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COMMENTARY

New Technologies and Applications in Sacral Neuromodulation: An Update

Stefan De Wachter · Charles H. Knowles · Dean S. Elterman · Michael J. Kennelly · Paul A. Lehur · Klaus E. Matzel · Stefan Engelberg · Philip E. V. Van Kerrebroeck

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ABSTRACT

Recently rechargeable devices have been introduced for sacral neuromodulation (SNM) with conditional safety for full-body magnetic resonance imaging (MRI). Currently a recharge-free SNM device represents the standard implant; however, it is only approved for MRI head scans. As further new technologies with broader MRI capabilities are emerging, the advantages as well as disadvantages of both rechargeable versus recharge-free devices will be briefly discussed in this commentary from the perspective of patients, healthcare professionals, and providers.

Keywords: Fecal incontinence; Magnetic resonance imaging; Overactive bladder; Rechargeable battery; Sacral neuromodulation; Stimulator; Urology

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S. De Wachter (✉)
Department of Urology, University Hospital Antwerpen, Antwerp, Belgium
e-mail: stefan.dewachter@uantwerpen.be

S. De Wachter
Department of Urology, Antwerp Surgical Training, Anatomy and Research Centre (ASTARC), Faculty of Medicine and Health Sciences, Wlrijk, Belgium

C. H. Knowles
Blizard Institute, Barts and the London SMD, Queen Mary University of London, London, UK

D. S. Elterman
Division of Urology, University Health Network, Department of Surgery, University of Toronto, Toronto, Canada

M. J. Kennelly
Department of Urology, Carolinas Medical Center, Atrium Health, Charlotte, NC, USA

P. A. Lehur
Coloproctology Unit, Ospedale Regionale di Lugano, Lugano, Switzerland

K. E. Matzel
Chirurgische Klinik, Universität Erlangen, Erlangen, Germany

S. Engelberg
Medtronic Intl Sarl, Tolochenaz, Switzerland

P. E. V. Van Kerrebroeck
Department of Urology, Maastricht University, Maastricht, The Netherlands

Key Summary Points

This article reports on new technical advancements in sacral neuromodulation, such as the need for having full-body MRI-safe devices

In detail, the pros and cons of rechargeable versus recharge-free devices with some recommendations for patient selection are discussed

INTRODUCTION

With more than 300,000 patients implanted worldwide, sacral neuromodulation (SNM) has become an established minimally invasive therapy for refractory overactive bladder, non-obstructive urinary retention, and fecal incontinence. Recently, rechargeable and conditional magnetic resonance imaging (MRI)-safe devices (Axonics r-SNM System™, Irvine, CA) have been introduced in both Europe and USA. The clinical effectiveness of this system appears to be similar to that of the current recharge-free InterStim™ II device (Medtronic, Minneapolis, MN) [1]. Newer InterStim devices have been submitted for CE mark and FDA approval [2] in order to improve patient preference and provide full-body MRI safety for both 1.5 and 3 Tesla with the latter field strength having become the clinical standard. This article is based on previously conducted studies and does not contain any studies with human participants or animals performed by any of the authors.

OBJECTIVE AND METHODS

This commentary mainly assesses the benefits and limitations of new devices for SNM including MRI-safe devices and rechargeable systems in comparison with recharge-free devices. For that purpose, a literature review was performed in EMBASE and Medline databases on July 10, 2019. Included were articles on deep brain and spinal cord stimulation as well as SNM. Exclusion criteria were case reports with less than five patients and articles on cost-effectiveness. The literature review served as a base to initiate discussion meetings with leading and highly experienced SNM implanters in Europe and USA.[1] The literature review and the discussion meeting outcomes form the scientific basis of this commentary. The design of this article is in accordance with ethical standards. Since there are no head-to-head studies between the two manufacturers of SNM devices, no device specific recommendations can be given.

ROLE OF MRI

The desire for full-body MRI-safe devices is obvious, since at least half of patients with pacemakers or neurostimulators will have a clinical indication for an MRI examination over their lifetime [3], and up to 23% of SNM explantations are currently due to the need for MRI [4]. In neurogenic subpopulations, such as multiple sclerosis, the lack of MRI compatibility has been considered a relative contraindication to SNM even though clinical benefits have been demonstrated in small case series from this subpopulation [5]. A further group of patients with lower back pain may also be excluded on this basis, some of whom may have incontinence concomitant with cauda equina syndrome. In addition, patients with fecal incontinence due to low anterior resection syndrome (LARS) may also need regular MRI examinations for cancer surveillance. It is expected that these new technologies will therefore enable more patients to choose SNM as their preferred therapeutic option [4].

