### <u>original research</u>

# Observation of the Therapeutic Effect of Transcutaneous Electrical Stimulation Combined with Pelvic Floor Muscle Training on Post-Radical Prostatectomy Urinary Incontinence

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#### ABSTRACT

**Objective** • Exploring the clinical efficacy of transcutaneous electrical nerve stimulation (TENS) combined with pelvic floor muscle training (PFMT) on post-radical prostatectomy urinary incontinence (PPI).

**Methods** • Eighty patients with post-radical prostatectomy urinary incontinence, who were admitted to Tongji Hospital Affiliated with Tongji University from November 2021 to November 2022, were randomly divided into a TENS group and a PFMT group. The PFMT group received pelvic floor muscle training, while the TENS group received transcutaneous electrical nerve stimulation combined with pelvic floor muscle training. The bladder elevation, urodynamic parameters, pelvic floor muscle strength, treatment outcomes, and treatment efficacy were compared between the two groups of patients after treatment.

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#### INTRODUCTION

The most prevalent form of cancer in males, prostate cancer (PCa), is also one of the top causes of mortality for sufferers.<sup>1</sup> For patients with localized PCa, radical prostatectomy (RP) is recognized as the standard treatment.<sup>2</sup> However, after RP, patients are highly susceptible to experiencing a range of complications.<sup>3</sup> Among them, urinary incontinence (UI) is one of the major side effects that occur in patients after RP.<sup>4</sup>

Urinary incontinence (UI) is a disease that significantly impacts the quality of life for individuals and their families.<sup>5</sup> The incidence of UI after RP is between 2% and 65.5%.<sup>6</sup> It depends on several factors such as the patient's body mass

**Results** • In the TENS group, the bladder elevation time was shorter and the elevation speed was higher compared with the PFMT group. The TENS group also showed higher values of Qmax, MCC, MUCP, and VLPP than the PFMT group. Furthermore, the TENS group had lower total scores of ICI-Q-SF and less urine pad usage at 72 hours compared with the PFMT group. The treatment efficacy in the TENS group was higher than that in the PFMT group.

**Conclusion** • The combination of TENS and PFMT in PRPUI (Primary Recurrent Pelvic Organ Prolapse with Urinary Incontinence) patients can effectively build up the speed of bladder base elevation, reduce the elevation time, enhance pelvic floor muscle strength, improve patients' urodynamic parameters and urinary incontinence symptoms, and optimize treatment outcomes. (*Altern Ther Health Med.* [E-pub ahead of print.])

index (BMI), age, urethral length, preoperative incontinence, prostate volume, as well as the surgeon's experience and surgical technique.<sup>7</sup> PPI is particularly acute in the early postoperative period, and it may take three to six months for patients with urinary continence to recover.<sup>8</sup> However, reports have indicated that some patients still experience varying degrees of UI even one year after RP.<sup>9</sup> Additionally, PPI is significantly associated with increased levels of cognitive impairment, depression, and anger, and negatively impacts both physical and mental health.<sup>10</sup>

Transcutaneous electrical nerve stimulation (TENS) is an inexpensive therapeutic method that transmits electrical pulses through the skin.<sup>11</sup> Currently, TENS has a wide range of applications in treating various diseases.<sup>12</sup> Some studies have found that it has certain efficacy in treating pediatric enuresis (bedwetting).<sup>13</sup> However, there has been no relevant research on its use in treating PPI.

Pelvic floor muscle training (PFMT) is one of the recommended techniques for the prevention, treatment, and rehabilitation of complications associated with RP.<sup>14</sup> PFMT not only improves the physical condition of men after RP but also enhances their quality of life.<sup>15</sup> However, the effectiveness of

combining TENS with PFMT in the treatment of PPI has not been validated. Therefore, this study aims to explore the efficacy of using these two techniques together in treating PPI.

#### MATERIALS AND METHODS

#### General data of patients

From November 2021 to November 2022, 80 patients with post-radical prostatectomy urinary incontinence (PPI) treated at Tongji Hospital Affiliated with Tongji University were selected as the study subjects. The patients were assigned according to the sequence of their admission and randomly divided into a TENS group and a PFMT group using a random number table, with 40 patients in each group. The inclusion criteria for the study subjects were: (1) urinary incontinence with uncontrollable urination through the urethra; (2) a history of radical prostatectomy for prostate cancer, diagnosed as prostate cancer; (3) positive PAD test; (4) at least 1 month after radical prostatectomy; (5) voluntary participation in the study and signing of informed consent. The exclusion criteria were: (1) complete prostatectomy urinary incontinence after radical prostatectomy, indicating complete loss of function of the pelvic floor muscles and external urethral sphincter due to surgical injury of the perineal nerve; (2) urinary tract infection; (3) accompanying severe organ dysfunction, such as cardiac, hepatic, or renal dysfunction; (4) cognitive impairment. This study has been approved by the Ethics Committee of Tongji Hospital Affiliated with Tongji University, and written informed consent has been obtained from the patients or their relatives.

