Brief Report

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Effectiveness of ultrasound-guided pelvic floor muscle training in improving prolonged urinary incontinence after robot-assisted radical prostatectomy

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SUMMARY Persistence of urinary incontinence (UI) after robot-assisted radical prostatectomy (RARP) is a bothersome problem because of its negative effect on the patient's quality of life (QOL). This study aimed to evaluate the effect of transperineal ultrasound (TPUS)-guided pelvic floor muscle training (PFMT) on prolonged UI after RARP. Thirty men with stress UI persisting for > 1 year after RARP underwent biofeedback PFMT using TPUS once every 2-3 weeks for 3 months. The frequency and duration of sustaining pelvic floor muscle (PFM) contractions were assessed using ultrasound imaging. The severity of UI and UI-related QOL were evaluated using a 24-hour pad test and the incontinence quality of life (I-QOL) questionnaire. Twenty-four men (mean age, 72.2 years) completed the TPUS-guided PFMT. The mean duration from RARP to PFMT was 1,228.9 days. The mean cumulative session and the total duration of TPUS-guided PFMT were 4.6 times and 73.3 days, respectively. Compared with the data before TPUS-guided PFMT, the frequency of PFM contractions and duration of sustaining contraction significantly improved after TPUS-guided PFMT ($p < 0.05$). Additionally, the total amount of urinary leakage after TPUS-guided PFMT was reduced significantly (248.6 ± 280.6 g *vs*. 397.0 ± 427.0 g, $p = 0.024$). The I-QOL score was significantly increased after TPUS-guided PFMT (72.1 ± 16.8 *vs*. 61.0 ± 19.0, $p < 0.001$). TPUS-guided PFMT may be effective in improving prolonged UI occurring > 1 year after RARP.

Keywords biofeedback, physiotherapy, urinary leakage, quality of life, transperineal ultrasound

1. Introduction

Urinary incontinence (UI) after robot-assisted radical prostatectomy (RARP) is a common complication and has a negative effect on the patient's quality of life (QOL) (*1,2*). Approximately 90% of patients experience UI after RARP (*1,2*) and approximately 10% experience UI at 1 year after RARP (*3,4*). Although artificial urethral sphincter placement is recommended as the gold standard of treatment for these patients (*5,6*), inherent incidences of adverse events, such as device infection and malfunction, urethral erosion, and atrophy, have been reported (*7*). These risks deter possible placements of the artificial urethral sphincter in patients. However, patients with prolonged UI for > 1 year after RARP are reluctant to accept a lower QOL caused by UI. The long-term negative effects of UI on the QOL of these patients are concerning.

Generally, pelvic floor muscle training (PFMT) is advocated as the first choice of conservative treatment (*8*) for all patients immediately after RARP (*9*). This is because the main cause of UI is insufficient urethral closure because of urinary sphincter dysfunction following intraoperative nerve damage (*10*). PFMT promotes urethral closure by increasing the strength of the pelvic floor muscle (PFM). To reduce the amount of urinary leakage after RARP, the patients should relearn how to contract the PFM to close the urethra sufficiently. Modalities that utilize biofeedback (BF) for self-recognition of PFM contractions, such as digital palpation, electromyography (*11,12*), and ultrasound (US) imaging (*13*), have been recommended additions to PFMT. Our recent study (*14*) suggests that transperineal ultrasound (TPUS) guided PFMT effectively helps men after RARP relearn PFM contractions to reduce the amount of urinary leakage. US images showed the extent of urethral closure when a patient contracts the PFM. As a BF, TPUS allows visualization of urethral closures and facilitates self-awareness of urethral closure during PFM contractions.

Considering that patients presenting with prolonged UI are likely to have more severe damage to the urinary sphincter, TPUS may be more useful than digital palpation or electromyography in these patients. However, the effectiveness of TPUS-guided PFMT in improving prolonged UI after RARP has not been adequately studied. Therefore, this study aimed to evaluate the effect of PFMT with TPUS on prolonged UI that has lasted for > 1 year after RARP.

2. Materials and Methods

2.1. Study design and setting

This prospective interventional study was conducted between April 2018 and October 2019 at a university hospital in Tokyo. The study protocol was approved by the Research Ethics Committee of the authors' institute (approval no: 10921-(1), 2373-(2)). Each study participant provided written informed consent.

