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Integrative Physical Therapy Versus Pelvic Floor Muscle Training for Post-Prostatectomy Stress Urinary Incontinence: A Randomized Controlled Trial

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ABSTRACT

Introduction: Post-prostatectomy stress urinary incontinence (PPSUI) is a common complication of radical prostatectomy. This study aimed to compare the efficacy of integrative physical therapy (IPT) and supervised pelvic floor muscle training (PFMT) in managing PPSUI.

Materials and Methods: Sixty-six men aged 50–80 years with PPSUI were randomly assigned to IPT, PFMT, or control groups. The IPT program included electrotherapy, manual therapy, diaphragmatic breathing, and PFMT. The PFMT group received supervised PFMT. The control group received a sham form of electrotherapy. All interventions were delivered in 12 sessions over four weeks. Outcome measures included voided volume, fluid intake, micturition frequency, incontinence frequency, and health-related quality of life (QoL), assessed using the 12-item short-form (SF-12) questionnaire.

Results: Both IPT and PFMT significantly reduced micturition and incontinence frequency and improved SF-12 scores compared with the control group ($P<0.001$). The control group showed no significant improvements across any outcome measures. IPT demonstrated superior improvements relative to PFMT in micturition frequency, incontinence frequency, and SF-12 scores ($P<0.05$).

Conclusion: IPT and PFMT are effective for PPSUI, with IPT showing greater overall efficacy.

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Introduction

Radical prostatectomy (RP) is a common and effective treatment for localized prostate cancer; however, post-prostatectomy stress urinary incontinence (PPSUI) remains a substantial and persistent problem, impacting both men's physical function and quality of life (QoL) [1]. PPSUI arises primarily from disruption of the urethral sphincter mechanism, reduced periurethral support, and compromised neuromuscular coordination after surgery [2]. The rhabdosphincter and pelvic floor muscles are crucial for urinary continence, acting in concert with the diaphragm to regulate intra-abdominal pressure (IAP) and maintain urethral closure. When these structures are impaired, the ability to modulate IAP and sustain pelvic floor contraction diminishes, undermining postural-pelvic synergy and predisposing to leakage [3].

Given the interplay between muscular support and abdominal pressure, therapeutic strategies that simultaneously address pelvic floor activation and IAP regulation may offer superior benefits compared to interventions focused solely on isolated pelvic floor exercises [3, 4]. Pelvic floor muscle training (PFMT) is widely recognized as the first-line conservative therapy for PPSUI, with multiple studies showing improvements in sphincter strength and continence outcomes [5]. However, PFMT alone may not fully correct deficits in diaphragmatic coordination, lumbopelvic stability, or neuromotor recruitment, all of which significantly contribute to functional continence [6].

Integrative physical therapy (IPT) is a multimodal rehabilitative approach designed to target these complex mechanisms. IPT combines diaphragmatic breathing, electrotherapy, manual therapy, and PFMT to promote neuromuscular recruitment, optimize IAP modulation, and enhance pelvic floor function within a cohesive, functionally integrated framework [7-9]. Despite its theoretical advantages, there is limited empirical evidence directly comparing IPT with standard supervised PFMT in men with PPSUI.

Thus, this randomized controlled trial aimed to compare the effectiveness of IPT versus supervised PFMT in reducing urinary incontinence symptoms and improving health-related QoL (HRQoL) in men with PPSUI following RP. We hypothesized that IPT would yield greater improvements due to its multimodal, physiologically integrated design.

Materials and Methods

Study design:

This randomized controlled trial compared the effects of two active interventions, IPT and supervised PFMT, with a sham-controlled group in men with PPSUI. Participants were randomly assigned to PFMT, IPT, and control groups. The study protocol was independently reviewed and approved by the relevant ethics board. This study was approved by the Ethics Committee of the Rehabilitation Science School of the Shahid Beheshti University of Medical Sciences This study was registered in the Iranian Registry of Clinical Trials (IRCT).

This study was conducted in collaboration with the Urology Department of the regional hospitals. Patient recruitment occurred during routine visits between September 2020 and March 2021, after which the study procedures began. A total of 66 patients were selected according to study criteria and randomly assigned to one of three groups using a random-number generator: PFMT, control, or IPT. This study design, conduct, and reporting adhered to consolidated standards of reporting trials guidelines.