#### Intervention method

The PFMT group received only PFMT (Pelvic Floor Muscle Training) treatment. Professional rehabilitation physicians provided on-site guidance to patients for PFMT exercises, ensuring that the exercises met the standards. Patients were instructed to empty their bladder, contract the pelvic floor muscles for 2-6 seconds, and then relax for 2-6 seconds, repeating this cycle for 15-20 minutes. The exercises were performed 3 times a day, for a total of 8 weeks.

The TENS group received TENS (Transcutaneous Electrical Nerve Stimulation) combined with PFMT treatment. Building upon the PFMT group, the acupuncture site was disinfected using medical alcohol. Acupuncture needles were inserted from the inner ankle to the posterior head, reaching around the tibial nerve (approximately 5 cm), and grounding electrodes were placed on the same side of the sole. The electrodes were connected to a pulse therapy device, with the treatment frequency adjusted to 20 Hz. The current gradually increased from low to high (approximately 1-5 mA) until the patient's toes spread or dorsiflexion was achieved as the endpoint. Additionally, a pelvic floor electromyography (EMG) device was used to monitor the EMG waveform of the tibial nerve. The acupuncture needle position was adjusted based on the maximum peak of the EMG waveform, and the current value at this point was multiplied by 1.5 as the treatment current. The treatment was

administered once a week, with a duration of 30 minutes per session. Both groups received treatment for 8 weeks.

#### **Observation index**

General information and bladder prolapse. Data on patient age, BMI, and tumor stage were collected and analyzed. The T-stage of TNM staging was used to statistically analyze the staging of primary tumors in patients. Both groups used ultrasound (Mindray M9CV, Shenzhen Mindray Bio-Medical Electronics Co., Ltd.) to measure bladder baseline elevation level at the peak of pelvic floor muscle contraction. Bladder baseline elevation time, length, and velocity were calculated.

**Urodynamic testing.** Before and after treatment, both groups of patients were assessed using a urodynamic analysis device (LUD4100, Shanghai Jumu Medical Instruments Co., Ltd.) to measure the maximum urine flow rate (Qmax), maximum bladder capacity (MCC), maximum urethral closure pressure (MUCP), and abdominal leak point pressure (VLPP).

**Pelvic floor muscle tone.** Before and after treatment, the pelvic floor muscle strength levels of both groups of patients were measured using a biofeedback electrical stimulation device (MLD B2Plus, Nanjing MLD Medical Technology Co., Ltd.). The patients' muscle strength examination results were scored accordingly.

**Treatment outcome.** The International Consultation on Incontinence Questionnaire Short Form (ICI-Q-SF), designed by the International Consultation on Incontinence Committee, was used to assess the severity of urinary incontinence in both groups of patients before and after treatment. Higher scores indicated more severe urinary incontinence. Additionally, the usage of urinary pads was recorded for both groups of patients 72 hours before the start of treatment and 72 hours after the completion of treatment.

#### Treatment efficacy

To assess the effectiveness of the treatment, statistical analysis was conducted on the treatment outcomes of the patients. Based on their symptoms, the patients were divided into the following categories: Complete cure: Urinary incontinence symptoms were eliminated. Marked improvement: Urinary incontinence symptoms were significantly improved. Effective: Urinary incontinence symptoms showed some improvement. Ineffective: Urinary incontinence symptoms didn't improve or worsen. The clinical overall effective rate was calculated using the formula:

Clinical overall effective rate = [(number of complete cure cases + number of marked improvement cases + number of effective cases) / total number of cases]  $\times 100\%$ .<sup>16</sup>

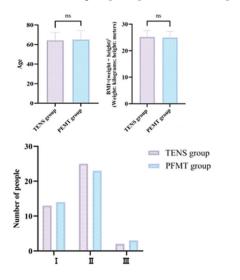
#### Adverse emotions

Before and after health education for patients, the Self Rating Anxiety Scale (SAS) and Self Rating Depression Scale (SDS) were used to evaluate the adverse emotions of both groups of patients before and after treatment. The higher the score on the scale, the more severe the adverse emotions. **Table 1.** General characteristics comparison between the two patient groups.