2.2. Patients

The study included male patients who underwent RARP using the peritoneal approach (*15*) at our institution and complained of stress urinary incontinence (SUI) persisting for > 1 year after RARP. The exclusion criteria were as follows: < 20 g per day of urinary leakage, urgency UI, disability-associated UI, severe mental disease or cognitive impairment, a known neurological disorder affecting the lower urinary tract function, restricted physical activity, and an inability to understand Japanese.

2.3. Procedure

Patients who met the inclusion criteria were introduced to the TPUS-guided PFMT protocol by their physicians. If the patient showed a willingness to take the TPUS-guided PFMT, they underwent TPUS-guided PFMT that was performed by a physiotherapist. The physiotherapist provided the patient with instruction on the anatomy of the pelvic floor and the mechanism of continence using a leaflet and an anatomical model of the pelvis. All participants attended TPUS-guided PFMT once every 2-3 weeks for up to 3 months. The frequency of PFMT depended on the patient's circumstances, such as work schedule and transportation difficulty. After receiving individual BF in every TPUS-guided PFMT session, the patient was instructed on the training load of PFMT at home.

2.4. TPUS-guided PFMT

The procedure of performing TPUS-guided PFMT has been described in our previous study (*14*). US observation was conducted with the patient in a lateral position, in which the penis and scrotum were not seen or touched when the US transducer was placed on the perineal area. A 1- to 5-MHz two-dimensional curved array ultrasound transducer was used (Noblus; Hitachi, Ltd., Tokyo, Japan) to visualize PFM contraction. When the US transducer was placed on the perineal skin in the midsagittal plane, the image showed the bladder neck, proximal urethra, paraurethral tissue, and PFM (Figure 1). When a patient contracted the PFM correctly, movement of the anorectal angle toward the posterior aspect of the pubic symphysis was observed, resulting in shortening of the diameter of the membranous urethra and closure of the bladder neck on US images. Therefore, patients could recognize the strength and sensation of optimal PFM contractions without the activity of other muscles, such as the abdominal muscles. When providing BF using US images, the physiotherapist gave verbal instructions to the patients to retract the penis, elevate the penis from the root, and pull the scrotum upward to help them become aware of the contractions of the PFM. If patients could contract the PFM correctly, the physiotherapist instructed the patients to perform the following two types of PFM contractions at maximum strength: the first type was to repeat the contractions up to 10 times, and the second type was to sustain the contraction for up to 10 seconds (*16*). Based on the patient's performance at each TPUS-guided PFMT, the physiotherapist discussed with the patient the individual PFMT load that should be performed at home.

2.5. Measurements

The function of PFM, the severity of urinary leakage, and QOL related to UI were measured before and after TPUS-guided PFMT. The function of PFM, including the frequency of PFM contractions, and the duration of maintaining the contraction, was evaluated by the physiotherapist. The frequency of PFM contractions was measured by counting the number of times the patients could repeat the contractions correctly at maximum strength on the US monitor. The duration of sustained contraction was evaluated by observing how long they could hold the maximum contraction on the US monitor.

The two-day data of the 24-hour pad test were used to evaluate the severity of UI. To determine the average effect of daily variation in physical activity, the average amount of urinary leakage for 2 days was calculated. QOL related to UI was measured using the Incontinence-QOL (I-QOL), which was previously validated for the Japanese language (*17*). The 22 items in the I-QOL, each with a 5-point Likert scale, were summed and then transformed to a scale of 0-100, with a high score representing a high QOL.

