

A Randomized Controlled Trial Comparing the Effects of Pelvic Floor Muscle Training Alone and Biofeedback Combined with Pelvic Floor Muscle Training on Urinary Incontinence after Laparoscopic Radical Prostatectomy

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Objective: To improve urinary continence recovery after laparoscopic radical prostatectomy, this randomized controlled trial (RCT) evaluated the effectiveness of combining biofeedback (BF) with pelvic floor muscle training (PFMT). Urinary incontinence significantly impacts patients' quality of life, and BF may enhance PFMT, making rehabilitation more effective than PFMT alone.

Materials and Methods: The present study included prostate cancer patients at Vajira Hospital between March 2022 and December 2024. Participants were randomized into two groups: group A (PFMT alone) and group B (BF+PFMT) completing a 12-week program. Urinary continence was assessed using the 1-hour pad test and ICIQ-UI Short Form scores at baseline, 4, 8, and 12 weeks post-catheter removal. Statistical analyses included t-tests, Mann-Whitney U tests, chi-square tests, and odds ratios.

Results: Sixty-eight patients, with 34 per group, were analyzed. Both groups had similar baseline characteristics. No significant differences were found in continence outcomes at later time points, but group B showed significantly greater improvement in the 1-hour pad test within the first four weeks ($p=0.009$). Patients in group B were 3.04 times more likely to experience early improvement ($p=0.027$).

Conclusion: PFMT and BF+PFMT improve urinary continence, with BF offering short-term benefits but no long-term advantage. PFMT remains a reliable intervention, while BF may aid early recovery. Patients should be counseled on potential early continence decline to set expectations and encourage adherence, supporting BF use in the early postoperative period, at four weeks. The study was limited by limited sample size, follow-up, and adherence, thus, a larger RCT is needed.

Keywords: Urinary incontinence; Pelvic floor muscle training; Biofeedback therapy; Laparoscopic radical prostatectomy; Post-prostatectomy incontinence; Urinary leakage recovery

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Post-prostatectomy incontinence (PPI) is a common and challenging complication after laparoscopic radical prostatectomy (LRP), significantly affecting patients' quality of life⁽¹⁾. Prostate cancer is the second most common malignancy in men worldwide⁽²⁾, with 1.1 million new cases annually⁽³⁾. In Thailand, it ranks fourth

after liver, lung, and colorectal cancer⁽⁴⁾. Radical prostatectomy (RP) remains a key treatment for localized prostate cancer but has a high incidence of urinary incontinence, with up to 90%^(5,6), leading to emotional distress and financial burdens⁽⁷⁾.

PPI primarily results from weakened pelvic floor muscles after prostate removal. Pelvic floor muscle training (PFMT) is the first-line conservative treatment, helping strengthen muscles for better urinary control^(1,5). PFMT is widely used in Thailand as a non-invasive management strategy, gaining recognition in clinical and rehabilitation settings.

Biofeedback (BF) therapy is an emerging adjunct that enhances PFMT by providing real-time feedback on muscle activity, optimizing engagement during rehabilitation⁽⁸⁾.

While both PFMT and BF have been individually effective, limited research compares the efficacy of their combination versus PFMT alone in PPI^(6,9-13).

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The present study aimed to fill this gap by evaluating PFMT alone versus PFMT combined with BF in Thai men with PPI. Findings could inform clinical practice and rehabilitation strategies, improving patient recovery and quality of life after prostate cancer surgery in Thailand.

MATERIALS AND METHODS

Ethics approval

The present study was approved by the Institutional Review Board, Faculty of Medicine, Vajira Hospital, under certificate of approval No. COA056/2565.

Study design

The present study was a randomized controlled trial. Participants received detailed explanations before intervention and provided informed consent, and data integrity was ensured through independent, accurate, and complete collection. Additionally, this clinical trial has been registered in the Thai Clinical Trials Registry (TCTR) with the identification number TCTR20250317014 (<https://www.thaiclinicaltrials.org/show/TCTR20250317014>).

