Predictors of Battery Life for the Activa® Soletra 7426 Neurostimulator

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Abstract

OBJECTIVE: To identify factors that effect battery life of the Soletra® Neurostimulator for deep brain stimulation (DBS). **BACKGROUND:** DBS is increasingly used for Parkinson's disease, essential tremor and other movement disorders. The average battery life is reported as approximately 4-5 years but can vary tremendously. Theoretic formulas exist to predict battery life as a function of parameter setting, but little empiric confirmation of these predictions has been reported. **METHODS:** We identified all battery replacements done at the Baylor College of Medicine, both for actual expired batteries and low voltage batteries. Demographic data was collected and the adjustable settings over the entire life of that battery were formulated longitudinally. The individual contribution of co-variables on the longevity of IPG devices was assessed by survival analysis based on the Kaplan-Meier estimator and log rank test and regression analysis (SPSS 12.0 for Windows; SPSS Inc., Chicago, IL, USA). Those co-variables with 0<p<0.2 in the log rank test were then entered as possible confounders in a Cox regression analysis. **RESULTS:** We have replaced a total of 122 batteries in 73 patients, 44 male (27 PD, 15 ET, 2 other). The mean age at implantation was 63.1±13.7 [range 24–80]. Patient demographics of this population were similar to those who have not yet had a battery replacement. The median life of all replaced batteries was 37.4±17.3 months [range: 4–93]. Patients with completely expired batteries were replaced sooner at 31.7±14.3 months [range: 4–74]. In this group, the main predictors of a shorter battery life were greater amplitude (p=0.002), pulse width (p=0.026), and not using exclusive bipolar settings (p=0.029). The implant location, underlying disease, and sex did not affect battery life. **CONCLUSIONS:** Higher settings and not using a bipolar montage did shorten battery life. The 11 month difference shorter longevity of expired batteries com-pared to low voltage batteries (voltage<3.65) was unexpected but is probably explained by higher settings in the expired batteries.

Introduction

- Deep brain stimulation (DBS), most commonly with Activa System®, Medtronic, Minneapolis, MN, is increasingly used for Parkinson's disease (PD), essential tremor (ET) and other movement disorders. The average battery life of the Soletra® Neurostimulator is often reported as 4-5 years but can vary tremendously. The lithium chloride Soletra® battery is designed to provide continuous current down to 3.5 V and then rapidly expire. In practice we have never observed a V of less than 3.63. Medtronic publishes estimated longevity tables including the variables for current, pulse rate, pulse width and amount of daily use. (1) For example 16 hour/day use at 3.0 volts, 130 Hz, and a pulse width of 120 Msec would be predicted to last 77 months. One can generally extrapolate between the provided increments that are listed. Some features do have linear correlations i.e. pulse frequency, however others do not. Battery longevity decreases at higher than 3.6 V as a double circuit is activated. Correction constants to predict the marked effects of polarity (monopolar vs. bipolar vs. multipolar) are also provided. Finally, impedance, which is derived from the interaction of the system current and the immediate environment also effects battery duration. This is only partially controlled by device adjustments.
- These formulas are based on basic electrical principles. In contrast, almost no empiric human data regarding battery life and the factors which may mitigate it has ever been reported. Given the surgical risks, cost of battery replacement, and the expected increase in DBS usage, understanding these factors is increasingly important.

Methods

- We identified all battery replacements done at the Baylor College of Medicine in patients who were followed here. This included both batteries that were dead as determined by telemetry and batteries that were still viable but demonstrated a voltage of less than 3.7 V. In some cases, especially with lower parameter settings, we did not recommend replacement until 3.65 V. Prior to the 8044 Physician Programmer, battery voltage could only be assessed to a single decimal place. Batteries were replaced prior to complete discharge to avoid the marked symptom exacerbation precipitated by the sudden loss of clinical effect, especially with tremor. Furthermore, despite being designed to maintain constant output until drained down to 3.5 V, we have frequently noticed worsening clinical features in relatively low voltage batteries that improves following replacement. We have also never actually recorded a battery voltage below 3.64 V, suggesting that the batteries expire before reaching 3.5 V.
- Demographic data was collected and the adjustable settings of the battery over the entire life of that battery were collected and formulated longitudinally. These included voltage, montage and polarity, pulse width, pulse frequency, and duration of use.
- The individual contribution of co-variables on the longevity of IPG devices was assessed by survival analysis based on the Kaplan-Meier estimator and log rank test and regression analysis (SPSS 12.0 for Windows; SPSS Inc., Chicago, IL, USA). Those co-variables with 0<p<0.2 in the log rank test were then entered as possible confounders in a Cox regression analysis. The "end-of-life" status, whether the battery was actually expired vs. possessed a voltage less than 3.65-3.70 V and was soon to expire, at time of IPG exchange was a predictor of IPG longevity, odds ratio (OR)=1.7 (CI95%: 1.1-2.6), p < 0.02; and therefore, we analyzed the actually dead batteries separately. The remaining co-variables were then entered together and assessed based on the backward stepwise (Wald) method. We also compared parameters in the expired vs. low voltage batteries.

