Primary Cell Battery Longevity in DBS: Results from the Product Surveillance Registry

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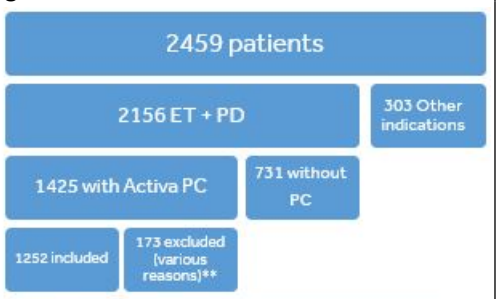
Background

Deep Brain Stimulation (DBS) is an effective and well-established treatment for Parkinson's disease (PD), essential tremor (ET), and dystonia. DBS is powered by an implantable pulse generator (IPG) and battery longevity varies by factors such as the number and types of system components, as well as changes in power demands over the patient and therapy life cycle. Additionally, battery longevity is often not analyzed using survival techniques, which may underestimate battery longevity (ref 1-2). With the increased applications of DBS, the longevity of an IPG is an important factor to patients, caregivers, and physicians. With these key factors considered, this analysis was conducted to assess the battery life in patients who underwent DBS for PD and ET in a real-world registry.

Methods

The Product Surveillance Registry (PSR) is a prospective, long-term, multi-center global registry for DBS to monitor the reliability and safety of Medtronic DBS systems. Patients included in this analysis were treated with DBS for PD or ET. Data from 1250 patients* with 1445 Activa PC IPGs were analyzed using Kaplan-Meier and Cox proportional Hazard analyses. IPGs were excluded from the analysis if adaptors (n =160) were used (Figures 1-2).

Figure 1. PSR DBS Enrollment Overview



*Patients may be included in both the initial and replacement categories in Table 2
**173 patients were excluded from the analysis due to adaptor use, unilateral stimulation in PD, no follow-up with IPG and unknown therapy status.

Figure 2. PSR DBS Registry Geographic Overview

Results

For PD patients, median estimate of battery longevity was 4.6 years for first-time implanted IPGs and 3.7 years for replacement IPGs. The median battery longevity for ET patients was 4.3 years for first-time implanted IPGs compared to 3.9 years for replacement IPGs (Tables 1-2).

The 3.5-year survival rate for first-time implanted IPGs was 80.4% for PD patients and 69.6% for ET patients (Figure 3).

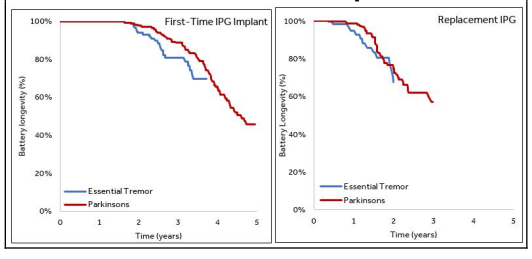
Table 1. Demographics

Variable	PD Mean ± SD	ET Mean ± SD
Age (years)	63.3±9.0	65.4±11.9
Sex (% male/female)	69.0/31.0	57.6/42.4
Initial/Replacement (%)	80.2/19.6	87.1/12.9
BMI	27.2±13.7	29.4±9.4
Diabetes (%)	8.9%	20.1%

Table 2. Median Primary Cell Battery Longevity

	Initial IPG Implant		Replacement IPG	
	PD	ET	PD	ET
No of patients	753	263	296	75
No. of Devices	753	263	340	91
Median Battery Longevity – years	4.6	4.3	3.7	3.9

Figure 3. Kaplan Meier survival analysis curves for PD and ET patients



Conclusions

This analysis demonstrated the expected performance of 3-5 years of battery longevity for DBS therapy from real-world data collected across diverse settings. Battery longevity is quite similar in PD and ET DBS patients but shorter in replacement IPGs compared to first-time implanted IPGs. While the device model is the same for the first-time implanted versus replacement IPGs, the shorter longevity may reflect either programming changes utilizing more power in replacement devices, or a change in electrical resistance over time (higher tissue impedance resulting in more power consumption for a given programmed setting over the life of the patient).

Learning Objectives

By the conclusion of this session, participants should be able to:

1) better understand the factors that predict DBS battery longevity

2) be exposed to more advanced statistical modeling for determining battery longevity

3) and be armed with more information to assist in selecting DBS patients for a primary cell or rechargeable IPG

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