



Electrical Stimulation of Dorsal Penis/Clitoris Nerve to Treat Neurogenic Detrusor Overactivity

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Abstract

Objective: To investigate the feasibility and therapeutic effect of percutaneous electrical stimulation of dorsal penile/clitoral nerve in the treatment of neurogenic bladder after SCI.

Methods: To select the patients who met the standard of post SCI and place surface electrodes on the surface of male penis and female clitoris. The treatment plan included 14 days of electrical stimulation and 2 rounds of urodynamic examination. The therapeutic effect of conditional electrical stimulation was evaluated through the observation of micturition volume and the improvement of bladder compliance. Spss22.0 software package was used for statistical analysis and paired sample rank test was used.

Results: 1. The tolerance of transcutaneous electrical stimulation was good, and the stimulation range was $37 \text{ MA} \pm 6 \text{ MA}$. No adverse reactions were observed after treatment. 2. The average urine output of the 5th, 10th and 15th day was significantly higher than that of the 1st day ($P < 0.05$), and there was no significant difference between the 10th and 15th day ($P = 0.333$, $P = 0.508$). 3. The frequency of electric stimulation and urinary incontinence decreased on the 5th, 10th and 15th day compared with the 1st day, the frequency of normal urination increased, the overall frequency of urination decreased, the difference was statistically significant. 4. During US1, there was a statistical difference in the mean bladder volume between electrical stimulation and non electrical stimulation; during US2, there was no statistical difference in the mean bladder volume between electrical stimulation and non-electrical stimulation; the bladder compliance was improved.

Conclusion: It is a noninvasive, simple, feasible and effective technique for the treatment of neurogenic bladder after SCI.

Keywords: Electrical stimulation; Spinal cord injury; Neurogenic bladder; Dorsal penile nerve; Clitoris nerve; Urinary incontinence

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Introduction

After Spinal Cord Injury (SCI), Due to the damage of the central nervous system or the conus spinal cord, which controls the urination function, most patients will have symptoms related to bladder and urinary dysfunction, which is called neurogenic bladder. Urodynamic examination found that such patients often have Neurogenic Detrusor Over activity (NDO), which is characterized by unconscious detrusor contraction during bladder filling, short-term high bladder internal pressure, low bladder volume and urinary incontinence, and easy to cause renal function damage and refractory urinary system infection in the late stage of the disease [1]. Therefore, the principle of treatment is to create a hypobaric bladder, increase bladder volume and reduce the ineffective contraction of detrusor.

At present, the treatment methods for such diseases include anticholinergic drugs, botulinum toxin injection into bladder detrusor and various bladder expansion operations, but there are some disadvantages, such as unsatisfactory effect, high cost, long treatment cycle, and many surgical complications. Until the advent of nerve electrical stimulation technology, it regulates bladder relaxation and contraction through electrical stimulation, so as to restore the urination and urine storage function of patients [2-4]. At present, there is no significant progress in the study of spinal cord regeneration. Neuroelectric stimulation technology will become an important means to reconstruct bladder compensatory function after SCI.

Previous studies have found that: In the process of sexual life of men and women, the dorsal penile nerve and clitoris nerve are continuously stimulated and excited, and finally men ejaculate

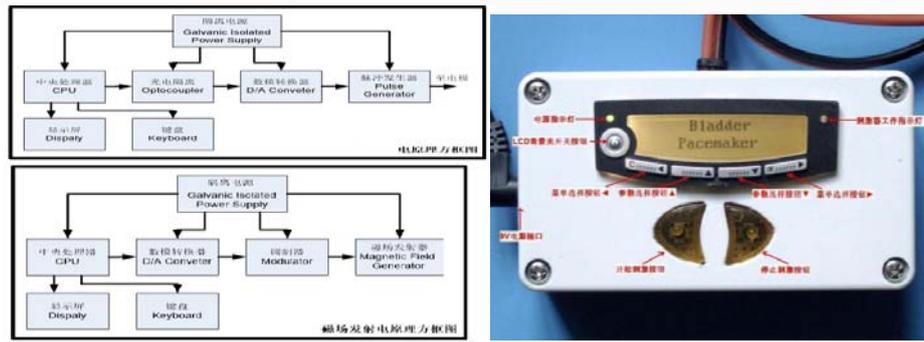


Figure 1: Medical neuroelectric stimulator 1.

