A Study of Battery Replacement Characteristics of Patients With Parkinson's Disease and Factors Influencing Battery Drain

Dear Editor,

The efficacy of deep brain stimulation (DBS) as an adjunct in the management of movement disorders is proven.[1] One major concern is the need to replace battery over time with nonrechargeable battery in the implantable pulse generator (IPG) having a shorter battery life compared to a rechargeable battery. The life of the battery also depends on other parameters, including amplitude, frequency of stimulation, and other settings (monopolar vs. bipolar). Life threatening complications like akinetic-rigid states like "DBS withdrawal syndrome" can occur on withdrawal of stimulation when the battery gets drained.[2,3] It is therefore vital that an estimate of battery life be made for all patients. The existing methods for estimation of the battery life use the battery capacity and current drain. This has inherent errors as it does not consider the device type, battery usage, impedance fluctuations, usage patterns, and self-discharge. Montuno *et al*.[4] proposed a web-based battery estimator and a clinical algorithm for management. The web-based battery estimator was based on mathematical formulations for each type of battery. To the best of our knowledge, there is a lack of studies concerning the clinical and technical aspects of battery replacements following DBS surgery from India. We aimed to study the clinical and stimulation profile of patients of Parkinson disease (PD) with DBS who had undergone battery replacement after end of service state of nonrechargeable battery and to identify the predictors of early battery drainage.

Methods

In this retrospective single-center study conducted at a tertiary care neurology institute from India, we reviewed the clinical features and the parameters of DBS stimulation in patients with PD who have undergone battery replacements. We objectively evaluated these patients and tried to correlate the stimulation data with the clinical features. The medical records of patients who underwent DBS between 2009 and 2021 were reviewed and demographic, clinical, and surgical details were tabulated. To correlate parameters, the study cohort was divided into groups based on age at onset (AAO) (<45 years and ≥45 years), Time from DBS surgery to Battery Replacement (TDBR) (<5 years and ≥5 years), and the type of stimulation (monopolar vs. interleaving). Statistical analysis of continuous variables was expressed in mean ± standard deviation, if the data had a normal distribution, or as median (IQR) if otherwise, and categorical variables are expressed in frequency and percentages. Spearman correlation, Mann-Whiney U test, and multiple linear regression statistics were applied to study the predictors of time to battery replacement in patients who have

undergone DBS. A *P* value ≤0.05 was considered as statistically significant and the statistical analysis was performed using SPSS v23. The institute ethics committee approved the study (NO. NIMH/DO/IEC (BS & NS DIV)/2021-22, Dated: 30/11/2021).

Results

Between 2009 and 2021, a total of 113 patients with PD underwent bilateral subthalamic nucleus DBS with conventional nondirectional leads, of whom 23 underwent battery replacements. The initial hardware implanted in all the patients was Medtronic Activa PC which has a nonrechargeable battery. The mean age at presentation to our hospital was 49.6 ± 10.2 years and the mean age of onset of motor symptoms of PD was 40.6 ± 8.2 years. The mean duration of the time from onset of disease to DBS was 11 ± 3.6 years. The mean levodopa equivalent daily dose (LEDD) in these patients prior to DBS surgery was 899.6 ± 225.6 mg/day.

The mean TDBR was 5 ± 1.78 years. Of the 23 patients, seven opted for replacement with a rechargeable battery. The reasons for battery replacement were battery drain in seven (30.4%), scheduled replacement in 12 (52.2%), and worsening clinical condition in four (17.4%). The clinical status showed worsening in most of the patients (n = 21) and two of them presented in an akinetic rigid state. There was a significant difference in the LEDD post-DBS (mean duration at follow-up: 4 ± 1.8 months) and prereplacement (448.6 ± 177.9 mg/day vs. 808.5 ± 307.8 mg/day).

