Rechargeable Pacemaker Technology in Deep Brain Stimulation: A Step Forward, But Not for Everyone

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ABSTRACT: Background: Rechargeable implantable pulse generator (IPG) technology has several advantages over non-rechargeable systems and is routinely used now in deep brain stimulation (DBS). Little is known about the occasional need and the circumstances for switching back to non-rechargeable technology. Cases: Out of a cohort of 640 patients, 102 patients received a rechargeable IPG at first implantation or at the time of replacement surgery. Out of these, 3 patients underwent preemptive replacement with non-rechargeable devices for the following reasons: dissatisfaction with handling and recharge frequency (pallidal DBS in advanced Parkinson's disease/dystonia), severe DBS OFF status subsequent to missed recharging (subthalamic DBS in Parkinson's disease) and twiddler's syndrome (nucleus accumbens DBS in alcohol dependency).

Conclusions: Although rechargeable IPG technology has been received well and is used widely, there are unexpected scenarios that require replacement surgery with non-rechargeable IPGs.

Deep brain stimulation (DBS) has become standard of care in the treatment of movement disorders.¹ There have been marked technological innovations within the last decade concerning both hardware and stimulation algorithms.² Rechargeable implantable pulse generator (IPG) technology has been improved and such devices are being implanted more and more frequently both at the time of primary surgery and at the time of IPG replacement. Rechargeable IPGs were originally considered well suited when higher voltage stimulation was needed, in particular for patients with dystonia, who, therefore, required fewer replacement operations. Considering the overall high patient satisfaction, there is a great tendency for the routine use of these devices, in general, including Parkinson's disease (PD).^{3,4}

Although there is ample information on patient outcome and satisfaction after primary implantation of rechargeable IPGs or after conversion from non-rechargeable technology,^{5,6} there is practically no data available on the need for conversion from rechargeable IPG to non-rechargeable technology.

Here, we present our experience with 3 patients out of a total cohort of 640 patients, who underwent implantation of DBS electrodes or IPG replacement surgery over a period of 15 years with rechargeable and non-rechargeable devices. Rechargeable IPG technology was increasingly used since its introduction 10 years ago and 102 of 640 patients were identified who had a rechargeable IPG at first implantation or at the time of replacement surgery. Details about the surgical procedure have been outlined elsewhere.⁷

Case Series

Case 1

A 64-year-old man with advanced PD presented with motor fluctuations accompanied by dystonic trunk torsion and camptocormia. The Hoehn and Yahr Scale was 4/3 (off/on), and the Mini Mental Examination Score was 28. He underwent bilateral

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Published online 13 August 2021 in Wiley Online Library (wileyonlinelibrary.com). DOI: 10.1002/mdc3.13306

MOVEMENT DISORDERS CLINICAL PRACTICE 2021; 8(7): 1112-1115. doi: 10.1002/mdc3.13306

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Keywords: deep brain stimulation, implantable pulse generator, movement disorders, Parkinson rechargeable pacemaker.

Relevant disclosures and conflicts of interest are listed at the end of this article.

posteroventral lateral globus pallidus internus DBS with implantation of 2 non-rechargeable IPGs (Soletra bilateral, Medtronic, Minneapolis, MN). Pallidal DBS resulted in improvement of parkinsonian symptoms and motor fluctuations as well as of dystonia and camptocormia. Because of high energy consumption (4.5 V, 210 ms, 130 Hz, bipolar stimulation) the IPGs had to be replaced because of battery depletion at <2-year intervals. At the time of the third replacement on 5 years of chronic DBS, the patient underwent implantation of a rechargeable IPG (Activa RC, Medtronic) after thorough discussion with regard to the need of the frequent replacements and an emphasize on the recharging process.

The benefit of PD symptoms and dystonia was sustained, but 2 years later the patient requested to replace the IPG for a nonrechargeable device. Because of mild cognitive decline he had increasing difficulties handling the charging unit and he was dissatisfied with the frequent need for recharging the IPG. After replacement of the IPG for a non-rechargeable IPG (Activa PC, Medtronic) he continued to enjoy the benefit from chronic DBS.

Case 2

A 52-year-old man with advanced PD presented with motor fluctuations and dyskinesias. The Hoehn and Yahr Scale was 4/3 (off/on), and the Mini Mental Examination Score was 27. He underwent subthalamic nucleus (STN) DBS with primary implantation of a rechargeable IPG (Brio, St. Jude Medical). He benefitted from improvement of motor fluctuations, rigidity and bradykinesia, and his dopaminergic medication could be reduced markedly.

Over the following years, he had a cognitive decline and he missed his appointment to recharge his IPG on several occasions resulting in severe DBS off states without being able to reactivate the IPG by himself. With regard to the risk of developing a malignant DBS withdrawal syndrome in chronic PD, it was decided to replace the rechargeable IPG with a non-rechargeable device (Infinity, Abbott, Plano, TX). The further course was stable thereafter.

