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Kegel Exercise and Duloxetine Hydrochloride for management of Stress Urinary Incontinence (SUI)

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Abstract

Introduction: Stress Urinary Incontinence (SUI) affects the quality of life of at least one third of women globally. This problem is more common in India, where women usually do not seek treatment for their reproductive health problems and do not vocalize their symptoms. Kegel exercise and Duloxetine are said to be effective for the management of SUI. Hence it was tried to see the effects of these methods in the population of Jhalawar, Rajasthan.

Materials and Method: A total of 80 females having Stress Incontinence were included in the study and 40 women were advised Kegel exercises and remaining were prescribed kegel exercises along with Duloxetine for 8 weeks. After 8 weeks they were evaluated for their symptoms.

Results: Statistically significant improvement was observed after Kegel exercises alone and with combined Duloxetine and Kegel exercises but more improvement was seen when Duloxetine was added to Kegel exercises.

Conclusion: It can be concluded that Duloxetine along with Kegel exercises is more effective for controlling SUI in the study population as compared to kegel exercises alone.

Keywords: Kegal exercise, Stress urinary incontinence, Duloxetine, IIQ7 score, IEF.

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Introduction

Urinary incontinence is common problem of women which is nothing but the involuntary loss of urine. The most common type of urinary incontinence in women is Stress Urinary incontinence. Approximately 50% of women experience incontinence.(1) The International Continence Society recently defined the stress urinary incontinence as the complaint of involuntary leakage of urine during effort or exertion like sneezing or coughing.(2) A proper balance between urethral closure and detrusor muscle activity is the most important factor in maintaining the urinary continence. Basic cause of stress urinary incontinence is the weakness of pelvic floor muscles supporting the proximal urethra. When the intravesical pressure exceeds the maximal urethral pressure during exertion, incontinence results. Dr. Arnold Kegel described a pelvic floor exercise, more commonly called a Kegel exercise, consists of repeated contraction and relaxation of the muscles that form part of the pelvic floor, now sometimes colloquially referred to as the "Kegel muscles". Kegel exercise (perineal floor muscles exercise) improves strength of striated external sphincter urethrae which is responsible for voluntary continence & continence during rise of intra-abdominal pressure.(3)

The International Consultation on Incontinence (ICI) actually recommends that Kegel exercise may be augmented with appropriate drug therapy in treatment of SUI and mentions that dual serotonin (5-HT) and norepinephrine (NE) reuptake inhibitors are effective in SUI. Duloxetine is the first medication developed for SUI and has been also used for the treatment of depression and pain caused by diabetic peripheral neuropathy. The action of duloxetine is associated with the reuptake inhibition of 5-HT and NE at the presynaptic neuron in Onuf's nucleus (the pudendal nerve motor nucleus) of the sacral spinal cord.[4]Whereby it may increase the concentration of 5-HT and NE in the synaptic cleft. The neurons of Onuf's nucleus in the sacral spinal cord are responsible for innervation of the external urethral sphincter and for control of urethral function via postsynaptic nerves to the pudendal nerve. Duloxetine acts centrally in this spinal area to produce stronger urethral sphincter contractions and sustained sphincter tone during urine storage.

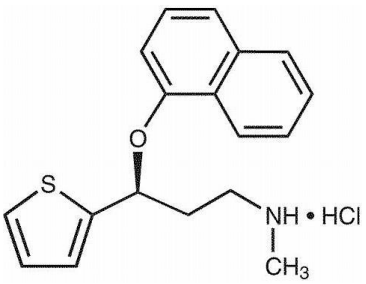


Fig. 1: Duloxetine chemical structure

Aims and Objectives

- To find effectiveness of Kegel exercise in SUI.

- To find effectiveness of Duloxetine + Kegel exercise in SUI.
- To compare effectiveness of Duloxetine + Kegel and only Kegel exercise in SUI.

