Iranian Journal of NEUROSURGERY

2022, Volume 8

Review Article

Evaluating the Longevity of Implantable Pulse Generator Used in Deep Brain Stimulation: A Systematic Review

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Citation Hanani S, Beigi-Khoozani A, Afshar-Zarandi A. Evaluating the Longevity of Implantable Pulse Generator Used in Deep Brain Stimulation: A Systematic Review. Iran J Neurosurg. 2022; 8:E7. http://dx.doi.org/10.32598/irjns.8.7

http://dx.doi.org/10.32598/irjns.8.7

Article info:

Received: 31 Dec 2021

Accepted: 05 Apr 2022

Available Online: 16 Jul 2022

Keywords:

Deep brain stimulation, Longevity, Electrodes, Implanted

ABSTRACT

Background and Aim: Deep Brain Stimulation (DBS) surgery is increasingly performed to treat movement disorders. In these patients, a rechargeable or non-rechargeable battery is placed under their subcutaneous chest after implantation of an electrode in the basal ganglia of the brain, which has different battery life.

Methods and Materials/Patients: In this study, three databases, including PubMed, ScienceDirect, Scopus without time limit, and Google Scholar search engine were examined by two independent researchers.

Results: In the initial search, a total of 338 data were found. Then, by reviewing the title and summary of articles, 17 articles were included in the study and then 13 articles were reviewed in full text. The results of the articles were divided into two subgroups of battery life related to the types or subtypes of movement disorders indicated by DBS and battery life related to the types of IPG models.

Conclusion: Battery life in Parkinson's movement disorder and tremor is longer than in dystonia. Also, the battery life of Soletra model is longer than Kinetra and Kinetra model is longer than Activa, and any battery replacement surgery reduces battery life.

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Highlights

- Battery life in Parkinson's movement disorder and tremor is longer than that of dystonia.
- The battery life of Soletra model is longer than that of Kinetra which is longer than Activa.
- Any battery replacement surgery reduces battery life.

Plain Language Summary

Deep brain stimulation (DBS) surgery is increasingly being performed to treat movement disorders. Over the past decade, DBS has emerged as the best treatment option for patients who have a poor response to medication. In these patients, electrode implantation in the basal ganglia of the brain is used to suppress abnormal activity and a rechargeable or non-rechargeable battery is used under the chest. Battery drain is the most common cause of additional surgery in DBS patients. Multiple battery replacements pose a risk of infection and wound healing problems. The aim of this study was to evaluate the lifespan of different types of batteries used in DBS surgery. The results showed that the battery life is longer in Parkinson's movement disorder and tremor compared with dystonia. Moreover, any battery replacement surgery reduces battery life.

1. Introduction

The basal ganglia are a group of subcortical nuclei in the brain that are important for integrating information and processing cortical input for motor and cognitive functions [1]. The basal ganglia play an important role in controlling voluntary movements [2, 3]. The striatum and Subthalamic Nucleus (STN) are the entry points of the basal ganglia and the inner part of the Globus Pallidus (Gpi) and the Cubstantia Nigra (SNr) are the exit stations of the basal ganglia. On the other hand, the outer part of the Gobus Pallidus (GPe) contains a relay core. Three corticalganglion pathways, including supra-direct, direct, and indirect transmit different information from the cerebral cortex to the globus pallidus and the corpus luteum. Direct path signals with GPi/SNr-thalamic inhibitory mechanism facilitate movements, while signals passing through direct and indirect pathways suppress voluntary movements [4]. Loss of neurons in specific areas of the corpus luteum and extensive accumulation of intracellular protein (α-synuclein) are characteristics of a neurodegenerative disease called Parkinson's Disease (PD), in which neurodegeneration in dopaminergic pigment neurons reduces dopamine production that is the main mechanism of symptoms of movement disorders in PD and causes disorders in these activities, such as Bradykinesia stiffness, vibration, cognitive changes, depression, and voluntary activities [4-6].

Over the past decade, Deep Brain Stimulation (DBS) in the inner part of the globus pallidus has emerged as the best treatment option for patients with debilitating primary dystonia who have a poor response to drug therapy [7-9]. DBS has also become a standard of care for movement disorders, especially PD, major tremors, and dystonia. DBS involves placing an electrode in an inefficient neural circuit and transmitting a continuous electric current to the structure to be electrically excited to suppress abnormal activity or conduct a low-power network [10-12].

