Am J Transl Res 2023;15(1):324-329
www.ajtr.org /ISSN:1943-8141/AJTR0146866

Case Report

Application of the first rechargeable sacral neuromodulation system for treatment of neurogenic lower urinary tract dysfunction in China: a case report

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Received October 7, 2022; Accepted December 13, 2022; Epub January 15, 2023; Published January 30, 2023

Abstract: Neurogenic lower urinary tract dysfunction (NLUTD) is caused by nervous system lesions and characterized by impaired micturition and urinary incontinence. The goal of treatment is to manage these symptoms, improve quality of life, prevent urinary tract infections, and maintain urinary function. Pelvic floor muscle training and medication are commonly used for treating it. Sacral neuromodulation (SNM) has been used in the treatment of NLUTD for >20 years worldwide, and its effectiveness and safety have been verified. Several countries have begun using a rechargeable SNM system, whereas the current sacral SNM system used in China is non-rechargeable. A 29-year-old man with persistent voiding dysfunction for >20 years presented with progressive symptoms 1 year ago. He was admitted to our hospital in August 2022 for a rechargeable SNM system implantation. The patient underwent a video-urodynamic examination and the Short Form of a Urinary Quality of Life Questionnaire (SF-Qualiveen) before and 1 month after surgery. The video-urodynamic examination showed that the maximum bladder capacity significantly increased after surgery, bladder compliance improved, the phenomenon of uninhibited bladder contraction during filling decreased, and urine leakage was reduced. The SF-Qualiveen score showed the patient's quality of life significantly improved. To our knowledge, this is the first case of a rechargeable SNM system implantation in China, which shows that it is safe and effective. More clinical cases and long-term observation are still needed. In conclusion, a rechargeable SNM system has significance for health and the economy and has a broad clinical application prospect.

Keywords: Rechargeable sacral neuromodulation system, neurogenic lower urinary tract dysfunction, case report

Introduction

The functions of the lower urinary tract include urine storage and excretion, which require the coordinated control of the nervous system structures such as the brain, spinal cord, and peripheral ganglia [1]. Lower urinary tract dysfunction (LUTD) involves a variety of conditions, including improper emptying of the bladder and urine storage [2]. The symptoms can be divided into storage symptoms and urination symptoms [3]. Adult neurogenic LUTD (NLUTD) refers to an abnormal or impaired function of the bladder and urethra (and/or prostate in men) in mature individuals in the context of a clinically confirmed relevant neurological disorder [4]. Spina bifida can lead to various neurologic deficits and is the main cause of congenital urinary dysfunction. Eventually, the upper urinary tract function may become damaged due to weak bladder and high pressure in the bladder cavity [5]. Sacral neuromodulation (SNM) is widely used in the management of various refractory LUTDs, and increasing evidence shows that SNM is safe and effective for NLUTD. Chaabane et al. reviewed 62 patients with NLUTD and showed that SNM not only significantly improved urodynamic measures but also significantly relieved patients' symptoms [6].

At present, the non-rechargeable SNM system is mostly used in SNM surgery in China and abroad. The average device life of a non-rechargeable implantable pulse generator (IPG)

for SNM treatment is 4.4 years [7], and patients may have to undergo multiple operations to replace the device. Further, this problem may be exacerbated at higher stimulation levels when battery consumption is increased. Rechargeable SNM system have a longer lifespan; the rechargeable Axonics® Sacral Neuromodulation (R-SNM™) system, which has regulatory approval in Europe, Canada, and Australia, lasts for at least 15 years in vivo [7]. Some studies have shown that the use of the R-SNM system for SNM is safe and effective and can significantly improve symptoms and the quality of life of patients with overactive bladder [8].

There are few reports on the application and treatment effect of the rechargeable SNM system in NLUTD. The successful development of the first rechargeable SNM system in China provides a new option for the treatment of NLUTD. In this case report, the therapeutic effect of the rechargeable SNM system in a patient with NLUTD is evaluated, and the advantages and disadvantages of the rechargeable and non-rechargeable SNM systems are discussed.

