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Application of Internet+-based Tsinghua PINS Remote Tech to improve sacral neuromodulation programming procedure

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Abstract

Objective To explore the feasibility and safety of the Tsinghua PINS Remote Tech to facilitate sacral neuromodulation programming procedure.

Method For 22 patients who had previously participated in the phase III clinical trial for treating overactive bladder with the Tsinghua PINS sacral neuromodulation system during several Hospital, PINS Remote Tech was applied to perform postoperative parameter adjustment in order to evaluate the safety and reliability of this new technique. Telephone surveys on Remote Tech-related questionnaires were also conducted.

Results 17/22 patients underwent 26 parameter adjustments, average adjustment frequency was 1.53 times per person; the average adjustment time was 23.4 ± 5.1 min (15–32 min). The total effective rate of the Remote control was 14/17 (82.3%). 7/17 (41.1%) patients' symptoms recurrence due to not knowing how to handle patient controller, these patients were instructed on how to use it correctly through Remote Tech even without reprogramming it. Other 10 patients received reprogramming. There was no discomfort during and after parameter adjustment. The questionnaire survey showed that the remote technology saved patients' time and lowered financial costs, significantly improved patient satisfaction. All patients expressed their willingness to recommend it to other patients.

Conclusion The PINS Remote Tech can significantly reduce the financial cost and provide a remote reprogram control service that is as safe and reliable as outpatient program control.

Keywords Sacral neuromodulation · Remote Tech · Long-term efficacy

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The U.S. Food and Drug Administration (FDA) currently allows that sacral neuromodulation (SNM) to be used as an effective treatment for refractory lower urinary tract dysfunction (urgent urinary incontinence, frequency–urgency syndrome and spontaneous, non-obstructive urinary retention) that cannot be effectively treated by traditional treatment methods [1–3]. Many patients who have undergone SNM treatment showed instant clinical effects, and subsequent follow-up has shown that the long-term efficacy is stable [1–4]. In 2012, SNM therapy was first officially introduced into mainland China, and it has recently been further developed and popularized [5–7]. The postoperative reprogram of the Medtronic's SNM products requires a hospital visit so that the physician can perform on-site program control of the parameters. However, SNM is a type of functional regulation therapy. After implanted pulse generator (IPG) implanted, various indications will have different degrees of symptom repetition and loss of efficacy, and the IPG parameters need

to be reprogrammed and adjusted postoperatively so that the long-term efficacy can be maintained to a certain extent [8–10]. In reality, in China, there was few medical centers can perform SNM operation and thereafter programming procedure, many patients need to travel across provinces and cities to find a well-known center to undergo SNM surgery and subsequent programming procedure. This kind of medical model led to many problems, including travelling back and forth, difficulty in making an appointment, difficulty in visiting the doctor and high financial cost. As a result, some patients have neglected program control and even given up program control, resulting in poor postoperative long-term efficacy. The first domestic SNM product developed by the Tsinghua PINS company has applied the their exclusive Remote control Tech, which allow patients received reprogramming at home with the new Remote Tech through the Internet or a mobile phone 4G network, thereby avoided many difficulties mentioned above, this technique was one completely different method of providing SNM reprogram than traditional face-to-face methods. From January 2018 to April 2018, Beijing Chao-yang Hospital, Beijing hospital, China Rehabilitation Research Centre, Hebei Yanda hospital and Xiyuan hospital performed the PINS remote reprogramming for those who received PINS SNM implantation during phase III clinical trial. IPG parameter adjustment and the remote reprogramming control process were both successful and reported as follows.