The most common target in PD-DBS is the Subthalamic Nucleus (STN) [13]. The device is powered by an Implantable Pulse Generator (IPG) that was originally designed by Medtronic to be non-rechargeable (single-channel IPG: Itrel I® and II®, Soletra®; and IPG Two channels: Kinetra®). Then in 2008, the DBS systems offered by Medtronic were designed to be non-rechargeable (single-channel Activa-SC® and dual-channel Activa-PC®, which replaced Kinetra®) or Rechargeable (RC) (Activa RC®). In France, a new generation of non-rechargeable generators (Activa-SC® & PC®) has been available to PD patients since 2012, and Activa-RC® generators since 2016. Non-rechargeable batteries have a limited life due to an internal chemical reaction that causes them to discharge spontaneously. For this reason, preembedded IPG devices have a useful life that is set to achieve the expected lifespan [14].

Battery drain is the most common cause of additional surgery in DBS patients [12, 15, 16]. Although IPG replacement is a minor surgery compared to primary brain surgery, multiple IPG replacements during treatment and the patient's illness can increase the patient's health risk, such as the increased risk of post-implant infection and wound healing problems [17].

However, the extent to which patients are involved in the choice of battery for DBS and the factors that are important to them have not been well studied [18] and patients are required to check the battery status or have to charge the battery regularly using a handheld device. The recharging method, although not difficult for healthy people, can be challenging for patients with PD because most of them are elderly with varying degrees of motor and cognitive impairment [17]. According to previous studies, more than 1% of people over the age of 60 have PD [19] and the prevalence is increasing day by day, with an estimated 6.1 million people worldwide in 2016 with PD, which is 2.4 times more than in 1990 [20]. Due to the increasing use of this surgery and the use of non-rechargeable IPGs in Iran, as well as due to the different lifespans of batteries that can be used in DBS and its importance in people with mobility disorders, the aim of this study was to investigate the different lifespans of different types of batteries used in DBS surgery. Also, we evaluated the lifespan findings of the types of batteries used in DBS surgery.

2. Methods and Materials/Patients

In this systematic review, a Prisma tool was used to clarify the present report. The question considered in this study is: How long are the different batteries used in DBS surgery?

Search strategy

In the present study, researchers reviewed articles published in PubMed, ScienceDirect, and Scopus databases with no time limit until August 8, 2021, and the Google Scholar search engine was reviewed for a closer look. It should be noted that the findings based on book chapters and conference abstracts were among the limitations. The authors also reviewed the reference list of eligible articles. Selected keywords in the search strategy included DBS AND "deep brain stimulator" AND lifetime AND longevity AND battery.

Data were collected in EndNote X20 software and duplicate studies were eliminated. The title and abstract of all obtained articles were screened and irrelevant articles were removed. The full text of the remaining articles was included in the study to find relevant studies that fit our inclusion criteria. It should be noted that data extraction was done by two researchers separately.

Inclusion and exclusion criteria

Studies that simultaneously investigated DBS and the life of used non-rechargeable batteries were included in the study, and editorial, notes, reviews, and letters to the editor were excluded.

3. Results

The process of searching for articles and selecting them is shown in Table 1. In the initial search, a total of 338 articles from three databases and the Google Scholar search engine were found with restrictions on original articles and no time limit, and after removing 33 duplicates in EndNote X20 software, 305 articles remained and articles by title were reviewed that 24 articles remained in the end. By reviewing the titles and abstracts of the remaining articles, 17 articles were entered and seven articles were removed. Finally, after reviewing the full text of the articles, four articles were removed due to not mentioning the IPG model used, predicting the accuracy of battery life predictors, or using a rechargeable model, and 13 articles remained and were divided into two subgroups of battery life related to the types or subtypes of movement disorders indication of DBS performance and battery life related to the types of IPG models.

4. Discussion

According to the research findings, the lifespan of IPGs embedded in DBS surgery depends on various factors, including different battery models made by different companies, physical and chemical parameters involved in battery manufacturing, location of electrodes used in DBS surgery, and abnormalities. The purpose of this study was to investigate the battery life of different rechargeable models.

Battery life is associated with a variety of subtypes of movement disorders

To prevent battery failure and adverse symptoms, knowledge about battery life and IPG battery management is essential [21]. Therefore, the average battery life is estimated by the manufacturer; 42 months is predicted for patients with PD and 14 months for patients with severe tremors. However, in studies, this