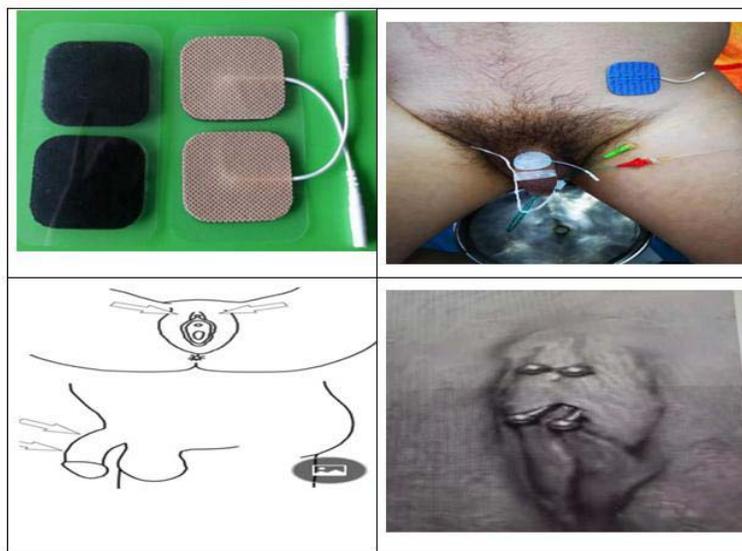


Figure 2: Electrode pattern and placement position for male and female.

to complete the whole process, but during sexual intercourse, there is no leakage of urine, because urine will kill sperm and make women unable to conceive [5]. The principle is that when the nerve fibers of dorsal penile nerve/clitoris nerve are stimulated, the action potential is transmitted to the spinal cord blocks the bladder's motor output, which is a normal conditioned reflex. The previous study of our group also found that: electrical stimulation of the afferent branch of the pudendal nerve can also inhibit the excessive contraction of the detrusor muscle of the bladder, increase the volume of the bladder, so as to restore the neurogenic bladder function of urine storage [6]. Can we construct a transcutaneous electrical stimulation system to stimulate the afferent branch of the pudendal nerve (dorsal penile nerve/clitoral nerve) to inhibit the ineffective contraction of the bladder, so as to restore the bladder function of storing urine in SCI patients? The premise of putting forward this idea is that because the main part of the pubic nerve is located in the ischioanal fossa, the position of anatomy is complex, so the operation risk is high, but the pubic nerve has many branches of sensory and motor nerves that control the genitalia, urethra, rectum and pelvic floor, while the dorsal penile nerve and the female clitoris nerve have superficial anatomical location, constant position, and easy to carry out electrical stimulation.

Based on this, through independent innovation and multi-disciplinary integration, the research group has developed a new

type of nerve electrical stimulation with full independent intellectual property rights, innovatively established a transcutaneous electrical stimulation treatment device, used safe and effective electrical stimulation parameters to stimulate the dorsal penis nerve/clitoris nerve, and then inhibited the detrusor invalid contraction, so as to increase the bladder capacity, objective to improve bladder volume, treat urinary incontinence and restore bladder function [7].

Materials and Methods

Preparation of medical nerve stimulator

(Completed and applied for patent, Figure 1) [7]. Design principle and circuit composition of medical nerve stimulator: Hardware design the system is mainly composed of five parts: Central processor, photoelectric isolation circuit, digital to analog converter, transmitter, receiver, etc. It is powered by two 5 batteries, which is convenient and safe to use.

Preparation of medical surface electrode

For men: The surface self-adhesive electrode is made of non-toxic conductive carbon paste and carbon fiber for human body and the external wire is connected. The electrode piece has the characteristics of good conductivity, strong adhesion with skin, safety and reliability, and can be reused. The preparation specification meets the size of various penis models (Figure 2).

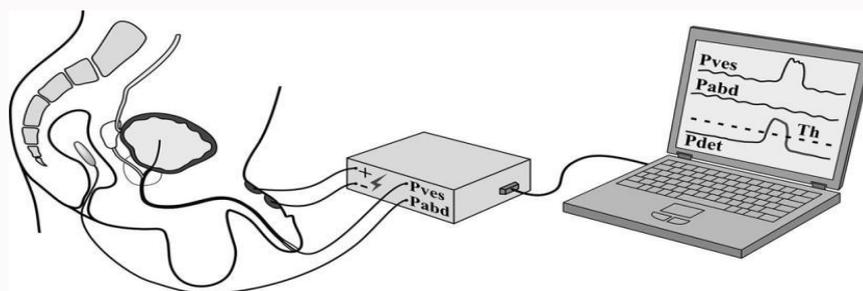


Figure 3: Pattern of electrical stimulation system.



