

Comparison of Supervised versus Video-Assisted Pelvic Floor Muscle Training Combined with Tolterodine in the Treatment of Urge Incontinence: A Randomized Controlled Trial

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Abstract

Objective: This study aimed to compare the clinical efficacy of physiotherapist-supervised versus video-assisted pelvic floor muscle training (PFMT) combined with tolterodine therapy in women with urge incontinence.

Material and Methods: In this prospective randomized controlled trial, 120 women aged 18–60 years with urge incontinence were randomized into two groups. Both groups received tolterodine 4 mg/day. The Video group (n = 60) performed home-based Kegel exercises with instructional video support. The Supervised group (n = 60) attended twice-weekly physiotherapist-supervised sessions. Outcomes were assessed by the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) at baseline and 16 weeks. Adverse effects and treatment discontinuation were recorded.

Results: A total of 102 patients completed the trial (Video: 52; Supervised: 50). Both groups showed significant improvement in ICIQ-SF scores ($p < 0.001$), with superior improvement in the Supervised group ($p = 0.017$). Adverse event rates were similar ($p > 0.05$), and no serious adverse events were reported.

Conclusion: PFMT combined with tolterodine improves urge incontinence symptoms. Supervised training yields greater benefit, though video-assisted PFMT remains a cost-effective and accessible alternative.

Keywords: urge incontinence, pelvic floor muscle training, randomized controlled trial, tolterodine

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INTRODUCTION

Urge incontinence is defined as the involuntary loss of urine accompanied by a sudden and compelling desire to void, and it can severely impair quality of life in women. Its prevalence has been reported to range between 11% and 36% (1). This condition negatively affects not only the physical but also the psychosocial aspects of patients' lives (2). Current treatment strategies are primarily based on pharmacological agents such as antimuscarinics and β_3 -adrenergic agonists; however, the side effects of these medications and poor adherence rates have increased the importance of conservative approaches (3).

Pelvic floor muscle training (PFMT) is a low-cost, non-invasive, and evidence-based intervention (4,5). Nevertheless, the optimal method of exercise delivery remains controversial. Recent randomized controlled trials have demonstrated that supervised PFMT is superior to unsupervised home-based exercises in terms of symptom control (6). Furthermore, meta-analyses published in 2023 confirmed that supervised training is more effective than home programs in improving both quality of life and symptom management (7). On the other hand, digital health applications and video-based training programs have emerged as promising tools to enhance patient adherence (8,9).

In this study, we aimed to compare the effectiveness of two different PFMT approaches (supervised by a physiotherapist and video-assisted) when combined with tolterodine therapy in women diagnosed with urge incontinence.

MATERIAL AND METHODS

Study Design

This study was designed as a superiority randomized controlled trial, aiming to compare the clinical effectiveness of supervised versus video-assisted pelvic floor muscle training combined with tolterodine therapy.

Participants

Between October 2024 and August 2025, a total of 120 women who presented to the Urology Department of our university hospital and were diagnosed with urge incontinence according to ICS criteria were enrolled. Inclusion criteria were: age 18–60 years and presence of symptoms for at least

3 months. Exclusion criteria were pregnancy, active urinary tract infection, history of pelvic radiotherapy or major pelvic surgery, neurological diseases affecting bladder function (such as multiple sclerosis, spinal cord injury, Parkinson's disease), severe cardiac failure, and contraindications to tolterodine use. Urge urinary incontinence was diagnosed according to International Continence Society (ICS) criteria, defined as involuntary leakage of urine accompanied by urgency.

Randomization

Participants were randomized into two groups using a computer-generated block randomization method with a block size of four. The randomization sequence was generated by an independent researcher who was not involved in patient recruitment or assessment. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes, which were opened only after patient enrollment.

Interventions:

Video Group (n = 60):

Patients in the video-assisted group followed a standardized pelvic floor muscle training protocol demonstrated in an instructional video prepared by a certified physiotherapist. Each training session consisted of 3 sets of 10 repetitions. Each repetition involved a 5-second sustained pelvic floor muscle contraction followed by a 5-second relaxation period. Patients were instructed to perform one session per day, at least five days per week, resulting in a total daily training time of approximately 15 minutes. The program was continued for 16 weeks.