Population

The researchers enrolled male patients diagnosed with prostate cancer who underwent non-nerve-sparing LRP, which was the sole surgical approach used at the present hospital, between March 1, 2022, and December 31, 2024. Sixty-eight patients with urinary incontinence were initially screened. The inclusion criteria were male patients who had undergone non-nerve-sparing LRP. Exclusion criteria included those who did not consent, regained immediate continence, were lost to follow-up, had neurological deficiencies, other causes of incontinence, prior pelvic radiation, or contraindications to fluid restriction. Sixty-eight patients were included in the final analysis.

Randomization and intervention

Patients were randomized into two groups by Block of four into group A receiving PFMT alone and group B performing BF and PFMT.

Procedure

Before training, patients were educated on pelvic floor muscle anatomy and the purpose of the exercise program⁽¹⁴⁾. Both groups received verbal instructions on Kegel exercises, incorporating slow-twitch and fast-twitch contractions.

For slow-twitch contractions, patients performed

a full pelvic floor contraction, holding for five seconds, followed by a five-second rest, repeating five times. For fast-twitch contractions, they contracted forcefully, then relaxed immediately, resting five seconds before repeating five times. Each set included 10 repetitions, with patients instructed to complete at least 30 repetitions, or three sets, per day, at least four days a week in their preferred position.

Group B utilized BF therapy with the Urostym device (Laborie Medical Technologies Inc.). Electrodes were placed peri-anally at 10 o'clock and 2 or 3 o'clock positions, with a ground electrode. For abdominal monitoring, two electrodes were placed one inch apart on the lower abdomen, aligned with the hips, plus a separate ground electrode.

Patients sat in a chair while electrodes were positioned. The BF program was customized based on individual needs, with Beginner Incontinence Treatment, Incont. at the start of treatment, or Incont. at the end of treatment. Medical personnel supervised the procedure to ensure patient safety, monitoring for any adverse effects throughout the treatment.

Primary and secondary results

The primary outcome was urinary leakage volume, measured by the 1-hour pad test. Participants drank 500 mL of water and performed activities like coughing, sneezing, and sitting-to-standing movements to induce leakage. The pad was weighed after one hour to determine urine loss. The secondary outcome was urinary incontinence severity, assessed using the International Consultation on Incontinence Questionnaire-Urinary Incontinence (ICIQ-UI) Short Form (Thai version)⁽¹⁵⁾, a self-reported measure of incontinence impact. The data would be collected in weeks 0, 4, 8, and 12 after foley catheter removal.

Statistical data analysis

All statistical analyses were conducted using JASP software (version 0.19.1.0). For continuous variables, normality was assessed using the Shapiro-Wilk test. If the data were normally distributed, comparisons were made using the independent Student's t-test. For non-normally distributed data, the Mann-Whitney U test was used. Categorical variables and binary variables were compared using chi-square tests, and odds ratios (OR) with 95% confidence intervals (CI) were calculated for binary outcomes to assess the strength of associations.

RESULTS

The demographic and clinical characteristics of

Table 1. Basic demographic and clinical characteristics

	Group A (n=34)	Group B (n=34)	p-value
Age (years); mean±SD	68.47±7.32	68.59±6.37	0.944
Weight (kg); mean±SD	66.75±10.92	70.53±11.81	0.176
Height (m); mean±SD	165.71±6.03	166.18±6.38	0.756
BMI (kg/m ²); mean±SD	24.27±3.50	25.56±4.07	0.167
Underlying disease; n			
DM			0.779
• Yes	8	9	
• No	26	25	
HT			1.000
• Yes	22	22	
• No	12	12	
DLP			0.462
• Yes	18	21	
• No	16	13	
Preoperative PSA*; median (IQR)	12.29 (6.25 to 23.53)	11.43 (6.51 to 14.70)	0.367
Clinical T; n			0.657
T1			
• T1a	0	1	
• T1b	2	2	
• T1c	26	24	
T2			
• T2a	3	3	
• T2b	3	2	
• T2c	0	2	
T3			
• T3a	-	-	
• T3b	-	-	
T4			
• T4a	-	-	
• T4b	-	-	
• T4c	-	-	