Figure 4: Urodynamic examination.

For women: Because the clitoris is small and close to the urethra, women are easy to be affected by urine and are not easy to attach self-adhesive electrodes. So after a lot of research in the early stage, our research group got inspiration from female ear holes, and innovatively designed the subcutaneous tunnel electrode of clitoris (patent has been applied). The material is medical titanium alloy, which has good tissue compatibility, conductivity, corrosion resistance and fatigue resistance. Sex, can be used for a long time. When the electrode is used, the connecting wire can be used.

Patient selection

According to the symptoms and urodynamics of patients, 10 patients with post SCI NPO were selected. The treatment plan should be discussed and approved by the ethics committee of the hospital. All patients were treated in hospital. One week before hospitalization, patients were asked to record their daily urine volume, drinking water volume and urinary incontinence frequency at home. See Table 1 for details of patients.

Indications

- Age between 18 to 70
- Proved (N) DO (with urodynamics)
- DO related incontinence
- Sensation related to bladder contraction: SCI patients with NDO sense bladder-filling sensations and undesired detrusor contractions to some extent [8]. Bladder sensation in these patients can be specific or nonspecific. Non-specific bladder sensation is abdominal fullness, tingling feelings or vegetative symptoms like flushes, perspiration, and pilo-erectations.
- Bladder capacity below 300 ml to 350 ml
- Motivated to used the stimulation system

Contraindications

- Reduced cognitive function/drug abuser
- Implanted cardiac pacemaker
- Pregnancy
- Peripheral nerve issues (multiple sclerosis, uncontrolled diabetes)
- No or very limited hand function
- Bladder capacity below 50 ml H₂O
- Genital skin lesions

Treatment process

The treatment plan of all patients included 14 days of electrical stimulation treatment and 2 rounds of urodynamic examination (US1, US2) (the first day and the 15th day of electrical stimulation treatment respectively) (Figure 3,4).

Attach the anode stimulation electrode to the back of penis for male, and to the subcutaneous tunnel type metal electrode for female: Attach the cathode stimulation electrode to the lower abdomen for male and female, and connect the electrode wire with the electric stimulator. The stimulation parameters of each patient are determined during the first urodynamic examination (see below). When the patient feels the need to urinate, he can actively press the button. The stimulation lasts for 30 seconds and then turns off automatically. If you feel the need to urinate again. The patient must start the stimulation again, and the electric stimulator is fixed on the waist of the patient with a belt clamp.

Two rounds of urodynamic examination were carried out for the patients: Each round of urodynamic examination includes two times of filling and emptying. The purpose of the first filling of US1 was to determine the bladder capacity, and to check whether the

Table 1: Basic information of patients.

	Gender	Age	Injured segment	ASIA Classification	Bladder management	NDO time (Year)
1	M	37	C6	B	Urine receiver	3.8
2	M	29	T4	C	IC	4.1
3	M	56	L1	C	IC	3.0
4	M	40	C5-C7	D	IC	4.0
5	M	22	T12-L1	C	IC	2.0
6	M	47	C4-C5	B	CIC	5.0
7	F	61	T6-T8	C	IC+Oxybutynin	4.0
8	F	35	T12-L1	C	IC	3.0
9	F	37	C6-T1	D	CIC+Tamsulosin Hydrochloride	4.0
10	F	46	L1	C	IC	1.5

patients had the feeling of bladder contraction. This process was not stimulated by electric stimulation. The second filling of US1 was to check whether the patients had the feeling of bladder contraction, test whether the electric stimulation could inhibit the contraction, and determine whether the electric stimulation could inhibit the contraction. Stimulation amplitude: The stimulation amplitude of bulbocavernosus reflex was recorded by naked eye observation or external anal sphincter surface electromyography. The stimulation amplitude was 1.5 to 2 times of that of bulbocavernosus reflex. The other stimulation parameters were: Pulse width 200 us, frequency 20 Hz. At the same time, tell the patient where to place the electrodes and how to operate the stimulator. The bladder filling rate was 40 ml/min.