Case presentation

A 29-year-old man presented with persistent voiding weakness of >20 years. One year ago, the patient's symptoms of urination weakness worsened, accompanied by frequent and incomplete urination, nocturia, and overflow urinary incontinence, which could not be completely relieved by abdominal pressure urination. Magnetic resonance imaging at another hospital showed a space-occupying lesion at the L5-S2 level, tethered spinal cord, dilated central spinal canal at the L2-L4 level, spina bifida at L4, and L4/5 intervertebral disc herniation. In August 2021, spinal cord lesion resection and nerve root adhesion release were performed in the other hospital; however, symptoms of urinary weakness were not significantly relieved after surgery.

In August 2022, the patient was admitted to our hospital for a video-urodynamic examination. After perfusion of 90 mL, the patient had some initial feeling; after 140 mL, he felt the initial urgency; and after 160 mL, the bladder showed uninhibited contraction and urine leakage. The maximum bladder capacity was 190 mL, residual urine was 150 mL, and bladder compliance was 4.76 mL/cmH_2O. The patient showed detrusor overactivity during the filling period, and there was no significant detrusor contraction during the voiding period. Bladder compliance decreased, and maximum bladder capacity decreased. Synchronous X-rays during filling showed a rough bladder wall with diverticulum formation and no vesicoureteral reflux (**Figure 1**).

After evaluating the examination results and obtaining the patient's informed consent, the first stage of the rechargeable SNM system implantation was performed. After a 2-week observation period, the patient was satisfied with the effect and accepted permanent implantation of the rechargeable SNM system. The rechargeable SNM system uses wireless charging (**Figure 2A**), which has strict requirements for the distance between the implantable pulse transmitter and the charging coil. During implantation, the stimulator should not be implanted too deep under the skin, and the maximum thickness of the IPG front to the skin surface should not exceed 1 cm (**Figure 2B**).

Patients can avail themselves of the program-controlled charger for wireless charging of the device, for which patients need to get themselves in a good position, establish wireless communication, select the charging gear, and start charging. The rechargeable SNM system has a 0-volt protection function, which allows the battery to be stored for a long time in the deep discharge state (near 0 voltage) without permanent loss of battery capacity due to low and 0 voltage. The challenge in the rechargeable SNM system use is that the charging temperature needs to be accurately controlled. The pulse transmitter is based on the rechargeable technology of the external temperature measurement and protection and the double closed-loop control technology, which can increase the temperature control accuracy up to 0.1°C.

One month after the operation, when a follow-up video-urodynamic examination was performed again, the patient felt an initial sensation at a perfusion of 358 mL; the patient was asked to cough when the perfusion reached 200 mL, and no urine leakage was observed. The maximum bladder capacity had increased to 489 mL, and the residual urine volume was 120 mL. Bladder compliance was 12.50 mL/cmH_2O. No