	Group A (n=34)	Group B (n=34)	p-value
Preoperative grade group; n			0.730
1	9	11	
2	16	17	
3	4	1	
4	2	2	
5	3	3	
Operation time (minutes); mean±SD	212.79±38.40	201.77±36.58	0.230
Estimated blood loss (mL)*; median (IQR)	200 (200 to 400)	200 (162.50 to 375)	0.671
Pathological grade group; n			0.532
1	3	6	
2	20	13	
3	7	10	
4	1	1	
5	3	4	
Pathological T; n			0.613
T2	15	17	
T3			
• T3a	6	8	
• T3b	3	2	
T4	2	0	
R1	8	7	
Prostate volume (g)*; median (IQR)	42.50 (35.25 to 59.75)	39.50 (34.25 to 43.25)	0.134
Catheter removal time (days); mean±SD	21.00±4.95	19.68±4.80	0.267

BMI=body mass index; DM=diabetes mellitus; HT=hypertension; DLP=dyslipidemia; PSA=prostate specific antigen; SD=standard deviation; IQR=interquartile range

* Non-normally distributed data, data are presented as median (IQR, 25th to 75th percentiles)

the participants in both groups are summarized in Table 1. The mean age was comparable between group A at 68.47±7.32 years and group B at 68.59±6.37 years, with no statistically significant difference (p=0.944). Similarly, body weight, height, and body mass index (BMI) showed no significant differences between the groups, with p-values of 0.176, 0.756, and 0.167, respectively. Regarding comorbidities, both groups had similar distributions of underlying conditions with no significant differences observed. Preoperative prostate-specific antigen (PSA) levels were higher in group A, with a median of 12.29 (IQR 6.25 to 23.53) ng/mL compared to group B with a median of 11.43 (IQR 6.51 to 14.70) ng/mL, but this difference was not statistically significant (p=0.367). The clinical T staging was comparable between the groups, with most participants classified as T1c. Similarly, there were no significant differences in preoperative grade group distributions or pathological grade group distributions following surgery. The

mean operation time was slightly longer in group A at 212.79±38.40 minutes compared to group B at 201.77±36.58 minutes, but this difference did not reach statistical significance (p=0.230). Estimated blood loss (EBL) was also similar between the groups at 200 (200 to 400) mL versus 200 (162.50 to 375) mL (p=0.671). Pathological T staging and margin status (R1) showed no significant differences, with similar distributions observed in both groups. The prostate volume was slightly higher in group A at 42.50 (35.25 to 59.75) grams compared to group B at 39.50 (34.25 to 43.25) grams, but the difference was not statistically significant (p=0.134). Finally, the duration of catheterization was comparable between the groups, with mean durations of 21.00±4.95 days and 19.68±4.80 days for group A and group B, respectively (p=0.267).

At weeks 0, 4, 8, and 12, the results of the 1-hour pad test showed no statistically significant differences between group A and group B. At week 0, the median

Table 2. Comparison of primary results and secondary results among groups and within the group

	Group A	Group B	p-value
1-hour pad test; median (IQR)			
Baseline (0 week)	46(20 to 80)	81.5 (28.75 to 116.33)	0.053
After 4 weeks	27.8 (15.6 to 60.38)	26 (10.43 to 49.75)	0.564
After 8 weeks	19 (10 to 31.8)	20 (11.55 to 53)	0.348
After 12 weeks	13.9 (8.38 to 31.3)	11.08 (9.15 to 30.45)	0.956
ICIQ-UI Short Form score (Thai version); mean±SD			
Baseline (0 week)	8.82±4.30	9.74±4.43	0.392
After 4 weeks	10.21±3.02	10.5±2.30	0.653
After 8 weeks	9.62±2.31	8.97±2.38	0.259
After 12 weeks	8.53±2.73	8.38±2.64	0.822

