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Comparative Effectiveness of Duloxetine and Pelvic Floor Exercises for Stress Urinary Incontinence in Postmenopausal Women: A Quasi-Experimental Study in a Secondary Care Setting, Islamabad

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ABSTRACT

Stress urinary incontinence has great impact on female daily activities, emotional well-being, and overall quality of life; hence the need of most effective treatment is mandatory. **Objective:** To evaluate the effectiveness of Duloxetine and Pelvic Floor Muscle Training (PFMT) in the management of Stress Urinary Incontinence (SUI) in postmenopausal women.This study also aims to estimate symptom reduction, adherence rates, quality of life, and associated factors. **Methods:** Sample consist of 100 participants who were randomly assigned to two groups: Duloxetine (n=50) and PFMT (n=50). Reduction in weekly incontinence episodes over the period of 12 weeks was considered as the primary outcome.Improvement in quality of life, adherence rates, strengthening pelvic floor muscle and reduction in adverse effects was considered as the secondary outcome. **Results:** A considerable reduction in the weekly incontinence episodes was seen in both groups and no statistically significant difference ($p = 0.08$) was found among two groups.Similarly, quality of life scores was also improved significantly ($p < 0.001$), post intervention with PFMT group exhibiting a marginal advantage.Only the PFMT group exhibited significant pelvic floor muscle strengthening ($p < 0.001$). Mild adverse effects, including nausea and fatigue, were reported in 12% of participants in the Duloxetine group, while PFMT had no reported side effects. **Conclusions:** Both Duloxetine and PFMT effectively reduced SUI symptoms and improved quality of life. However, PFMT had advantages in adherence, safety, and pelvic floor muscle strengthening, making it the preferred first-line treatment.

INTRODUCTION

Urinary Incontinence (UI), a stern concern that often fallouts in frustration, community avoidance, and distress, affects lots of postmenopausal women. It has a big influence on daily life, making relationships and chores thought-provoking [1]. Stress Urinary Incontinence (SUI) and Mixed Urinary Incontinence (MUI) are the furthermost common forms between postmenopausal women. In addition to involuntary urine outflows caused by SUI, laughing and sneezing put additional pressure on the bladder. Urgency Urinary Incontinence (UUI) and SUI combined to form MUI, which is characterized by a solid need to urinate that roots leakage [2]. Because of hormonal and physiological changes that are essential to onset of UI, women are more susceptible to UI during postmenopausal phase [3].Lack of estrogen in postmenopausal women results in structural changes in urethra, including deceased collagen, synthesis, thinning of the epithelium and impaired closure mechanisms. Given these factors targeted therapy for SUI and MUI is clinically required [4].The importance of specific treatment

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strategies is also highlighted by the rising incidence of UI in aging persons [5]. Pelvic floor muscle dysfunction, which is often exacerbated by age-related muscle weakness and past birth trauma, exacerbates the symptoms of urinary incontinence [6]. The management of SUI within MUI in postmenopausal women primarily includes pharmacological and non-pharmacological interventions [7]. Duloxetine, a Serotonin-Norepinephrine Reuptake Inhibitor (SNRI), has emerged as a promising pharmacological treatment for SUI and MUI [8]. Duloxetine acts by enhancing neurotransmitter activation's nucleus of the sacral spinal cord, leading to bigger contraction of the urethral sphincter and higher urinary control [9]. Clinical investigations have established that duloxetine boostsvalue of life, lessens the frequency of incontinence occurrences, and reduces the intensity of signs as informed by patients [10]. However, side effects such tiredness, dry mouth, nausea, and light-headedness often limit its use and can influence patient compliance [11]. The effectiveness of duloxetine in relation to non-pharmacological methods, including Pelvic Floor Muscle Training (PFMT), is currently being investigated, despite the fact that it is regarded as a second-line pharmaceutical treatment for UI [12]. Additionally, more research is required to ascertain whether duloxetine medication is long-term tolerable and adhered to by postmenopausal women. Numerous RCTs have confirmed PFMTs effectiveness in lowering incontinence episodes, enhancing muscle performance, and increasing patient satisfaction. PFMT being the first-line conservative treatment for SUI and MUI, provides a long-term, safe alternative to pharmacological treatments because it carries fewer risks [13]. However, the efficacy of PFMT depends on patient adherence, proper technique, and the availability of supervised training [13]. Regardless of its frequency and effect, UI is still underdiagnosed and poorly treated in Low-Middle-Income Countries (LMICs), where patients find it hard to pursue treatment due to societal standards and a lack of medicinal resources. Numerous females suffer in quiet as a consequence, which intensifies their emotional and psychological health problems. Despite extensive research on duloxetine and PFMT as separate interventions, direct comparative studies remain limited, particularly in LMICs where healthcare disparities pose challenges to UI diagnosis and treatment. In Pakistan, cultural stigmas, inadequate access to specialized continence care, and inconsistent healthcare-seeking behaviors contribute to these challenges. To fill this gap, this study will conduct a quasi-experimental trial in a secondary care hospital in Islamabad, Pakistan.