All participants provided written informed consent before enrollment, with explicit acknowledgment of their right to withdraw from the study at any time without penalty. Upon entry, comprehensive baseline assessments were conducted, encompassing demographic data (age, height), detailed medical history, and complete medication reconciliation. Furthermore, baseline HRQoL status and voiding patterns (including voided volume (mL), fluid intake (mL), micturition frequency (per day), and incontinence frequency [per day]) were characterized through the administration of the 12-item short-form (SF-12) health survey and 7-day voiding diaries before the start of the study, before randomization.

Eligibility criteria

Participants were male patients aged 50-80 years with a diagnosis of PPSUI confirmed by urological specialists. The exclusion criteria included pre-existing major neurological conditions (e.g. Parkinson's disease, multiple sclerosis, central nervous system anomalies); uncontrolled diabetes mellitus; peripheral neuropathy or other conditions affecting the peripheral nervous system; significant orthopedic comorbidities of the spine or pelvis; current use of duloxetine or other pharmacologic treatments for incontinence; and prior post-surgical rehabilitation for incontinence. Patients with a history of radiotherapy or chemotherapy for cancer were also excluded. The interval between RP and study enrollment was 1_3 months [3, 10].

Outcome measures:

HRQoL was evaluated using the SF-12 health survey, which is a validated and reliable instrument commonly used in similar studies [11]. A previously validated Persian translation of the SF-12 was employed [12]. This instrument assesses HRQoL across eight domains: physical functioning (limitations in physical activities due to health problems), social functioning (limitations in social activities due to physical or emotional problems), role-physical (limitations in usual role activities due to physical health problems), bodily pain, mental health (psychological distress and well-being), role-emotional (limitations in usual role activities due to emotional problems), vitality (energy and fatigue), and general health perceptions. SF-12 composite scores were interpreted according to established cut-points: 37-48 indicating good HRQoL, 25-36 indicating moderate HRQoL, and 12-24 indicating low HRQoL according to established cut-off points previously validated in HRQoL research [13]. Voiding diaries were utilized to assess incontinence parameters, including voided volume, fluid intake, micturition frequency, and incontinence frequency. The validity and reliability of voiding diaries for this purpose have been previously demonstrated [14].

Procedure

To mitigate potential bias, a randomized, assessor-blinded, sham-controlled trial was conducted. The outcome assessor was blinded to group allocation; however, participants were aware of their assigned group due to the nature of the interventions. Participants were allocated to receive either 12 sessions of active physiotherapy (IPT or PFMT groups) or a sham intervention (control group) over one month. A blinded assessor, independent of the treatment allocation, collected all outcome measures at baseline and immediately following the intervention.

Baseline assessments included demographic data (height, weight, and age), a one-week pre-intervention voiding diary, and the SF-12 health survey to evaluate baseline HRQoL. Weekly voiding diary entries were recorded by participants throughout the one-month intervention period, with an additional week of data collected post-intervention. The SF-12 health survey was readministered at the end of the intervention to assess changes in HRQoL.

Intervention

The IPT group received 12 sessions of a multimodal intervention comprising interferential current (IF) electrotherapy, neuromuscular manual therapy, and a targeted therapeutic exercise program (diaphragmatic breathing, the “knack” maneuver, and PFMT).

The rationale for this combined approach was to leverage synergistic effects. Electrotherapy and manual therapy were aimed at facilitating targeted musculature and optimizing patient performance of breathing and pelvic floor exercises [3]. Diaphragmatic breathing was incorporated to modulate IAP, thereby enhancing the efficacy of PFMT [7]. Each treatment session in the multimodal arm lasted approximately 55 minutes, and both groups completed 12 sessions over four weeks (three sessions per week).

Electrotherapy: IF was administered for 15 minutes at 100 Hz frequency, using a bipolar cross-configuration with electrodes placed bilaterally on the medial thighs and lower abdomen. This modality was employed to prepare the pelvic floor musculature for exercise and facilitate voluntary contractions, demonstrating positive effects on urinary incontinence [15].

