

Effects of Appropriate Prolonged Sacral Neuromodulation Testing in Improving Implantation Rate of a Permanent Implantable Pulse Generator in Patients with Refractory Lower Urinary Tract Dysfunctions in Mainland China

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Abstract

Background: Sacral neuromodulation (SNM) has become an effective method for treating lower urinary tract voiding dysfunction during the past 20 years. Because of the expensive cost, the number of implantable pulse generator (IPG) implantations per year in China is far lower than that in Western developed countries since 2012. This study was to summarize the effects of the appropriate prolonged SNM testing time in improving the implantation rate of a permanent IPG in patients with refractory lower urinary tract symptoms (LUTS) in mainland China.

Methods: From January 2013 to June 2016, 51 patients with refractory LUTS received SNM therapy. In this study, we compared the conversion rate 2 weeks after the Stage I test and final actual conversion rate. We also observed the complications (such as pain, infection, and electrode displacement) and effectiveness. We tried to improve an appropriate prolonged test time which was favorable for improving the SNM conversion rate while ensuring safety and effectiveness.

Results: Among 51 patients receiving SNM therapy, 19 patients (mean age 45.0 ± 16.9 years) had poor Stage I test results, and on an average, the electrode was removed 27.4 ± 9.6 days after the surgery. In one patient, the electrode was removed within 2 weeks; when the remaining 18 patients were questioned 2 weeks after testing, none of the patients wanted to terminate the test, and all the 18 patients desired to prolong the testing time to further observe the treatment effect. The remaining 32 patients (mean age 46.7 ± 15.3 years) received Stage II permanent implantation at 19.6 ± 10.4 days after the surgery. The overall Stage I–II conversion was 62.7% (32/51) in this study. Within 2 weeks after the surgery, only eight patients received Stage II permanent implantation, and the conversion rate was only 15.7% (8/51), which was much lower than the overall conversion rate of 62.7%. Nearly 84.4% (27/32) of the patients received Stage II implantation within 4 weeks. None of the patients had incision infections. In one patient, the entire system was removed 1 month after Stage II implantation due to pain in the implantation site.

Conclusions: Appropriate extension of the Stage I testing time of an SNM-barbed electrode could significantly improve the Stage II permanent implantation rate in Chinese refractory LUTS patients; there were no wound infections, and the postoperative complication rate was low. This study recommended that Stage I period of SNM therapy should be 4 weeks according to safety and successful conversion rate.

Key words: Lower Urinary Tract Symptoms; Sacral Neuromodulation; Wound Infection

INTRODUCTION

In the past 20 years, sacral neuromodulation (SNM) has become an effective method for lower urinary tract voiding dysfunction that cannot be treated by conservative treatment. Although SNM is considered a mature therapy with confirmed efficacy in Europe and the United States, it is still a novel method for the vast majority of patients suffering

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from intractable lower urinary tract symptoms (LUTS) in mainland China. This therapy was formally introduced in China in early 2012. The number of implantable pulse generator (IPG) implantations per year in mainland China is far lower than that in Western developed countries. In mainland China, SNM is not yet included in the universal health-care system, and the entire costs for the two stages of treatment (nearly RMB 90,000 Yuan) have to be paid by the patients. Reportedly, the potential cost for SNM long-term follow-up (such as surgical repair, re-operation, or replacement of the battery) is also considerable.^[1] Therefore, it is crucial for Chinese patients and physicians to improve the conversion rate of Stage I to Stage II and the long-term efficiency of SNM as much as possible.

The testing time for the traditional percutaneous stimulation electrode (PNE) is usually 4–7 days. With the application of novel barbed electrodes, patients may undergo longer durations of testing.^[2,3] Clearly, under the premise of no complications, a longer testing period of implantation allows patients to fully experience the treatment effect and to better understand and accept the therapy, leading to higher Stage I to Stage II conversion rates. However, both PNE and barbed electrodes are connected to an extension cord that penetrates from inside the body to connect to a temporary pulse generator and implant removal because SNM postoperative infection is a problem that cannot be ignored. The SNM perioperative infection rate was reportedly 0–12%,^[3,4] and could be as high as 16% for patients with diabetes.^[5] To avoid more complications (such as infections) caused by a longer testing time, the mainstream literatures recommend that the Stage I period of SNM therapy should be no more than 2 weeks. However, recent reports have shown that appropriate extension of the Stage I can increase the Stage I–II conversion rate (76%), without significantly increasing the incidence of postoperative infection; furthermore, the reported postoperative infection rate was between 5% and 7%, which was not higher than that of the group with standard test times.^[6,7] We hypothesized that appropriately extending the Stage I testing period from 2 to 4 weeks could enable patients to fully experience the treatment effect. Appropriately extending testing time could be useful to improve the IPG implantation rate and to reduce their potential economic losses. This study was to summarize the effects of the appropriate prolonged SNM testing time in improving the implantation rate of a permanent IPG in patients with refractory LUTS in mainland China.