Supervised Group (n = 60):

Patients in the supervised group participated in physiotherapist-led pelvic floor muscle training sessions twice weekly for 16 weeks. Each supervised session lasted approximately 30 minutes and followed the same standardized protocol as the video group (3 sets of 10 repetitions with 5-second contraction and 5-second relaxation). Correct muscle activation, breathing technique, and avoidance of accessory muscle use were actively monitored and corrected by the physiotherapist during each session. All patients received extended-release tolterodine (tolterodine ER) at a dose of 4 mg once daily throughout the 16-week treatment period.

Adherence Assessment

Adherence in the Video group was assessed using patient self-reported exercise logs, which were reviewed during routine outpatient clinic visits at weeks 4, 8, and 16. During these visits, patients were asked to report the frequency and regularity of their home-based exercise sessions. No objective monitoring devices were used. Adherence in the Supervised group was inherently ensured through attendance at scheduled physiotherapist-led sessions

Assessments: The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was administered face-to-face by a trained clinician to all participants at baseline and at the 16-week follow-up visit. Due to the nature of the intervention, blinding of participants and treating physiotherapists was not feasible. The investigator administering the ICIQ-SF questionnaire was not involved in the delivery of the interventions. However, complete blinding of the outcome assessor to group allocation was not feasible and this was considered a methodological limitation of the study.

Adverse events were assessed during scheduled follow-up visits and were also recorded when reported spontaneously by patients. All adverse events were documented using standardized case report forms throughout the study period. Outcome assessment was performed using a standardized questionnaire applied in a uniform manner to all participants. Discontinuation due to adverse events was recorded as an intercurrent event and considered in the intention-to-treat analysis.

The study protocol was approved by the Clinical Research Ethics Committee of Van Yüzüncü Yıl University (Approval No: 2024/09-28; Date: October 6, 2024). Written informed consent was obtained from all participants prior to enrollment. All procedures were conducted in accordance with the principles of the Declaration of Helsinki.

Statistical Analysis

Sample size calculation was based on detecting a minimum clinically important difference of 2 points in ICIQ-SF scores between groups, with a statistical power of 80% and a two-sided alpha level of **0.05**. Based on previously published randomized controlled trials evaluating supervised versus

unsupervised pelvic floor muscle training, the standard deviation of ICIQ-SF scores was assumed to be approximately 3 points, corresponding to an expected moderate effect size (Cohen's $d \approx 0.65$). According to this estimation, a minimum of 52 patients per group was required. To compensate for potential dropouts, a total of 120 patients were recruited. The primary analysis was conducted according to the intention-to-treat (ITT) principle, including all randomized patients. A secondary per-protocol analysis was also performed among patients who completed the intervention as planned.

RESULTS

A total of 120 women were enrolled in this study. During the treatment period, 8 patients (13.3%) in the Video group and 10 patients (16.6%) in the Supervised group discontinued treatment due to drug-related adverse effects. These patients were included in the primary intention-to-treat (ITT) analysis irrespective of treatment discontinuation.

Consequently, 102 patients completed the full treatment protocol and were evaluated only in the secondary per-protocol analyses, while all 120 randomized patients constituted the primary ITT population (Table 1).

At week 16, both groups demonstrated a significant reduction in ICIQ-SF scores (Video: 11.93 $\rightarrow$ 9.83; Supervised: 12.38 $\rightarrow$ 8.11; $p < 0.001$). The improvement in the Supervised group was significantly greater compared with the Video group ($p = 0.017$). Treatment discontinuation rates were similar between the two groups ($p > 0.05$) (Figure 1) (Table 2)

Adverse event rates were also comparable between groups ($p > 0.05$). The most frequently reported side effect was dry mouth, occurring in 18% of the Video group and 16% of the Supervised group. Mild-to-moderate constipation (Video: 8%; Supervised: 10%) and dizziness (Video: 6%; Supervised: 5%) were also observed. No serious adverse events were reported in either group (Table 3).

Between-group comparison of ICIQ-SF score reduction demonstrated a statistically greater improvement in the Supervised PFMT arm ($p = 0.017$). However, video-assisted exercises may still represent an important alternative in clinical practice due to their cost-effectiveness, accessibility, and feasibility for home-based implementation.

