

**ORIGINAL ARTICLE****Comparison of Darifenacin and Trospium in overactive bladder**

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**ABSTRACT:**

**Background:** Overactive bladder (OAB) is a condition characterized by a frequent and urgent need to urinate, which may be accompanied by urinary incontinence. The present study was conducted to compare Darifenacin and Trospium in overactive bladder. **Materials & Methods:** 74 patients with overactive bladder of both genders were divided into 2 groups of 37 each. Group I received darifenacin 7.5 mg OD and group II received trospium extended release 60 mg OD. Treatment response was monitored using overactive bladder symptom score (OABSS). The severity of constipation was assessed using McMillan & Williams Constipation assessment scale (CAS), Bristol stool form scale and Knowles-Eccersley-Scott-Symptom (KESS) questionnaire score administered at baseline, and 4 weeks of treatment. **Results:** In group I and group II, defecations / day was 1.06 and 1.01, OABSS was 9.7 and 9.2, McMillan and Williams CAS was 0.26 and 0.51, KESS questionnaire score was 3.5 and 3.2 and Bristol stool consistency was 2.8 and 3.1 respectively. The difference was significant ( $P < 0.05$ ). There was significant difference in frequency, nocturia, urgency, urge urinary incontinence and OABSS at baseline and 4 weeks in both groups ( $P < 0.05$ ). **Conclusion:** Both trospium and darifenacin have a rather acceptable patient acceptability rate, are comparably tolerable in terms of constipation, and successfully reduce the symptoms of overactive bladder.

**Keywords:** Overactive bladder, constipation, darifenacin

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**INTRODUCTION**

Overactive bladder (OAB) is a condition characterized by a frequent and urgent need to urinate, which may be accompanied by urinary incontinence. OAB can significantly impact quality of life, causing disruptions in daily activities and emotional distress.<sup>1</sup> The exact cause of OAB is not always clear, but it may involve conditions like multiple sclerosis, Parkinson's disease, or stroke can affect bladder control, issues such as bladder stones, tumors, or infections, certain medications can increase urine production or affect bladder function, excessive caffeine or alcohol intake. Particularly in postmenopausal women, increased pressure on the bladder.<sup>2</sup>

Over 75 years of age, men had a higher prevalence of OAB (42%) than women (31%). In Asia, OAB is present in about 53.1% of cases. The treatment of overactive bladder (OAB) includes bladder exercises, medication, and behavioral and lifestyle changes, either separately or in combination. The preferred pharmacotherapy for OAB is antimuscarinic drugs, which includes trospium, oxybutynin, tolterodine, darifenacin, and solifenacin.<sup>3</sup> Despite the fact that the effectiveness of the aforementioned antimuscarinics has been shown in a number of randomized controlled trials, variations in their pharmacokinetics, organ selectivity, and affinity for different muscarinic receptor subtypes may result in different adverse effect profiles. Constipation and dry mouth are the most frequent side effects that have

been noted in numerous research. Malnutrition, fecal impaction, and abdominal pain are all consequences of constipation that can have a major effect on quality of life.<sup>4</sup> Darifenacin, a new M3 selective antimuscarinic agent, has an advantage of reliving detrusor contraction with a favorable side effect profile due to its selective action.<sup>5</sup> Dry mouth is the most common adverse effect with darifenacin, followed by constipation ( $\leq 21\%$ ), with  $\sim 33\%$  of them requiring concomitant laxative use. Trospium chloride, a non-selective muscarinic receptor antagonist, is a quaternary ammonium compound which crosses the blood-brain barrier to a limited extent.<sup>6,7</sup> The present study was conducted to compare Darifenacin and Trospium in overactive bladder.

**MATERIALS & METHODS**

The present study was conducted on 74 patients with overactive bladder of both genders. All were informed regarding the study and their written consent was obtained.

Data such as name, age, gender etc. was recorded. Patients were divided into 2 groups of 37 each. Group I received darifenacin 7.5 mg OD and group II received trospium extended release 60 mg OD. Treatment response was monitored using overactive bladder symptom score (OABSS). The severity of constipation was assessed using McMillan & Williams Constipation assessment scale (CAS), Bristol stool form scale and Knowles-Eccersley-Scott-Symptom (KESS) questionnaire score administered at

baseline, and 4 weeks of treatment. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

**RESULTS**

**Table I Assessment of parameters**

Parameters	Group I	Group II	P value
Defecations / day	1.06	1.01	0.85
OABSS	9.7	9.2	0.12
McMillan and Williams CAS	0.26	0.51	0.01
KESS questionnaire score	3.5	3.2	0.94
Bristol stool consistency	2.8	3.1	0.48