			Tumor stag		stage
Category	Age (years)	BMI(kg/m <sup>2</sup> )	I	II	III
TENS group $(n = 40)$	64.33±8.05	25.17±2.42	13	25	2
PFMT group $(n = 40)$	65.10±9.34	24.93±2.36	14	23	3
$t/\chi^2$	0.3950	0.4490		0.055	9
P value	.6940	.6546		.813	1

Note: Data are given as  $(x \pm s)$ .

**Figure 1.** Compared with the PFMT group, the TENS group had a younger age and higher BMI, with P > .05. In both groups, the majority of patients had stage II tumors. These results indicated that there is no significant difference in the general information when compared between the two groups of patients, and the two groups of patients are comparable.



#### Statistical analysis

Statistical analysis was performed using SPSS version 23.0 statistical software. Continuous data were expressed as (mean  $\pm$  standard deviation) and analyzed using independent *t* tests for comparison between the two groups. Categorical data were presented as [n (%)] and analyzed using the chi-square test. A significance level of *P* < .05 was considered statistically significant, indicating that the differences were statistically meaningful.

#### RESULTS

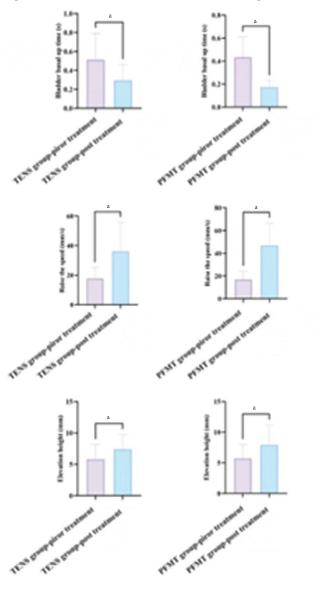
#### Comparison of general patient characteristics

There was no statistically significant difference between the two groups of patients in terms of age, BMI, and tumor stage (P > .05). (Table 1, Figure 1)

#### Comparison of bladder elevation in two patient groups

According to the comparison, before treatment, there was no statistically significant difference between the two groups of patients in terms of bladder baseline elevation time, length, and speed (P > .05). After treatment, the bladder baseline elevation time in the TENS group was lower than that in the PFMT group (P < .05), but the bladder

**Figure 2.** Both the PFMT and TENS groups showed improvement in bladder base elevation time, elevation length, and elevation speed compared to before treatment, with P < .05. These results indicated that the application of PFMT or PFMT combined with TENS had significant effects on promoting the improvement of bladder floor elevation in PRPUI patients.



<sup>a</sup>Compared with Before treatment, P < .05.

Table 2. Comparison of bladder elevation in two patient groups

	Bladder base elevation time (s)			se elevation (mm/s)	Bladder base elevation height (mm)		
	Before	After	Before	After	Before	After	
Category	treatment	treatment	treatment	treatment	treatment	treatment	
TENS group $(n = 40)$	0.43±0.17	0.17±0.06ª	16.92±7.36	46.98±19.57ª	5.74±2.25	7.94±3.25ª	
PFMT group $(n = 40)$	0.51±0.28	0.29±0.16ª	17.80±7.50	36.23±19.63ª	5.81±2.34	7.42±2.32 <sup>a</sup>	
t	1.5446	4.4414	0.5297	2.4528	0.1364	0.8236	
P value	.1265	<.05	.5979	.0164	.8919	.4127	

<sup>a</sup>Compared with Before treatment, P < .05.

Note: Data are given as  $(x \pm s)$ .

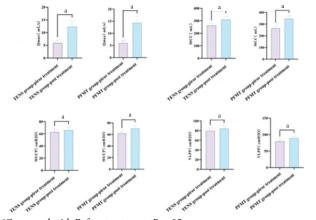
Table 3. Comparison	of urodynamic	parameters in two	patient groups

Category	Qmax (mL/s) MCC (		(mL) MUCP (		cmH,O)	VLPP (cmH <sub>2</sub> O)		
	Before	After	Before	After treat-	Before	After	Before	After
	treatment	treatment	treatment	ment	treatment	treatment	treatment	treatment
TENS group $(n = 40)$	6.05±1.03	$14.37 \pm 2.72$	265.78±22.24	346.86±22.92	62.14±4.13	70.56±5.53	79.88±5.61	89.96±6.08
PFMT group $(n = 40)$	5.99±1.09	12.43±2.33	262.75±17.89	310.94±24.67	63.25±4.80	66.35±4.65	79.82±5.73	84.57±5.74
t	0.2530	3.4258	0.6714	6.7464	1.1087	3.6852	0.0473	4.0770
P value	.8009	<.05	.5039	<.05	.2710	<.05	.9624	<.05

<sup>a</sup>Compared with Before treatment, P < .05.