ICIQ-UI=International Consultation on Incontinence Questionnaire-Urinary Incontinence; SD=standard deviation; IQR=interquartile range

* Non-normally distributed data, data are presented as median (IQR, 25th to 75th percentiles)

pad weight (IQR, 25th to 75th percentiles) was 46 (20 to 80) mL in group A, compared with 81.5 (28.75 to 116.33) mL in group B ($p=0.053$). At week 4, the median values were 27.8 (15.6 to 60.38) mL for group A and 26 (10.43 to 49.75) mL for group B ($p=0.564$). At week 8, group A recorded a median pad weight of 19 (10 to 31.8) mL, while group B had 20 (11.55 to 53) mL ($p=0.348$). At week 12, the median pad weights were 13.9 (8.38 to 31.3) mL for group A and 11.08 (9.15 to 30.45) mL for group B ($p=0.950$).

Similarly, the ICIQ-UI Short Form scores (Thai version) revealed no significant differences between the two groups at any time point. At week 0, group A had a mean score of 8.82 ± 4.30 , while group B had a mean score of 9.74 ± 4.43 ($p=0.392$). At week 4, the mean scores were 10.21 ± 3.02 for group A and 10.50 ± 2.30 for group B ($p=0.653$). At week 8, the scores were 9.62 ± 2.31 and 8.97 ± 2.38 for group A and group B, respectively ($p=0.259$). Finally, at week 12, the mean scores were 8.53 ± 2.73 for group A and 8.38 ± 2.64 for group B ($p=0.822$) (Table 2).

The authors observed a notable decrease in urinary leakage from baseline to week 4 in group B (PFMT+BF) based on the 1-hour pad test. To further analyze this improvement, the authors assessed the mean change over time to determine the extent of BF's early impact on urinary continence recovery.

The 1-hour pad test results showed varying degrees of improvement between the two groups. In group A, the median (IQR) reductions were -2 (-20.5 to 8.95) mL at 0 to 4 weeks, -7.95 (-41.13 to 0.75) mL at 0 to 8 weeks, and -18.5 (-55.68 to 5.78) mL at 0 to 12 weeks. In contrast, group B demonstrated greater reductions, with median (IQR) values of -22.65 (-83.25 to -3) mL, -30 (-91.05 to 6.68) mL, and -33 (-87.65 to 17.19) mL over the same intervals. A

statistically significant difference between the groups was observed at 0 to 4 weeks ($p=0.009$), suggesting that BF may enhance the short-term effectiveness of PFMT. However, no significant differences were found at 0 to 8 weeks ($p=0.189$) or 0 to 12 weeks ($p=0.071$), indicating that the long-term benefit of adding BF may be less pronounced.

In contrast to the 1-hour pad test, the ICIQ-UI Short Form scores (Thai version) did not exhibit significant differences between the two groups at any time point. At 0 to 4 weeks, group A showed a mean change of 1.38 ± 5.31 , compared to 0.77 ± 4.34 in group B ($p=0.601$). At 0 to 8 weeks, the median (IQR) changes were 1 (-1.75 to 4.75) in group A and -1 (-3.75 to 2) in group B ($p=0.127$). At 0 to 12 weeks, the mean changes were -0.29 ± 5.45 for group A and -1.35 ± 4.79 for group B ($p=0.398$). These results suggested that neither intervention provided a significant advantage in improving quality-of-life measures over the study period (Table 3).

To further investigate the comparative effectiveness of the two interventions (Table 4), this study assessed their effectiveness by analyzing the mean percentage changes from baseline for both the 1-hour pad test and the ICIQ-UI Short Form scores (Thai version) over multiple time points.