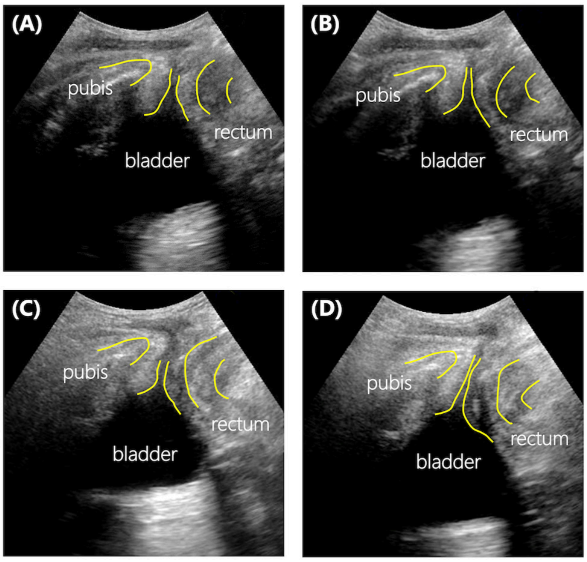

Figure 1. Transperineal ultrasound images of a patient who underwent RARP shows urethral closure in the midsagittal plane. First TPUS-guided PFMT **(A)** at rest and **(B)** during contraction of the pelvic floor muscle. Last TPUS-guided PFMT **(C)** at rest and **(D)** during contraction of the pelvic floor muscle. RARP, robot-assisted radical prostatectomy; TPUS, transperineal ultrasound; PFMT, pelvic floor muscle training.

The patients' demographic data and perioperative parameters (nerve-sparing, lymph node dissection, resected prostate volume) were obtained from their medical records.

2.6. Statistical analysis

Means and standard deviations were used for descriptive data. A paired *t*-test was performed to compare data obtained before and after TPUS-guided PFMT. All p-values were two-sided. A *p*-value of < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows version 23.0 software (IBM Corp, Armonk, NY, USA).

3. Results and Discussion

3.1. Patients

Among the 30 patients who met the inclusion criteria, three were excluded because of lack of data on urinary leakage before TPUS-guided PFMT, and three other patients withdrew from the study because of difficulty in visiting the hospital regularly. Thus, 24 patients who completed the TPUS-PFMT regimen were included in the analysis (Figure 2).

The patients had a mean age of 72.2 years (range, 60-79 years) and mean body mass index of 23.8 ± 1.9 kg/m^2. Of them, 13 patients (54.2%) were employed; 6 patients (25.0%) regularly took medications for lower urinary tract symptoms; and 5 patients (20.8%) had received additional radiation or androgen deprivation therapy after RARP (Table 1). There was no change in

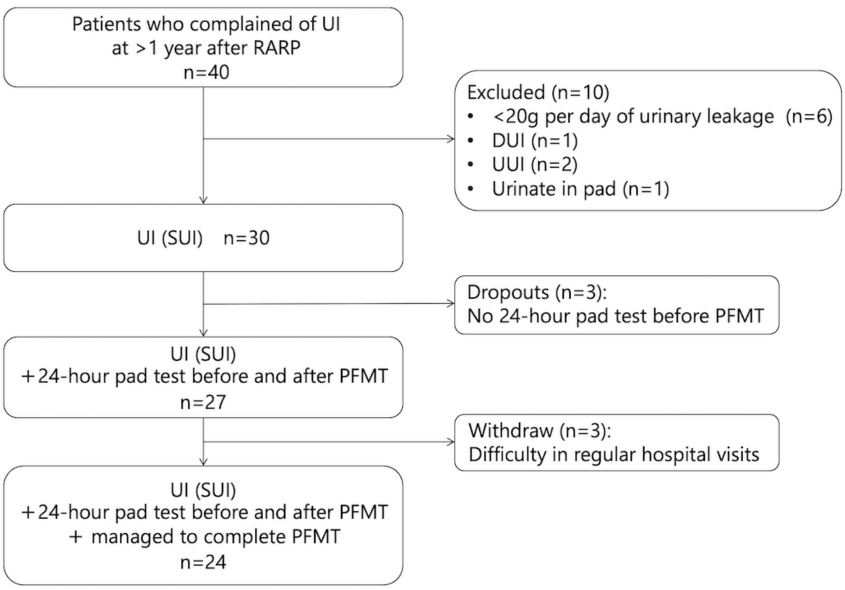

Figure 2. Flow chart of the participants in the study. UI, urinary incontinence; RARP, robot-assisted radical prostatectomy; DUI, disability-associated UI; UUI, urgency UI; SUI, stress UI; PFMT, pelvic floor muscle training.

medication during the period of TPUS-guided PFMT.