RECHARGEABILITY

But what then of the ability to recharge? Does this result in significant benefits to the patient? Several factors merit discussion.

[1] The expert meetings have been supported by Medtronic.

Device Size Comparison

First, rechargeable batteries result in smaller volume implantable pulse generators (IPGs). These may result in more comfort for patients with low body mass index (BMI), and intuitively at first glance, the much smaller size will be more attractive to the patient than the current InterStim II IPG. Currently available SNM systems include the recharge-free InterStim II system (14 cm^3 volume) and the rechargeable Axonics system (5.5 cm^3 volume) [6]. The emerging InterStim Micro technology (2.8 cm^3 volume) reduces the size by about 80% when compared with the InterStim II and will be approximately 49% smaller than the current available Axonics rechargeable SNM device.

However, much smaller rechargeable SNM devices will not be a benefit to all patients because about 40% of the global adult population has body weight issues [7]. In a large, multicenter, prospective study of 272 patients with overactive bladder only 7% reported implant site pain with the current recharge-free InterStim II device [8]. For comparison, with smaller, rechargeable SNM devices pain at the neurostimulator site has been observed in less than 2% of the patients [9]. Therefore, although the smaller size of a rechargeable device does matter for some patients, the vast majority of patients will do equally well with the InterStim II device, which is about the size of a heart pacemaker. Moreover, the correct implantation of a small rechargeable device with the necessity for frequent recharges may be more challenging in obese patients, since the angle and distance between the superficially implanted IPG and recharger may change significantly between recharging sessions, thus making the recharge more cumbersome for obese patients. Furthermore, the stability of the IPG inside the fat tissue could be compromised and/or the patient might be more likely exposed to twiddler's syndrome [10]. The latter occurs when patients manipulate or rotate their device leading to a dislodgment of the leads with subsequent malfunction of the modulation system.

Device Longevity

A second issue relates to the requirement for battery (IPG) changes. The battery life of rechargeable devices has been estimated as 15 years compared to the longevity of the current InterStim II (IPG), which in clinical practice is about 5–7 years [11–13]. As a result of the claimed longer battery life of a rechargeable IPG, it has therefore been suggested that this therapy is associated with a reduced need for reoperation [14]. This assumption, however, ignores other important facts. For various reasons some patients will not need device longevity of 15 years. In a long-term study of 325 patients with a mean follow-up of 7.1 years it was shown that up to 39% of patients drop out because of loss of follow-up, death, dementia, lack of efficacy, device problems, or infections, thereby eliminating any need for future battery replacements [15]. Thus, life expectancy based on the biological age will be an important determinant when considering rechargeable devices. Furthermore cognition and patient's dexterity will also be important to consider in the aging population when deciding between rechargeable versus recharge-free systems. Additionally, many revision surgeries are due to lead issues (i.e., lead breakage, lead migration, or loss of effectiveness). In the same large cohort, a new lead was required in 37.8% of patients over a mean follow-up period of 7.1 years [15]. A longer-lasting IPG will have no bearing on lead-related surgeries (although it must be acknowledged that in real-life practice it may often be difficult to predict up-front which patients will need an extended longevity of more than a decade). Although the lead revision rate has been reduced to 13% in other studies, it cannot be neglected [16]. Finally, the recent adoption of an optimized tined lead placement technique allows for lower amplitudes and thus even longer battery life could be expected from rechargeable and recharge-free systems [17].

Finally, patient expectations of having only one surgery over a period of 15 years for rechargeable devices may also turn out to be an illusion. Battery life may be shorter, if battery fade is taken into account. In that respect

different manufacturers may have different technologies [18] and industry deserves merit for the advancements in battery technology. However, only future observation (long-term studies) can ultimately show if battery fade will eventually be an issue.

Treatment Compliance and Disease Awareness

There are also other less obvious but significant pitfalls associated with rechargeable devices. First, patients must be compliant and have the cognitive capability and the manual dexterity to recharge their IPG on a weekly or biweekly basis [9] over a period of 15 years. Although the recharging process with modern technologies can be done conveniently at home without being connected to a power socket, the therapeutic non-compliance of patients has been an issue for decades [19]. Typically, the compliance rate of long-term medication is between 40% and 50%, while the compliance for lifestyle changes is low at 20–30%. Since a lack of compliance will lead to a loss of effectiveness and/or an increased burden for the healthcare professionals, careful screening of the patient before implantation of a rechargeable device is imperative. One neuromodulation device manufacturer reported that one of the most frequent patient questions addressed to its helpline related to charging issues in rechargeable devices (Medtronic, private communication). In a well-selected study population (that may differ from real life), patients were recruited and followed in a strict and intensively controlled protocol: 17% of patients did not agree at 1-year follow-up that recharging their IPG was moderately or very easy [20]. In a real-life study with recharge-free SNM devices only 50–63% of the implanted patients had a good understanding of the previous InterStim patient programmer (iCon 3037) or acceptable skills in handling the device [21]. With simpler patient programmers and an increased usage of smartphones (even in an elderly patient population), familiarity with technical devices may improve significantly over time. Nevertheless, recharge-free devices require no regular or frequent interactions with the patient programmer and patients with a poorer compliance may better qualify for recharge-free SNM.