Manual therapy: Neuromuscular therapy was integrated to modulate IAP via targeted treatment of the diaphragm and iliopsoas musculature, with the potential to mitigate urinary incontinence. This mechanism is hypothesized to involve trigger points and myofascial release, promoting restoration of musculoskeletal and central nervous system homeostasis. Modulation of IAP can optimize PFMT, as pelvic floor muscle contraction can inadvertently elevate IAP, potentially exacerbating PPSUI. Furthermore, this technique may enhance diaphragmatic excursion, supporting the subsequent breathing exercises [3].

Exercise therapy: All participants in the treatment group received initial instruction and a standardized home exercise program. Subsequent sessions included therapist supervision and exercise correction [16]. The frequency of home exercises was individualized based on the participant’s presentation and capacity. The exercise program consisted of: diaphragmatic breathing exercises to regulate IAP fluctuations during PFMT, mitigating the risk of PPSUI exacerbation [7]; the “knack” maneuver to enhance pelvic floor muscle awareness and control during activities that elicit increases in IAP [17], with potential synergistic benefits from the preceding diaphragmatic breathing exercises; and PFMT,

initiated after participants demonstrated adequate pelvic floor muscle awareness and control [16]. The IPT group received training in diaphragmatic breathing from physiotherapists, in addition to knack and Kegel exercises [7]. Home exercise adherence was monitored using participant-reported daily logs, which were checked at each treatment session.

The PFMT group received a targeted therapeutic exercise program (the "knack" maneuver and PFMT) for 12 sessions (three sessions per week). The IPT and PFMT group received training from physiotherapists for knack exercise first to get familiarized with pelvic floor muscles and then Kegel exercise to improve the performance of pelvic floor muscles in control of incontinence [5, 16].

The control group received 12 sessions of sham electrotherapy, utilizing identical electrode placement (bilateral medial thighs and lower abdomen) but without current. The control group received only sham electrotherapy and did not undergo any therapeutic exercise.

Data analysis

The sample size was calculated a priori using G*Power (version 3.1). Assuming a medium-to-large effect size (Cohen's f=0.40) for between-group differences on the primary outcome (incontinence frequency), with an alpha level of 0.05 and power (1−β) of 0.80 for a one-way analysis of variance (ANOVA) with three groups, the required sample size was 60 participants (20 per group) [18]. To account for an anticipated 10% attrition rate, the final target sample size was set to 66 participants. The assumed effect size (f=0.40) was based on previous randomized controlled trials evaluating PFMT and multimodal rehabilitation interventions for post-prostatectomy urinary incontinence, which reported effect sizes in a comparable range [19, 20]. Statistical analyses were performed using SPSS (version 22). The Kolmogorov-Smirnov (K-S) test was used to assess the normality of the baseline and demographic variables. Since the K-S test showed no significant deviation from normality, ANOVA was then employed to compare the groups (IPT, PFMT, and control). Finally, where ANOVA revealed significant differences between groups, post hoc Tukey's honestly significant difference (HSD) tests were used for multiple comparisons between three groups. The significance level was set at $P < 0.05$.

Results

A total of 66 participants completed the study (control, n=22; PFMT, n=22; IPT, n=22). Table 1 presents demographic characteristics, baseline clinical variables, and

Table 1. Demographic and baseline characteristics of participants in each group (control, n=22; PFMT, n=22; IPT, n=22) and K-S test results

Variables	Control Group (n=22)		IPT (n=22)		PFMT (n=22)	
	Mean±SD	K-S Result	Mean±SD	K-S Result	Mean±SD	K-S Result
Height (cm)	170.4±2.2	0.2	170.2±2	0.2	169.8±2.1	0.2
Weight (kg)	67.1±3.1	0.2	68.4±3.6	0.142	68.5±3.7	0.135
BMI (kg/m²)	23.1±1.2	0.2	23.6±1.4	0.2	23.7±1.5	0.2
Age (y)	64.4±3.5	0.158	64.6±3.7	0.2	65.5±2.8	0.2
SF-12	29.1±0.9	0.2	30.4±0.9	0.2	36±0.7	0.2
Voided volume (mL)	1611.7±82.1	0.2	1601.6±66.7	0.2	1611±42.9	0.2
Fluid intake (mL)	2031.5±120.9	0.2	1979.5±125.17	0.2	2198.8±150.3	0.2
Micturition frequency (per day)	10.1±0.4	0.2	9.8±0.4	0.2	10.2±0.4	0.2
Incontinence frequency (per day)	7.1±0.4	0.117	8±0.5	0.112	7.2±0.5	0.115

