Rechargeable vs. Nonrechargeable Internal Pulse Generators in the Management of Dystonia

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Objective: To test if deep brain stimulation (DBS) treatment of dystonia was similar in patients before and after implantation of rechargeable internal pulse generators (IPGs).

Materials and Methods: The Burke–Fahn–Marsden Dystonia Rating Scale (BFMDRS) severity and disability scores were compared in patients before DBS insertion, 24 months after DBS insertion with a nonrechargeable IPG, and after implantation of a rechargeable IPG.

Results: No significant differences were observed between dystonia control in patients before and after implantation of a rechargeable IPG.

Conclusions: Rechargeable IPGs should be the IPGs of choice for dystonic patients receiving DBS as IPGs offer similar treatment efficacy to nonrechargeable IPGs with advantages in terms of costs and reductions in reimplantation frequency.

Keywords: deep brain stimulation, dystonia, internal pulse generators

INTRODUCTION

Deep brain stimulation (DBS) has become the surgical treatment of choice for drug refractory dystonia (1). Nonetheless, DBS for dystonia has disadvantages. A major disadvantage is that the treatment parameters required to control dystonia often limit the life span of nonrechargeable internal pulse generators (IPGs) to approximately two years, thus necessitating repeat surgery to replace the IPGs frequently, with attendant risks of morbidity and financial costs (2).

A possible solution to this disadvantage is to implant rechargeable IPGs. The projected lifespan for rechargeable batteries is approximately 9–10 years, reducing the frequency of reimplantation surgeries with attendant reductions in surgical morbidity and costs.

However, the general physical properties of batteries may, in theory, mean that the management of a patient’s dystonia may be adversely affected by implantation of an IPG with a rechargeable battery compared with a nonrechargeable battery. Electromotive force (voltage) of a battery is not a constant, but varies with battery internal resistance. Battery internal resistance in turn varies with the amount of charge stored within the battery. In the case of rechargeable batteries, as the battery charges and discharges frequently, internal resistance will consequently vary frequently. Since voltage, current, and resistance are intimately related according to Ohm’s law, as resistance fluctuates during the charge–discharge cycle, so also may the battery output, thereby having an influence on therapeutic effect of the IPG. Adjustment of treatment parameters in this context would have limited utility since the output of the battery would be constantly changing depending on charge status. The same problem could apply to nonrechargeable batteries, but given the long discharge period of nonrechargeable IPGs, periodic adjustments in output settings may overcome this problem.

If this theoretical problem applies to rechargeable IPGs in practice, the practical consequence of this could manifest as deterioration in dystonic symptoms in patients with DBS who have changed from nonrechargeable to rechargeable batteries. The specific mechanism by which DBS treats dystonia is not certain, but clinical studies emphasize that improvement depends on continuous delivery of treatment over an extended period of time (3). Indeed, patients may not achieve maximal benefit until a year or more after the onset of therapy. Conversely, cessation of DBS can lead to clinical deterioration within minutes to hours.

We compared dystonic scores in patients with generalized dystonia for whom we had preoperative DBS, postoperative DBS with...
nonrechargeable IPG, and postimplantation of rechargeable IPG scores to attempt to identify if there was a difference between dystonia control with rechargeable vs. nonrechargeable IPGs.

MATERIALS AND METHODS

Thirty-six dystonic patients in our practice have rechargeable IPGs implanted currently (22 Activa RC, Medtronic, Minneapolis, MN, USA; 14 Brio, St Jude Medical Inc., St Paul, MN, USA): 22 generalized dystonia, seven focal, one multifocal, three segmental, two drug-induced, and one hemidystonia. The principal technical difference between the two units is that Activa RC has constant voltage and constant current delivery modes, whereas Brio is a constant current delivery mode only device. Seventeen patients had onset of dystonia in adulthood and 19 had pediatric onset. All patients in this group had bilateral globus pallidus interna (GPI) stimulation leads inserted. Operations and follow-up took place in the John Radcliffe Hospital, Oxford between 2000 and 2012. Preoperative dystonia status and postoperative response to treatment were assessed using the Burke–Fahn–Marsden Dystonia Rating Scale (BFMDRS) or the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS). Of the 36 patients, eight had rechargeable units inserted at original DBS surgery and are not included in analysis. Of the remaining 28, 13 patients had assessments preoperatively, 24 months postoperatively, and at least three months after implantation of a rechargeable IPG unit (range: three months to three years). All 13 of these patients had generalized dystonia; therefore, no patient included in this analysis had focal dystonia. The remainder did not have assessments at all, three of these time points largely owing to geographical reasons: our unit treats patients from Republic of Ireland and Northern England, many of whom we have found to be reluctant to attend routine follow-up in Oxford in the absence of a problem potentially requiring surgery (e.g., battery change, loss of treatment efficacy). These 13 patients are the basis of the results described below. Results are expressed as mean ± standard error of the mean. Paired two-tailed Student’s t-tests were used to test the null hypothesis that there was no difference in mean score between the two groups tested. We have not distinguished between treatment effects in patients with Brio and patients with Activa RC devices as our data do not allow a robust comparison (four Brio vs. nine Activa RC).

RESULTS

All patients in this sample benefited from DBS with nonrechargeable IPGs (Figs. 1 and 2). The mean preoperative severity score (BFMDRS) in the sample was 62.9 (±5.4), improving to a mean postoperative score at 24 months of 37.9 (±5.2). Similarly, disability improved from a mean of 15.0 (±1.4) to 8.7 (±1.42).