Subjects and methods

General information

All 22 cases in this study were patients with refractory overactive bladder, they don't have severe cardiovascular diseases and other severe disease, none of them received any other operations except SNM operation. All patients received lifestyle modification, such as caffeine/habits/intake modified but failed and all failed medicine therapy (such as M receptor blocker and B3 receptor agonist). All patients were Asian and all had high school education or above at least and they were all implanted IPG successfully including seven males and 15 females, with an average age of 43.6 ± 18.0 years (17–74 years old). All patients were Chinese people and they all had no medical comorbidities and complications after SNM stage II. All patients had no devices infection, one male patient and two female patients had mild discomfort in IPG site but no more surgical treatment is needed. By January 2018, the average postoperative follow-up time was 17.30 ± 3.29 months (12–22 months). The main preoperative clinical manifestations of patients with SNM included two cases (9.09%) of frequency + nocturia, one case (4.55%) of frequency + urgency + urgent urinary incontinence, 17 (77.27%) cases of frequency + urgency + nocturia and two (9.09%) cases of frequency + urgency + urgent urinary incontinence + nocturia. Multiple sclerosis, complete spinal cord injury, stroke and other nervous system diseases as well as stress urinary incontinence were clearly excluded prior to SNM surgery. 17 patients underwent PINS remote program control after the operation, including four males and 13 females, with an average age of 49.03 ± 15.57 years.

Method of program control and questionnaires

Introduction of the PINS remote control system

The novel SNM product developed by Tsinghua PINS Company adopted independently developed, patent-protected PINS Remote Tech. The following describes the entire system in detail:

System overview In the present study, the real-time remote monitoring system mainly consisted of four modules: a Physician Client, a Patient Client, a Server Station and a Video Communication System. Providing web service interfaces on the Internet, the Server Station established a virtual link between the Physician and the Patient Client. Via the communication link, the Physician Client assisted caregivers in viewing sufficient information about the patients and sending adjustment instructions to the Patient Client. The Patient Client transmitted adjustment parameters through a wireless link to a programmer. The programmer was set to be the near field communicator with the implanted stimulators. After executing instructions, the Patient Client uploaded results and follow-up history records to the Server Station. The entire remote monitoring and controlling progress was accompanied by synchronistical visual communication provided by the video communication system. Figure 1 shows the general architecture of the real-time remote monitoring system.

The Physician Client was designed to be located at caregivers' offices, such as hospitals or clinics. The main functionalities of the Physician Client are as follows: (1) Provide a caregiver with an interface to log on or off the system with specified username and secured password authentication. (2) Present a caregiver with his personal information and a regularly updated on-line patients list. (3) Inform the Server Station of a caregiver's choice of patients and redirection the browser to the programming page. (4) Receive a caregiver's input and lodge adjustment parameters to the Server Station (5) Display executing results and follow-up history. To ensure the security of the data transmission, the Physician Client was equipped with a client certificate as an identity authentication which would be examined by the Server Station before the browser gets data.

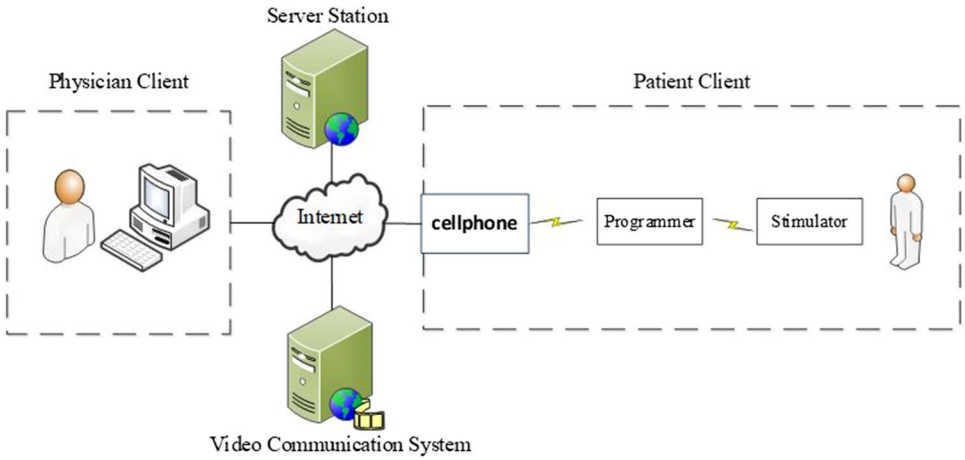

Fig. 1 The general architecture of the real-time remote monitoring system

The Patient Client was designed as a home terminal aiming at assisting patients in setting new adjustment parameters and uploading follow-up history records. The entire client hardware consists of three parts: an app in the patient's cellphone, a Bluetooth patient programmer, and an in vivo sacral stimulator. The Bluetooth patient programmer was equipped with a Bluetooth slave unit to exchange data the patient's cellphone to the in vivo stimulator. The hardware communication link ensures safety of the system in case the Internet communication hacked. The patient's cellphone is equipped with a special patient client software. It helped patients to connect with their caregivers and receive adjustment parameters. Communication link between the Patient Client and the Server Station used SSL protocol and certificate identity authentication.