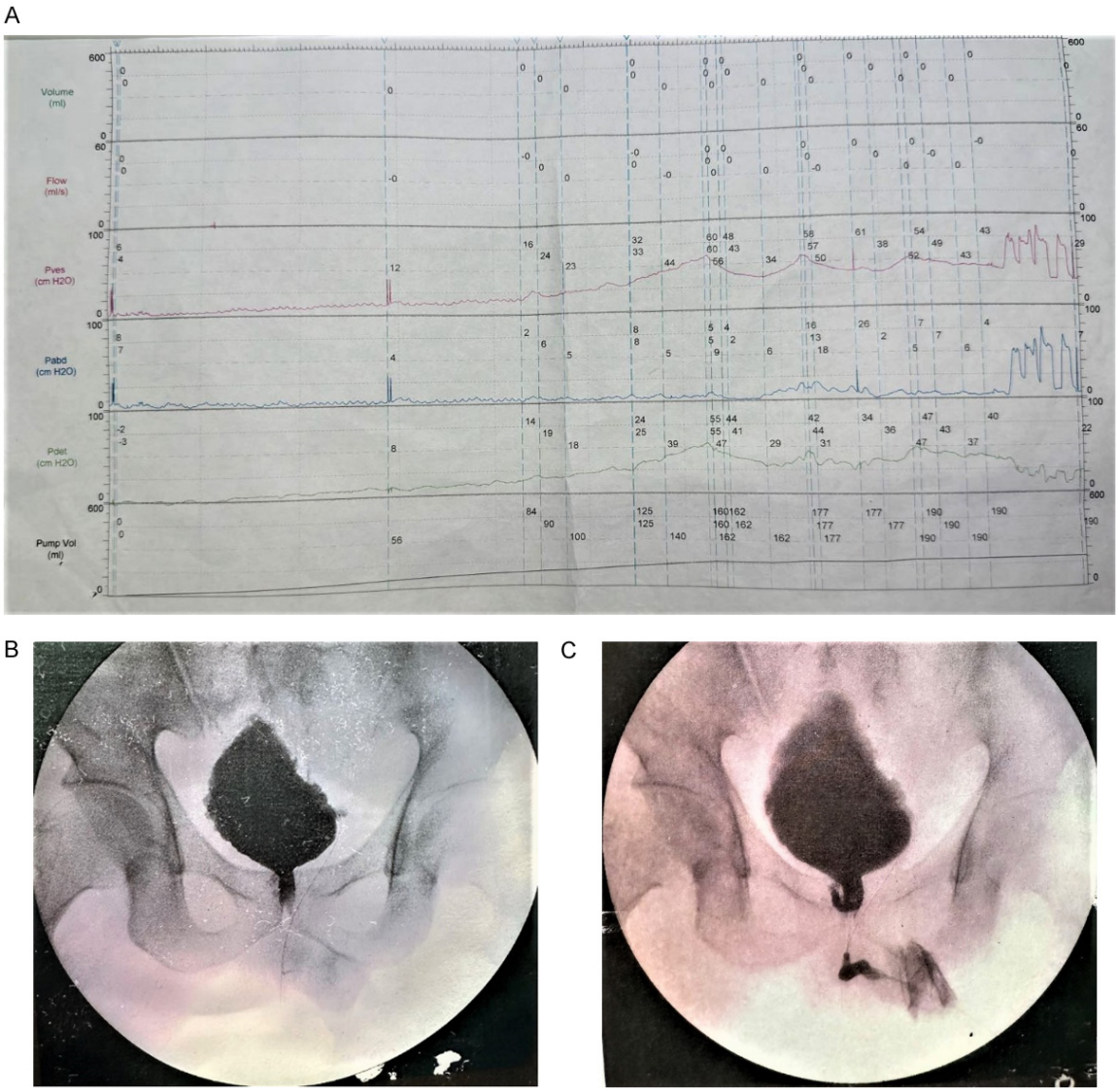

Figure 1. Preoperative video-urodynamic results. A. The maximum bladder capacity was 190.0 mL, and bladder compliance was 4.76 mL/cmH_2O. B. Cystography during the filling period. C. Cystography during the voiding period.

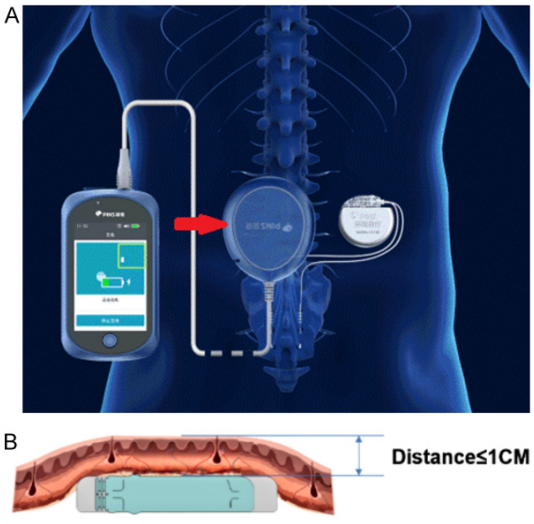

Figure 2. A. A schematic diagram of wireless charging; the red arrow indicates the wireless charging coil. B. The maximum thickness of the front face of the stimulator should not exceed 1 cm from the skin surface at the time of implantation.