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Abbreviations: K-S: Kolmogorov–Smirnov test; BMI: Body mass index; IPT: Integrative physical therapy group; PFMT: Pelvic floor muscle training group.

Note: Kolmogorov–Smirnov tests were conducted on baseline data only (pre-intervention).

Table 2. ANOVA results for dependent variables before and after intervention (control, n=22; PFMT, n=22; IPT, n=22)

Variables		Mean±SD			P
		Control	IPT	PFMT	
SF-12	Before	29.1±0.9	30.4±0.9	36±0.7	P=0.593
	After	30.8±1	42±0.5	36±0.7	P<0.001*
Voided volume (mL)	Before	1611.7±82.1	1601.6±66.7	1611±42.9	P=0.982
	After	1514±83.7	1343.3±74.4	1229.7±70.1	P=0.036*
Fluid intake (mL)	Before	2031.5±120.9	1979.5±125.17	2198.8±150.3	P=0.392
	After	1895.5±124.2	1683.6±124.28	1639.05±116.1	P=0.288
Micturition frequency (per day)	Before	10.1±0.4	9.8±0.4	10.2±0.4	P=0.756
	After	9.2±0.3	6.9±0.2	8.1±0.2	P<0.001*
Incontinence frequency (per day)	Before	7.1±0.4	8±0.5	7.2±0.5	P=0.334
	After	6.5±0.4	1.1±0.2	3.9±0.4	P<0.001*

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Abbreviations: IPT: Integrative physical therapy group; PFMT: Pelvic floor muscle training group; ANOVA: Analysis of variance; SF-12: 12-item short-form.

*Significant difference.

Kolmogorov–Smirnov (K-S) test results for each group. No statistically significant baseline differences were observed among the groups for demographic or clinical variables (all P>0.05). K-S test values reflect baseline (pre-intervention) normality assessment.

Baseline clinical measurements, including fluid intake (P=0.39), voided volume (P=0.98), micturition frequency (P=0.75), incontinence frequency (P=0.33), and SF-12 composite score (P=0.59), showed no significant differences between groups (Table 1). This confirmed suitability for subsequent parametric analyses.

Table 2 summarizes pre- and post-intervention values for all outcome variables. ANOVA revealed significant between-group differences following the intervention for SF-12 (P<0.001), voided volume (P=0.036), micturition frequency (P<0.001), and incontinence frequency (P<0.001), whereas fluid intake showed no significant group effect (P=0.288).

SF-12 scores increased in all groups post-intervention, with the IPT group demonstrating the greatest improvement, followed by the PFMT and control groups. Post hoc Tukey tests indicated significantly higher SF-12 scores in both IPT (P<0.001) and PFMT (P<0.001) compared with the control group, and significantly higher scores in IPT compared to PFMT (P<0.001) (Table 3).

The voided volume decreased in all three groups after the intervention. However, the reduction was significantly greater in the PFMT group compared with the control group (P=0.028), while no significant difference was observed between IPT and PFMT (P=0.547) or between IPT and control (P=0.261).

Fluid intake decreased slightly in all groups, with no statistically significant differences between groups (P=0.288), indicating comparable fluid behavior across groups during the intervention period.

Micturition frequency decreased in all groups following the intervention, with the IPT group showing the greatest reduction. Post hoc analysis revealed that IPT has significantly lower micturition frequency than the control (P<0.001) and PFMT (P=0.036) groups. The PFMT group also showed a significant reduction compared with the control group (P=0.045).

Incontinence frequency decreased in all groups, with the IPT group showing the most pronounced reduction. Tukey HSD tests showed that both IPT (P<0.001) and PFMT (P<0.001) significantly outperformed the control group, and IPT demonstrated significantly lower incontinence frequency than PFMT (P<0.001).