The results demonstrated mean percentage changes of -37.22% , -52.82% , and -61.66% , respectively, for the 1-hour pad test and 11.57% , 0.16% , and -8.87% , respectively, for the ICIQ-UI Short Form scores (mean excluding three samples with a baseline score of 0). Lower percentage changes were considered indicative of better treatment effectiveness, whereas higher percentage changes (above the mean) corresponded to less improvement. The chi-square test produced p-values

Table 3. Comparison of mean change in primary results and secondary results

	Group A	Group B	p-value
1-hour pad test; median (IQR)			
Change after 4 weeks	-2 (-20.5 to 8.95)	-22.65 (-83.25 to -3)	0.009
Change after 8 weeks	-7.95 (-41.13 to 0.75)	-30 (-91.05 to 6.68)	0.189
Change after 12 weeks	-18.5 (-55.68 to 5.78)	-33 (-87.65 to -17.19)	0.071
ICIQ-UI Short Form Score (Thai version)			
Change after 4 weeks; mean±SD	1.38±5.31	0.77±4.34	0.601
Change after 8 weeks; median (IQR)	1 (-1.75 to 4.75)	1 (-3.75 to 2)	0.127
Change after 12 weeks; mean±SD	-0.29±5.45	-1.35±4.79	0.398

ICIQ-UI=International Consultation on Incontinence Questionnaire-Urinary Incontinence; SD=standard deviation; IQR=interquartile range

* Non-normally distributed data, data are presented as median (IQR, 25th to 75th percentiles)

Table 4. Comparative effectiveness of the two interventions

Mean			Less than mean		Chi-square p-value	Odds ratio	95% CI
		No	Yes				
% change 1-hour pad test							
After 4 weeks	−37.22%	Group A	24	10	0.027	3.04	1.11 to 8.27
		Group B	15	19			
After 8 weeks	−52.82%	Group A	21	13	0.089	2.31	0.87 to 6.10
		Group B	14	20			
After 12 weeks	−61.66%	Group A	18	16	0.460	1.42	0.55 to 3.70
		Group B	15	19			
% change ICIQ-UI Short Form score (Thai version)							
After 4 weeks	11.57%	Group A	17	17	0.627	1.26	0.49 to 3.29
		Group B	15	19			
After 8 weeks	0.16%	Group A	19	15	0.808	1.13	0.43 to 2.92
		Group B	18	16			
After 12 weeks	−8.87%	Group A	20	14	0.146	2.04	0.77 to 5.36
		Group B	14	20			

ICIQ-UI=International Consultation on Incontinence Questionnaire-Urinary Incontinence; CI=confidence interval

of 0.027, 0.089, and 0.460, respectively, indicating a statistically significant association between the treatment type and improvement status at 4 weeks.

Additionally, the OR at 4 weeks was calculated as 3.04 (95% CI 1.11 to 8.27), suggesting that patients in group B were approximately 3.04 times more likely to experience improvement compared to those in group A. For the other time points, both the chi-square test and OR did not indicate statistically significant differences between the treatment groups.

For the ICIQ-UI Short Form scores (Thai version), the mean percentage changes recorded at weeks 4, 8, and 12 were 11.57%, 0.16%, and 8.87%, respectively. No significant differences were observed between groups across all time points, as indicated by chi-square test p-values of 0.627, 0.808, and 0.146, respectively. The corresponding ORs were 1.26 (95% CI 0.488 to 3.289), 1.13 (95%

CI 0.43 to 2.92), and 2.04 (95% CI 0.77 to 5.36).

DISCUSSION

The present study compared PFMT alone to PFMT with BF (PFMT+BF) in improving urinary continence after non-nerve-sparing LRP. While both interventions led to improvements over 12 weeks, BF did not show significant advantages over PFMT alone. Discussion is divided into three main points.