There was a significant negative correlation between the age of onset of PD and TDBR (r = -0.587, *P* =0.003) [Table 1]. There was no significant correlation between LEDD at time of DBS to the TDBR (r = -0.334, *P* =0.12). The stimulation parameters were analyzed and correlated with TDBR. The mean amplitude setting at the time of battery replacement was 3.08 ± 0.62V with median frequency of 125 Hz (range 60-180) and pulse width of 60 microseconds (range 30-120). There was a significant negative correlation between TDBR and the pulse width values prior to replacement (Spearman correlation, r = -0.475, *P* =.02) [Figure 1] but no significant correlation with amplitude or frequency [Table 2]. There was no significant difference between type of stimulation (monopolar vs. interleaving) and the TDBR [Table 2]. Survival analysis showed no difference in TDBR (Chi-square χ^2 was 2.932 with *P* value of. 08) between the groups and the plot is shown in Figure 2. When comparing the group of AAO <45 years (n = 13) and ≥45 years (n = 10), there was a significant difference in TDBR between these two groups (*P* =.002) [Supplementary Table 1]. Postreplacement mean amplitude settings were 2.68 ± 0.65V with a reduction in LEDD to 586.8 ± 271.2 mg/day. Apart from lower AAO in patients with ≥5 years TDBR compared to those with <5 years TDBR, other clinical and stimulation parameters did not have a significant difference [Supplementary Table 2]. Multiple linear regression was nonsignificant for AAO, duration to DBS, LEDD before DBS, amplitude, frequency and pulse width before replacement as independent variables, and TDBR as dependant variable.

Discussion

Battery longevity is dependent on multiple factors—usage characteristics, hardware factors of the device, impedance, and stimulation characteristics. Of these, only the stimulation parameters are under the control of the treating neurologist. All the stimulation parameters that the neurologist can control may influence the battery longevity. These parameters are used to calculate the average charge density and the total power which can be used to predict battery life. A comparison of neurostimulators Kinetra and Activa-PC between 1987 and 2017 in 654 patients with PD who underwent DBS showed that Kinetra devices had a longer survival of 2,379 days (6.5 years) as compared to Activa-PC, which had a mean survival of 1,666 days (4.6 years). In comparison, the mean survival (TDBR) of battery was 5 years in our study. The type of neurostimulator, the total electrical energy delivered, and number of subsequent neurostimulator implantations influenced the battery life.[5] Some of the newer physician programmers have incorporated a battery life estimator that provides an estimated battery replacement time.

The present study found a negative correlation between pulse width settings of DBS and the TDBR. This indicated that a higher pulse width may result in an earlier battery replacement. The pulse width determines the amount of current delivered and the tissue volume activated. However, a correlation between amplitude (voltage) and frequency was not found. The type of DBS lead configuration (monopolar vs. interleaving) also did not influence the battery drain. This lack of significant correlation may be due to smaller sample size of the study. The age of onset correlated negatively with the duration to battery replacement suggesting a possibility that young onset PD may respond better to DBS at lower stimulation amplitudes and battery may last longer in these cases. However, lower but nonsignificant amplitude, pulse width, and frequency were noted in young onset PD group which might have had a confounding effect to this finding. As all DBS neurostimulators in this cohort were of the same make and all opted for a

Table 1: Correlation of TDBR and clinical characteristics

Parameters	Correlation Coefficient	*P*
Age at Onset of PD	-0.587	0.003
Duration of PD at presentation	-0.130	0.553
Duration of PD at DBS	-0.945	0.015
LEDD at presentation	-0.260	0.231
LEDD at DBS	-0.017	0.939
LEDD at replacement	-0.334	0.120
UPDRS III at presentation	-0.04	0.858
UPDRS III at DBS	-0.90	0.699
UPDRS III at replacement	-0.341	0.166

DBS, Deep brain stimulation; LEDD, Levodopa equivalent daily dose; PD, Parkinson Disease; TDBR, Time from DBS surgery to battery replacement; UPDRS III, Unified Parkinson disease rating scale part-III

nonrechargeable battery, a comparison between IPG models and battery types was not possible.