uninhibited bladder contraction was observed in the filling period, and no active detrusor contraction was observed in the voiding period. Bladder compliance had improved, and the maximum bladder capacity had significantly increased. Synchronous X-ray showed a rough bladder wall, no reflux in the bilateral ureters, an open bladder neck, and satisfactory urethra imaging. The SF-Qualiveen scores were obtained before and after surgery to assess symp-

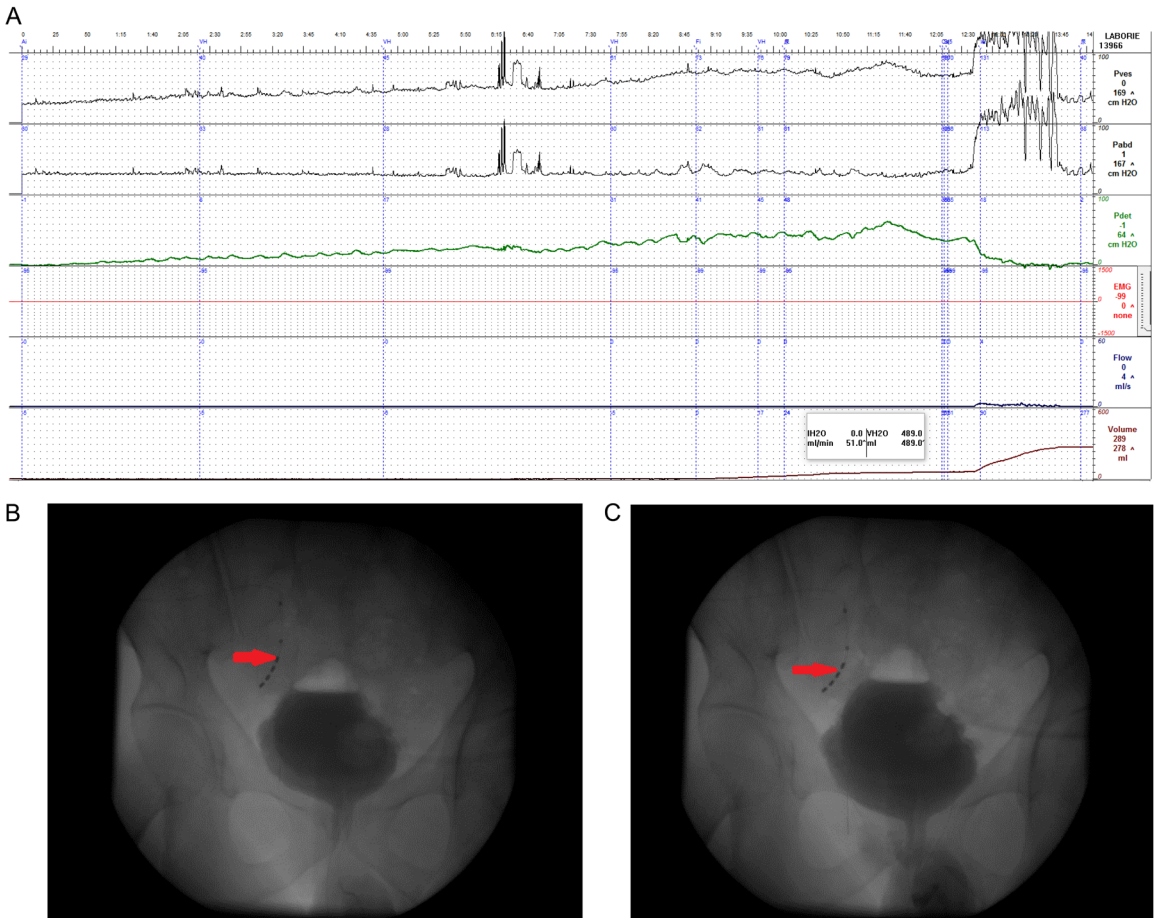

Figure 3. Postoperative video-urodynamic results. A. The maximum bladder capacity was 489.0 mL, bladder compliance was 12.50 mL/cmH_2O, and the patient was instructed to cough at a perfusion of 200 mL, following which no urine leakage was observed. B. Cystography during the filling phase; the red arrow indicates the electrode. C. Cystography during the voiding period; the red arrow indicates the electrode.

tom improvement (**Figure 3**). The preoperative patient score was 30 points, and the patient's quality of life was poor, whereas the postoperative patient score was 15 points, and the quality of life had significantly improved [9].

