surgery. Simultaneously, the number of centers offering DBS has proliferated dramatically and patients are increasingly referred to tertiary care centers complaining of suboptimal results. We present a retrospective analysis of adverse events (AEs) in 319 patients treated with DBS at our institution by one neurosurgeon (RS) from 1995-2005.

## METHODS

- **Patients were recruited from the Baylor College of Medicine (BCM) Parkinson's Disease Center and Movement Disorders Clinic (PDCMDC).**
- **All patients, regardless of indication, displayed functional impairment related to their movement disorder despite optimal pharmacologic therapy.**
- **Patients were excluded if they had moderate to severe cognitive impairment or a comorbid disease that would likely increase the risk of surgically-related complications.**
- **The final decision for implantation was made in a multi-disciplinary meeting, including a neurosurgeon, movement disorder specialist (s), clinical nurse (s), and a neuropsychologist.**
- **All patients treated with DBS at the PDCMDC from November 1995 to June 2005 were retrospectively assessed for intraoperative, perioperative, and long term AEs.**
- **The "perioperative" period was arbitrarily chosen as 2 weeks after implant. "Long term" AEs, therefore, occurred 15 days or more after DBS placement.**
- **Charts from 3 sources were scrutinized including the PDCMDC, the neurosurgeon's clinic notes, and hospital records.**
- **Transient stimulator-induced symptoms were not included as AEs, as this phenomenon is expected during the programming of a properly placed electrode.**
- **To determine the percentage of patients experiencing an AE, a denominator of 319 was chosen rather than the total number of procedures, 413 (simultaneous bilateral placement, staged procedures, and revisions).**

**Table 2. Adverse Event Summary**

| | Adverse Event | N (# of Patients) | % |
|---|---|---|---|
| Intraoperative | | | |
| | Vasovagal response | 8 | 2.5 |
| | Syncope | 4 | 1.3 |
| | Severe cough | 3 | 0.9 |
| | Intraventricular hemorrhage | 2 | 0.6 |
| | Intracerebral hemorrhage | 2 | 0.6 |
| | Arrhythmia (junctional rhythm) | 1 | 0.3 |
| | Confusion | 1 | 0.3 |
| | Extreme Anxiety | 1 | 0.3 |
| | Laceration of soft palate | 1 | 0.3 |
| | Transient ischemic attack | 1 | 0.3 |
| Perioperative (<2 weeks) | | | |
| | Headache | 48 | 15.0 |
| | Confusion | 16 | 5.0 |
| | Hallucination | 9 | 2.8 |
| | Nausea/vomiting | 5 | 1.6 |
| | Seizure | 4 | 1.3 |
| | Dysarthria | 3 | 0.9 |
| | Dyskinesia | 2 | 0.6 |
| | Hypertension | 2 | 0.6 |
| | Paranoia | 2 | 0.6 |
| | Paresthesia | 2 | 0.6 |
| | Sore throat | 2 | 0.6 |
| | Transient ischemic attack | 2 | 0.6 |
| | Urinary retention | 2 | 0.6 |
| | Angina | 1 | 0.3 |
| | Arrhythmia (right bundle branch block) | 1 | 0.3 |
| | Deep vein thrombosis | 1 | 0.3 |
| | Depression | 1 | 0.3 |
| | Dizziness | 1 | 0.3 |
| | Insomnia | 1 | 0.3 |
| | Pulmonary edema | 1 | 0.3 |
| | Subdural hematoma (evacuated) | 1 | 0.3 |
| Long Term (>2 weeks) | | | |
| | Infection | 14 | 4.4 |
| | Cognitive dysfunction | 13 | 4.0 |
| | Dysarthria | 13 | 4.0 |
| | Worsening gait | 12 | 3.8 |
| | Paresthesia | 4 | 1.3 |
| | Agitation | 5 | 1.6 |
| | Depression | 3 | 0.9 |
| | Headache | 2 | 0.6 |
| | Psychogenic tremor | 2 | 0.6 |
| | Urinary incontinence | 2 | 0.6 |
| | Blepharospasm | 1 | 0.3 |
| | Emotional lability | 1 | 0.3 |
| | Insomnia | 1 | 0.3 |
| | Metallic taste | 1 | 0.3 |
| | Suicide | 1 | 0.3 |

**Table 1. Primary Indication for DBS**

| Indication | Nucleus | STN | | | VIM | | | GPi | | | VIM/STN |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | Unilateral | Bilateral | | Unilateral | Bilateral | | Unilateral | Bilateral | | |
| | | | Simultaneous | Staged | | Simultaneous | Staged | | Simultaneous | Staged | |
| Parkinson's disease | 182 | 18 | 77 | 24 | 35 | 4 | 16 | 1 | 1 | 1 | 5 |
| Essential Tremor | 112 | - | - | - | 68 | 19 | 24 | - | 1 | - | - |
| Dystonia | 19 | - | - | - | 3 | 1 | - | 1 | 12 | 2 | - |
| Multiple Sclerosis | 3 | - | - | - | 2 | 1 | - | - | - | - | - |
| Hemiballismus | 2 | 1 | - | - | 1 | - | - | - | - | - | - |
| Myoclonus | 1 | - | - | - | - | - | - | 1 | - | - | - |

## RESULTS

- ✓ **To our knowledge, this is the largest and most diverse population of DBS patients reported from one center (Table 1).**
- ✓ **Although a sizable number of patients experience some type of AE (43.3%), most DBS-related AEs, such as headache or confusion, are benign and transient (Table 2).**
- ✓ **Some patients, however, develop more serious AEs, such as dysarthria, worsening gait, or cognitive dysfunction.**
- ✓ **In our patient population, serious vascular events were uncommon, occurring in 5/319 (1.6%) patients: 2 ICH, 2 IVH, and 1 SDH.**
- ✓ **In large DBS patient populations, seizures are reported to occur in 0.9%-9.1% and infection in 3.7-6.5%. Our complication rates for these two AEs compare favorably: 1.2% and 4.4%, respectively.**
- ✓ **One patient (0.3%) in this cohort committed suicide, a complication reported to be as frequent as 4.3%.**
- ✓ **Previous investigators report a rate of 4.3-8.4% per electrode-year for hardware-related complications (lead fracture, lead migration, electrode dysfunction, and infections). Using similar methodology, our hardware-related complication rate is only 2.5% per electrode-year.**

## CONCLUSIONS

- **The number of institutions implanting DBS has proliferated greatly in the past 5 years.**
- **It is imperative that institutions publish their safety data to set the standard of care and inform referring physicians about institutional-specific surgical morbidity and mortality.**
- **In our ten-year experience, DBS is safe for the treatment of medically-refractory movement disorders.**

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