By comparing the effectiveness of duloxetine and PFMT, evaluating patient adherence and satisfaction, and analyzing treatment sustainability, this research aimed to generate valuable insights into the barriers and facilitators influencing UI management in a resource-limited setting.

METHODS

This quasi-experimental study was conducted at Federal General Hospital, Chak Shahzad, Islamabad, a secondary care hospital. Ethical approval No. F.3-144/ADMN-EC-FGH was obtained from the Ethics Review Committee (ERC) of the said institute.Before study initiation and written informed consent was secured from all participants, ensuring confidentiality and compliance with ethical guidelines. Sample size was calculated using the Cohen's power analysis formula based on the assumption that have two independent groups with statistical power (80%), moderate effect size (d = 0.3) and 5% significance level.

$$n = (((Z\,a/2 + ZB)\text{^}2\ .2\sigma\ /(d)2)¦)$$

Where, $z\frac{a}{2}$ the critical value for the chosen significance level (1.96 for 5%) and *ZB* is the critical value for the desired power (0.84 for 80%).According to this calculation the sample size calculated is 50 for both groups.This formula helps to decrease the risk of Type I and Type II errors while maintaining feasible sampling and reliable study outcomes [14]. The study was conducted over three months/12 weeks (July 2024 – September 2024).This time period was selected based on prior research studies and time required to produce expected treatment outcomes, ensuring optimum time for Duloxetine's neurochemical effects and PFMT-induced muscle adaptation.The study included postmenopausal women (≥45 years) with confirmed menopausal status, experiencing at least two episodes of Stress Urinary Incontinence (SUI) per week within Mixed Urinary Incontinence (MUI), and with no prior UI treatment in the past six months.The optimal age limit for menopause in Asian women fall in this range as reported by a recent study in India [13, 14].This ensures the inclusion of hormonally stable patients, having sufficient clinical symptoms and susceptibility to treatment with removal of all confounding factors.Exclusion criteria included urgency-predominant UI, severe overactive bladder symptoms, history of pelvic surgeries, neurological disorders, severe pelvic organ prolapse, uncontrolled diabetes, recurrent UTIs, chronic kidney disease, medications affecting urinary function (e.g., alpha-blockers, diuretics, estrogen therapy, anticholinergics), and severe psychiatric or cognitive conditions affecting adherence.Participants were assigned to one of two intervention groups.The Duloxetine Group received duloxetine 40 mg twice daily for 12 weeks, with regular monitoring for adherence, side effects, and symptom improvement.The PFMT Group underwent a structured Pelvic Floor Muscle Training (PFMT) program for 12 weeks, which included weekly supervised sessions with a physiotherapist and daily home-based exercises.Data were collected at baseline, 6 weeks, and 12 weeks through structured bladder diaries, questionnaires, clinical