Materials and Method

A total of 80 subjects of confirmed cases of SUI were enrolled for the study. Inclusion criteria is age between 20 to 65 years who volunteered and gave consent to participate in the study. Initial demographic and clinical characteristic were similar in both groups. Evaluation of SUI was done by thorough history, voiding diary, physical examination including cough stress test, urine-analysis, post void residual urine. Patients suffering from neurological dysfunction, genital prolapse, history of previous surgery for stress incontinence, previous or present pelvic malignancy, urinary tract infection, patient had taken previous physiotherapy for stress incontinence, urinary fistula and pregnant patients were excluded from the study. Study was conducted in Jhalawar Medical College, Jhalawar. Study period was between June –Dec 2015. All the subjects divided into 2 groups by systemic allocation method. All the subjects asked to fill IIQ7 questionnaire and to keep a diary in which number of incontinence episodes over seven days were recorded. After 7 days patients were asked to return with void diary of 7 days. Their void diaries were studied and depending on level of physical activity at which they developed incontinence they were subdivided into 3 groups and their IEF and IIQ7 scores were recorded.

3 groups according to level of physical activity at which incontinence occurred[5]

Mild	Incontinence during cough & sneezing
Moderate	Incontinence during mild exercise like running, jumping, climbing
Severe	Incontinence during postural changes or lying down position

Group I: Kegel exercise was given for 8 weeks
Group II: Kegel exercise along with Duloxetine 40 mg BD was given for 8 weeks.

The patients were asked to be in lying position and lift their vagina and anus upward and inward as she does at conclusion of defecation or to imagine that she is voiding urine and then to go through the motion of interrupting the stream suddenly.[6] Contract pelvic muscle and hold the contraction for 10-12 seconds and relax for 10-12 seconds. Repeat this for 15 times (one session). Patients were asked to do 3 session per day.

Assessment of effectiveness of treatment was done by Incontinence episode frequency (IEF) & Incontinence Impact Questionnaire (IIQ-7 score) after 8 weeks.[7]

Incontinence Impact Questionnaire contains 7 questions. Which describes how much patient activities, relationships, and feelings are being affected by urine leakage. Each question has score 0-3.

0 for "not at all," 1 for "slightly," 2 for "moderately," and 3 for "greatly." The average score is calculated. The average, which ranges from 0 to 3, is multiplied by 33 and 1/3 to put scores on a scale of 0 to 100. In this way we calculated scores before and after treatment in each groups.

Statistical analysis was done by paired and unpaired T test for comparison of mean.

Results

80 women were included in the study. At the end of study, we had complete data of 56 patients (27 in group 1 and 29 in group 2). Total 24 patients did not come for follow up.

There is 70% reduction in IEF and 57% reduction in IIQ7 Score in mild incontinence, 46% reduction in IEF and 47% reduction in IIQ7 Score in moderate incontinence, 41% reduction in IEF and 42% reduction in IIQ7 score in severe incontinence in group 1. While 85% reduction in IEF and 67% reduction in IIQ7 score in mild incontinence, 73% reduction in IEF and 67% reduction in IIQ7 score in moderate incontinence and 62% reduction in IEF and 60% reduction in IIQ7 score in severe type incontinence in group 2.

Overall there is 45.9% reduction in IEF and 46.46% reduction in IIQ7 score in group1. While 73.05% reduction in IEF and 65.14% reduction in IIQ7 score is seen in group 2.

When we compared the scores of IIQ7, IEF scores before and after given treatment in group 1, and group 2 there was statistically significant improvement ($p < 0.001$) in each group (Table 2, Table 3, Graph 1, Graph 2) but there is more improvement in IIQ-7, IEF scores in group 2(Table 4, Graph 3)

Table 1: Distribution of patients in group 1 and group 1 according to severity of incontinence

Severity of incontinence	Group 1	Group 2
Mild incontinence	13	13
Moderate incontinence	10	11
Severe incontinence	4	5