A study of battery drainage patterns following DBS in 320 patients who underwent battery replacements between 2002 and 2012 found that there was a significant negative correlation between total power and charge density with the battery life.[6] The Medtronic helpline and the University of Florida estimator were found to predict battery drain better than battery status indicators on the devices. In 38 patients, there was an improvement in symptoms suggesting that battery drain was the cause of worsening.[7] Replacements were preceded by an increase in voltage due to worsening of symptoms in 27.3% (15/55), a full depletion or low IPG reserve for voltage adjustment in 25.5% (14/55) and 21.7% did not get a voltage increase due to safety concerns or because the date for battery replacement was close.[7] Clinically well controlled disease was seen in 25.5% (14/55) prior to replacement. The duration to replacement ranged from 1.2 to 9 years and the mean battery voltage when replaced was 3.39V.[7] In comparison, in the present study, more than 90% had clinical worsening prior to the battery replacement, duration to replacement ranged from 2.75 to 12 years with a median of 5 years, and the mean battery voltage at the time of replacement was 3.08V.

Table 2: Correlation of TDBR and Stimulation parameters

Parameters	Mean±S.D	Value	*P*
Amplitude at the time of replacement	3.08±0.62V	-0.146	0.506
Frequency at the time of replacement*	125Hz (90,130)	-0.279	0.198
Pulse width at the time of replacement	65.6±17.3 μsec	-0.475	0.022
Type of stimulation (Mean TDBR)			
Monopolar (*n*=19)	5.2±1.9 years	22 (Z -1.307)	0.218
Interleaving (*n*=4)	4.3±0.62 years		

TDBR, Time from DBS surgery to battery replacement; S.D, Standard deviation. *-Median (Range)

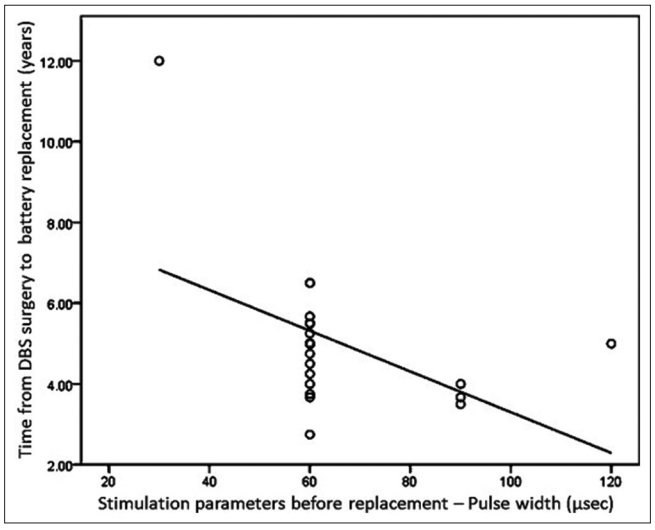

Figure 1: Scatter plot showing distribution of pulse width values (y-axis) and total duration to battery replacement (TDBR) values (x-axis) in the cohort. There was a significant negative correlation between the pulse width values prior to replacement and TDBR (Spearman correlation, r = -0.475, *P* =0.02)

The type of stimulation used can influence battery life by drawing more power and leading to drain. A comparison between bipolar and monopolar (single and double) stimulation showed significantly higher battery life with bipolar stimulation (56.1 ± 3.4 months vs. 44.2 ± 2.1 months vs. 37.8 ± 5.6 months; *P* =0.006 and. 014) as the area stimulated is smaller.[8] The interleaving configuration in Medtronic devices uses different stimulation parameters for contacts on the same electrode with a common frequency, leading to changes in the volume of tissue activation. Reduced battery life has been demonstrated with this setting.[9] Constant-current stimulation ensures constant delivery of a fixed amount of electricity despite changes in impedance and voltage over time. However, these dynamic changes in voltage lead to faster battery drain in comparison to constant voltage stimulation. This difference was less evident on long-term follow-up.[10]

An important concern is the inability to undergo battery replacement due to poor financial status which may result in life threatening DBS withdrawal state.[2,3] It is imperative to explain to the patients at the time of DBS surgery that battery replacement is a necessity and they should be prepared for the same. Moreover, estimating the remaining time to battery replacement can provide necessary time to the patients to prepare for the battery replacement financially and also to the clinician to slowly step up the dopaminergic medications so that the life-threatening worsening can be avoided.

