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Effect of 4 weeks of whole-body vibration training in treating stress urinary incontinence after prostate cancer surgery: a randomised controlled trial

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Abstract

Background Stress urinary incontinence is common in men after prostate cancer surgery. Rehabilitative interventions incorporate pelvic floor muscle training, biofeedback, electrical stimulation, lifestyle changes, or a combination of these strategies. However, little is known about the physiological impact of whole-body vibration for stress urinary incontinence after radical prostatectomy.
Objective To investigate the effect of whole-body vibration training on stress urinary incontinence after prostate cancer surgery.
Design Randomised controlled trial.
Setting Tertiary university hospitals.
Participants Sixty-one patients with mild stress urinary incontinence after radical prostatectomy.
Intervention Group 1 included 30 patients who performed pelvic floor muscle training and whole-body vibration training with a frequency and amplitude of 20 Hz/2 mm for the first two sessions and 40 Hz/4 mm for the rest of the intervention. Group 2 included 31 patients who performed pelvic floor muscle training alone. The intervention in both groups was conducted three times per week for 4 weeks.
Main outcomes Incontinence Visual Analogue Scale (I-VAS) score, International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) score and 24-hour pad test result.
Results I-VAS score, ICIQ-UI-SF score and 24-hour pad test result showed significant within-group differences at each assessment with the exception of the baseline and post-intervention I-VAS score in Group 2. For example, Group 1 I-VAS score had a median difference of 3.9 cm [95% confidence interval (CI) −4.0 to −3.8] from baseline to first follow-up, and a median difference of −2.0 cm (95% CI −2.2 to −1.8) at 4-week follow-up. Comparisons between the groups demonstrated significant differences in favour of Group 1 after 4 weeks of intervention and at follow-up for all measured parameters.
Conclusion Whole-body vibration training is an effective modality for treating patients with stress urinary incontinence after prostatectomy.

Trial registration Clinicaltrial.gov (NCT03325660).

Keywords: Whole-body vibration; Pelvic floor muscle training; Urinary incontinence; Prostate cancer; Rehabilitation; Quality of life

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Introduction

Prostate cancer shows increasing incidence, and currently affects 1.1 million people/year worldwide [1]. Radical prostatectomy (RP) is the most common treatment for prostate cancer [2], and an estimated 60 000 RP procedures are performed annually in the USA [3].

The incidence of urinary incontinence (UI), the most common adverse effect of RP, is 17% to 77%, 7% to 53% and 3% to 38% at 1, 3 and 6 months after RP, respectively [4], and it becomes more prevalent with pre-existing lower urinary tract symptoms and surgery [5]. Stress UI (SUI) in men is the involuntary leakage of urine secondary to insufficient bladder outlet resistance. It has become an increasingly common urological problem, with a prevalence of 2.5% to 90% after prostatectomy and a cost burden of $19 to $32 billion in the USA [6].

The temporal and spatial phases of urethral movement are prompted by the contraction of the striated urethral sphincter (SUS), levator ani and bulbocavernosus muscles [7]. SUS incompetence is generally considered to be the most important contributing factor to incontinence following RP. Maximal urethral closure pressure seems to be reduced post-operatively, with rates up to 41% [8]. Egawa *et al.* demonstrated that the innervation of the SUS lies only 0.3 to 1.3 cm from the apex of the prostate, making it highly susceptible to injury during apical dissection. In addition to the urethral sphincter, the bladder is also affected by RP, with effects on detrusor innervation and function [9]. Therefore, a positive association was found between a longer membranous urethra before surgery and return of continence in men after RP [10].

Rehabilitation for the treatment of UI after RP incorporates pelvic floor muscle training (PFMT), biofeedback, transcutaneous electrical stimulation, pelvic floor electrical stimulation with endo-anal electrodes, and a combination of these techniques. Conservative treatment must be paired with lifestyle changes such as physical activity, bladder muscle training, and reduction or elimination of caffeine intake and smoking. However, the efficacy of the different modalities of rehabilitative interventions for UI after RP remains dubious [11].

Pelvic floor muscle training (PFMT) is the first-line rehabilitative intervention for SUI in female patients, as this improves PFM function, contributes to sphincter strength, and enhances PFM timing and coordination [12].