Discussion

In this case report, after implantation of a rechargeable sacral neuromodulation (SNM) system, active contraction of the detrusor muscle was not observed in the voiding phase during urodynamic examination. Further, uninhibited bladder contraction was not observed in the filling phase of the patient, bladder compliance was improved, and maximum bladder capacity was significantly increased.

SNM is used for the treatment of lower urinary tract and bowel dysfunction, which has achieved promising results in patients with overactive bladder, non-obstructive urinary retention, and fecal incontinence [10]. The lower urinary tract function is controlled by spinal, supraspinal, and cerebral networks. Due to the complexity of the control system, damage to one component may lead to NLUTD. NLUTD affects the upper urinary tract and may lead to renal failure and impair patients' quality of life [11]. A multicenter retrospective study from China in 2020 showed that SNM was an effective and reliable method for the treatment of NLUTD [10].

According to a literature review, since the clinical application of SNM, only a few foreign countries have used rechargeable SNM systems, whereas in China, non-rechargeable SNM systems are exclusively used. The Axonics R-SNM system received regulatory approval in Europe

and Canada in 2016 [12] and in Australia for the treatment of overactive bladder, non-obstructive urinary retention, and fecal incontinence. The system includes a rechargeable IPG that was validated to last at least 15 years in vivo [7]. The Axonics R-SNM system is safe and effective for SNM in patients with overactive bladder and can significantly improve symptoms and the quality of life [8]. A prospective, multicenter study of a novel miniature rechargeable SNM system by Blok et al. demonstrated similar safety and efficacy to the non-rechargeable SNM system [7].

The rechargeable SNM system has an extended device life and decreases the need for surgeries required for frequent device replacement. The battery life of the rechargeable device is estimated to be 15 years, whereas the current InterStim II (IPG) life is approximately 5-7 years [13]. In a patient satisfaction survey of the rechargeable occipital nerve stimulation system, 68 of 92 patients (74%) thought the battery was convenient to charge, and 37 of 48 patients (77%) who switched from a non-rechargeable battery preferred the current rechargeable battery [14]. Sciacca et al.'s 12-month patient satisfaction survey of the R-SNM system showed that all patients could charge their devices and that 84% of patients were highly or moderately satisfied with the R-SNM treatment outcomes [7]. A study on 95 French patients reported that 71% preferred the new rechargeable SNM device over the non-rechargeable one [15]. In addition, an important advantage of the rechargeable SNM device is that it is cost-effective compared to non-rechargeable devices. Noblett et al. constructed a cost-consequence model and demonstrated that the adoption of the rechargeable device is expected to save the US healthcare system up to $12 billion over a 15-year period [16].

However, the rechargeable SNM system requires patients to have certain cognitive and practical abilities; further, patients are required to charge the device on time, which may make the patient continuously aware of the disease. In contrast, patients can forget about the SNM system and their medical condition after implantation of a non-rechargeable SNM system. In addition, proper implantation of small charging devices requiring frequent charging may be more challenging for obese patients because the angle and distance between the surface-implanted IPG and the charger may change during charging [13].

Conclusions

The rechargeable SNM system has achieved similar therapeutic effects to the non-rechargeable SNM system so far, and most patients are satisfied with the use of the rechargeable SNM system. Our patient also achieved a satisfactory therapeutic effect and experience after receiving a rechargeable SNM system implantation. However, as there are few relevant cases at present, long-term observation is still needed to support our conclusions. The rechargeable SNM system has a longer service life and economic benefits, but its shortcomings and limitations cannot be ignored. This case report will provide a reference for doctors on whether to choose a rechargeable SNM system in clinical practice.

Acknowledgements

This work was supported by the National High Level Hospital Clinical Research Funding (BJ-2021-184) and National Key Research and Development Program of China (2018YFC-2002202).

Disclosure of conflict of interest

None.

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