METHODS

This study received ethical approval from the Institutional Review Board of Beijing Chaoyang Hospital, Capital Medical University. Written informed consent was obtained from each patient or patient's guardians.

Patients

The 51 LUTS patients (26 males and 25 females), who received SNM therapy in the Department of Urology, Beijing Chaoyang Hospital from January 2013 to June 2016,

were retrospectively analyzed. The clinical manifestations of LUTS included urinary frequency, urgency, urge incontinence, dysuria, urinary retention, and suprapubic pain and discomfort when holding urine (which was alleviated after urination), and patients could have one or a combination of multiple symptoms. Before admission, all patients were treated with long-term conservative treatment (including physical therapy and drug therapy) with a mean preadmission treatment time of 6.6 ± 2.1 years, which yielded poor efficacy or were invalid. Among these 51 patients, there were four patients with refractory urinary frequency, one with urge incontinence, 20 with interstitial cystitis/pelvic pain syndrome, three with neurogenic bladder, 14 with sphincter spasm, and nine with nonobstructive urinary retention. Patients in whom comprehensive preoperative examination and urodynamic results detected the presence of uncontrolled urinary tract infections, low compliance bladder (bladder contracture), organic bladder outlet obstruction, urinary epithelial tumors, and upper urinary tract dilatation were excluded from this study.

Sacral neuromodulation Stage I electrode implantation

All patients underwent the standard “two-step” unilateral electrode implantation surgery. We used the SNM Stage I electrode (3889) (Medtronic Inc., USA) for testing. The surgical methods are shown in Figure 1. Patients were placed in the prone position with the lumbosacral area appropriately boosted, and iodine disinfection was conducted. The preferred puncture position was the 3rd sacral foramina (S3). If the neural response was not satisfactory, we selected the 4th sacral foramina (S4). S3 was positioned by measuring 9 cm rostrally from the tip of the coccyx, and one finger width from the midline or one finger width from the intersection between the bilateral sciatic notch connection and the midline. With 1% lidocaine local anesthesia, the needle penetrated the skin at a 60° angle. When penetrating the appropriate sacral foramina, there was a sense of penetration and then emptiness. Electrical stimulation tests led to bellows-like contraction of the pelvic floor and a big-toe plantar flexor reflex, suggesting accurate positioning of S3.

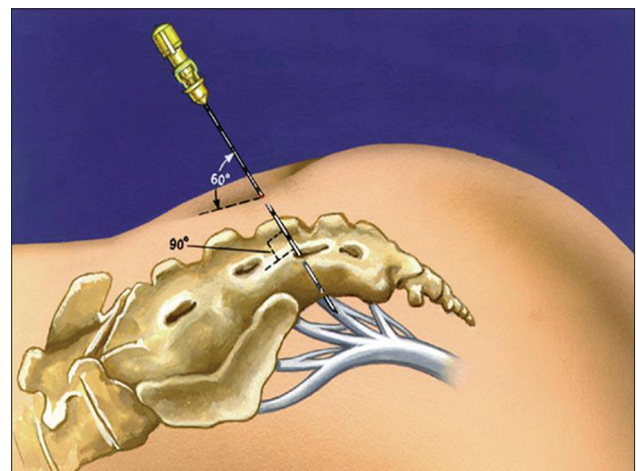


Figure 1: Schematics for the implantation of the sacral neuromodulation Stage I self-fixed electrode.