The mean duration from RARP to TPUS-guided PFMT was 1,228.9 ± 610.7 days. The cumulative session of TPUS-PFMT was 4.6 ± 0.9 times. The interval between each session was 20.3 ± 4.8 days. The total duration of TPUS-guided PFMT was 73.3 ± 17.4 days (Table 2).

Table 1. Demographic data and surgical outcomes of the participants (n = 24)

Variable	
Age (years)	72.2 ± 5.1
Body mass index (kg/m^2)	23.8 ± 1.9
Having a job (yes)	13 (54.2%)
Leisure activity (yes)	12 (50.0%)
Disease	
Hypertension	11 (45.8%)
Diabetes	4 (16.7%)
Heart disease	3 (12.5%)
Hyperlipidemia	1 (4.2%)
Surgery of inguinal hernia	6 (25.0%)
Drug related to LUTS*	
Anticholinergic drugs	2 (8.3%)
β3 adrenoceptor agonists	4 (16.7%)
Initial serum PSA	12.0 ± 13.5
Nerve sparing (yes)	5 (20.9%)
Unilateral (yes)	4 (16.7%)
Bilateral (yes)	1 (4.2%)
Lymph node dissection (yes)	6 (25.0%)
Resected prostate volume (ml)	39.3 ± 13.4
Radiation therapy after RARP (yes)	2 (8.3%)
Androgen deprivation therapy after RARP (yes)	3 (12.5%)

Mean ± standard deviation (range), n (%). *LUTS: lower urinary tract symptoms; PSA: prostate-specific antigen; RARP: robot-assisted radical prostatectomy.

Table 2. Attendance of clinic pelvic floor muscle training

Variable	
Starting day of training after RARP* (days)	1228.9 ± 610.7 (431-2,618)
Cumulative session of PFMTs (times)	4.6 ± 0.9 (3-6)
Interval between each session (days)	20.3 ± 4.8 (11-42)
Total duration of PFMTs (days)	73.3 ± 17.4 (40-101)

Mean ± standard deviation (range). *RARP: robot-assisted radical prostatectomy; PFMT: pelvic floor muscle training.

3.2. Change of the PFM function after the TPUS-guided PFMT

Table 3 summarizes the changes in the function of the PFM, UI amount, and I-QOL score after TPUS-guided PFMT. The frequency of PFM contractions after TPUS-guided PFMT was significantly higher than that before TPUS-guided PFMT (pre-PFMT; 7.5 ± 2.5 *vs*. post-PFMT; 10.0 ± 0 times, $p < 0.001$); furthermore, all patients could repeat PFM contractions 10 times. The duration of maintaining the contraction was significantly longer after TPUS-guided PFMT than before training (pre-PFMT 2.6 ± 1.8 *vs*. post-PFMT 9.0 ± 1.9 s, $p = 0.017$). The average amount of urinary leakage for 2 days after TPUS-PFMT was significantly lower than the pre-training amounts (pre-PFMT 397.0 ± 427.0 *vs*. post-PFMT 248.6 ± 280.6, $p = 0.024$). The I-QOL score after TPUS-guided PFMT was significantly higher than that before TPUS-guided PFMT (pre-PFMT 61.0 ± 19.0 *vs*. post-PFMT 72.1 ± 16.8, $p < 0.001$).

3.3. Change of urinary leakage after the TPUS-guided PFMT

The amount of urinary leakage decreased significantly after TPUS-guided PFMT with a mean total duration of 73.3 ± 17.4 days (Table 3). The 3-month duration has been recommended for PFMT in both male and female patients (*18,19*), as it takes approximately 3 months for the PFM, a skeletal muscle, to be strong enough to continuously close the urethra (*20,21*). Generally, men use quick contraction of the PFM to squeeze urine out of the urethra after urination, and this sensation of muscle contraction is retained even after RARP. These quick contractions can maintain urethral closure during momentary increases in intra-abdominal pressure, such as when coughing or standing up. The sustained contractions keep the urethra closed during activities of daily living (ADL), such as walking and performing housework (*22*). Enhancement of the ability to sustain these contractions is the target of PFMT to ensure urethral closure during ADL. Thus, the 3-month PFMT