Table 1. Baseline demographic and clinical characteristics of the study population

Variable	Video Group (n = 60)	Supervised Group (n = 60)	p value
Age (years), mean $\pm$ SD	42.1 $\pm$ 7.6	42.8 $\pm$ 7.4	0.64
Body mass index (kg/m ²), mean $\pm$ SD	27.4 $\pm$ 3.9	27.1 $\pm$ 4.1	0.72
Parity, mean $\pm$ SD	2.3 $\pm$ 1.1	2.5 $\pm$ 1.2	0.48
Duration of symptoms (months), mean $\pm$ SD	14.2 $\pm$ 6.8	15.1 $\pm$ 7.2	0.59
Baseline ICIQ-SF score, mean $\pm$ SD	11.93 $\pm$ 2.81	12.38 $\pm$ 3.05	0.41
Previous PFMT or medication for UI, n (%)	18 (30.0%)	20 (33.3%)	0.69
Comorbidities, n (%)	16 (26.6%)	19 (31.6%)	0.54
Concomitant medication use, n (%)	22 (36.6%)	24 (40.0%)	0.71
Smoking or toxic habits, n (%)	6 (10.0%)	7 (11.6%)	0.77
Patients discontinuing due to AEs, n (%)	8 (13.3%)	10 (16.6%)	0.62

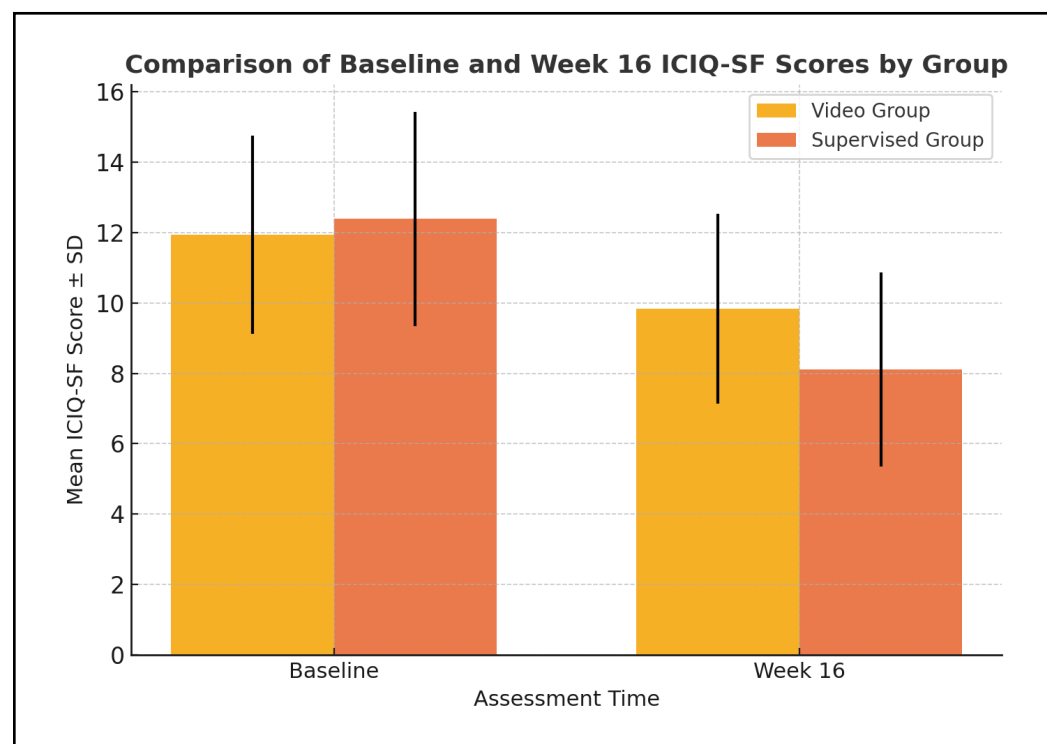


Figure 1. Both groups demonstrated a significant reduction in ICIQ-SF scores ($p < 0.001$). Improvement in the Supervised group was significantly greater compared with the Video group ($p = 0.017$). Error bars represent ± 1 SD.

Table 2. Pre- and Post-Treatment ICIQ-SF Scores

Group	Baseline Score (Mean $\pm$ SD)	Week 16 Score (Mean $\pm$ SD)	p-value (Within-group)
Video (n = 52)	11.93 $\pm$ 2.81	9.83 $\pm$ 2.70	<0.001
Supervised (n = 50)	12.38 $\pm$ 3.05	8.11 $\pm$ 2.76	<0.001

Between-group comparison (Week 16 scores): $p = 0.017$

Table 3. Distribution of Adverse Effects in Tolterodine-Combined Therapy

Adverse Effect	Video Group (n = 60)	Supervised Group (n = 60)	p value
Dry Mouth	18% (11)	16% (10)	0.78
Constipation	8% (5)	10% (6)	0.74
Dizziness	6% (4)	5% (3)	0.82
Serious Adverse Events	0	0	–
Total	20 (33.3%)	19 (31.6%)	0.87