We then implanted the self-fixed electrode, and the electrode wire was guided subcutaneously to the upper-lateral ¼ side of the contralateral hip. We then opened the skin to implant the temporary test guide wire, and the temporary extension cord was guided to the puncture sacral foramina to the upper-lateral ¼ side of the ipsilateral hip, pulled out of the skin, and connected to the external pulse generator. During the testing, stimulation parameters were adjusted through the temporary pulse generator, and the principle was that electrode stimulation did not cause discomfort. During the testing period, we simultaneously recorded daily voiding and changes in symptoms. Clinical symptom improvement $\geq 50\%$ was considered to be effective and to indicate that the patients should be considered for Stage II permanent pulse generator implantation; clinical symptom improvement $\leq 50\%$ was considered to indicate poor efficacy, and these patients were recommended for other treatment.^[8-10]

Implantation of the Stage II permanent pulse generator

The Stage II permanent pulse generator was the first-generation (generation I) IPG (3023; adopted before June 2014) and generation II IPG (3058; used after June 2014) from Medtronic Inc. During Stage II surgery, patients were placed in the prone position with an appropriate booster on the hips. The original incision site where electrode conversion occurred was draped with povidone-iodine disinfection towels and then opened to remove the temporary connection equipment, while paying attention not to damage the electrodes embedded subcutaneously. The electrode tip was firmly connected to the generation I (3023) or generation II (3058) IPG. The pulse generator was embedded in a sac either subcutaneously or above the muscle fasciae. The product trademarks faced the skin. After normal resistance was obtained, the incision was closed.

Evaluation methods and anti-infection method

We surveyed and summarized the willingness and actual conversion rates for IPG implantation of the patients at 2 and 4 weeks after the electrode implantation or upon the actual conversion time. We recorded the incision infection and other complications when patients finally accepted the removal of the electrode or IPG was implanted, and 3 months after the surgery.

Prophylactic administration of antibiotics before and after SNM Stage I and Stage II surgeries and intraoperative measures were as follows: (1) Before Stage I, all patients received skin test of cefoxitin, which was used for intravenous injection. Patients with negative skin test results received an intravenous injection of 2 g of cefoxitin 30 min before the surgery,^[11] followed by another dose 12 h later. During the surgery, the wounds were flushed with large quantities of sterile distilled water after completion of the puncture and connection of the extension cable and before incision closure. The 3-0 absorbable suture was used for intradermal suturing to close the incisions. On the 2nd day, patients were started with oral administration of cefdinir at 100 mg/tid for 1 week. Those with a positive skin test received levofloxacin at 0.5 g/day and oral administration of levofloxacin for 1 week after

the surgery (at a dose of 0.4 g/day). The remaining procedures were the same as those received by patients with negative skin test results. (2) For patients with failed Stage I testing and with the necessity to remove the electrode, on the day of the surgery removing the electrode, large quantities of sterile distilled water were used to repeatedly flush the incisions, and a 3-0 absorbable suture was used for intradermal suturing to close the incisions. On the 2nd day, the patients were started with oral administration of the appropriate antibiotics for 1 week. The electrode tip and the extension cable connector inside the body were sent for bacterial culture examination. (3) Thirty minutes before the Stage II surgery, prophylactic antibiotics were administered similar to the antibiotic administration procedures in the Stage I surgery. The postoperative intravenous injection of antibiotics was not to exceed 48 h, then being switched to oral administration of the respective types of antibiotics for 1 week. During the surgery, the extension cable connectors inside the body were sent from some patients for bacterial culture examination, and the remaining operations were conducted as described above.

Statistical analysis

Statistical analyses were performed using the SPSS software version 17.0 for Windows (SPSS Inc., Chicago, IL, USA). The continuous variables were shown as mean \pm standard deviation (SD). Independent-sample *t*-test was used to assess differences between patients with and without Stage II permanent implantation. A value of $P < 0.05$ was considered statistically significant.

RESULTS

Among the 51 patients, there were 26 males and 25 females, and the mean age was 45.8 ± 15.9 years (ranging from 16 to 76 years). All the 51 patients received local anesthesia while undergoing the surgery for SNM Stage I. The mean duration of Stage I surgery for all the 51 patients was 1.1 ± 0.6 h, and the mean Stage I testing was 23.7 ± 10.6 days (ranging from 5 to 60 days).