Another factor is one of disease awareness. One of the greatest benefits that patients describe is their ability to forget about their medical condition once an SNM is implanted. A recharge-free system allows the patient to set and forget their SNM system. In a rechargeable SNM system, the patient is reminded of their condition every 1–2 weeks. While it has yet to be studied formally, the authors believe the psychological and patient perception of disease will be experienced differently between rechargeable and recharge-free populations.

Although there are currently no patient preference studies of SNM in terms of rechargeable versus recharge-free devices, some conclusions can be drawn from patient surveys in spinal cord stimulation (SCS) or deep brain stimulation (DBS) therapies, where rechargeable devices have been used for more than 10 years. In a survey of 30 patients with movement disorders visiting a pre-DBS clinic (mean age 65, range 45–79 years), 63% chose the recharge-free device compared to 37% for the rechargeable device, even though the battery longevity of the recharge-free device was estimated at only 3–5 years [22]. In a multicenter, retrospective study with 352 explanted SCS patients it was reported that patients with rechargeable devices terminated their therapy earlier than patients with recharge-free devices [23]. This observation may be consistent with an increased burden for therapy maintenance, which could be related to a higher probability of device removal [23]. Additionally, it seems that industry's attitude towards rechargeable devices has changed over the years from an initial technical enthusiasm towards a sobering experience with nowadays preferring a more patient-centered approach [24]. Age may be a factor in this. Lam and Rosenow reported that patients in whom the recharging burden outweighed benefits of increased battery life were significantly older (74 years) than those who felt that the tradeoff was worthwhile (56 years) [25]. However, in other surveys an age or gender dependency has not been found [22].

Table 1 Criteria for patient selection: recharge-free versus rechargeable devices

Recharge-free SNM preferred	Patient's choice and the impact of external factors	Rechargeable SNM preferred
History of therapeutic non-compliance	Patient choice versus physician recommendation	Technology-savvy, compliant, and highly motivated patient
Reduced compliance expected in the next 10–15 years	Reimbursement and socioeconomic factors	Need for a high energy stimulation with expected battery life of 3 years or less
Patients with forgetfulness; lack of motivation	Helpline in case of technical questions?	Thin patient
Patients with physical difficulties (finding the right spot to recharge)	Easy access in case of lost recharger?	Patient with a history of pain
Lack of technical knowledge	Cost issues (insurance in case of lost recharger?)	Patient with significant infection risk for device replacements
Incompatibility with lifestyle (e.g., frequent travelling)		

DECISION-MAKING REGARDING RECHARGEABLE VS RECHARGE-FREE STIMULATORS

How does the above discussion translate into decision-making for the individual patient? The authors acknowledge that good indications for rechargeable devices are seen in technology-savvy, compliant, and highly motivated patients or in patients who are in need of high energy stimulation with expected battery life of 3 years or less, slim patients with insufficient fat tissue at the implant site, patients with a history of pain, or patients with significant infection risks for device replacements (e.g., due to immunosuppressive medication) (Table 1). When assessing patient compliance for rechargeable SNM it is recommended to look at all factors that may impact therapeutic non-compliance [19]. These include demographic factors (age, gender, education, available caregiver); psychosocial factors (motivation, attitude), health literacy, patient knowledge, physical difficulties, forgetfulness, or history of good compliance; complexity of therapy maintenance (finding the right spot to recharge); potential side effects of therapy maintenance (potential discomfort due to mild heating depending on battery technology [26]); compatibility with lifestyle (frequent travelling); lack of accessibility for therapy maintenance (frequent travelling, easy access in case of lost recharger, helpline in case of technical questions); cost issues (insurance in case of lost recharger); and patient motivation.

A shared decision-making process between each individual patient and physician is recommended by making the patient aware of all advantages and disadvantages of each system. Nevertheless, reimbursement, socioeconomic, and cultural factors may differ from country to country and may also have an impact on the therapy decision. Last but not least, patient and physician preferences may also change over time. It is the authors' view that recharge-free devices are expected to remain the gold standard in the near future, since the majority of patients may prefer a maintenance-free system without being reminded of their disease on a regular basis. Time will tell.

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