Note: Data are given as  $(x \pm s)$ .

**Figure 3.** After treatment, the Qmax, MCC, MUCP, and VLPP of both the PFMT and TENS groups were increased compared to before treatment, with P < .05. These indicated that the application of PFMT or PFMT combined with TENS can significantly improve the urodynamic indicators of PRPUI patients.



<sup>a</sup>Compared with Before treatment, P < .05.

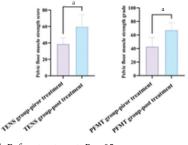
**Table 4.** Comparison of pelvic floor muscle strength scores in two patient groups

Category	Before treatment	After treatment
TENS group $(n = 40)$	42.85±13.26	67.20±10.93ª
PFMT group $(n = 40)$	38.69±7.49	59.66±14.75 <sup>a</sup>
t	1.7276	2.5976
P value	.0880	.0112

<sup>a</sup>Compared with Before treatment, P < .05.

Note: Data are given as  $(x \pm s)$ .

**Figure 4.** After treatment, the pelvic floor muscle strength score of both the PFMT and TENS groups was increased compared to before treatment, with P < .05. These results indicated that the application of PFMT or PFMT combined with TENS could enhance pelvic floor muscle strength in PRPUI patients.



<sup>a</sup>Compared with Before treatment, P < .05.

baseline elevation speed was higher than the PFMT group (P < .05). However, there was no statistically significant difference between the two groups in terms of bladder baseline elevation height (P > .05). (Table 2, Figure 2)

### Comparison of urodynamic indices between two patient groups

Before treatment, there was no statistically significant difference between the two groups

of patients in terms of Qmax, MCC, MUCP, and VLPP (P > .05). After treatment, the TENS group patients gained higher Qmax, MCC, MUCP, and VLPP values than the PFMT group (P < .05). (Table 3, Figure 3)

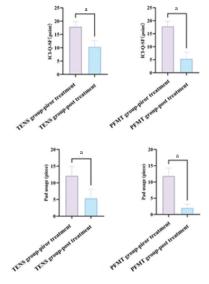
## Comparison of pelvic floor muscle strength in two patient groups

There was no statistically significant difference in pelvic floor muscle strength score between the two groups of patients before the treatment (P > .05). After treatment, the TENS group patients had higher pelvic floor muscle strength scores compared with the PFMT group (P < .05). (Table 4, Figure 4)

#### Comparison of treatment effectiveness in two patient groups

According to the comparison, before treatment, there was no statistically significant difference in ICI-Q-SF scores and 72-hour pad usage between the two groups of patients (P > .05). However, the TENS group patients had lower ICI-Q-SF scores and 72-hour pad usage after treatment compared with the PFMT group (P < .05). (Table 5, Figure 5)

**Figure 5.** After treatment, the ICI-Q-SF score and the amount of 72h pad usage were decreased in both the PFMT and TENS groups compared to before treatment, with P < .05. These results indicated that the application of PFMT or TENS combined with PFMT improves the severity of urinary incontinence in patients with prostate cancer after radical surgery.



<sup>a</sup>Compared with Before treatment, P < .05.

 Table 5. Comparison of treatment effectiveness in two

 patient groups

			The quantity of u	rinary pads used
	ICI-C	ICI-Q-SF		eces)
Category	Before treatment	After treatment	Before treatment	After treatment
TENS group $(n = 40)$	17.83±1.94	5.33±2.58	11.88±2.44	2.02±1.12
PFMT group $(n = 40)$	17.92±1.85	10.37±2.38	12.13±2.73	5.38±2.71
t	0.2123	9.0812	0.4318	7.2470
P value	.8324	<.05	.6671	<.05

<sup>a</sup>Compared with Before treatment, P < .05.

Note: Data are given as  $(\overline{x \pm s})$ .

#### Comparison of treatment efficacy rates in two patient groups

The treatment effectiveness rate in the TENS group was higher than in the PFMT group (P < .05). (Table 6, Figure 6)

#### Comparison of adverse emotions among patients

After comparison, there were no statistically significant differences in the levels of negative emotions between the two groups of patients before intervention (P > .05), however, after intervention, the SAS and SDS scores of both groups of patients decreased (P < .05), After intervention, the SAS and SDS scores of patients in the TENS group were lower than those in the PFMT group (P < .05), these results were shown in Table 7.

