Subsequent Pulse Generator Replacement Surgery does not Increase the Infection Rate in Patients with Deep Brain Stimulator Systems: A Review of 1537 Unique Implants at a Single Center

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Introduction

Deep brain stimulation (DBS) is a well-recognized treatment for patients with movement disorders and other neurological diseases. The implantable pulse generator (IPG) is a fundamental component of the DBS system. Although IPG implantation and replacement surgeries are comparatively minor procedures relative to the brain lead insertion, patients often require multiple IPG replacements during their lifetime with each operation carrying a small but possibly cumulative risk of complications. To better educate our patients and improve surgical outcomes we reviewed our series of patients at our institution.

Methods

Using electronic health record data, we retrospectively reviewed all initial and subsequent IPG surgeries from patients who underwent at least one IPG surgery between the years of 2010 and 2015 at the Cleveland Clinic main campus. Each surgical site was counted as a unique case. We used this methodology because a patient who developed a unilateral infection during bilateral surgery would still be able to maintain a functional DBS system for one side. The criteria for posoperative infection included elevated temperature or inflammatory markers, wound tenderness and/or purulent discharge in the pulse generator wound. We calculated infection rates for initial IPG implantation surgeries and the infection rate for subsequent replacements. Fisher's exact tests were used to evaluate the chance of an infection between the initial implantation and replacement. Fisher's exact tests and simple logistic regression analyses were used to determine the predictive ability of selected demographic and clinical variables.

Results

Our final sample included 234 patients with bilateral IPGs and 229 with unilateral IPGs, for a total of 697 operative surgical sites and 1537 surgeries. In total we identified twenty infections.

For all patients, the infection rate at the first surgery was 2.01%; at the second surgery, it was 0.44%; and at the third surgery, it was 1.83%. There were no infections in any third to eighth replacement (n=173) and no patient had more than eight replacements. When compared to initial implantation surgery, the first replacement surgery showed a 79% reduction in odds of infection (OR .218; 95% CI .049- .962;p=.036) (table 1).

Table 1

	Primary	1st	2nd	3rd	4th- 8th
IPG Surgeries	696	450	218	114	59
Major Infections	14	2	4	0	0
Infection rate	2.0%	0.4%	1.8%	0.0%	0.0%

Infection rate with subsequent implantable pulse generator

When considering only patients that underwent at least 3 replacement surgeries (n=114) the infection rate did not change in a significant manner with subsequent interventions compared to the first replacement.
No other variable of interest was a significant predictor of infection (table 2).

Table 2

Variables	Odds Ratio (95% IC)
Age at Surgery	1.0 (0.96 - 1.04)
Male	0.89 (0.27 - 2.86)
BMI	1.03 (.95 - 1.12)
Movement Disorder	1.115 (.143 - 8.723)
Steroid use	0.98 (0.97 - 0.99)
Anticoagulant use	0.98 (0.97 - 0.99)
Aspirin use	0.99 (0.22 - 4.51)
Hypertension	0.91 (.30 - 2.74)
Coronary Artery Disease	0.51 (0.06 - 3.91)
Diabetes	0.85 (0.19 - 3.86)

Odds for infection

Conclusions

We did not find increasing rates of infection with IPG replacemente surgery compared to primary surgery. We observed a higher incidence of infection in the second replacement when compared to the first. Future prospective studies should further clarify this issue and also look for predicting factors for infection in order to inform better infection control strategies.

References

1. Hamani C, Lozano AM. Hardware-related complications of deep brain stimulation: A review of the published literature. Stereotact Funct Neurosurg. 2006;84(5-6):248-251. doi:10.1159/000096499.

2. Bhatia R, Dalton A, Richards M, Hopkins C, Aziz T, Nandi D. The incidence of deep brain stimulator hardware infection: the effect of change in antibiotic prophylaxis regimen and review of the literature. Br J Neurosurg. 2011;25(5):625-631. doi:10.3109/02688697.2011.566384.

3. Bjerknes S, Skogseid IM, Sæhle T, Dietrichs E, Toft M. Surgical site infections after deep brain stimulation surgery: Frequency, characteristics and management in a 10-year period. PLoS One. 2014;9(8). doi:10.1371/journal.pone.0105288.

4. Pepper J, Zrinzo L, Mirza B, Foltynie T, Limousin P, Hariz M. The Risk of Hardware Infection in Deep Brain Stimulation Surgery Is Greater at Impulse Generator Replacement than at the Primary Procedure. Stereotact Funct Neurosurg. 2013;91(1):56-65. doi:10.1159/000343202.

5. Fytagoridis A, Heard T, Samuelsson J, et al. Surgical Replacement of Implantable Pulse Generators in Deep Brain Stimulation: Adverse Events and Risk Factors in a Multicenter Cohort. Stereotact Funct Neurosurg. 2016:235-239. doi:10.1159/000447521.

6. Thrane JF, Sunde NA, Bergholt B, Rosendal F. Increasing infection rate in multiple implanted pulse generator changes in movement disorder patients treated with deep brain stimulation. Stereotact Funct Neurosurg. 2014;92(6):360-364. doi:10.1159/000365576.

Learning Objectives

By the conclusion of this session, participants should be able to: 1) Discuss the rates of infection among