Whole-body vibration training (WBVT) is a novel modality for improving aspects of the neuromuscular system [13,14], and enhancing muscle strength and endurance [15] by stimulating the muscle spindles to recruit more motor units, thereby exerting greater power [16]. Furthermore, WBVT activates the proprioceptors (muscle spindle), positively affects muscle strength [17], enlarges slow- and fast-twitch fibres, and causes hormonal changes [14].

WBVT is also effective for strengthening weak muscles, particularly in patients with various chronic diseases that make the muscles unable to contract [18–21]. WBVT was recently added as a modality for strengthening the PFMs. Mechanical vibration can be used to provide neuromuscular stimulation of weakened PFMs in women with UI [19].

To the best of the authors' knowledge, reports on the use of WBVT as a treatment modality for SUI after RP are lacking. Due to the need to find other treatment methods besides medications and surgical procedures for the management of SUI, WBVT was selected as a rehabilitative intervention without any adverse effects. Consequently, this study aimed to investigate the effect of WBVT on SUI after prostate cancer surgery.

Methods

This study was approved by the Research Ethical Committee (P.T. REC/012/001250) of the Faculty of Physical Therapy, Cairo University. The clinical trial is registered at Clinicaltrial.gov (Identifier No. NCT03325660).

Participants

Patients who had experienced mild SUI for at least 6 months after RP were recruited from Cairo University Hospitals. The diagnosis was confirmed by the referring physician using the 24-hour pad test. Mild SUI was defined as <100 g increase in the weight of the pad(s) worn by the patient [22].

The exclusion criteria were: use of an artificial pacemaker, body mass index >35 kg/m^2, urinary infection, bleeding from the urinary bladder or digestive tract, polyuria, diabetes mellitus, detrusor over-activity, neuromuscular disorder, ear problems, or any other medical condition that could affect participation in the training programme.

Power analysis was initially performed to calculate the sample size. Estimates of mean difference and standard deviation (SD) for the Incontinence Visual Analogue Scale (I-VAS) were collected from a previous study [19] that included 43 women, as data from a male cohort were not available, who received a similar treatment programme; the mean difference and SD were 4.42 and 1.89, respectively (two-tailed test with $\alpha = 0.05$ and power of 80%). The present study required a sample size of 26 patients for each group. In total, 32 patients were enrolled in each group to account for a dropout rate of 20%.

On the basis of the previously mentioned exclusion criteria and sample size calculation, of the 70 patients screened for eligibility, two patients were excluded because of urinary infection and one patient was excluded due to a history of surgical intervention for UI. Furthermore, three other patients were excluded, two because of an inner ear problem and one because of the patient's refusal to complete the study. Eventually, 64 patients were included in the study, and were assigned at random into two groups (32 participants in each group).

During the intervention, there were dropouts from both groups. One patient dropped out because of transportation issues, one due to other reasons and one because of discomfort. Therefore, the final study sample comprised of 61 participants (30 in Group 1 and 31 in Group 2), as presented in Fig. 1.

Randomisation

The patients were randomised using Statistical Package for the Social Sciences (IBM Corp, Armonk, NY, USA) into Group 1, which received WBVT and PFMT, and Group 2, which received PFMT alone. The study protocol was explained to the patients, and an informed consent form was signed by each patient before the intervention commenced. The patients were blinded to their group assignment.

Intervention

Whole-body vibration training

Group 1 received WBVT (Fitvibe Excel; N.V. Gymna Uniphy, Bilzen, Belgium), three times weekly for 4 consecutive weeks (12 sessions), according to the following protocol based on previous studies [18–21]: for the first two sessions, the parameters were a frequency of 20 Hz, peak-to-peak displacement of 2 mm, and duration of each set of 45 seconds followed by 60 seconds rest were applied. Three sets were performed. For the remaining 10 sessions of the intervention, the parameters of the vibration training were changed to a frequency of 40 Hz, peak-to-peak displacement of 4 mm, and duration of each set of 60 seconds followed by 60 seconds rest. The number of sets increased by two sets every three sessions.

During the 2-month follow-up period, the patients underwent two refresher sessions at the end of each month with the respective intervention in each group. In addition, all patients in both groups were advised to conduct home routine exercises for the PFMs; they were provided with illustrated handouts containing detailed descriptions for guidance and for progression of the exercises.