1. Early-phase urinary leakage (4 weeks)

Urinary leakage peaked at four weeks postoperatively, with the PFMT+BF group experiencing greater reduction with a median of -22.65 (IQR -83.25 to -3) versus -2 (-20.5 to 8.95), ($p=0.009$). The treatment effectiveness was significant (chi-square, $p=0.027$), and PFMT+BF patients were 3.04 times more likely to improve (95%

CI 1.11 to 8.27). BF may aid early motor learning⁽¹⁶⁾, particularly enhancing slow-twitch muscle function crucial for continence.

Factors contributing to temporary worsening over the four weeks include:

- 1) Early muscle adaptation: PFMT-only patients may lack neuromuscular control, while BF provides real-time visual cues, enhancing learning.
- 2) Increased physical activity: Resuming daily tasks at 4 weeks may temporarily worsen incontinence.
- 3) Psychological adaptation: PFMT-only patients may struggle to identify and activate the correct muscles.

2. Long-term outcomes (8 and 12 weeks)

Both groups improved at 8 and 12 weeks, with PFMT+BF showing greater leakage reduction, though differences were statistically insignificant. The Thai ICIQ-UI Short Form showed better symptom reduction in PFMT+BF, though this was not significant ($p=0.822$).

A trend toward significance was observed in the 1-hour pad test at 8 weeks (chi-square, $p=0.089$). Using a 90% CI may suggest a potential association between PFMT+BF and improved symptoms.

3. Objective (the 1-hour pad test) versus subjective (ICIQ-UI Short Form scores) outcomes

The 1-hour pad test consistently demonstrated a reduction in urinary leakage in both groups, confirming the effectiveness of PFMT. However, baseline leakage was higher in the PFMT+BF group than in the PFMT-only group at 81.5 (28.75 to 116.33) mL versus 46 (20 to 80) mL ($p=0.053$), which may have influenced the results.

ICIQ-UI Short Form scores increased slightly in the first four weeks, possibly due to heightened symptom awareness post-treatment. Psychological factors may delay quality-of-life perception, meaning subjective improvement may take longer to align with objective measures.

LIMITATIONS AND FUTURE RESEARCH

The present study has limitations, including a small sample size, short follow-up duration of 12 weeks, and potential variability in patient adherence to PFMT exercises. These factors may have affected the ability to detect significant differences. Future research should involve larger trials with longer follow-ups of 6 to 12 months to assess the long-term benefits of BF-assisted PFMT, with adherence

tracking for more accurate analysis.

CONCLUSION

PFMT is a key rehabilitation method for improving urinary continence after non-nerve-sparing LRP. It provides gradual improvements and should remain a standard part of recovery programs.

Adding BF did not show long-term benefits but helped accelerate early recovery, improving continence 3.04 times faster within the first four weeks. It may boost confidence and neuromuscular adaptation in the early phase.

Patients should be informed about temporary worsening of leakage to set realistic expectations and encourage adherence. Further research is needed to explore BF's long-term impact beyond 12 weeks.

WHAT IS ALREADY KNOWN ABOUT THIS TOPIC?

PPI is a common complication after RP, with incidence reported as high as 90%. The primary mechanism of PPI is pelvic floor muscle weakness resulting from prostate removal. PFMT is the first-line conservative treatment and improves urinary continence outcomes. BF enhances PFMT by providing real-time feedback, improving pelvic floor muscle engagement.

WHAT DOES THIS STUDY ADD?

Both PFMT and BF+PFMT improve urinary continence after LRP. BF provides short-term benefits within the first four weeks but no long-term advantages. PFMT remains effective, with BF potentially aiding early recovery and patient adherence.

AUTHORS' CONTRIBUTIONS

PT: Conceptualization, study design, data collection, data analysis, and writing of the original draft. SS: Supervision, methodology, and critical review and editing of the manuscript.

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CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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