Table 2: IIQ-7 SCORE Pre & Post Treatment

Grade of incontinence	Treatment	Group I			Group II		
		Mean	SD	P value	Mean	SD	P value
Mild incontinence	Pre treatment	6.42	1.42	0.0002	6.39	0.97	<0.0001
	Post treatment	3.01	1.25		1.79	0.83	
Moderate	Pre treatment	17.13	1.72	<0.0001	18.29	2.36	<0.0001

incontinence	Post treatment	9.43	1.28		6.14	0.85	
Severe incontinence	Pre treatment	26.71	1.57	0.0004	26.71	1.28	0.0008
	Post treatment	15.09	0.86		11	1.25	

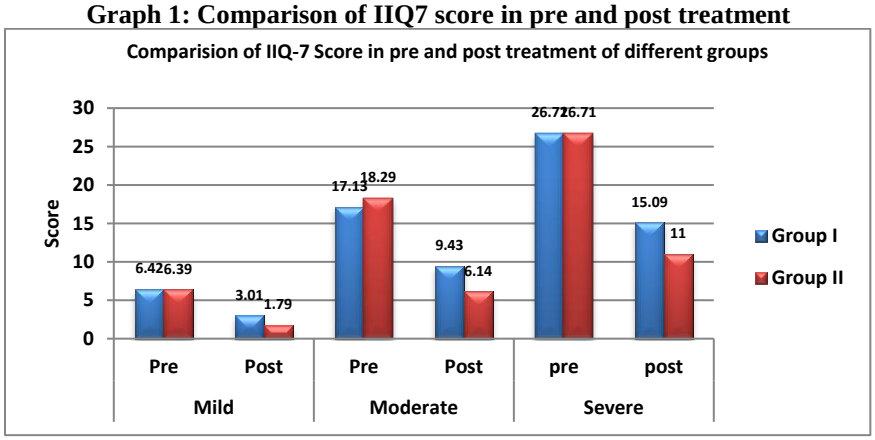
Table 3: Incontinence Episode Frequency Pre & Post Treatment

Grade of incontinence	Treatment	Group I			Group II		
		Mean	SD	P value	Mean	SD	P value
Mild incontinence	Pre treatment	5.83	1.11	<0.0001	5.79	0.80	<0.0001
	Post treatment	2.92	1.24		0.86	0.72	
Moderate incontinence	Pre treatment	8.80	0.63	<0.0001	9.36	1.00	<0.0001
	Post treatment	4.7	0.82		2.45	0.52	
Severe incontinence	Pre treatment	20.00	1.63	0.0004	18.6	2.41	<0.0001
	Post treatment	11.75	0.96		7.00	1.58	

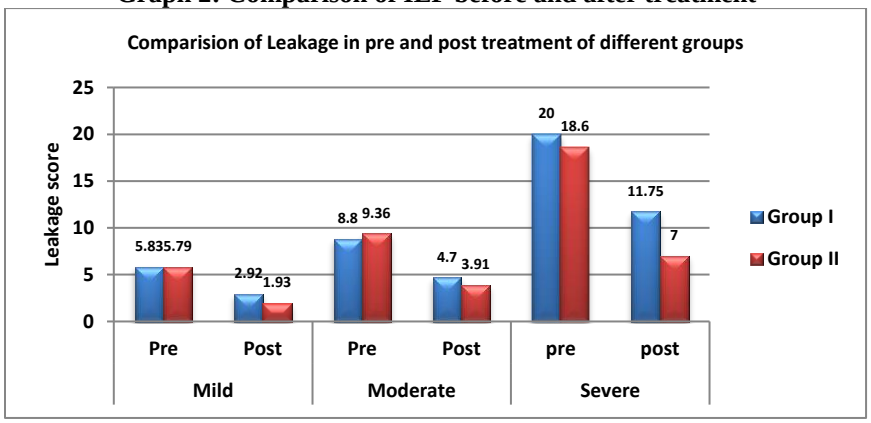
Table 4: Significance of Addition of Duloxetine to Group II