#### DISCUSSION

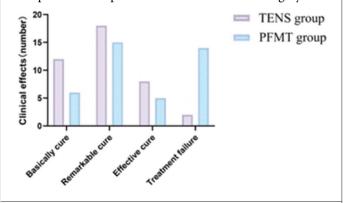
PPI has become an increasingly common urological issue.<sup>17</sup> Despite advances in surgery, UI is inevitably a consequence of RP.<sup>18</sup> This is due to the extensive dissection during surgery, which damages the internal sphincter, external striated sphincter, urethral support structures, and neurovascular bundles, and may even result in fibrosis postoperatively.<sup>19</sup> As a result, PPI is one of the most feared postoperative complications.<sup>20</sup>

Research has found that after RP, patients experience a prolonged duration of bladder neck elevation and a decreased rate of elevation, which is associated with the occurrence of PPI.<sup>21</sup> Additionally, PPI patients have been found to have smaller and weaker sphincter muscles,<sup>22</sup> leading to changes in their urodynamic parameters.<sup>17</sup> Urodynamic studies have been used to better understand functional changes in PPI patients.<sup>23</sup> It has been shown that the pelvic floor muscles play a crucial role in urinary continence,<sup>24</sup> and strengthening the pelvic floor muscles can effectively treat PPI.<sup>25</sup> Moreover, the ICI-Q-SF and pad tests have been proven to be effective in evaluating the severity of PPI.<sup>26</sup>

TENS is a technique that provides mild electrical stimulation throughout the entire surface of the skin.<sup>27</sup> TENS therapy facilitates muscle activation and increases the excitability of motor neurons.<sup>28</sup> This makes TENS a promising approach to improving muscle strength.<sup>29</sup> More importantly, researchers have demonstrated that electrical stimulation therapy has a certain therapeutic effect in treating PPI patients.<sup>30</sup>

PFMT is considered to be the most common non-invasive intervention for PPI.<sup>31</sup> It has been shown to have significant effectiveness in improving PPI.<sup>32</sup> PFMT aims to activate the

**Figure 6.** Most patients in the PFMT and TENS groups showed significant improvement after treatment. The PFMT group had a larger number of patients with ineffective treatment. This results indicated that the application of PFMT or TENS combined with PFMT had effective therapeutic effects on urinary incontinence symptoms in most patients with prostate cancer after radical surgery.



**Table 6.** Comparison of treatment efficacy rates in two

 patient groups

	Complete	Marked			The overall
Category	cure	improvement	Effective	Ineffective	effectiveness rate
TENS group $(n = 40)$	12	18	8	2	95
PFMT group $(n = 40)$	6	15	5	14	65
χ <sup>2</sup>	11.2500				
P value	.0008				

**Table 7.** Comparison of adverse emotions among patients

Cataoon	SDS score		SAS score		
Category	Before treatment	After treatment	Before treatment	After treatment	
TENS group $(n = 40)$	50.29±5.07	43.61±4.02 <sup>a</sup>	54.79±5.70	45.02±4.41ª	
PFMT group $(n = 40)$	51.37±5.28	37.14±3.71ª	55.08±5.85	37.13±3.85ª	
t	0.9331	7.4803	0.2246	8.5241	
P value	.3536	<.05	.8229	<.05	

<sup>a</sup>Compared with Before treatment, P < .05.

Note: Data are given as  $(x \pm s)$ .

pelvic floor muscles, improve pelvic organ support, enhance urethral resting pressure, increase the functional length of the urethra, and activate the surrounding striated muscles around the urethra, thereby increasing the resting tone of the anal sphincter.<sup>15</sup> During PFMT, patients primarily engage in exercise training.<sup>33</sup> The combination of exercise training with electrical stimulation is more effective than exercise training alone.<sup>34</sup>

This study compared PPI patients undergoing TENS combined with PFMT therapy with the patients who received PFMT therapy alone and found that after undergoing TENS combined with PFMT therapy, patients had shorter bladder neck elevation time and higher elevation speed. Additionally, their urodynamic parameters including Qmax, MCC, MUCP, and VLPP improved. Furthermore, their ICI-Q-SF total score and 72-hour pad usage decreased, with a significant increase in the effectiveness of the treatment. This indicated that TENS combined with PFMT therapy has shown good therapeutic effects in PPI patients.

In summary, performing TENS combined with PFMT in PPI patients effectively improves bladder neck elevation speed, reduces bladder neck elevation time, enhances pelvic floor muscle strength, improves urodynamic parameters, and alleviates urinary incontinence symptoms, thus enhancing the overall treatment effectiveness. TENS combined with PFMT can be considered as a treatment modality for PPI patients.

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