Mean severity scores after implantation of a rechargeable IPG were 31.0 (±4.9). This score was not significantly different from scores recorded at 24 months after the original operation. Mean disability scores were 9.5 (±1.0), which were not significantly different from scores recorded 24 months after original surgery. Improvements in severity and disability were statistically significant (paired t-test, p < 0.001) compared with preoperative status with rechargeable IPGs. Results are summarized in Figure 3.

One patient suffered a postoperative wound infection after implantation in this group. None of the 13 patients has required reoperation for device malfunction.

DISCUSSION

In this sample, implantation of a rechargeable IPG did not adversely affect dystonia management compared with a nonrechargeable IPG: patients who benefited from DBS with a nonrechargeable battery continued to experience a measurably similar level of benefit to a rechargeable unit. The study does not allow conclusions to be drawn about any opportunity costs involved in using rechargeable IPGs rather than nonrechargeable IPGs, for example, whether patients with nonrechargeable IPGs improve over time to a greater extent than patients with rechargeable IPGs. Our patient database does not allow robust comparisons at this stage between long-term effects of nonrechargeable IPGs and rechargeable IPGs on treatment efficacy.

In our unit’s experience of DBS, we would argue that rechargeable IPGs should be the first choice of IPG to implant in patients...
undergoing DBS for dystonia of whatever etiology. The main advantages we observed in our practice are: reduction in operation frequency and reduction in costs. The group of 36 patients described above had, on average, required a new nonrechargeable IPG every 15 months. Over the lifetime of one rechargeable IPG, patients in the group could potentially require eight nonrechargeable IPGs. Despite the greater purchase costs of a rechargeable IPG, money can be saved in the longer term by a combination of reduced number of IPGs purchased and reduced number of surgeries per patient. At 2011 prices in our area, using a rechargeable IPG saves the department approximately £150,000 per decade per patient in the absence of complications, assuming rechargeable IPGs will achieve the advertised lifetimes in this patient group. Additionally, money is saved by reducing the number of complications suffered per patient in line with the reduced number of surgeries. A recent study (4) suggests the risk of infection, the most frequent complication of DBS surgery, is three times greater during IPG reimplantation surgery than during original surgery (i.e., intracranial lead placement with IPG insertion surgery).

We have not systematically compared patient satisfaction with rechargeable IPGs with nonrechargeable IPGs, nor have we compared satisfaction with Brio IPGs with Activa RC IPGs. Our experience is that the Brio device is easier to charge because it can be located deeper under the skin; therefore, the charging antenna does not need to be so exactly over the IPG unit to charge effectively. In contrast, the Activa RC unit must be less than 1 cm under the skin to allow effective percutaneous charging; therefore, the charging antenna must be more fastidiously positioned during charging. Nonetheless, no patients, to our knowledge, have had significant problems with the charging process itself. Certainly none have required revision IPG surgery to reposition a functioning rechargeable IPG to allow effective recharging where recharging has been ineffective after original implantation surgery. The principal drawback we have observed with rechargeable IPGs is the design of the recharging antenna and power pack. Some of our patients have experienced breakage of the recharging unit (specifically the connection between the antenna and power pack), necessitating replacement.

In summary, rechargeable IPGs appear to perform as well as nonrechargeable IPGs in the management of dystonia, and offer additional benefits that make them the IPG of choice in the management of dystonic patients.

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Authorship Statements

M. Gillies carried out the data analysis, literature review, and composition of the article. C. Joint, B. Forrow, C. Fletcher, and A. Green were responsible for acquisition of data (arranging appointments for patients to have BFMDRS tests, processing results, entry into departmental database).

T. Aziz developed the study design and had editorial oversight of the article composition and acquisition of funding to allow research more generally within the department.
REFERENCES


COMMENTS

This is a retrospective review of a selected group of 13 patients being treated with bilateral pallidal deep brain stimulation for dystonia, comparing clinical efficacy with use of a non-rechargeable vs. a rechargeable stimulation system. Although the study is retrospective in nature and involves a heterogeneous group of very highly selected patients, the results are worthy of publication. It is important to be able to discuss with patients and their families the option of a rechargeable system because of the high energy brain stimulation requirements for these patients. It is nice to be able to say with a certain level of confidence that the results are similar with a rechargeable system, with the potential of not committing these needy patients to a battery change operation every 1-2 years. The cost savings appear to be very significant as well. Efficacy and cost savings with rechargeable systems for spinal cord stimulation therapy for chronic pain conditions is well known. For some dystonia patients, a rechargeable system is not manageable. People should be reminded that the STN as a target could also be considered, especially since power requirements seem to be less with STN as the therapeutic target.

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Rechargeable internal pulse generators (IPGs) for deep brain stimulation (DBS) procedures are a welcome addition to the clinical management of dystonia. In this movement disorder the high voltage stimulation parameters that are often required lead to frequent battery replacements with a surgical procedure giving more inconvenience/discomfort to the patient. Rechargeable IPGs also reduce the cost to the healthcare provider of these extra procedures. This study clearly shows that there is no difference to the patients clinical benefit from DBS by having a rechargeable IPG vs the single use model. Rechargeable IPGs should be standard of care in treatment of dystonia with DBS.

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Comments not included in the Early View version of this paper.