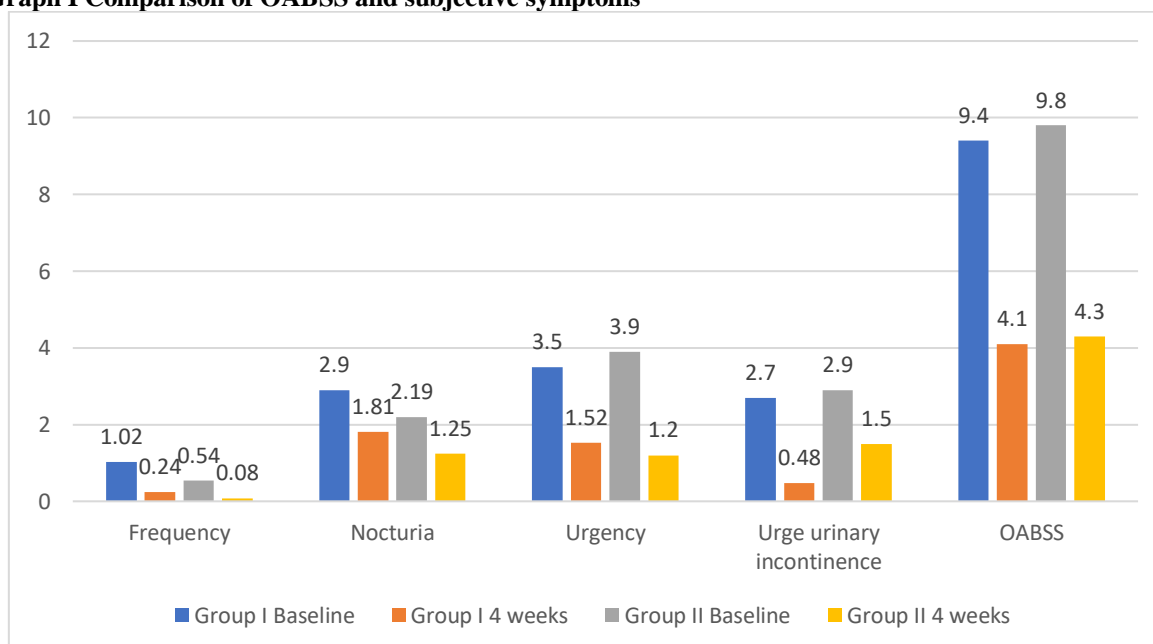
Table II shows that in group I and group II, defecations / day was 1.06 and 1.01, OABSS was 9.7 and 9.2, McMillan and Williams CAS was 0.26 and 0.51, KESS questionnaire score was 3.5 and 3.2 and Bristol stool consistency was 2.8 and 3.1 respectively. The difference was significant (P< 0.05).

**Table II Comparison of OABSS and subjective symptoms**

Parameters	Group I		P value	Group II		P value
	Baseline	4 weeks		Baseline	4 weeks	
Frequency	1.02	0.24	0.01	0.54	0.08	0.01
Nocturia	2.9	1.81	0.05	2.19	1.25	0.03
Urgency	3.5	1.52	0.02	3.9	1.2	0.04
Urge urinary incontinence	2.7	0.48	0.01	2.9	1.5	0.05
OABSS	9.4	4.1	0.01	9.8	4.3	0.01

Table II, graph I shows that there was significant difference in frequency, nocturia, urgency, urge urinary incontinence and OABSS at baseline and 4 weeks in both groups (P< 0.05).

**Graph I Comparison of OABSS and subjective symptoms**



**DISCUSSION**

Overactive bladder (OAB) is a clinical diagnosis defined by the International Continence Society as the presence of urinary urgency, usually accompanied by frequency and nocturia, with or without urge incontinence, in the absence of a urinary tract infection or other obvious pathology.<sup>8</sup> OAB has a considerable impact on patient quality of life, although it does not affect survival.<sup>9,10</sup> The present

study was conducted to compare Darifenacin and Trospium in overactive bladder.

We found that in group I and group II, defecations / day was 1.06 and 1.01, OABSS was 9.7 and 9.2, McMillan and Williams CAS was 0.26 and 0.51, KESS questionnaire score was 3.5 and 3.2 and Bristol stool consistency was 2.8 and 3.1 respectively. Manjunatha et al<sup>11</sup> found that OABSS improved significantly,  $-5.80 \pm 3.99$  (p = 0.0005) and  $-5.27 \pm$

2.98 ( $p = 0.0005$ ) in darifenacin and trospium groups respectively. However, the difference between the two groups was not significant either at 2 weeks ( $p = 0.952$ ) or 4 weeks ( $p = 0.654$ ) of treatment. A significant decrease in stool consistency was noted with darifenacin treatment ( $p < 0.05$ ), but the same was not seen with trospium ( $p = 0.076$ ). There was no significant difference in scores of KESS questionnaire between baseline, 2 weeks and 4 weeks, both within the group and between the groups ( $p > 0.05$ ). McMillan & Williams CAS scores increased at week 2 and week 4, in comparison with baseline scores in both darifenacin and trospium treated patients, however, the difference between the two groups was not statistically significant ( $p > 0.05$ ).

We found that there was significant difference in frequency, nocturia, urgency, urge urinary incontinence and OABSS at baseline and 4 weeks in both groups ( $P < 0.05$ ). Zinner et al<sup>12</sup> evaluated the efficacy of trospium 20 mg OD showed a decrease of -2.4 and -15.4 in the episodes of frequency / day and UUI / week respectively, during the 12 weeks treatment period. Systematic review by Lam S et al., observed that trospium 20 mg OD decreased the number of episodes of frequency / day and UUI / week by -2.7 and -16.1 respectively, during the 12 weeks treatment period.

The shortcoming of the study is small sample size.

## CONCLUSION

Authors found that both trospium and darifenacin have a rather acceptable patient acceptability rate, are comparably tolerable in terms of constipation, and successfully reduce the symptoms of overactive bladder.

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