Procedure. Each participant was instructed to remain on the platform, loading their feet consistently with the knee and hip joints bent at 35° and the upper limbs stretched horizontally forwards while clutching a railing. The hip and knee flexion ranges of motion were measured to guarantee that each

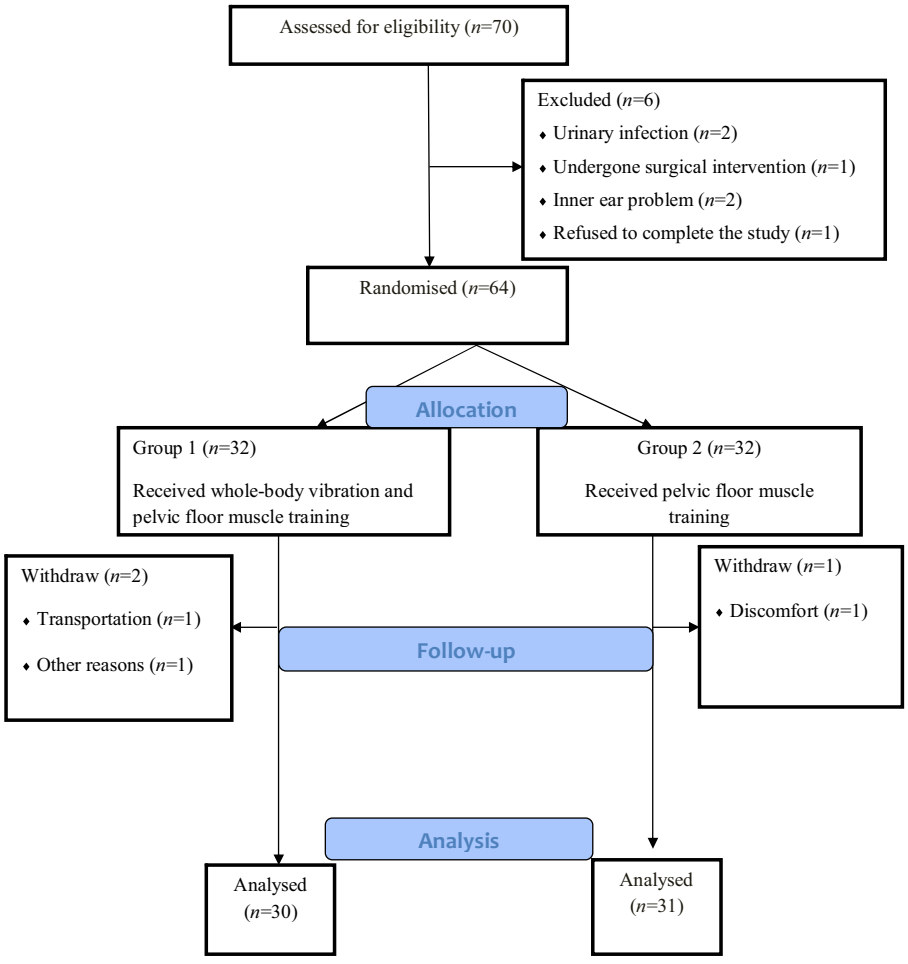

Fig. 1. Flowchart diagram of the study.

participant maintained the required position. This position is recommended because knee flexion reduces the measurement of vibration that reaches the head [23].

Pelvic floor muscle training

All participants in both groups underwent PFMT. The participants were instructed to empty their bladder before each treatment session so that they felt comfortable and relaxed during the session. The optimal instructions for activating PFMs are those that induce the greatest amplitude of PFM shortening with minimal increase in abdominal muscle activity and intra-abdominal pressure. Stafford *et al.* [24] reported that the best instruction to achieve the greatest dorsal displacement of the mid-urethra and shorten the SUS is 'shorten the penis' or 'stop the flow of urine'.

In this study, the verbal instruction used to activate the PFMs was 'stop the flow of urine'. The literature shows inconsistency in terms of PFMT repetition, intervals, and contraction and relaxation times [19,25–27]. Furthermore, studies on different training interventions for the slow- and fast-twitch fibres are lacking. Therefore, the training protocol used in the current study was designed by the authors. Each participant was taught a PFMT programme to perform each day in lying, sitting and standing positions, consisting of a 10-second contraction followed by a 10-second relaxation period, repeated 15 times each session. The contraction and relaxation times were increased by 1 second every week as training for the slow-twitch muscle fibres [28]. In contrast, the fast-twitch muscle fibres were trained by asking participants to contract and relax their PFMs quickly, 20 times, followed by a 10-second rest. This was repeated for two sets, with this increased gradually to four sets of contractions per session. To ensure the correct execution of PFM contraction, the verbal instruction was accompanied by observation of contraction of the base of the penis using a mirror [26].