Assessment Method	Grade of incontinence	Group I Post treatment		Group II Post treatment		P value
		Mean	SD	Mean	SD	
IIQ-7 SCORE	Mild	3.01	1.25	1.79	0.83	0.0069
	Moderate	9.43	1.28	6.14	0.85	<0.0001
	Severe	15.09	0.86	11	1.28	0.0007
IEF	Mild	2.92	1.24	0.86	0.77	<0.0001
	Moderate	4.70	0.82	2.45	0.52	<0.0001
	Severe	11.75	0.96	7.00	1.58	0.0012

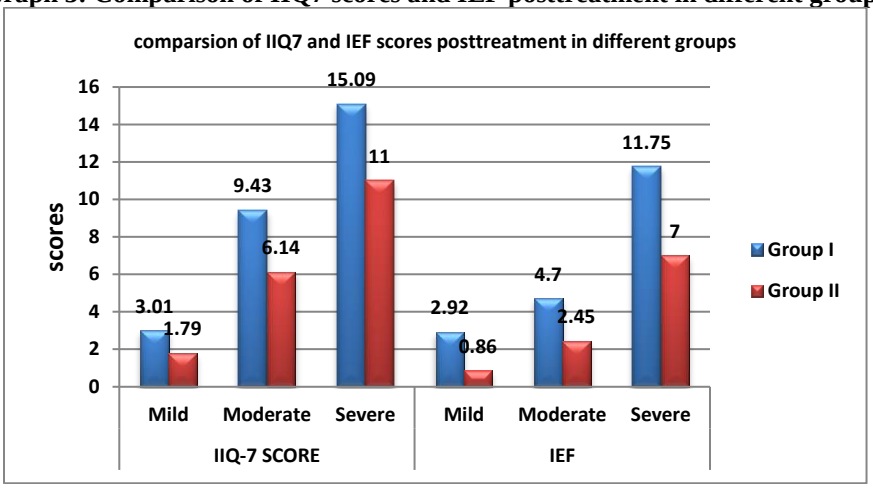
Graph 1: Comparison of IIQ7 score in pre and post treatment



Graph 2: Comparison of IEF before and after treatment



Graph 3: Comparison of IIQ7 scores and IEF posttreatment in different groups



Discussion

Urinary incontinence creates tremendous psychological, economic and social problems in females which affect their overall health seriously. There are three major types of incontinence in females namely stress, urge, and mixed with different treatment modalities including conservative or behavioral modifications, pharmacotherapy, and surgical interventions. Among conservative management Kegel exercise has prominent and important role.

Rodrigo A Castro opined that pelvic floor muscle exercise should be offered as the first choice of treatment of stress urinary incontinenc.[8] Lagro-Janssen et al in 1991 conducted subjective study in which they found 85% improvement after pelvic floor muscle training in SUI. But they also pointed out that among all the cases only 21% cases felt completely dry after treatment.[9] Cavkaytar S et al in their study found 68.4% improvement in IEF with kegel exercise.[10] We also found usefulness of Kegel exercise in stress urinary incontinence in our studied population. Millard RJ et al conducted a study in which they found 54% reduction in incontinence episode frequency with Duloxetine.[11] Van Kerrebroeck P et al concluded in their study that IEF in SUI decreases significantly with Duloxetine by 54%.[12] Ghoniem et al in their study found Duloxetine in combination with Kegel exercise significantly ($p < 0.05$) reduced IEF by 57%, compared with 35% reduction with kegel exercise alone.[13] While in our study there is 45.9% reduction in IEF with kegel exercise alone, compared with 65.14% reduction with combined treatment.

Conclusion

Duloxetine is approved for the treatment of women of SUI. Kegel exercise, alone and in combination with Kegel exercises, significantly reduced ($p < 0.05$) in incontinence episode frequency and IIQ7 Score. Combined treatment (duloxetine and pelvic floor training) was superior and show more improvement in quality of life. Hence, combination with pelvic floor training is more appropriate. Thus Duloxetine widens the spectrum of treatment options for this indication.

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