Table 3. Tukey HSD post hoc comparisons for dependent variables (control, n=22; PFMT, n=22; IPT, n=22)

Variables	Group I	Group J	Mean Difference	SE	P
Incontinence frequency (per day)	Control	IPT	5.36	0.549	P<001*
	Control	PFMT	2.63	0.549	P<001*
	IPT	PFMT	-2.72	0.549	P<001*
Voided volume (mL)	Control	IPT	170.68	107.97	0.261
	Control	PFMT	284.22	107.97	0.028*
	IPT	PFMT	113.45	107.97	0.547
Micturition frequency (per day)	Control	IPT	2.31	0.465	P<001*
	Control	PFMT	1.13	0.465	0.045*
	IPT	PFMT	-1.18	0.465	0.036*
SF-12	Control	IPT	-11.27	1.12	P<001*
	Control	PFMT	-5.27	1.12	P<001*
	IPT	PFMT	6	1.12	P<001*

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Abbreviations: SE: Standard error; IPT: Integrative physical therapy group; PFMT: Pelvic floor muscle training group; HSD: Honestly significant difference.

*Significant.

Discussion

This study investigated the effectiveness of PFMT and a novel IPT approach for managing PPSUI. Our findings confirm that therapist-supervised PFMT, incorporating the "knack" maneuver alongside Kegel exercises, yields significant improvements in key clinical parameters, including incontinence, micturition frequency, voided volume, and HRQoL. These results are consistent with previous studies demonstrating the positive impact of PFMT on post-prostatectomy urinary incontinence [5, 16]. The inclusion of the "knack" maneuver, designed to optimize pelvic floor muscle contraction during increased IAP, likely contributed to the observed improvements by enhancing patients' ability to proactively support the rhabdosphincter's function during periods of increased abdominal pressure. This is crucial, as the rhabdosphincter plays a vital role in maintaining continence, particularly after prostatectomy when other continence mechanisms (proximal intrinsic sphincter and urethral suspensory mechanism) may be compromised [21]. Previous studies have shown that the knack maneuver improves pelvic floor muscle function and reduces the frequency of stress incontinence episodes [10, 21].

However, recognizing the limitations of isolated PFMT in addressing the complex interplay of factors contributing to PPSUI, we explored the potential benefits of IPT intervention. This multimodal approach, combining electrotherapy, manual therapy, and therapeutic exercise, aimed to synergistically target pelvic floor muscle function, IAP regulation, and their coordination, ultimately supporting optimal rhabdosphincter function. Previous studies have reported that combining electrical stimulation and manual therapy with pelvic floor exercises can enhance continence outcomes compared with pelvic floor exercises alone [3, 6, 8, 9, 15]. The IPT group also experienced significant improvements in incontinence, micturition frequency, and HRQoL compared to both the control and PFMT groups, suggesting that this comprehensive strategy may offer advantages over PFMT.

The rationale for the IPT approach was to address the multifaceted nature of PPSUI. To address the common challenge of patients struggling to activate the pelvic floor muscles during PFMT, IF was included in the treatment. IF aims to stimulate muscle contractions, potentially increasing muscle strength. This enhanced muscle strength may improve the function of the rhabdosphincter, a critical muscle for urinary continence, by provid-

ing indirect support [22]. Manual therapy targeting the diaphragm and iliopsoas aimed to optimize IAP regulation, a critical factor in continence, by improving pelvic stability and the coordinated action of the pelvic floor and diaphragm, which in turn influences the functional environment of the rhabdosphincter [3]. Previous evidence supports the use of diaphragmatic breathing and targeted manual therapy to improve IAP regulation and optimize pelvic floor function [4, 7]. Furthermore, the inclusion of breathing exercises, particularly diaphragmatic breathing, was aimed at further enhancing IAP control and relaxing abdominal muscles during PFMT, potentially maximizing the effectiveness of the exercises and reducing strain on the rhabdosphincter [7].