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assessments, and follow-up interviews. The primary outcome was a reduction in weekly incontinence episodes, measured using a bladder diary.Secondary outcomes included quality of life improvement, assessed using the I-QOL and UDI-6 questionnaires which are widely used validated open assess questionnaires used for the said purpose. These questionnaires were utilized in different setting and it demonstrated internal consistency and reliability in various settings with a Cronbach's alpha value ranging from 0.77–0.99 [15-18]. It is used in this study without any modification as it exhibited universal acceptance and participants also reported no difficulty in its understanding. The I-QOL score range from 0 to 100 and a higher score indicates better quality of life whereas UDI-6 scores also range from 0 to 100 and a higher score here indicates more a higher tendency of symptom distress. Adherence rates were recorded via self-reported logs and follow-up interviews. Adherence rates were recorded via self-reported logs and follow-up interviews. Pelvic floor muscle strength was measured using a simple handheld air filled perineometer in the PFMT group by an experienced physiotherapist. Training was provided to the patients by the physiotherapist for home-based exercises and their understanding was evaluated and improved on each weekly visit. Adverse effects were documented through self-reports and clinical monitoring in the duloxetine group. Descriptive and inferential statistics was used to evaluate the results. Shapiro wilk test was used to assess the normality of the data. Continuous variables e.g., age, BMI, weekly incontinence episodes were reported as Mean ± Standard Deviation (SD) whereas categorical variables e.g., education level, adherence rates were represented as frequencies and percentages. Based on normality of data paired t-test was used to find differences in the same group outcomes, pre and post intervention whereas independent t-test was used to find differences in outcomes between groups. All collected data were recorded on standardized Case Report Forms (CRFs), manually reviewed for completeness, and entered into SPSS (version 23.0) for statistical analysis.Data entry was double-checked for accuracy, and any discrepancies were resolved through cross-verification with original records.

RESULTS

The baseline demographic and clinical characteristics were comparable, with no statistically significant differences in age, duration of menopause, BMI, parity, baseline incontinence episodes, or comorbid conditions ($p > 0.05$).

Table 1: Baseline Demographic and Clinical Characteristics (n=100)

Characteristics	Group A (Duloxetine) Mean ± SD/ Frequency (%)	Group B (PFMT) Mean ± SD/ Frequency (%)	p-Value
Age (Years)	58.4 ± 5.2	57.9 ± 5.5	0.65
Duration of Menopause (Years)	8.1 ± 3.7	8.4 ± 3.5	0.72
BMI (Kg/m^2)	27.8 ± 3.1	27.4 ± 3.0	0.54
Education Level			
Primary	12 (24%)	10 (20%)	0.78
Secondary	18 (36%)	20 (40%)	
Higher	20 (40%)	20 (40%)	
Parity (Number Of Children)	3.2 ± 1.1	3.4 ± 1.0	0.43
Baseline Weekly SUI Episodes	9.8 ± 2.3	10.1 ± 2.1	0.58
Hypertension	15 (30%)	14 (28%)	0.82
Diabetes Mellitus	10 (20%)	12 (24%)	0.63
History of UTI	8 (16%)	9 (18%)	0.79

Note: Continuous variables are presented as Mean ± SD (for normal data) or Median (IQR) (for non-normal data).