Assessment procedure

The primary outcome measure was the I-VAS score, and the secondary outcome measures were the Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) score and the 24-hour pad test result. The assessments were performed before treatment, after 4 weeks of treatment, and at 2-month follow-up.

For the I-VAS, patients were asked to depict their subjective burden of incontinence on a 100-mm VAS. The question above the VAS line was: 'How annoyed are you by incontinence currently?' The 100-mm VAS scale scores ranged from 0 ('not irritated') to 10 ('extremely disturbed'). A 100-mm line labelled from 0 to 10 was used, with patients asked to mark their answer on the line. The I-VAS is a valid, reproducible and responsive tool for UI treatment and improving the quality of life of patients after urogynaecologic surgery [29,30].

The ICIQ-UI-SF includes three scored items and involves low patient burden. The straightforwardness of this scale renders it particularly helpful in clinical practice, where time and resources are restricted [31].

The CIQ-UI-SF is simple and has high validity, reliability and responsiveness. It is easy to use for a wide variety of patients, including men and women, young and elderly patients, and patients in clinics and in communities worldwide [32].

The results for the 24-hour pad test were classified as follows: mild incontinence (<100 g/24 hours), moderate incontinence (100–400 g/24 hours) and severe incontinence (>400 g/24 hours) [22]. Pad weight or pad number is used to quantify UI [33]. The 24-hour pad test is considered as the gold standard for objective measurement of post-prostatectomy incontinence [34].

Statistical analysis

All numerical data were subjected to tests of normality using the Kolmogorov–Smirnov test. Normally distributed data were described in terms of mean and SD, whereas non-normal data were described as median and interquartile range (IQR). The two study groups were compared using Student's *t*-test for normally distributed data, and the Mann–Whitney U-test for non-normally distributed data. For the 24-hour pad test results, within-group comparison between time points was done using repeated-measures analysis of variance followed by paired *t*-test as post-hoc multiple two-group comparisons. For the VAS and ICIQ-UI-SF scores, comparison between time points was performed using Freidman's test with Wilcoxon signed rank test for paired (matched) samples as post-hoc multiple two-group comparisons. All comparisons were performed after applying Bonferroni's adjustment for multiple comparisons. *P*-values <0.05 were considered to indicate statistical significance. All statistical calculations were performed using Statistical Package for the Social Sciences Version 22.

Results

The bio-demographic data of all participants at baseline showed homogeneity and non-significant differences between the two groups in terms of age, weight, height and body mass index ($P > 0.05$) (Table 1).

For the clinical outcomes, within-group comparisons of the three time points (at baseline, after 4 weeks of treatment and at 2 months follow-up) for the I-VAS score, ICIQ-UI-SF score and 24-hour pad test result showed significant changes ($P = 0.001$) over time in both groups (Table 2).

In the post-hoc test, Group 1 showed significant differences ($P = 0.001$) at different times (i.e. between baseline and post-intervention, baseline and follow-up, and post-intervention and follow-up) for all measured parameters (Table 2). Furthermore, the percentages of improvement in

Table 1
Demographic data for both groups.

Variable	Group 1 (WBVT) ($n = 30$) Mean (SD)	Group 2 (controls) ($n = 30$) Mean (SD)	*P*-Value
Age (years)	64.3 (5)	63.6 (5.8)	0.604
Weight (kg)	85 (7.1)	84.3 (6.8)	0.698
Height (m)	1.7 (0.09)	1.7 (0.08)	0.165
Body mass index (kg/cm^2)	30.1 (3.8)	28.9 (4)	0.223

WBV, whole-body vibration training; SD, standard deviation.

Group 1 after 4 weeks of treatment and in the follow-up measurements were as follows: for the I-VAS score, 51% and 74%; for the ICIQ-UI-SF score, 43% and 64%; and for the 24-hour pad test result, 51% and 67%, respectively.

