

**ORIGINAL RESEARCH**

# Efficacy of duloxetine in stress urinary incontinence in women

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**ABSTRACT**

**Background:** Stress urinary incontinence (SUI) is a common condition characterized by the involuntary leakage of urine during activities that increase abdominal pressure, such as coughing, sneezing, laughing, or physical exertion. The present study was conducted to assess efficacy of duloxetine in stress urinary incontinence in women. **Materials & Methods:** 48 women with stress urinary incontinence of both genders. All were informed regarding the study and their written consent was obtained. Data such as name, age, etc. was recorded. Patients received duloxetine 20 mg twice daily for 12 weeks. The variables included the IEF and improvement in quality of life. Incontinence episode frequency/week (IEF/week) was recorded. **Results:** IEF at baseline was 12.8, after 1 month was 9.5, after 2 months was 7.2 and after 3 months was 6.4. IEF at baseline in patients those shows improvement was 12.7 and those not responding was 13.5 and at 1 month in patients those shows improvement was 9.1 and those not responding was 12.7. The difference was non-significant ( $P > 0.05$ ). PGI-I score 1 was seen in 29%, score 2 in 37% and score 3 in 34%. The difference was significant ( $P < 0.05$ ). **Conclusion:** Duloxetine is a potential treatment for women with stress urinary incontinence.

**Keywords:** duloxetine, estrogen, Stress urinary incontinence

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**INTRODUCTION**

Stress urinary incontinence (SUI) is a common condition characterized by the involuntary leakage of urine during activities that increase abdominal pressure, such as coughing, sneezing, laughing, or physical exertion. This condition primarily affects women, though it can also occur in men, especially following prostate surgery.<sup>1</sup>

The main causes of SUI involve the weakening of the pelvic floor muscles and tissues that support the bladder and urethra. Factors contributing to this weakening include vaginal delivery can stretch and weaken the pelvic floor muscles.<sup>2</sup> The pelvic muscles naturally lose strength and elasticity with age. Decreased estrogen levels can lead to tissue thinning. Excess weight increases abdominal pressure on the bladder and pelvic muscles. Conditions causing chronic cough, such as smoking or lung disease, can strain pelvic floor muscles. Procedures like hysterectomy can weaken the pelvic support.<sup>3</sup> The primary symptom of SUI is urine leakage during activities that increase intra-abdominal pressure. The amount of leakage can vary from a few drops to a larger volume, depending on the severity of the condition.<sup>4</sup> Duloxetine is a balanced dual serotonin and

norepinephrine reuptake inhibitor that is taken orally. Preclinical pharmacologic data that showed minimal variation in the relative affinity for duloxetine in binding to the NE and 5-HT transport sites are used in this context to define balance.<sup>5</sup> The present study was conducted to assess efficacy of duloxetine in stress urinary incontinence in women.

**MATERIALS & METHODS**

The present study was conducted on 48 women with stress urinary incontinence of both genders. All were informed regarding the study and their written consent was obtained.

Data such as name, age, etc. was recorded. Patients received duloxetine 20 mg twice daily for 12 weeks. The variables included the IEF and improvement in quality of life. Incontinence episode frequency/week (IEF/week) was recorded. The patient global impression on improvement scale (PGI-I) was recorded as 1- very much better, 2- much better, 3- a little better, 4- No change, 5- A little worse, 6- Much worse and 7- Very much worse. Data thus obtained were subjected to statistical analysis. P value  $< 0.05$  was considered significant.

**RESULTS****Table I Assessment of IEF**

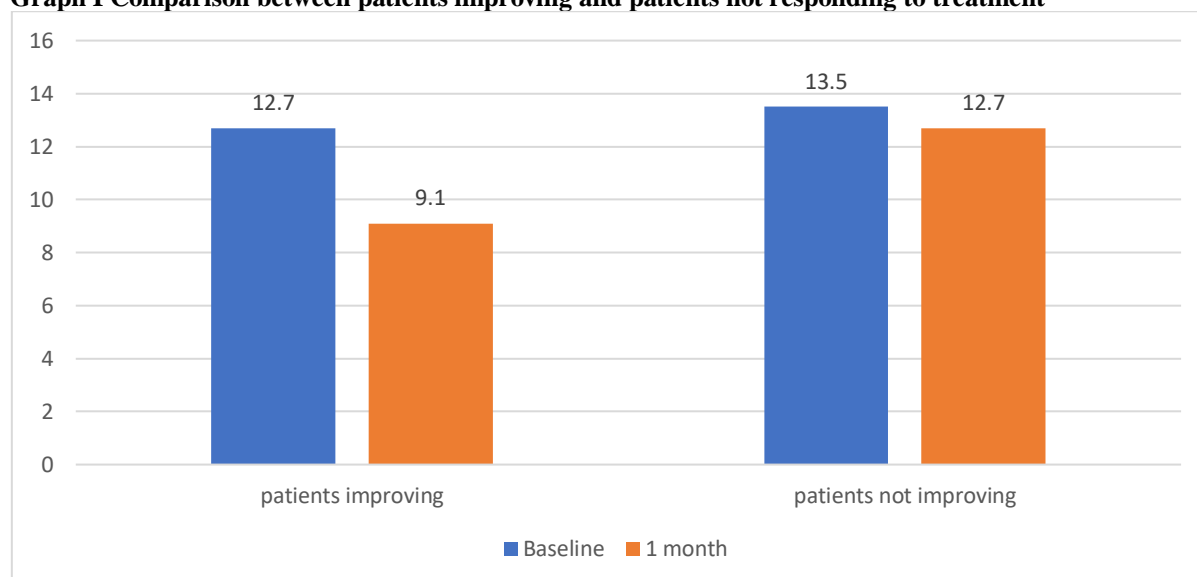
Period	Mean	P value
Baseline	12.8	0.01
1 month	9.5	
2 months	7.2	
3 months	6.4	

Table I shows that IEF at baseline was 12.8, after 1 month was 9.5, after 2 months was 7.2 and after 3 months was 6.4.