No life-threatening or hospitalization-requiring serious adverse events were observed. Reported adverse effects leading to discontinuation were mild-to-moderate in severity, primarily dry mouth, constipation, and dizziness

DISCUSSION

In this randomized controlled trial, we compared two different PFMT approaches combined with tolterodine in the treatment of urge incontinence: physiotherapist-supervised training and video-assisted home exercises. Our findings demonstrated that both methods significantly improved symptoms; however, supervised sessions proved superior in symptom control. Supported by a moderate effect size (Cohen's $d = 0.45$), this result is consistent with existing literature suggesting that professional supervision enhances patient motivation and ensures correct exercise performance(1).

The findings of our study align with the broader literature highlighting the efficacy of PFMT in the management of urinary incontinence. Numerous previous studies have repeatedly emphasized PFMT as an important conservative treatment option. For example, in their Cochrane review, Hay-Smith et al. reported that pelvic floor muscle education is considered a first-line management strategy for women with incontinence (1). Similarly, the studies by Dumoulin and Hay-Smith confirmed that supervised programs are more effective than self-directed training (2). More recently, randomized controlled trials reported the significant improvements in symptom scores only in patients undergoing supervised training (3). Furthermore, current meta-analyses demonstrated that supervised PFMT provides greater benefits in terms of quality of life and pelvic floor function compared to home-based exercises (4). Our results are in concordance with these data.

Nevertheless, video-assisted programs also offer important practical advantages. Literature indicates that such methods

may be feasible alternatives owing to their lower cost, greater accessibility, and the opportunity for patients to exercise within their own environment (8,9). The major limitation of this approach, however, is the inability to objectively verify whether exercises are performed regularly and correctly. In our study, adherence in the video group was assessed solely based on patient self-report, representing a methodological limitation. Future integration of mobile health applications, biofeedback devices, or sensor-based systems could allow more objective monitoring of adherence, thereby increasing the reliability of video-assisted training. Indeed, recent studies on the integration of digital health technologies into PFMT have suggested promising improvements in patient compliance (8,9).

Regarding adverse events, the most frequently observed side effect associated with tolterodine in both groups was dry mouth, with similar incidence rates (18% vs. 16%, $p > 0.05$). Other side effects, including constipation and dizziness, were reported at lower frequencies, and no serious adverse events were encountered. These findings are consistent with the established safety profile of tolterodine (5,7). Although no between-group differences were observed in adverse event rates, the relatively limited statistical power of our study may have prevented the detection of small differences.

The strengths of our study include its randomized design, adequate sample size, and comparison with up-to-date literature. However, some limitations should be noted: the 16-week follow-up period, the single-center design, and the lack of objective adherence assessment. In addition, the absence of a cost-effectiveness analysis restricted the extrapolation of our findings to real-world practice.

CONCLUSIONS

Pelvic floor muscle training (PFMT) in combination with pharmacological therapy represents an effective conservative approach for symptom control in the management of urge incontinence. In our study, physiotherapist-supervised PFMT was shown to provide more pronounced symptomatic improvement compared with video-assisted training. Nevertheless, video-based exercises remain a feasible alternative in clinical practice due to their cost-effectiveness and accessibility.

In clinical settings, particularly among young and middle-aged women, supervised PFMT delivered by trained specialists may enhance treatment success. However, video-based training, when supported with appropriate monitoring and feedback mechanisms, can serve as an effective alternative in cases where cost and accessibility pose challenges.

Future studies are warranted to evaluate long-term outcomes, assess different patient populations, investigate the role of mobile health technologies and biofeedback-supported approaches, and perform cost-effectiveness analyses.

Conflict of Interest: The authors declare that there are no conflicts of interest.

Funding: No financial support was received for this study.

Ethical Approval: This study was approved by the Clinical Research Ethics Committee of Van Yüzüncü Yıl University (Approval No: 2024/09–28; Date: October 6, 2024). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Informed Consent: Informed consent was obtained from all participants.

Author Contributions:

Dr. Nedim Bedir: Study design, data collection, statistical analysis, manuscript drafting and final approval.

Dr. Kasım ertaş: Data collection, literature review, manuscript drafting and final approval.

Other authors: Contribution to study execution, manuscript revision, and approval.

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