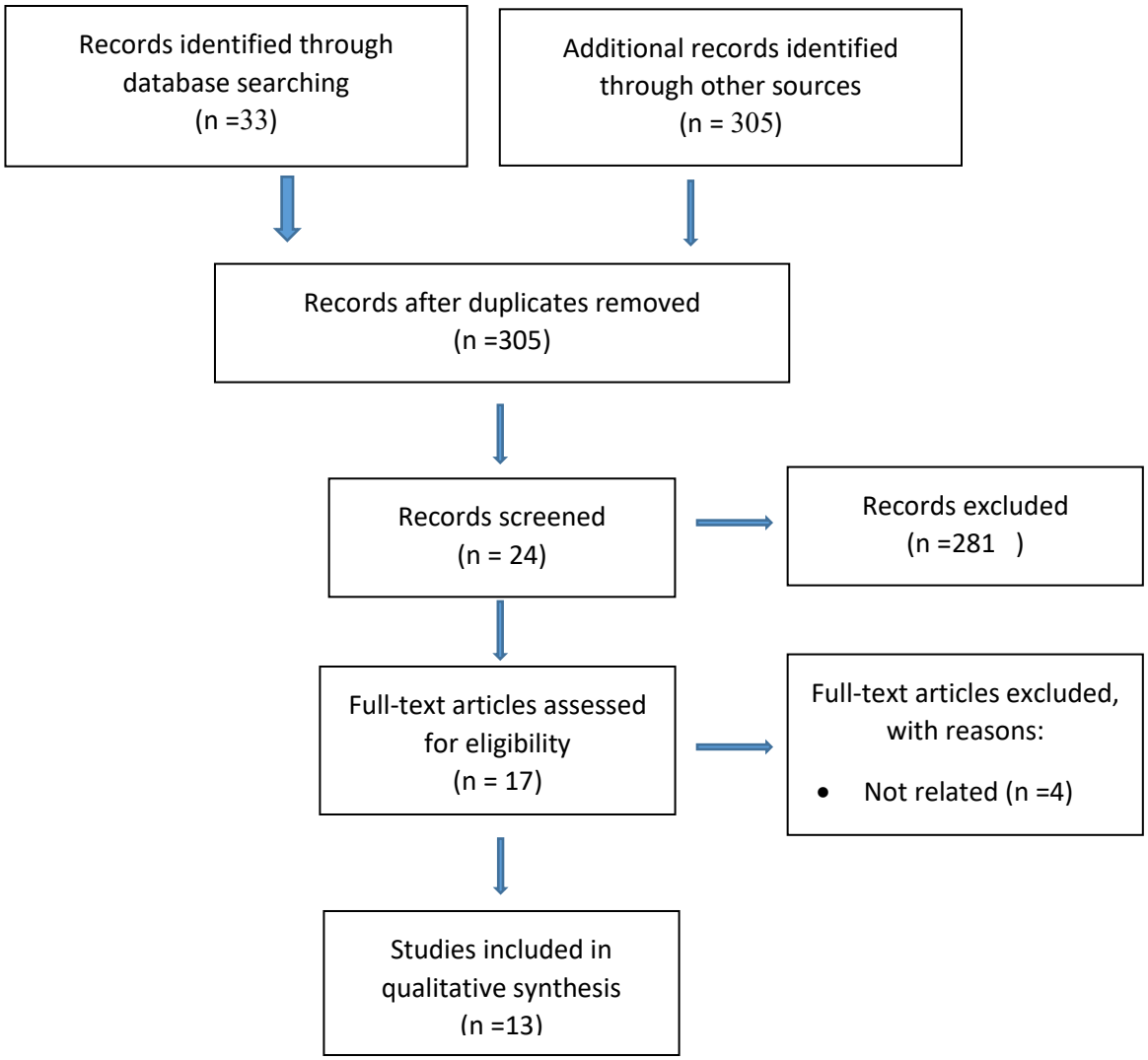

Figure 1. Flow diagram of the study selection for the review process

rate has increased so that the average battery life used in patients with PD was 47 months and in patients with tremors was 21 months [22]. Other studies have shown that DBS in the corpus luteum for dystonia is associated with a shorter lifespan than IPG in patients with severe tremor and PD [23], which is consistent with a study by Van Reisen et al. showing that the length of battery life of dual-channel IPGs (Kinetra 7428) is shorter in dystonic motor dysfunction against PD and severe tremor. One of the reasons for this is the stimulation of more electrodes in dystonia, which causes the battery to discharge faster, and in patients with tremors, it is recommended to turn off the device at night, which can be a reason for longer battery life [24]. Therefore, it can be explained that in addition to the life expectancy estimated by the manufacturer, the type of movement disorder and the location of excitation electrodes in the brain are also effective factors in estimating battery life (Figure 1).