A marked decrease ($p < 0.001$, paired t-test) in weekly incontinence episodes was seen in both intervention groups and at 12 weeks.But the results dictate absence of any significant results between two groups ($p = 0.08$, independent t-test).The duloxetine group demonstrated a mean reduction of 5.6 episodes per week (95% CI: 5.0–6.2, $p < 0.001$), while the PFMT group showed a slightly greater reduction of 6.2 episodes per week (95% CI: 5.7–6.7, $p < 0.001$). But it should be noted that this is only the numerical advantage, and does not yield any statistically significant difference, demonstrating that treatments in both intervention groups was effective in alleviating symptoms with PFMT exhibiting a slightly greater but comparable benefit. Quality of life scores assessed using the Incontinence Quality of Life (I-QOL) and Urogenital Distress Inventory (UDI-6) scores, showed significant improvements in both groups as study participants in the duloxetine group experienced an average increase of 18 points in the I-QOL score, while those in the PFMT group showed a slightly higher improvement of 20 points ($p < 0.001$, paired t-test). Meanwhile, the reduction in UDI-6 scores was 8 points in the duloxetine group and 9 points in the PFMT group ($p < 0.00$, independent t-test), which indicates a significant decrease in urinary distress symptoms. Although PFMT showed a slightly greater improvement in quality of life, both interventions were effective in reducing the impact of incontinence. The results of the study showed that the PFMT group had significantly higher treatment adherence, with 88% of participants finishing the entire training program, compared to 74% in the duloxetine group. The duloxetine group's reduced adherence rate could be the result of worries about drug side effects, which could have affected

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the effectiveness of treatment as a whole. This implies that for postmenopausal women with stress urine incontinence, a non-pharmacological therapy option such as PFMT may be a more viable and enduring option. According to perineometer readings, the PFMT group showed a significant increase in pelvic floor muscle strength, while the duloxetine group showed no such changes. Perineometer readings increased by an average of 10 cmH20 in participants undergoing PFMT ($p < 0.001$), indicating increased muscular strength and function. On the contrary, the duloxetine group showed no measurable improvement in pelvic floor strength, indicating the mechanical benefits of structured muscle training in managing stress urinary incontinence. Mild adverse effects were reported exclusively in the duloxetine group, with 12% of participants experiencing nausea and fatigue, while no adverse effects were observed in the PFMT group. This highlights the well-tolerated nature of pelvic floor muscle training as a non-invasive intervention, whereas duloxetine, despite its efficacy, may present mild side effects that could impact patient adherence and overall satisfaction with treatment. Chi-square analysis of demographic factors and treatment outcomes showed that higher education was significantly associated with better adherence ($p = 0.015$). Women with higher education levels were more likely to adhere to treatment, with adherence rates of 67.5% in the higher education group compared to 57.9% in the secondary education group and 23.8% in the primary education group. A significant correlation was also observed between parity and quality-of-life improvement, with women having fewer children (≤2) experiencing greater benefits ($p = 0.048$). This suggests that lower parity may be associated with better treatment response and improved quality of life.

Table 2: Chi Square score of education and adherence level

Education Level	High Adherence (≥80%) Frequency (%)	Low Adherence (<80%) Frequency (%)	p-Value
Primary	5 (23.8%)	16 (76.2%)	0.015*
Secondary	22 (57.9%)	16 (42.1%)	
Higher	27 (67.5%)	13 (32.5%)	

Note: $p \leq 0.05$ is considered statistically significant and is marked with an asterisk()*.

Both duloxetine and PFMT effectively reduce stress urinary incontinence episodes and improve quality of life in postmenopausal women.However, PFMT had some advantages over duloxetine that includes higher adherence rates (88% vs. 74%), no adverse effects, and significant increase in pelvic floor strength.Also, demographic variables played a key role, with women who had higher education levels exhibiting better adherence and those with fewer children experiencing greater quality-of-life improvements.These findings suggest that PFMT may be the favourite first-line intervention, while duloxetine remains a workable alternative for those unable to commit to exercise-based therapy.

Table 3: Association of parity and quality of life

Parity	I-QOL Improvement ≥15 Frequency (%)	I-QOL Improvement <15 Frequency (%)	p-Value
≤2 children	25 (73.5%)	9 (26.5%)	0.048*
>2 children	22 (53.7%)	19 (46.3%)	

Note: $p \leq 0.05$ is considered statistically significant and is marked with an asterisk()*.