**Table II Comparison between patients improving and patients not responding to treatment**

Parameters	patients improving	patients not improving	P value
Baseline	12.7	13.5	0.64
1 month	9.1	12.7	0.81

Table II shows that IEF at baseline in patients those shows improvement was 12.7 and those not responding was 13.5 and at 1 month in in patients those shows improvement was 9.1 and those not responding was 12.7. The difference was non-significant ( $P > 0.05$ ).

**Graph I Comparison between patients improving and patients not responding to treatment****Table III Assessment in improvement in quality of life**

PGI- I	Percentage	P value
1	29%	0.71
2	37%	
3	34%	

Table III shows that PGI- I score 1 was seen in 29%, score 2 in 37% and score 3 in 34%. The difference was significant ( $P < 0.05$ ).

**DISCUSSION**

The involuntary leakage of pee caused by strenuous activities like running, jumping, or lifting, as well as by sneezing and coughing, is known as stress urinary incontinence, or SUAI. The quality of life can be significantly impacted by urinary incontinence (UI). Stress urine incontinence is linked to social isolation and loneliness, higher health care consumption, and significant costs. Our understanding of the mechanisms underlying SUI is lacking.<sup>6</sup> Numerous factors are at play, including the urethra's endothelial cushion and sealing ability being preserved, the bladder base's muscular and ligament support, the lack

of bladder spasms (detrusor overactivity) during bladder filling, the integrity of neurological innervation, and the interaction of neurological, vascular, connective tissue, and urethral components. But by keeping bladder capacity below the threshold, continence can be preserved even in cases of minor sphincter mechanism damage.<sup>7,8</sup> The present study was conducted to assess efficacy of duloxetine in stress urinary incontinence in women.

We observed that IEF at baseline was 12.8, after 1 month was 9.5, after 2 months was 7.2 and after 3 months was 6.4. Deepak et al<sup>9</sup> assessed the efficacy of duloxetine, a selective inhibitor of serotonin and

norepinephrine reuptake, in the treatment of stress urinary incontinence (SUI) in women. The study included 50 women aged above 18 years with a predominant symptom of stress urinary incontinence (SUI). The case definition included a predominant symptom of SUI with a weekly incontinence episode frequency (IEF) of seven or greater and a positive cough stress test. All the patients received duloxetine 20 mg twice daily for 12 weeks. The primary outcome variables included the IEF and improvement in quality of life. The improvement with duloxetine treatment was found in 40 out of 50 patients. Remaining 10 patients did not show any improvement with duloxetine and discontinued the treatment. In 40 patients, the mean baseline IEF was 12.5/week. At the end of three months treatment, IEF was six/week. This shows a statistically significant reduction in the IEF. Also, there was a good improvement in quality of life with 65% of patients in the "very much better" and "much better" categories according to PGI-I scale. In the remaining 10 patients, there was no significant improvement after one month of treatment and patients underwent surgery.

We found that IEF at baseline in patients those shows improvement was 12.7 and those not responding was 13.5 and at 1 month in in patients those shows improvement was 9.1 and those not responding was 12.7. Olke et al<sup>10</sup> evaluated the safety and tolerability of duloxetine with SUI. Various unpleasant adverse effects exist, among which nausea is the most frequent, but is mild to moderate and transient in most cases. Dose escalation upon initiation of treatment improves the tolerability of duloxetine. The use of duloxetine appears safe as it lacks the cardiovascular adverse effects of older amine reuptake inhibitors.

We observed that PGI- I score 1 was seen in 29%, score 2 in 37% and score 3 in 34%. Dmochowski et al<sup>11</sup> evaluated duloxetine's effectiveness and safety in treating women with stress urinary incontinence (SUI). There were 683 enrolled women in North America, ages 22 to 84. Subjects were randomized to receive either a placebo (339) or 80 mg duloxetine daily (344) as 40 mg twice day for 12 weeks following a 2-week placebo lead-in phase. 436 patients (64%) had a baseline IEF of 14 or higher, with a mean baseline IEF of 18 weekly. When comparing duloxetine to a placebo, there was a large drop in IEF (50% vs. 27%,  $p < 0.001$ ), but there were also comparable gains in quality of life (11.0 vs. 6.8,  $p < 0.001$ ). Those taking duloxetine experienced a 50% to 100% reduction in IEF, while those receiving a placebo experienced a 34% decrease. These duloxetine improvements were seen across the range of incontinence severity and were linked to a considerable increase in the voiding interval when compared to placebo (20 vs. 2 minutes,  $p < 0.001$ ). The most frequent reason for discontinuation (6.4%) was nausea. The discontinuation rate for adverse events was 4% for placebo and 24% for duloxetine ( $p < 0.001$ ). The most frequent adverse effect, mild to

severe nausea, was usually temporary, going away in a week or a month. Out of the 78 women who took duloxetine and developed treatment-emergent nausea, 58 (74%) finished the experiment by keeping bladder volume below the point at which leaking happens, continence can be preserved.

The shortcoming of the study is small sample size.

## CONCLUSION

Authors found that Duloxetine is a potential treatment for women with stress urinary incontinence.

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