Battery life associated with a variety of IPG models

Ondo et al. showed that the average battery life of the Activa® Soletra 7426 model is 45 months [25], which is consistent with the result of a study by Pavan Rawal et al. who showed that the life of single-channel batteries (Soletra, Medtronic Inc., Minneapolis, MN) is 44.9±1.4 months (mean: 39.7 months) [23]. While Blahack et al. in their study showed that the average battery life of the studied battery, regardless of the unipolar or bipolar state of the device, is 25 months, which is consistent with the result of other studies with a larger statistical population on life expectancy. The batteries for dystonia are comparable, with an average battery life of 24

Table 1. Battery life results of different models

Row	Authors' Name	Year of Study	Country of Research	Type of Study	Number of Participants in the Research	Agent Performing DBS	IPG Model Used	Findings
1	Argon et al. [36]	2020	Sweden	Retrospective study	39	Dystonia	Kinetra, Activia PC, and Medtronic	Battery life did not differ in different models.
2	Blahak et al. [27]	2011	Germany	Prospective series	20	Dystonia	Soletra model 7426	IPG (Implanted Pulse Generator) life used was 25 months.
3	Fakhar et al. [35]	2013	USA	Cohort study	320	Parkinson's disease, dystonia, severe tremor, and OCD (Obsessive Compulsive Disorder)	Soletra and Kinetra	Battery life did not differ between Soletra and Kinetra models.
4	Fisher et al. [29]	2018	UK	Retrospective cohort	183	Parkinson's disease	Kinetra and Activa PC	The battery life of the Kinetra is 2.1 years longer than that of the Activa.
5	Halpern et al. [28]	2011	USA	Retrospective series	399	Parkinson's disease tremor and dystonia	Unilatteral Kinetra and bilatteral Soletra	Soletra battery life is significantly longer than Kinetra.
6	Daniel et al. [32]	2019	Israeli	Prospective cohort	69	Parkinson's disease	Kinetra® and Activa-PC®	The Kinetra has a longer lifespan than the Activia. The lifespan of IPGs (Implanted Pulse Generator) in alternative surgeries is shorter than before.
7	Lumsden et al. [14]	2012	UK	Case series	54	Dystonia	Soletra®, Kinetra® and Activa® RC	No difference in Kinetra and Solatra batteries was observed. No difference in battery life of different models was observed. The lifespan of IPGs in alternative surgeries is shorter than before.
8	Niemann et al. [31]	2018			47	Parkinson's disease, tremor, and dystonia	Medtronic, Activa, and Kinetra	Activa has a shorter lifespan than Kinetra. People who already had a Kinetra battery have a shorter battery life than those who have never used one. Higher TEEDs (Total electrical energy delivered) and frequent IPG switches reduce battery life.
9	Ondo et al. [25]	2007	USA	Retrospective	73	Parkinson's disease, tremor, dystonia, and tremor caused by multiple sclerosis	Activa® Soletra 7426	The average battery life was 45 months.
10	Rawal et al. [23]	2014	USA	Retrospective	229	Parkinson's disease, tremor, and dystonia	Single-channel devices (Soletra, medtronic Inc, minneapdis, MN)	The life of single-channel batteries (Soletra, Medtronic Inc, Minneapolis, MN) is 44.9±1.4 months (average, 39.7 months).

Row	Authors' Name	Year of Study	Country of Research	Type of Study	Number of Participants in the Research	Agent Performing DBS	IPG Model Used	Findings
11	Sette et al. [30]	2019		Retrospective cohort	845	Parkinson's disease, tremor, and dystonia	Kinetra® and Activa® PC	Kinetra has a lifespan of 2.5 years longer than Activa.
12	Riesen et al. [24]	2016	Germany	Retrospective	464	Parkinson's disease, tremor, multiple sclerosis, - Tourette's syndrome, - Huntington's disease, cerebral palsy, depression, - advanced myoclonic epilepsy, and multisystem atrophy	Itrel, Soletra 7246, Kinetra 7248, and Activa RC/PC	The battery life of dual-channel IPGs (Kinetra (7428) used for two-way DBS was shorter in dystonia versus Parkinson's disease vibration. IPG lifetime in STN (Subthalamic nucleus) double-sided DBS varies significantly between different PD subtypes, with shorter battery life and higher TEED if the vibration is predominant. There was no statistical difference in IPG lifetime for dystonia subtypes.
13	Bin-Mahfood et al. [22]	2003	Canada	Retrospective	109	Pain, epilepsy, movement disorders, Parkinson's disease, tremor, and dystonia	Itrell II, Itrell III, and medtronic	The average battery life was 45 months. Battery life in patients with vibration indication is shorter than in those with Parkinson's disease. The average battery life in Parkinson's disease is 47 months and in patients with tremors is 21 months.

months [26, 27]. Based on the available evidence, it is expected that different settings of the devices under study or different movement disorders in the patients participating in the study have increased or decreased the life of the batteries.