The urodynamic process is as follows: Two transurethral catheters are inserted into the bladder, including a 5Fr catheter to measure bladder pressure and a 10Fr saline perfusion catheter. A rectal balloon catheter was placed 10cm from the anus to measure rectal sphincter pressure. Fill the bladder slowly (40 ml/min). Empty the bladder and refill it again. When the patient feels that he wants to urinate or the urodynamic electromyogram checks that the bladder has invalid contraction, the electrical stimulation starts. The stimulation intensity (pulse width 200 us, frequency 20 Hz) starts at 5 mA, each time increases 5 mA, slowly increases to 40 mA. The maximum stimulation intensity is not allowed to exceed 60 mA, and the stimulation parameters are recorded (during this process, the patient is asked whether he can feel the electrical stimulation, if the patient has slight pain, the stimulation intensity can be appropriately reduced, and later the patient is asked to carry out electrical stimulation according to the stimulation parameters every day). The duration of each continuous stimulation is 20s to 45s (the risk of nerve injury is caused by exceeding 45s). When the patient's Pdet exceeds 50 cmH₂O or the maximum bladder when the volume reaches 500 ml or leakage occurs, stop filling. The purpose of this examination was to determine the parameters of electrical stimulation for complete detrusor suppression in each patient. All patients were infused up to 500 ml. After that, the patients were instructed to conduct electrical stimulation according to the stimulation parameters every day for 20s to 45s; the interval between each stimulation was at least 30 min.

Observation indicators

The total urine volume, the times of normal urination, the times of urinary incontinence and the times of electrical stimulation were recorded before treatment, on the 1st, 5th, 10th and 15th day of treatment. Each electrical stimulation was defined as a patient using

the stimulator at least half an hour apart.

Urodynamic parameters were bladder capacity, bladder detrusor pressure (Pdet), and bladder compliance (bladder volume at leak - initial bladder volume/detrusor pressure at the beginning of detrusor contraction - initial detrusor pressure). During the period of hospitalization, the patients are advised not to change their living habits easily, such as daily liquid intake.

Statistical analysis

The data of urodynamics were analyzed by spss22.0 software package (SPSS in., Chicago, U.S.), to compare cystometric outcomes within the same urodynamic study or between urodynamic studies, the nonparametric two-tailed Wilcoxon signed rank test was used. P<0.05 was statistically significant. All the values are expressed as the mean ± SD or as the mean and range.

Results

Electrical stimulation tolerance and adverse reactions

All 10 patients completed the experimental treatment, and the general tolerance of percutaneous electrical stimulation was good. No adverse reactions were observed after treatment. The average stimulation amplitude was 37 ± 6 mA. All patients had no discomfort, symptoms and local skin reactions.

Comparison of urine volume

The bladder micturition data showed that the average micturition volume on the 5th, 10th and 15th day was significantly higher than that on the 1st day (95.55 ± 6.59 ml), 113.58 ± 7.40 ml (P<0.05), 126.25 ± 11.66 ml (P<0.05), 166.03 ± 16.98 ml (P<0.05), respectively. In addition, there was no significant difference in the mean urine output between the 10th and 15th day (P=0.333, P=0.508) (Table 2 and Graph 1).