Table 3. Changes in PFM strength, amount of urinary incontinence per day, and QOL before and after the US-guided PFMT

Variable	Before	After	p
Frequency of PFM contraction (times)	7.5 ± 2.5	10.0 ± 0	< 0.001
Duration of keeping contraction (sec)	2.6 ± 1.8	9.0 ± 1.9	0.017
Total urine leakage (g)	397.0 ± 427.0	248.6 ± 280.6	0.024
QOL*			
I-QOL	61.0 ± 19.0	72.1 ± 16.8	< 0.001

Mean ± standard deviation. Paired t test. *QOL: quality of life; US: ultrasound; PFM: pelvic floor muscle; PFMT: pelvic floor muscle training; I-QOL: Incontinence-QOL.

for prolonged UI in our study is useful in improving the function of the PFM to prevent urinary leakage, and our findings are comparable to those of previous studies (*23*).

A previous study (*24*) showed that behavioral therapy, including PFMT, bladder control strategies, fluid management, and self-monitoring with bladder diaries improved prolonged UI of > 1 year after RARP. However, their study could not demonstrate the added value of BF using surface electromyography. Given that patients with UI after RARP are presumed to have decreased awareness of the contraction of the PFM around the urethra, BF would be beneficial for patients who are relearning how to perform PFM contractions. Based on our previous study (*14*) that showed the advantages of visualizing the urethra by TPUS as BF, we hypothesized that TPUS facilitates relearning of PFM contractions as well as controlling optimal contractions to close the urethra even years after RARP. In the present study, patients with prolonged UI could not sustain maximum PFM contractions for more than 3 seconds at the commencement of TPUS-guided PFMT. However, after 3 months of TPUS-guided PFMT, the strength of the PFM improved significantly enough to sustain maximum contractions for up to 9 seconds. TPUS allowed the patients to visualize the correct PFM contraction required to close the urethra. This is an advantage of TPUS, giving patients the ability to strengthen the PFM any time without supervision (*e.g.*, self-training at home). TPUS is speculated as an ideal BF for promoting self-awareness of urethral closure for patients with prolonged UI.

Our data show that the I-QOL score improved after 3 months of TPUS-guided PFMT, despite the mean amount of urinary leakage being 248.6 g per day (Table 3). Changing pads a few times a day for moderate amounts of urinary leakage is still burdensome to patients. The I-QOL score improved possibly because of the reduction in overall urinary leakage, which gave patients the confidence that PFMT will eventually improve their UI, even years after RARP. In a previous study (*25*), I-QOL scores increased when the amount of urinary leakage decreased immediately after RARP. The patients felt accomplished when they could successfully manage their incontinence even though they only had small improvements in their symptoms. Another explanation could be that being able to control PFM contraction, thereby preventing urinary leakage, helped the patients to regain their self-esteem.

Generally, patients receive PFMT once every 2-4 weeks (*18,23*). Owing to the more severe damage of the PFM, patients with prolonged UI should undergo frequent sessions to retrain the PFM. In our TPUS-guided PFMT regimen, patients visited the hospital once every 2-3 weeks. TPUS-guided PFMT allowed patients to look at images and repeatedly match the sensations of PFM contraction to the actual contractions. The awareness of the correct contraction gave patients the confidence to continue PFMT at home and minimize the frequency of hospital visits. Most patients undergo RARP in their early 70s. Half of them still have jobs or engage in leisure activities. Considering that a few participants withdrew from the study because of the difficulty in visiting the hospital regularly, the TPUS-guided PFMT protocol has the advantage of maintaining the patient's lifestyle.

This study has several limitations. First, this study did not have a control group to confirm the efficacy and feasibility of the TPUS-guided PFMT for prolonged UI. A randomized controlled trial is required to verify the effectiveness of this treatment strategy. Second, this study included a few patients with severe urinary leakage of > 500 g per day. These patients are considered to have more severe damage to the PFM. Thus, the effectiveness of the TPUS-PFMT in these patients with severe UI needs to be interpreted cautiously, which require further investigation.

In conclusion, our results suggest that the TPUS-PFMT may improve UI prolonged for > 1 year after RARP by increasing the strength of PFM.

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