Among 51 patients receiving SNM therapy, 19 patients (including 9 males and 10 females, with a mean age of 45.0 ± 16.9 years) had poor Stage I testing results and had the electrode removed at mean 27.4 ± 9.6 days after the surgery (ranging from 12 to 60 days). In one patient, the electrode was removed within 2 weeks. None of the remaining 18 patients, when asked at 2 weeks after the surgery, was willing to terminate the test, they all expressed the desire to extend the test time to continue to observe the test effect. In nine patients, the electrode was removed within 2–4 weeks, and the other nine patients removed the electrode more than 4 weeks after the surgery. The removed electrodes from all the 19 patients were subject to bacterial culture, and the bacterial culture results were negative. There were no wound infections at 1 month and 3 months after the surgery, and there were no other complications.

The remaining 32 patients (including 17 males and 15 females) had good testing results. The mean age of

these patients was 46.7 ± 15.3 years, and these patients received Stage II permanent implantation at a mean of 19.6 ± 10.4 days after the initial surgery. Therefore, the overall conversion rate of Stage I–II was 62.7% (32/51) in this study. Among these 32 patients, eight cases received Stage II permanent implantation within 2 weeks after the surgery, only accounting for 25.0% (8/32) of all patients with conversions; 19 cases underwent conversion within 2–4 weeks, accounting for 59.4% (19/32) of all patients with conversions; and five cases underwent conversion more than 4 weeks after the surgery, accounting for 15.6% (5/32) of patients with conversions. The actual Stage I–II conversion rate within 2 weeks for this study was 15.9% (8/51), which was much lower than the overall conversion rate of 62.7%. However, 84.4% (27/32) of the patients received Stage II implantation within 4 weeks. The connectors removed from all the 32 patients in Stage II were all subject to bacterial culture, and the bacterial culture results were negative. There were no wound infections in any of the patients at 1 month and 3 months after the Stage II implantation. In one patient, the entire system was removed 1 month after Stage II implantation due to pain in the implantation site (electrode position). Postoperative culture of the electrode removed from inside the body showed no signs of infection. This patient had a Stage I testing period of 23 days. In other patients, the entire system was removed 30 months after Stage II IPG implantation due to recovery, and there was no recurrence after removing the system. The comparison of clinical characteristics between patients with and without Stage II permanent implantation is shown in Table 1.

DISCUSSION

Since Tanagho and Schmidt^[12] invented SNM therapy in the 1980s, SNM has gradually become the standard treatment for refractory LUTS. In recent years, with the increase in the number of SNM clinical applications and improvements in clinical operating skills and apparatus,^[13] the postoperative complications have been significantly reduced.^[14,15] Hijaz *et al.*^[14] reported that, in 161 cases of patients receiving SNM treatment, the most common reason for postoperative surgical intervention was unstable clinical efficacy, not postoperative complications.

Previously, because PNE has more incision infection and shift of electrode localization, the testing period was only 4–7 days. The application of barbed electrodes enables stable, long test periods and has largely improved the success rate of the testing period, making it possible for more patients who can potentially benefit from SNM and be free from issues due to LUTS.^[2,3] However, infection issues inherent to SNM Stage I electrode implantation could not be completely avoided.^[3–5] The possible reasons were as follows: (1) the surgical site is close to the lumbosacral area and anus, and consequently, the local infection rate is most likely higher than other implantation locations; (2) connecting to the temporary external pulse generator requires the extension cord to pierce and extend outside the body, making it impossible to completely avoid infection by bacteria moving retrogradely along the extension cord; (3) the sacral foramina puncture hole is deep, the electrodes must be moved through subcutaneous tunnels, and infection of blood accumulating in the tunnel may occur; (4) in some refractory cases (such as urinary retention), a longer test time may act synergistically with the above factors to induce infection; (5) patient factors, such as age, diabetes, obesity, poor nutrition, cancer, immunosuppression, smoking, and alcohol, may also contribute to infection-related issues.^[16,17] Therefore, some studies recommended a testing time of no longer than 2 weeks. In addition to the infection problem, shifting of the electrode/pulse generator, electrode/pulse generator implant site pain, short-term nerve irritability of the sacral foramina, unexpected bowel dysfunction, and technical reasons are all factors constraining the conversion between Stage I and Stage II of SNM therapy. Therefore, whether it is appropriate to extend the test time to improve the SNM therapy success rate has not been determined.