Table 1.
Univariate Predictors of Shorter Battery Life

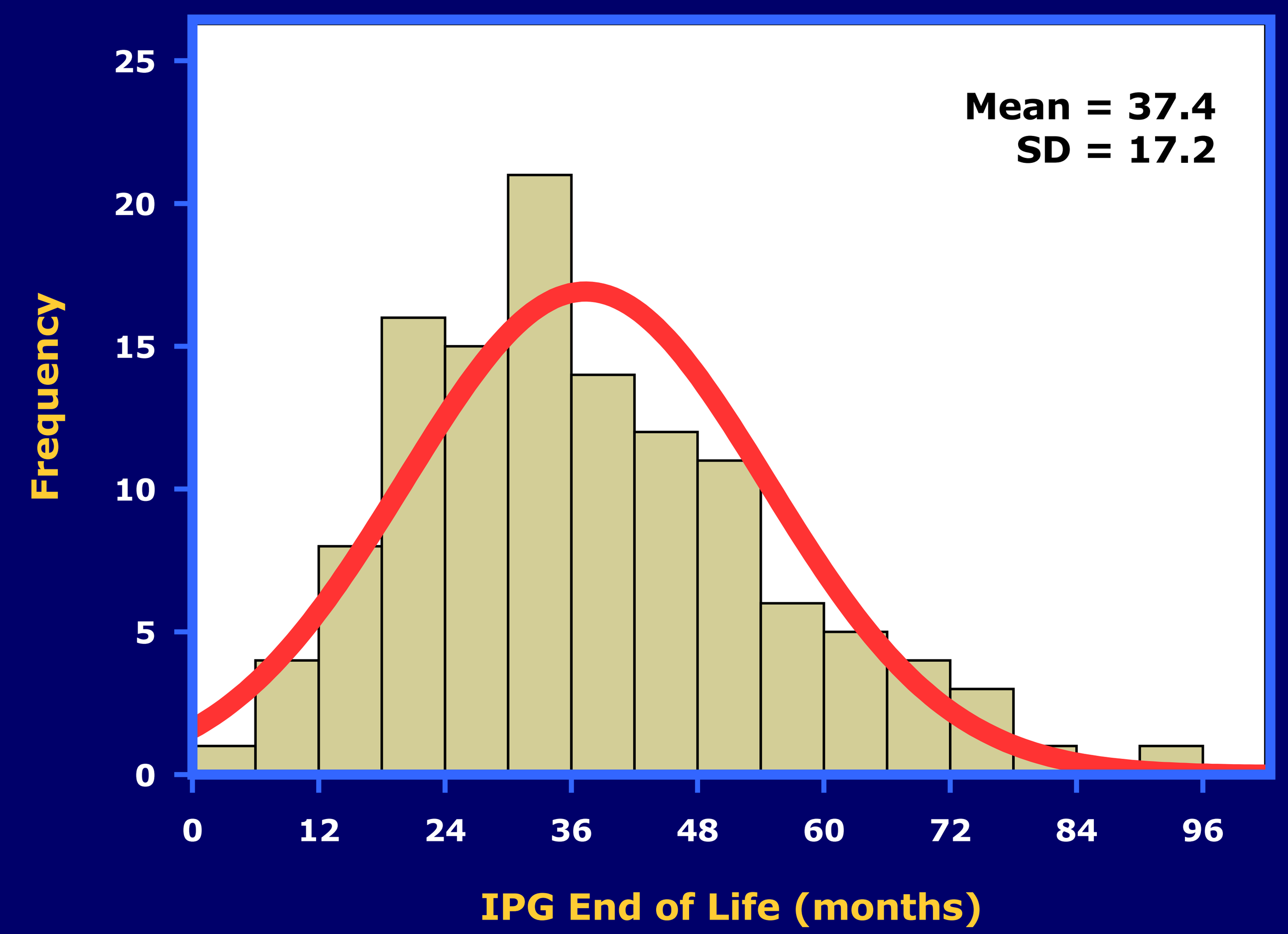
Variable	N	Log rank	P value
Male sex	43 male 18 female	1.7	0.20
Disease	30 PD, 29 ET, 1 Dystonia, 1 MS	3.3	0.34
Target	55 VIM, 5 STN, 1 GPi	2.4	0.50
Monopolar Only	6	0.9	0.33
Multipolar Only	34	4.6	0.03
Mixed	20	2.9	0.09