Although IPT is more resource-intensive than standard PFMT, its design aims to overcome the limitations of conventional physiotherapy for PPSUI. The superiority of IPT over PFMT was quantitatively evident in several outcomes. The incontinence frequency decreased by 2.72 episodes per day in the IPT group compared with PFMT, corresponding to a large effect size (Cohen's d≈1.06). Micturition frequency also decreased by 1.18 episodes/day, representing a moderate effect size (d≈0.54). Additionally, HRQoL improved by 6 points on the SF-12, a change associated with a large effect size (d≈1.14) and exceeding established MCID thresholds. These findings indicate that the statistically significant improvements observed in the IPT group also translate into clinically meaningful benefits for continence and QoL. By integrating synergistic modalities, the IPT approach aimed to more effectively address the complex pathophysiology of PPSUI, particularly the often-overlooked role of IAP dysregulation and its impact on rhabdosphincter function [23]. Unlike previous multi-modal physiotherapy programs, the IPT protocol in this study incorporates several distinct elements. Earlier studies typically combined electrical stimulation with PFMT alone [3, 15]. In contrast, our approach integrates targeted manual therapy to the diaphragm and iliopsoas specifically to modulate IAP, followed by structured diaphragmatic breathing retraining to optimize pelvic floor–diaphragm coordination. This sequencing (manual release → breathing correction → IF-assisted activation → supervised PFMT) has not been previously applied in patients who underwent prostatectomy. Additionally, most multimodal reports have focused on non–post-prostatectomy populations [7, 9], while our protocol was designed for the unique continence mechanism deficits following RP. These distinctions support IPT's novelty and may explain its superior clinical outcomes compared with PFMT. The combination of enhanced pelvic floor muscle activation through IF, coupled with targeted IAP management through manual therapy and breathing exercises, may explain the observed benefits of the IPT intervention by optimizing the rhabdosphincter's ability to effectively contribute to continence. These findings align with previous studies indicating that multimodal interventions can more effectively improve continence outcomes than isolated PFMT [3, 8, 9, 15]. Future research comparing IPT directly to PFMT is warranted to definitively determine the relative efficacy of these approaches and to further explore the mechanisms by which IPT exerts its effects, particularly its influence on rhabdosphincter function and its interaction with IAP. Furthermore, investigations into the long-term effects of both PFMT and IPT are necessary to inform clinical practice and optimize the management of PPSUI.

Conclusion

The findings demonstrated that the IPT intervention resulted in significantly greater reductions in incontinence and micturition frequencies, along with significantly improved HRQoL scores, compared to the PFMT group. These findings suggest that the IPT approach offers superior efficacy in managing PPSUI. The observed benefits of combining IF with PFMT are consistent with previous research demonstrating the enhanced effects of combined electrotherapy and exercise. Similarly, the inclusion of breathing exercises aligns with studies indicating their synergistic benefits when combined with PFMT for improving UI outcomes.

PPSUI presents a significant clinical challenge with various management strategies available. The substantial improvements observed in both the IPT and the PFMT groups further support the value of targeted physiotherapy in managing this condition.

Limitation and suggestion

The main limitation of this study was the lack of long-term follow-up due to limited patient visits. Future studies should follow up with patients to assess the long-term effects of treatments.

Ethical Considerations

Compliance with ethical guidelines

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki (2002) and the ethical standards of the country in which the research was conducted. This study was approved by the Research Ethics Committee of Shahid Beheshti

University of Medical Sciences, Tehran, Iran (Code: IR.SBMU.RETECH.REC.1399.1317). This study was registered with the Iranian Registry of Clinical Trials (IRCT), Tehran, Iran (Code: IRCT20151028024751N1). All participants provided written informed consent before inclusion in the study.

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Authors' contributions

Conceptualization and study design: Mohammad Sheibanifar and Farshad Okhovatian; Intervention implementation: Mohammad Sheibanifar and Zahra Ebrahimabadi; Data collection: Hoda Niknam; Formal analysis: Farshad Okhovatian and Alireza Akbarzadeh Baghban; Writing the original draft: Mohammad Sheibanifar and Zahra Ebrahimabadi; Review and editing: Marzieh Mortezanejad.

Conflict of interest

The authors declared no conflict of interest.

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