Kessler *et al.*^[2] reported that the application of barbed electrodes might extend the SNM testing time and more accurately screen patients suitable for implantation. In their study, when the testing period was 2 weeks, 50% of the patients received Stage II permanent implantation. In contrast, 80% of the patients received Stage II permanent implantation when the testing time was extended to 4 weeks. Therefore, this study strongly recommended extending the testing period and promoted it as a standard procedure. Amend *et al.*^[7] also reported similar results, showing that

Table 1: Comparison of clinical characteristics between patients with and without Stage II permanent implantation

Characteristics	Group without Stage II permanent implantation (<i>n</i> = 19)	Group with Stage II permanent implantation (<i>n</i> = 32)	<i>t</i>	<i>P</i>
Age (years), mean ± SD	45.0 ± 16.9	46.7 ± 15.3	0.178	0.859
Test time (days), mean ± SD	27.4 ± 9.6	19.6 ± 10.4	-2.514	0.015
Male/female (<i>n</i>)	9/10	17/15		
Implantation site of Stage I electrode (<i>n</i>)				
Third sacral foramina	19	28		
Fourth sacral foramina	0	4		
Positive bacterial culture (<i>n</i>)	0	0	-	-
Wound infection after 3 months (<i>n</i>)	0	0	-	-
Complications (<i>n</i>)	0	0	-	-

–: Not applicable; SD: Standard deviation.

when the average Stage I testing period of the barbed electrode was 52.3 days, 76% (16/21) of the patients had significant treatment effects and accepted Stage II permanent implantation; furthermore, although the presence of bacteria was found in 42.9% of the patients and bacterial attachment was found on the extension cord in 38.2% of the patients, no patients who received Stage II permanent implantation experienced problems such as clinical infection or delayed wound healing.

As mentioned above, SNM therapy has not been included in the scope of universal health insurance reimbursement in mainland China. Patients have to pay the entire cost of this therapy themselves. Even if patients only tried implantation for SNM testing, they might still face great economic losses (test failure and component removal). Given the poor doctor–patient relationship in mainland China, physicians are relatively cautious when recommending this therapy to patients, it is one of the main reasons for significantly more difficult to promote SNM therapy in mainland China than the Western countries.

Our data showed that in 19/51 patients with final invalid test results and electrode removal, only one patient removed electrodes within 2 weeks, the other 18 patients all expressed strong desire to extend the testing time for further observation of the treatment effect, and one patient had the longest testing period of 60 days. Thirty-two of 51 patients received Stage II permanent implantation, of which only 8 patients received IPG implantation within 2 weeks, and the remaining 24 patients all chose testing periods more than 2 weeks to better appreciate the treatment efficacy. If we followed the time point of 2 weeks recommended by literatures and calculated the Stage II permanent implantation rate at this time point, we obtained a conversion rate of only 15.9% (8/51), which was much lower than the actual overall conversion rate of 62.7% (32/51). We therefore would most likely lose patients who were suitable for Stage II permanent implantation, which not only made most patients miss a possible way to cure the disease but also produced extremely negative impacts on the promotion of SNM therapy in mainland China, due to the low test successful rate.

The data in this study fully demonstrated that, based on the current economic income and reimbursement systems in mainland China, the vast majority of patients, especially patients with poor test results, would expect to extend the test period to further appreciate the treatment effect of SNM, thereby avoiding test failures and large economic losses. It is encouraging that, under the conditions of our comprehensive anti-infection measures,^[11] an appropriate extension of the test period can significantly improve the SNM testing success rate in refractory LUTS patients in mainland China, without increasing the incidence of postoperative complications. In all the 51 patients, including patients with the removal of electrode parts and those with successful implantation of Stage II permanent implantation, the bacterial culture results were negative for all testing samples, including the electrode tip and extension cable connector inside the body. No wound

infections were observed 1 month and 3 months after the surgery, and there were no complications.

This study have several limitations. This is a retrospective study and enrolled only a small number of cases; moreover, we did not conduct randomized grouping to compare the success rates at the standard testing time and at the extended test time, which will be confirmed by further studies in the future.

In conclusion, appropriate extension of the Stage I testing time of an SNM-barbed electrode could significantly improve the Stage II permanent implantation in Chinese refractory LUTS patients; there were no wound infections, and the postoperative complication rate was low. This study recommended that Stage I period of SNM therapy should be 4 weeks according to safety and successful conversion rate.

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Conflicts of interest

There are no conflicts of interest.

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