The Server Station has three servers: (1) the Windows Communication Foundation (WCF) server; (2) the website server; and (3) the database server. The foundation of communication service is the WCF server and the main functionality of the website is to transmit data between the Physician Client and the WCF server. The website server together with the Physician Client constitutes the browser/server architecture. The database server is designed to store users' personal information and follow-up history records. Data links of the Server Station are shown in Fig. 2. The video communication system is also located at the Server Station's computer room, but it works separately on the Internet. We chose embedded flash controls as video publisher and displayer.

Self-designed questionnaires (seen in the Appendix)

Self-designed questionnaires were sent to all patients who underwent remote program control through email. The contents of the questionnaire included impressions of remote program control, expected program control frequency, possible financial costs for each outpatient program control, how remote program control can help patients, the extent

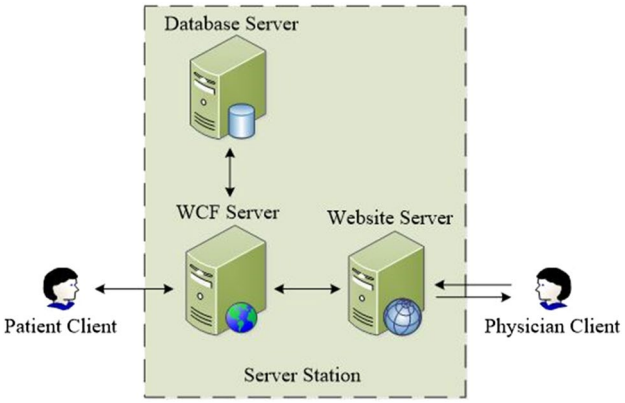

Fig. 2 Data links of the Server Station

to which the remote program control helps the patient and the willingness of recommending this technology to other patients. After all questionnaires were collected, data were summarized and analyzed.

Results

Among the 22 patients, five patients can come to the hospital to have the regular follow-up and receive traditional reprogram face to face, other 17 patients submitted remote program control application, and after being approved by Tsinghua PINS Company, the patients accepted the PINS Remote Tech parameter adjustment starting in January 2018. The 17 patients underwent a total of 26 remote program control parameter adjustments, with an average adjustment frequency of 1.53 times/person; the average program control time/adjustment was 23.4 ± 5.1 min (15–32 min). The total effective rate of remote program control after SNM implantation was 14/17 (82.3%). Among the 17 patients who received program control, the reason for the recurrence of

the symptoms in seven (41.1%) patients after the surgery was because these people did not know how to use their controller (for example, the patient did not know how to adjust the voltage and did not know how to change the stimulation parameters) and were unable to self-adjust the default parameters in the stimulators, thereby causing postoperative recurrence of symptoms. These patients eventually mastered the correct use of their controller after instruction through remote program control. Although the stimulator was not reprogrammed during the remote program control process, these patients still achieved the expected program control result after the Remote Tech service. All of the remaining ten patients received reprogramming of the stimulator and instructions regarding parameter adjustment, and the remote parameter adjustment for these ten patients were completed at one time. The adjustment of the parameters in the stimulator was completed safely and reliably at one time, and none of the patients had discomfort after parameter adjustment. Figure 3 shows an interface of the remote control program on computer, and Fig. 4 is the recording of an actual program control process.