Comparison of urination times and electric stimulation times

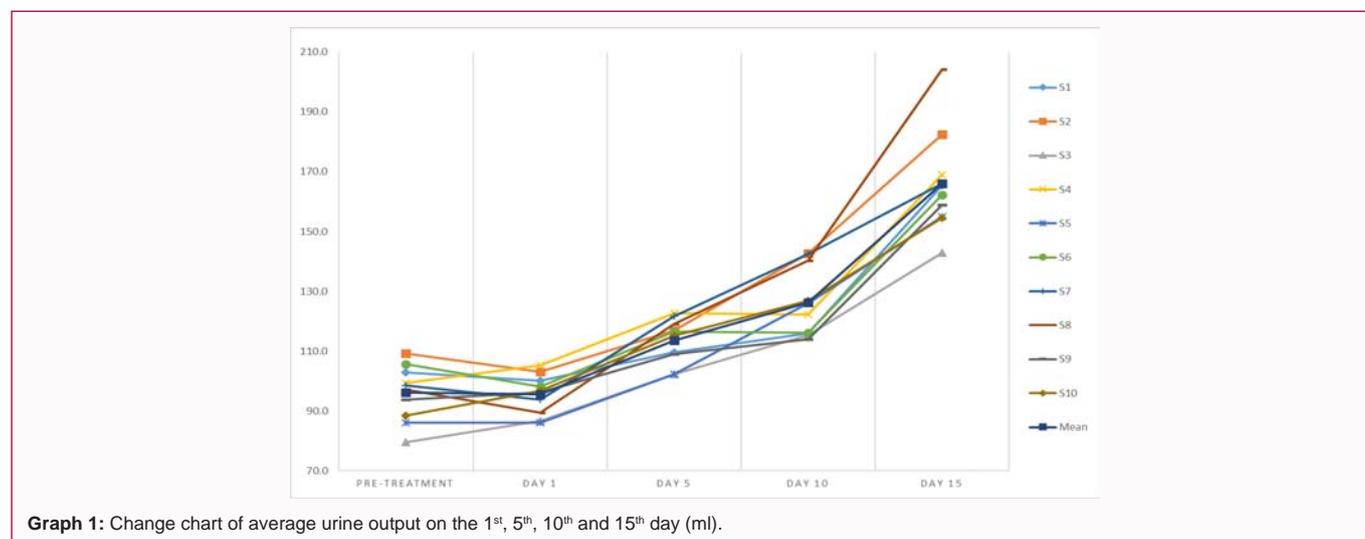
In terms of electrical stimulation, the number of times of using electrical stimulation on the 5th, 10th and 15th day was 22.20 ± 2.74 times, 19.80 ± 2.20 times and 17.30 ± 2.00 times, respectively, compared with that on the 1st day (27.60 ± 3.31 times). The difference was statistically significant (P<0.05).

In terms of urination, the frequency of incontinence on the first day was much higher than that on the 15th day, 15.70 ± 1.06 times and 2.00 ± 0.82 times, respectively, P<0.05, with statistical significance; the frequency of normal urination on the first day was lower than that

Table 2: The change of average urine output of patients (ml).

	Before treatment	Day 1	Day 5	Day 10	Day 15
1	102.9	100.2	109.7	115.9	165.5
2	109.2	103.1	117	142.8	182.4
3	79.7	86.8	102.4	115.5	142.8
4	99.3	105.3	122.8	122.3	168.9
5	86.1	86	102.3	126.1	154.9
6	105.7	98.1	116.6	116.2	162.3
7	98.5	93.7	121.7	142.5	166
8	97.2	89.4	119.1	140.3	204.2
9	93.8	96.1	109	114.1	158.8
10	88.4	96.8	115.2	126.8	154.5
$\bar{x} \pm s$	96.08 ± 9.19	95.55 ± 6.59	113.58 ± 7.40	126.25 ± 11.66	166.03 ± 16.98

Note: Average urination volume = total urination volume/times of urination per day



on the 15th day, respectively, 2.80 ± 0.92 times and 8.60 ± 1.08 times, $P < 0.05$, with statistical significance. In terms of the total number of urination, the difference was statistically significant ($P < 0.05$) (Table 3 and Graph 2).

Improvement of bladder compliance

During the period of US1, the average bladder volume of 10 patients was 128.70 ± 12.43 ml during the period of no electrical stimulation, and 252.40 ± 42.37 ml during the period of electrical stimulation, the difference was statistically significant ($P < 0.05$). On the other hand, for the US2 test, the average bladder volume was 250.50 ± 43.23 ml without electric stimulation and 260.90 ± 42.41 ml with electric stimulation. There was no significant difference between the two groups ($P = 0.114$).

Bladder compliance during US1 and US2 was evaluated. At the first bladder measurement (no electrical stimulation) (14.33 ± 6.75 ml/cmH₂O), US1 recorded the lowest mean bladder compliance. The rest (US1 with electrical stimulation, US2 without electrical stimulation and US2 with electrical stimulation) were significantly higher than that of US1 (20.73 ± 7.95 ml/cmH₂O, $P = 0.007$, 21.94 ± 10.99 ml/cmH₂O, $P = 0.007$, 23.64 ± 7.39 ml/cmH₂O, $P = 0.013$, respectively) (Table 4).