In Group 2, the I-VAS score showed no significant difference ($P = 0.512$) between baseline and post-intervention, but there was a significant difference ($P = 0.001$) between baseline and follow-up and between post-intervention and follow-up (Table 3). The ICIQ-UI-SF score and 24-hour pad test result showed significant differences between baseline and post-intervention ($P = 0.002$ and 0.001, respectively). Moreover, comparisons between baseline and follow-up and between post-intervention and follow-up showed significant differences ($P = 0.001$) for the two variables (Table 3). In addition, the percentages of improvement in Group 1 after 4 weeks of treatment and in the follow-up measurements were as follows: for the I-VAS score, 0.5% and 14%; for the ICIQ-UI-SF score, 7% and 23%; and for the 24-hour pad test result, 32% and 41% at the same periods of measurements, respectively.

For between-group comparisons, the I-VAS score, ICIQ-UI-SF score and 24-hour pad test result were not significant ($P = 0.739$, 0.498 and 0.801, respectively) at baseline. However, there was a significant difference ($P = 0.001$) in favour of WBVT (Group 1) compared to PFMT (Group 2) after 4 weeks of intervention and in the follow-up measurements (Table 2).

Discussion

The impact of WBVT on the strengths of different muscles has been explained in several studies [13,15,16]. As such, this study used a 4-week treatment period to determine the effect of WBVT on the I-VAS score, ICIQ-UI-SF score and 24-hour pad test result in patients with SUI following prostatectomy.

The significant differences in the pre and post-treatment parameters of Group 1 may be attributed to PFM activation resulting in an increase in intra-abdominal contractions induced by the effect of WBVT, which is perceived to have stimulated the PFMs and recovered their capacity [19]. Similarly, other potential reasons for the differences between the pre and post-treatment results of Group 1 may be changes in the timing, coordination and speed of muscle contraction and changes in PFM endurance when WBVT was introduced. These factors are perceived to be primarily affected in cases of SUI, in addition to the positive changes in muscle tension after WBVT [19]. However, variations in PFM strength are not the only impact of WBVT. Additional perspectives of muscle action that were not measured in this study, such as abdominal muscle contraction and its positive effect on PFM strength in patients with UI [35], electromyography activities, and contraction endurance and speed, require further investigation to fully correlate these parameters with PFM contraction in relation to WBVT. Furthermore, WBVT is considered to be a somatosensory provocation for proprioceptors, along with its lasting postural impact [18]. Type Ia and II afferent nerves embedded in the muscle spindles of PFMs are very sensitive to minor changes in muscle length caused by the vibratory effect of the WBVT device. This causes a stimulatory effect resulting in stretch and skin reflex enhancement [14]. Moreover, the longstanding effect of WBVT that was measured at follow-up (2 months after the study commenced) may be attributed to the incremental increase in the firing rate generated in muscle units, the tonic effect of the vibration reflex, the recovery of cell–cell communication of muscle fibres, the hypertrophy of muscle fibres, and the multitude of signals sent to the spinal pathways [17,20,36].

Previously, Luo *et al.* [37] reported that the vibration frequency should range between 30 and 50 Hz for the most efficient activation of muscles. The present study used a frequency of 20 Hz and an amplitude of 2 mm for the first two sessions, as preparation and orientation for the vibration intervention, and a frequency of 40 Hz and an amplitude of 4 mm for the remaining 10 sessions, which is consistent with the protocol of Stania *et al.* who found that vibrations of 40 Hz and peak-to-peak displacement of 4 mm led to an increase in the mean activity of the PFMs [38]. This finding reiterates that WBVT could be an efficient modality to strengthen the muscles needed to control urinary flow, and reduce the incidence of SUI following prostatectomy. The positive results of the treatment protocol with WBVT and the improvement in patients' quality of life might be due to the enhancement of all body muscles that control the passage of urine through the bladder [21], and resulted in a considerable decrease in urine loss after prostatectomy [39].

This study contradicts the findings of Farzinmehr *et al.* [19], who compared the effects of WBVT and PFMT in the

Table 2
Outcome results of all parameters at baseline, after 4 weeks and at 2-month follow-up.