The results of the PINS Remote Tech questionnaire showed that, in terms of patient satisfaction with Remote Tech, the proportion of patients very satisfied with the technique, satisfied, basically satisfied to a certain extent and who had a poor result was three (17.6%), six (35.2%), six (35.2%), and two (12%), respectively. Only two patients (11.9%) suggested that the remote program control had no effect on maintaining their efficacy. In terms of program control frequency selection, one patient (5.88%) wished to have the remote program control once per week, eight patients (47%) wished to have the program control once every 1–3 months, and eight patients (47%) wished to have the program control once every 3 months. In terms of outpatient program control cost, the proportion of the outpatient program control cost each time was < 200 yuan, 200–500 yuan, 500–1000 yuan and more than 1000 yuan for five (29.4%), three (17.6%), one (5.8%) and eight patients (47%), respectively. From the multiple-choice questions to assess the help provided by remote control program to patients, most patients indicated that remote control program could provide expert-level and timely program control, obviate traveling,

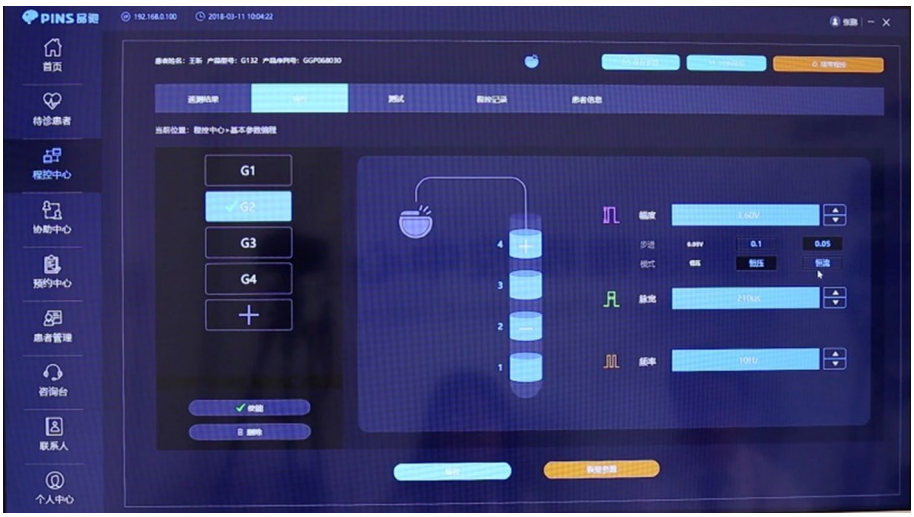

Fig. 3 The interface of a remote program control computer

Fig. 4 Recording of an actual program control process

save costs and improve their overall condition. All patients expressed a willingness to recommend this technique to other patients.

Discussion

SNM is currently one of the most important and widely accepted minimally invasive therapies for the treatment of lower urinary tract dysfunction. Its therapeutic advantages are minimal invasiveness, complete reversibility and certain long-term efficacy. However, due to the uniqueness of this therapy, electrode component-related issues and stimulator component- and pocket-related issues, mechanical connection- and circuit-related issues, disease progression and other factors, some patients can suffer from reduced efficacy or even loss of efficacy during the long-term follow-up after IPG implantation [1–3, 6, 7]. Therefore, postoperative program control is, to some extent, an indispensable means to maintain the long-term efficacy of SNM.

Many studies describe the proportion of surgical interventions after SNM [1, 2]. Van Kerrebroeck et al. [2] reported that among the 152 patients who underwent InterStim implantation at 17 centers worldwide, at 5 years of follow-up, 39.5% of patients needed surgical interventions. Of them, 23.7% had the implants replaced, 14.5% had the implants repaired, and 13.1% of patients had the electrode replaced. The reoperation rate after IPG implantation as reported by Datta [11] was 53%. Al-zahrani [1] reported the long-term effective rates of non-obstructive urinary retention, urgent urinary incontinence and painful bladder syndrome were 87.5%, 84.8% and 73%, respectively. After the operation, 39% of patients required a secondary surgical intervention to maintain efficacy, and many patients needed to be reprogrammed of the IPG. The postoperative loss of efficacy (58.5% of the cases) was the main reason for performing the second surgery, and this reason was also confirmed by van Voskuilen et al. [12]. The adoption of these reoperations must be on the basis of ineffective postoperative program control of the parameters. However, unfortunately, very few foreign papers reported how many patients underwent program control of the parameters, the effect of program control on the parameters, the interval between two program controls and the number of program controls.