Discussion

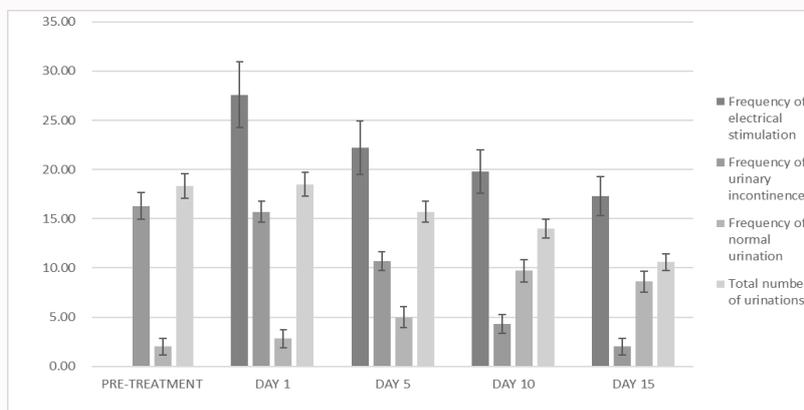
The transcutaneous electrical stimulation system designed by our

research group is composed of external electrical stimulator, lead and surface electrode. Through a large number of animal experiments and clinical applications in the early stage, it is found that the nerve electrical stimulator is simple in operation, safe in use, good in performance, and safe and stable in output of stimulation parameters [9,10]. Because the surface electrode needs to be applied to the skin, it must be considered safe, reliable and reduced Skin irritation and many other factors, especially for female patients. At present, there is no surface electrode for female clitoris in the world, so we specially designed a kind of subcutaneous tunnel surface electrode (Figure 2). The results show that all 10 patients can well tolerate the transcutaneous electrical stimulation system in the whole 15 days of treatment, and no patients have electrical stimulation intolerance or adverse reactions.

In this study, there was no statistical difference in the average micturition volume, times of micturition, times of urinary incontinence and total times of micturition of all patients on the first day compared with those before treatment. However, with the continuous treatment of electrical stimulation, all indicators were improved. The specific manifestations were: The average amount of micturition gradually increased, and the average amount of micturition on the fifth day was at least 18.9% higher than that on the first day. However, when no electrical stimulation was carried out on the 15th day, the average urine output increased by 75% compared with that on the 1st day. For the

Table 3: Table of urination and electric stimulation ($\bar{x} \pm s$) (Times).

	Before treatment	Day 1	Day 5	Day 10	Day 15
Number of electrical stimulation	0	27.60 ± 3.31	22.20 ± 2.74	19.80 ± 2.20	17.30 ± 2.00
Number of incontinence	16.30 ± 1.34	15.70 ± 1.06	10.70 ± 0.95	4.30 ± 0.95	2.00 ± 0.82
Number of normal urination	2.00 ± 0.82	2.80 ± 0.92	5.00 ± 1.05	9.70 ± 1.16	8.60 ± 1.08
Total number of urinations	18.30 ± 1.25	18.50 ± 1.18	15.70 ± 1.06	14.00 ± 0.94	10.60 ± 0.84



Graph 2: Table of urination and electric stimulation ($\bar{x} \pm s$) (time).

Table 4: Urodynamics.

	US1						US2					
	No electrical stimulation			electrical stimulation			No electrical stimulation			electrical stimulation		
	Cap (ml)	Pdet (cmH ₂ O)	Comp (ml/cmH ₂ O)	Cap (ml)	Pdet (cmH ₂ O)	Comp (ml/cmH ₂ O)	Cap (ml)	Pdet (cmH ₂ O)	Comp (ml/cmH ₂ O)	Cap (ml)	Pdet (cmH ₂ O)	Comp (ml/cmH ₂ O)
1	136	69	24.6	312	66	24.4	279	113	25.9	296	118	29.9
2	144	80	20.7	268	88	22.9	314	110	23.9	303	101	30
3	106	71	17	285	57	25.1	294	78	50.1	280	71	9.6
4	128	95	3.5	311	103	14.3	302	145	10.1	331	138	28.4
5	113	71	7.2	269	76	7.7	243	126	16.4	274	160	19.8
6	142	121	13.9	231	93	33.4	212	161	17.2	244	145	32.3
7	139	83	16.6	217	78	20.1	195	59	15.4	202	70	19.2
8	126	77	20.5	196	80	23.5	207	82	24.4	225	91	29.1
9	131	68	8.8	206	64	9.7	225	72	18.6	213	76	16.8
10	122	130	10.5	229	61	26.2	234	112	17.4	241	106	21.3
$\bar{x} \pm s$	128.7 ± 12.43	86.5 ± 22.18	14.33 ± 6.75	252.40 ± 42.37	76.6 ± 14.94	20.73 ± 7.95	250.50 ± 43.23	105.8 ± 32.95	21.94 ± 10.99	260.90 ± 42.41	107.6 ± 32.06	23.64 ± 7.39