Case 3

A 56-year-old woman presented with chronic alcoholism with marked craving. After extensive psychiatric treatment without yielding consistent benefit, she was included in an experimental study protocol and underwent bilateral DBS in the nucleus accumbens with implantation of a non-rechargeable IPG (Kinetra, Medtronic). She benefited markedly with respect to restriction of alcohol consumption and particularly craving behavior. She needed almost annual IPG replacements because of high energy consumption of the battery (4.5 V, 90 ms, 130 Hz, double monopolar). After 4 years of chronic DBS, it was decided to implant a rechargeable IPG (Activa RC, Medtronic) at the time of regular IPG replacement.

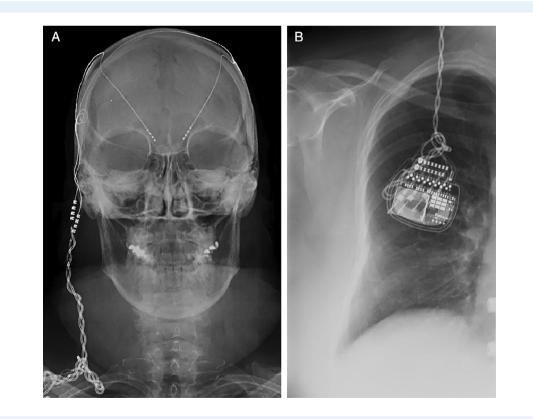


FIG. 1. X-rays of case 3. (A) Head, ap projection. (B) Chest, ap projection. There is braiding of the extension cables starting below the connectors. The IPG is flipped in the subclavicular pocket making recharging impossible.

Two years later, the craving reappeared and on testing of the IPG, no contact could be established. The patient reported that in the previous month at some times she could recharge the IPG properly, but at other times she could not establish contact with the IPG. X-ray imaging showed braiding of the extension cables starting below the connectors and flipping of the IPG in the subclavicular pocket despite 2-point fixation of the IPG to the fascia at the time of IPG surgery (Fig. 1). After multidisciplinary discussion, it was decided to revise the extension cables and to replace the IPG for a non-rechargeable device (Activa PC, Medtronic). After replacement of the IPG with continued chronic stimulation, she benefitted once more from sustained reduction in craving.

Discussion

Rechargeable pacemakers undoubtedly are a step forward in providing more patient comfort and safety. Many patients stand to benefit from rechargeable technology, smaller devices and fewer replacement operations. Patients with dystonia who generally have high-energy consumption and patients with PD without signs of dementia and good technical understanding are considered to benefit most.^{5,6,8} However, new technology may also be fraught with unexpected limitations. Although removal of a rechargeable IPG before end of service of the battery and replacement with a nonrechargeable pacemaker poses an undue economic burden, it may be the only solution under certain circumstances to maintain the benefit of chronic stimulation. Despite meticulous screening for suitability, we had to switch the IPG to non-rechargeable technology because of unforeseen difficulties in 3 patients.

Although it has been stated that rechargeable technology might be an excellent choice in PD and there were no instances to re-consider non-rechargeable technology in a series of 53 PD patients with STN DBS³ and in other series as well,⁴ special attention should be paid to this group of patients. Unexpectedly, patient 1 in our series experienced the recharging process as inconvenient and was unwilling to include it into his daily routine. There is evidence, that some patients, who switch from a non-rechargeable to a rechargeable system, are less satisfied than patients who were primarily implanted with a rechargeable device.^{5,9} Our second patient with PD suffered from cognitive decline while on chronic stimulation with a rechargeable IPG. If no caretaker is available to oversee the charging process, there is a risk of interruption of DBS resulting in neuroleptic-like malignant syndrome, which can be life-threatening.9 It should be mandatory to explain this risk to patients with PD and their families beforehand to allow a shared decision making process.

The scenario in our third case points to another problem in patients who switch systems. The rechargeable device, in general, is smaller than the non-rechargeable IPG, and therefore, the existing fibrous pocket is larger and allows accidental or voluntary flipping of the pacemaker possibly facilitating the development of twiddler's syndrome.¹⁰ Patients with obsessive and compulsive behaviors might need particular attention.

Our series exemplarily demonstrates that rechargeable IPG technology may be inferior to non-rechargeable systems despite

careful preoperative patient selection and counseling. It is conceivable that such instances usually remain unpublished and there is an unknown estimated number of unreported cases.

Author Roles

Research project: A. Conception, B. Organization,
C. Execution; (2) Statistical Analysis: A. Design, B. Execution,
C. Review and Critique; (3) Manuscript Preparation: A. Writing of the First Draft, B. Review and Critique.

J.R.: 1B, 1C, 3A J.M.N.: 1C, 3B A.S.: 1B, 3B C.S.: 1B, 3B J.K.K.: 1A, 1B, 3A, 3B

Disclosures

Ethical Compliance Statement: The principles outlined in the "Declaration of Helsinki" were followed. Informed patient consent was not necessary for this work. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

Funding Sources and Conflicts of Interest: No specific funding was received for this work. The authors declare that there are no conflicts of interest relevant to this work.

Financial Disclosures for the Previous 12 Months: J.K.K. is a consultant to Medtronic and to Boston Scientific. All other authors have no disclosures to report.

Acknowledgment

Open access funding enabled and organized by Projekt DEAL.

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