Apart from the smaller sample size, the major limitation of our study is the lack of impedance measurements and total

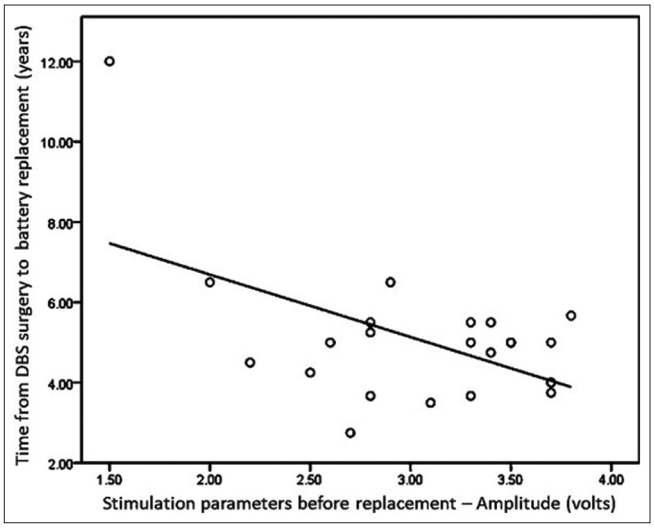

Figure 2: Kaplan-Meier survival curves showing comparison between cumulative survival in groups with monopolar (n = 19) and interleaving stimulation (n = 4) configurations. Survival analysis showed no difference in TDBR (Chi-square χ^2 was 2.932 with *P* value of .08) between the groups

electrical energy delivered (TEED) calculation which is one of the important predictors of battery drain. Although perioperative computed tomography was performed in all, postoperative imaging to confirm the active contact location was not performed in the majority which add to the limitation. In addition, the exact duration of monopolar and interleaving configuration in those patients who were on interleaving configuration was not available. Bipolar and double monopolar stimulation types were not identified in the current cohort and their effect on the drain could not be studied.

Conclusion

Battery drain can be potentially life threatening and neurologists may not be available in smaller cities and towns, especially in a resource poor country and developing economy like India. This study shows that later AAO and higher pulse width prior to battery replacement correlate with shorter battery life and should be closely followed up to avoid consequences of complete battery drain. Further longitudinal analysis is required to include patients who had a rechargeable battery placed during DBS surgery and those in whom a different neurostimulator was placed.

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Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Comparison between Groups with AAO <45 years (*n*=13) and ≥45 years (*n*=10)

Parameter	<45 years	≥45 years	*P*
TDBR (years)	5.8±2	4.1±0.78	0.002
Duration of PD at DBS (years)	11±4.2	11±3	0.879
UPDRS III scores (OFF) at DBS	47.7±19.4	53.6±12.6	0.410
LEDD at presentation (mg/day)	830±216.5	990±214.2	0.049
Amplitude value at replacement (Volts)	2.95±0.7	3.2±0.5	0.483
Frequency value at replacement (Hertz)	115.8±41.7	126.5±18.9	0.186
Pulse width value at replacement (μsec)	62.3±19.2	70±14.1	0.313

DBS, Deep brain stimulation; LEDD, Levodopa equivalent daily dose; PD, Parkinson Disease; TDBR, Time from DBS surgery to battery replacement; UPDRS III, Unified Parkinson disease rating scale part-III

Supplementary Table 2: Comparison between Groups with TDBR <5 years (*n*=10) and ≥5 years (*n*=13)

Parameter	<5 years	≥5 years	*P*
Age at onset (years)	45.9±6.9	36.5±6.7	0.004
Duration of PD at DBS (years)	11±3	11.2±4.15	0.693
UPDRS III scores (OFF) at DBS	46.9±16.2	53.25±17	0.563
LEDD at presentation (mg/day)	899±175.6	899.6±264	0.648
Amplitude value at replacement (Volts)	3.11±0.54	3.29±0.4	0.927
Frequency value at replacement (Hertz)	129.5±27.9	113.5±36.7	0.148
Pulse width value at replacement (μsec)	70±14.1	62.3±19.2	0.313

DBS, Deep brain stimulation; LEDD, Levodopa equivalent daily dose; PD, Parkinson Disease; TDBR, Time from DBS surgery to battery replacement; UPDRS III, Unified Parkinson disease rating scale part-III