Note: Cap = bladder volume; Pdet = Bladder detrusor pressure; Comp = Bladder compliance

analysis of the improvement of urinary incontinence, with the gradual deepening of electrical stimulation treatment, the situation of urinary incontinence gradually improved. Compared with the first day (15.70 ± 1.06 times) and the 15th day (2.00 ± 0.82 times), the difference was statistically significant; the improvement of urinary incontinence, at the same time, the number of normal urination gradually increased, and the total urine output was significantly different. The number of times of urination decreased gradually, and there was statistical difference on the 15th day compared with the 1st day. On the other hand, the number of times of daily electrical stimulation treatment was also gradually reduced. The number of times of using electrical stimulation on the 5th day (22.20 ± 2.74), the 10th day (19.80 ± 2.20) and the 15th day (17.30 ± 2.00) was 15.9%, 28.3% and 37.3% lower than that on the 1st day (27.60 ± 3.31), respectively. The above results show that: Transdermal electrical stimulation can not only effectively inhibit the ineffective contraction of the bladder, reduce urinary

incontinence, increase bladder capacity, effectively improve bladder storage function, but also produce legacy effects, reduce the spasm of bladder detrusor and urinary sphincter, inhibit their fibrosis, and ultimately improve bladder compliance, which is also verified by our urodynamic research results point: During the US1 period, the average bladder volume of 10 patients under the condition of electrical stimulation increased nearly 1 times, the difference was statistically significant. This showed that the stimulation of dorsal penis/clitoris nerve could not only increase bladder capacity and improve bladder compliance, but also had a residual effect when the stimulation stopped Lee et al. [11]. Also found the left over effect of electrical stimulation in neuroregulation studies of other types of bladder dysfunction, he explained that the improvement of bladder compliance is similar to "therapeutic memory".

In 1994 Wheeler et al. first reported the treatment follow-up of

8 patients with SCI and 1 patient with multiple sclerosis. However, only two patients completed the study, and the main reason for the patients to withdraw from the experiment was that the electrodes were extremely uncomfortable and could not tolerate electrical stimulation [12]. Later, Lee and Creasy optimized the stimulation electrode and electrical stimulation parameters and achieved success. The study showed that: A 35 year old male SCI patient was treated with electrical stimulation for 3 weeks [13]. The incontinence was improved and the amount of micturition was increased. In 2013 Opisso et al. [14] reported that a group of SCI patients with complete bladder sensation were treated by percutaneous nerve electrical stimulation through self-adhesive skin electrode, and the patients' urinary incontinence symptoms were obvious, but he did not carry out a comparative study on bladder compliance. The results of this study support the previous research conclusions. After the treatment of electrical stimulation, the patients' urinary incontinence was improved, the amount of urination was significantly increased, and the bladder was in good condition in this study, not only the amount of micturition, the number of incontinence, the total amount of micturition, the number of electrical stimulation and other aspects were discussed, but also the improvement of bladder compliance after electrical stimulation treatment was fully compared, which laid the foundation for the next step of extensive clinical application.

The results of this study show that the treatment of neurogenic bladder over activity after SCI by percutaneous electrical stimulation of dorsal penis/clitoris nerve is a noninvasive, simple, feasible and effective technique. All 10 patients were well tolerated for the entire 15 day treatment regimen. No patient had electrical stimulation intolerance or adverse reactions. Although the data of urodynamic study and micturition volume show that the percutaneous electrical stimulation treatment has good clinical value, there are still some limitations in this study. First, this is a relatively small study because only 10 patients were recruited. And the treatment plan is only 15 days, whether it is enough to observe the long-term effect of electrical stimulation on bladder capacity and compliance is questionable. Secondly, although the relatively objective data has been evaluated and analyzed, the quality of life and treatment satisfaction of patients have not been evaluated, such as questionnaire survey, which long-term large sample needs experiment to study.

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