DISCUSSION

Both duloxetine and PFMT considerably reduced weekly incontinence episodes over the period of 12 weeks but this was statistically non-significant within the same group but upon comparison of two groups, significant reduction in the PFMT group (6.2 vs. 5.6 episodes, $p = 0.08$) was observed. This suggests that both treatments are effective, with the choice depending on patient preference, tolerability, and long-term sustainability. These findings align with previous studieswhich demonstrated that structured PFMT led to greater long-term symptom benefits than pharmacological interventions alone [13]. Also, another study reported that patients with these conditions should undergo PFMT and can consider duloxetine as a second line treatment [19]. Furthermore, another study found that while Duloxetine provided rapid symptom relief, adherence rates were significantly lower due to side effects, making it less favourable for long-term management [20]. Both interventions significantly improved quality-of-life measures, including I-QOL and UDI-6 scores, with PFMT showing slightly greater benefits (+20 vs. +18 in I-QOL, $p < 0.001$). This highlights the added advantage of pelvic muscle strengthening in providing long-term relief and enhancing daily functioning. Adherence rates were higher in the PFMT group (88%) compared to the duloxetine group (74%), likely due to adverse effects such as nausea and fatigue, reported by 12% of participants. Although mild, these side effects affected medication compliance, a challenge noted in previous pharmacotherapy trials [21]. Additionally, the chi-square analysis revealed that education level significantly influenced adherence rates ($p = 0.015$), with higher-educated women more likely to adhere to both interventions [22]. This suggests that patient education and awareness play crucial roles in treatment success. Another important finding was the correlation between parity and treatment effectiveness. Women with ≤2 children experienced greater quality-of-life improvements ($p = 0.048$), possibly due toless pelvic floor damage from childbirth. Repeated pregnancies and vaginal deliveries are well-established risk factors for pelvic floor dysfunction, leading to weakened urethral support and higher SUI severity. This finding aligns with studies which suggest that women with multiple vaginal deliveries often require more intensive rehabilitation or surgical

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interventions to achieve comparable symptom relief due to decreased muscle tone [23]. Given the study findings, PFMT should be prioritized as the first-line intervention for SUI in postmenopausal women due to its higher adherence, superior pelvic floor strengthening effects, and absence of adverse effects. These results align with a study which reported PFMT to be the first line treatment option for SUI [24, 25]. Duloxetine remains a viable alternative for patients who cannot engage in structured PFMT or require rapid symptom relief, but clinicians should be mindful of potential side effects that may impact compliance. Moreover, patient education should be integrated into treatment plans, particularly for women with lower education levels, to enhance adherence and optimize outcomes. Parity should also be considered as multiparous women require longer rehabilitation programs or adjunct therapies to achieve similar improvements. The short duration of 12 weeks prevents conclusions about long-term effectiveness and adherence. Future research should assess outcomes over 6 to 12 months to evaluate sustained benefits and relapse rates. Additionally, we did not include a combination therapy group (duloxetine plus PFMT), which could have provided insights into potential synergistic effects. Future studies should explore the long-term sustainability of PFMT, the potential benefits of combination therapies, and the role of patient education in improving adherence and treatment success.

CONCLUSIONS

This study concluded that both duloxetine and PFMT successfully improve stress urinary incontinence in postmenopausal women.However, PFMT established higher adherence, greater pelvic floor muscle strengthening, better quality-of-life improvements, and no side effects, making it the preferable first-line treatment. Duloxetine remains a possible alternative but had lower adherence and mild adverse effects. Additionally, higher education was concurrent to better adherence, and lower parity was related with greater quality-of-life improvements. Based on these findings, PFMT should be prioritized for managing stress urinary incontinence, while future research should explore long-term outcomes and combination therapies.

Authors Contribution

Conceptualization: AR[1], AR[2]
Methodology: AR[1], AI, AR[2]
Formal analysis: AR[2]
Writing, review and editing: AR[1], AI, AA

All authors have read and agreed to the published version of the manuscript

Conflicts of Interest

All the authors declare no conflict of interest.

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