Chinese research group Zhang et al. [6] recently reported that in the follow-up of IPG implantation in 17 patients with non-obstructive urinary retention, 11 cases were relieved continuously, six patients with recurrent symptoms received postoperative parameter adjustment; of these, 4/6 patients had an effective program control of the parameter, while 2/6 had an ineffective program control of the parameter. Another study by Zhang et al. [7] showed that in a follow-up of 12 patients, the symptoms of nine patients were relieved; two cases showed temporary release of the original symptoms, which could be relieved by parameter adjustment; one patient had a severe repetition of the original symptoms (the primary illness was painful bladder syndrome) and required intermittent multiple parameter adjustments to barely maintain efficacy.

At present, the only product on the market in China mainland is Medtronic's InterStim II, and the program control of this product requires the patient to go to the doctor's office for a face-to-face reprogram control. China has a vast area and the medical development level varies greatly between regions. Further, SNM therapy is a relatively new therapy in China, and hospitals and surgeons who can perform these surgeries remain limited to a few medical centers in large cities, which forces many patients to travel across cities and provinces to undergo these surgeries. Even after a successful IPG implantation and the patients return to their place of residence, if the symptoms occur repeatedly and the local hospital cannot adjust the parameter, then the patients will need to travel across cities and provinces again to go to the hospital that performed the surgery and ask the surgeon who conducted the surgery to perform postoperative parameter adjustment.

Compared with the current process of applying SNM in Europe and America (many hospitals and doctors can perform SNM, and most patients can resolve their problem nearby), Tsinghua PINS Company took into account the special situation in mainland China, who developed PINS Remote Tech, which can allow the patient to perform real-time IPG parameter adjustment with their physician through a 4G network without leaving home. The statistical results in this study showed that during the PINS Remote Tech process for 17 patients, the overall program control satisfaction rate was 14/17 (82.3%); the reason that seven patients asked for program control was simply that they did not know how to use the patient program control device; these patients achieved program control through simple re-education. The other ten patients underwent actual IPG parameter adjustment. All patients who received remote program control completed their real-time parameter adjustment at one time. After network parameter adjustment was completed, no parameter mismatch problem occurred in the patient's IPG, and no discomfort symptoms emerged. The data from this study showed that remote program control can safely and reliably accomplish the reprogram procedure which only be previously solved face-to-face. In particular, for patient's simple reeducation tasks (for example, teaching the patient how to use the controller), the Remote Tech offered convenient, efficient technical advantages. The results of the patient questionnaires showed that most Chinese patients welcomed and appreciated the Remote Tech and expressed their willingness to introduce this technology to other patients. Nearly

50% of patients can save on average more than 1000 Yuan and much time through remote program control.

One limitation of this paper is that the number of enrolled patients was small. The areas covered by PINS Remote Tech cannot yet include all cities and provinces in China, and the involved population conditions (economic level, education level and customs) cannot cover the entire population in mainland China. Therefore, this study has some bias and deficiencies that prevent a full evaluation of the application of this new technique in mainland China, which will require a larger-scale, multi-center study for full evaluation. We look forward to larger-scale and more detailed data to support this new technology in mainland China and even globally.

The other limitation is that we had no comparison group. We could not elucidate whether some people used programming performed remotely must have more advantages than those without PINS remote control. We will improve these works when PINS SNM product were able to be used on market. We will compare two groups used same product in the future, other than compare the group used PINS product with the group used Medtronic's InterStim now. This is also our next major research work in the future.

In general, the Internet+-based PINS Remote Tech can provide safe and reliable protection and improve efficacy of SNM reprogramming procedure. The emergence of PINS Remote Tech can provide a postoperative program control service for patients who received Tsinghua SNM in mainland China safely, reliably, efficiently, conveniently and economically and is worthy of more widespread usage.

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Compliance with ethical standards

Conflict of interest There are no conflicts of interest.

Appendix

Self-designed questionnaire

1: Impressions of remote program control: ( ) (single answer)

A: very satisfaction B: satisfaction C: Basic satisfaction D: poor result

2: Expected program control frequency: ( ) (single answer)

A: once per week B: once every 1–3 months C: once every 3 months D none

3: Possible financial costs for each outpatient program control: ( ) (single answer)

A: 200 yuan B: 200–500 yuan C: 500–1000 yuan D: more than 1000 yuan

4: How remote program control can help patients: ( ) (multiple answers)

A: remote control program could provide expert-level
B: timely program control
C: obviate traveling, save costs
D: improve SNM efficiency probably

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