	Regression	Unstandardized Regression Coefficient	P value
Pulse Width	0.25	-0.05	0.06
Pulse Frequency	0.10	-0.05	0.46
Amplitude	0.39	-5.0	0.002

Results

- We have replaced 122 IPG units either due to either low voltage (60) or absent voltage (61) in 73 different patients, 50 (70.4%) male, with a mean age 62.3±14.3, [range:24-80]. In one subject exact battery status at time of replacement was not recorded. The age at initial implant and disease process was similar in this group to the DBS population in general (N=324). Batteries were replaced in patients with the following conditions: PD (42), ET (29), dystonia (2), multiple sclerosis tremor (1). DBS placement in these patients was in the thalamic ventral intermediate nucleus (VIM) in 52, the subthalamic nucleus (STN) in 13, the globus pallidus internus (GPi) in 4, and both the VIM and STN on opposite sides in 4. A single IPG replacement was performed in 47 patients, two replacements in 14 patients, three replacements in 7, four replacements in 2 patients, five replacements in 2 patients, and eight replacements in a single patient.
- Overall mean battery survival (N=122) was 37.4±17.3 months [range: 4-93 months]. Interestingly, the expired batteries were replaced at 31.7±14.3 months [range: 4-74 months] whereas the low voltage units were replaced at 42.9±19.3 months [range: 9-93]. This likely reflects higher current 3.5±1.1 vs. 2.9±1.2, (p=0.01) and pulse width 201±74 ?sec vs.157±64 ?sec, (p<0.001) in the expired group. Other variables were not significantly different. Within the expired battery group (N=61), the univariate analysis is summarized in Table 1. Subsequent multivariate analysis revealed that battery longevity was shortened by 1. greater amplitude (p=0.002, C.I.95%: 1.188 - 2.18), 2. not using bipolar exclusively (p=0.029, C.I.95%: 0.29 - 0.94), 3. greater pulse width (p=0.026, C.I.95%: 1.00 to 1.01. Greater pulse rate (p=0.09, C.I.95%: 0.97 - 1.00) tended to reduce longevity.

Figure 1.
Battery Longevity for All Replaced Units (N=122)



Discussion

- We empirically found that greater pulse width, greater amplitude, and not using exclusively bipolar montages significantly predicted shorter battery longevity. These are all consistent with published predictions. Our mean battery life was only 31.7 months, but this study was not actually designed to determine typical battery life, and reflected the relatively higher parameters of this group.
- The only other published empiric data on battery life reported that 14/163 IPGs had battery failure requiring replacement. (2) The median life span of the batteries was 45 months. Compared to batteries that did not fail, the failed batteries had higher total electrical energy delivered. They did not report single parameter predictors.
- Future research should determine the percentage of variance that can be predicted from the provided formulas, the role of impedance, compare these results to the Kinetra® silver vanadium oxide battery.

References

1. Medtronic. Activa System Users Manual. Columbia Heights MN, 1999.
2. Bin-Mahfoodh M, Hamani C, Sime E, Lozano AM. Longevity of batteries in internal pulse generators used for deep brain stimulation. Stereotactic & Functional Neurosurgery 2003;80(1-4):56-60.

Figure 2.
Battery Longevity for All Expired Batteries (N=61)