Variable	Group	Baseline	After 4 weeks	Follow-up	*P*-Value
I-VAS score (cm), median (IQR)	Group 1	7.9 (7.5 to 8.5)	4 (3.5 to 4.2)	2.0 (1.9 to 2.4)	<0.001[a]
	Group 2	7.7 (7.3 to 8.7)	7.8 (7.3 to 8.6)	6.8 (6.3 to 7.5)	<0.001[a]
P-value		0.739	<0.001[a]	<0.001[a]	
ICIQ-UI-SF score, median (IQR)	Group 1	15.5 (14 to 18)	9 (6.8 to 10.3)	5 (4 to 6)	<0.001[a]
	Group 2	17 (14 to 18)	15 (12 to 17.3)	12 (10.8 to 14)	<0.001[a]
P-value		0.498	<0.001[a]	<0.001[a]	
24-hour pad test result (g), mean (SD)	Group 1	90.5 (5)	44.1 (7.6)	29.6 (10.5)	<0.001[a]
	Group 2	90.0 (7.3)	61.1 (5.3)	52.7 (5.3)	<0.001[a]
P-value		0.801	<0.001[a]	<0.001[a]	

I-VAS, Incontinence Visual Analogue Scale; ICIQ-UI-SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form; SD, standard deviation; IQR, interquartile range.
[a] Significant difference.

Table 3
Mean differences in improvement for the Incontinence Visual Analogue Scale (I-VAS) score, International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF) score and 24-hour pad test result of both groups.

Group	Time	Time	I-VAS score (cm)		ICIQ-UI-SF score		24-hour pad test result (g)	
			Median difference	95% CI of median difference	Median difference	95% CI of median difference	Mean difference	95% CI of mean difference
Group 1	Baseline	After 4 weeks	−3.9[a]	−4.0 to −3.8	−6.5[a]	−7.2 to −5.8	46.5[a]	43.8 to 49.1
		Follow-up	−5.9[a]	−6.1 to −5.7	−10.5[a]	−11.1 to −9.9	61.0[a]	57.6 to 64.4
	After 4 weeks	Follow-up	−2.0[a]	−2.2 to −1.8	−4.0[a]	−4.6 to −3.4	14.5[a]	12.5 to 16.5
Group 2	Baseline	After 4 weeks	0.1	−0.01 to 0.21	−2.0[a]	−2.69 to −1.31	28.8[a]	25.5 to 32.2
		Follow-up	−0.9[a]	−1.1 to −0.7	−5.0[a]	−5.83 to −4.17	37.3[a]	34.6 to 40.0
	After 4 weeks	Follow-up	−1.0[a]	−1.19 to −0.81	−3.0[a]	−3.46 to −2.54	8.4[a]	6.6 to 10.3

[a] Significant difference.

treatment of SUI in women, and concluded that there was no significant difference between the two types of treatment. On the other hand, the present study parallels their findings in that WBVT produced a considerable effect in reducing SUI symptoms within a period of 4 weeks, and this effect was maintained until the follow-up measurements. For this reason, further studies are needed to compare the effects of WBVT in the treatment of SUI in both male and female patients.

This study found that patients with post-prostatectomy SUI achieve improvement and significant changes in all measured parameters after completing an exercise regimen for the PFMs. PFMT enhances muscle stiffness and tone [25,26]. Previous studies have recorded a rapid restoration of continence in those who performed PFMT systematically. In a study by Van Kampen *et al.* [27], a high percentage of patients who performed PFMT were fully continent 3 months after prostatectomy compared with those who did not receive this type of training. In a study conducted by Filocamo *et al.* [26], similar outcomes were noted in patients who performed PFMT compared with those who did not undergo the training protocol.

Limitations

The limitations of this study include the absence of a control group due to ethical issues, and insufficient supporting studies that used WBVT as a treatment modality for SUI following prostatectomy. Further studies using electromyography may be needed to determine the exact power measurements of the PFMs and other muscles that control the passage of urine.

Conclusion

Participants showed considerable improvement in symptoms of SUI after RP after 4 weeks of WBVT and at 2 months follow-up. The observed improvement included decreased I-VAS and ICIQ-UI-SF scores and decreased weight of pads in the 24-hour pad test. It can be concluded that WBVT is a novel effective modality that can be added to the treatment programme of patients with SUI. Further investigations with a larger sample, a longer study duration, and other types of incontinence could be conducted.

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Ethical approval: This study was approved by the Research Ethical Committee (P.T. REC/012/001250) of the Faculty of Physical Therapy, Cairo University.

Conflict of interest: None declared.

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