According to previous research, the battery life of the Soletra model is longer than that of the Kinetra model and the battery life of the Kinetra model is longer than that of the Activa model. Halpern et al. reported that the higher voltage used, the longer use of the unipolar mode, and the contact of more electrodes in the Soletra system have increased the battery lifespan [28]. In their study, Fisher et al. stated that the average battery life of the Kinetra model is 2.1 years longer than the Activa model [29]. Also, Sette et al. acknowledged that the average battery life of the Kinetra model is 2.5 years longer than the Activa model [30] and other studies conducted by Israeli-Korn et al. and Niemann et al. confirmed the higher battery life of the Kinetra model [31, 32]. However, in studies, the battery life of the Activa model is higher than in previous studies, which is related to the specific programming of the device, and by increasing the DBS excitation parameters the life of this battery has increased, but in general, it can be explained as follows: The type of nerve stimulus mainly affects the battery life and the shorter battery life of the Activa model is mainly due to its technical and structural features.

The Activa-PC® model offers functions not found in the Kinetra® model, such as constant current or constant voltage, excitation between outputs, and a maximum of four different excitation groups. It is assumed that the additional electronic features of the Activa model will drain the battery faster. Also, the volume of the Activa-PC® model is smaller than the Kinetra® model, which can indicate that the Kinetra model conserves more energy and also affects the capacity of the Activa model [30, 32-34]. On the other hand, Lumsden et al. acknowledged that no difference in battery life was observed between Soletra® and Kinetra® IPGs [14]. Fakhar et al. and Ågren et al. showed that battery life is not different in different models [35, 36]; thus, it can be concluded that the life of embedded batteries in addition to differ-

ent models also depends on different diseases because the settings of the DBS device are different for different patients. For example, depending on the type of malfunction, the lower the set frequency of the device, the longer the battery life is to 48 months [26, 37, 38], which can be seen in different statistical populations of studies.

Niemann et al. in their study concluded that the battery life is shorter in patients for whom the Kinetra model battery is first implanted and then in the next replacement, the Activa model battery is implanted. This may be due to the higher excitation settings in primary surgery because according to their observations, those with higher TEEDs had an Activa-PC® battery implanted with Kinetra in their surgical history [31]. Therefore, the higher the TEED, the shorter the battery life.

Most studies have shown that replacing the battery in subsequent surgeries reduces the life of the IPG [14, 31, 32], which is consistent with another study, in which the first battery replacement was done 40.9 months after the first surgery, the second battery replacement was performed 33.7 after the first surgery and third, fourth, and fifth replacements were done 30.8, 24.2, and 26.8 months after the first surgery, respectively [24]. To explain these findings, it can be said that the shorter lifespan of IPG in patients with repeated replacements indicates a longer duration of treatment with DBS and consequent disease progression. Progression of the disease may require higher DBS adjustments, thus reducing the life of the IPG. Also, the long history of treatment with DBS and the long time after implantation of the hardware in the body can lead to the aging process of the hardware, which affects its performance [31]. In addition, the side effects of multiple surgeries can affect the life of the battery. For example, infection in the surgical site can cause a buildup of fluid, which can interfere with the proper flow between the battery and the device.

5. Conclusion

In this study, the finding of the battery life of different models used in DBS surgery in previous studies was systematically investigated. The results showed that the battery life in addition to the amount predicted by the manufacturer depends on the type of movement disorder, the number of IPG replacement surgeries, and device settings in the initial surgery. The obtained results showed that the mentioned factors can affect the estimated lifespan of the device by the manufacturer, which will help neurologists and neurosurgeons in choosing the best device based on the patient's condition for the long-term treatment plan for patients with movement disorders.

Ethical Considerations

Compliance with ethical guidelines

There were no ethical considerations to be considered in this research.

Funding

This research did not receive any grant from funding agencies in the public, commercial, or non-profit sectors.

Authors' contributions

Conception and design: Atefeh Beigi-Khoozani; Data collection: Azimeh Afshar-Zarandi; Data analysis and interpretation: Atefeh Beigi-Khoozani, Azimeh Afshar-Zarandi; Drafting the article: Atefeh Beigi-Khoozani; Critically revising the article: Atefeh Beigi-Khoozani; Reviewing the submitted version of the manuscript: Sedigheh Hannani; Approving the final version of the manuscript: Sedigheh Hannani.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgements

This article is a systematic review study that does not have a code of ethics. This article is a study without human or animal samples. There were no ethical considerations in this study.

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