

# A Randomized Control Trial To Compare The Efficacy Of Solifenacin And Tolterodine In Women With Overactive Bladder Syndrome (OABS)

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## Abstract

**Introduction:** Overactive bladder syndrome (OABS) is a common urogynaecological problem which is usually treated by anti-cholinergic drugs.

**Methods:** A total of 60 patients diagnosed as OABS on history taking, examination and baseline investigations underwent urodynamic study (UDS), OABS Score and Incontinence Impact Questionnaire (IIQ). Subjects were randomised to 2 groups, Group 1 (solifenacin 5 mg) while Group II (tolterodine 4 mg) daily for 6 months and were followed up at 1, 3, and 6 months for OABS score, IIQ and any adverse events. UDS was repeated after 6 months.

**Results:** Mean baseline value of OABS score was 8.5±1.87 (group I) and 8.57±1.5 (group II) which reduced to 5.6 (group I) and 5.57 (group II) in 3 months further reducing to 3.13 and 3.8 in 6 months. Baseline Mean IIQ was 12.77±3.88 (group I) and 11.77±2.9 (group II) reducing to 8.17 (group I) and 4.67 (group II). On UDS, baseline detrusor overactivity was 70% (group I) and 73.3% (group II) which reduced to 3.33% (group I) and 6.66% (group II) after 6 months. Baseline Mean Qmax (maximum flow rate) was 31.88±6.68 (group I) and 32.28±5.80 (group II) reducing to 19.60±3.53 (group I) and 18.62±3.21 (group II). Mean T Void (total time to void) at baseline was 33.89±6.87 (group I) and 32.03±5.08 (group II) which increased to 42.91±6.47 (group I) and 36.84±3.78 (group II). Adverse effects was higher in group II as compared to group I (p=0.02).

**Conclusion:** Both, solifenacin and tolterodine are effective for OABS with solifenacin showing higher increase in T Void and higher reduction in OABS score.

## Introduction

Overactive bladder syndrome: (OABS) is a common urogynaecological problem which is usually treated by anti-cholinergic drugs.

## Methods and Materials

### METHODS

- Subjects: 60 patients
- Urodynamic study (UDS), OABS Score and Incontinence Impact Questionnaire (IIQ). Randomised : 2 groups
- Group 1 (solifenacin 5 mg)
- Group II (tolterodine 4 mg) 6 months
- Followed :1, 3, 6 months (OABS score, IIQ).
- Repeat UDS after 6 months.

Table 1. Incontinence impact questionnaire (IIQ) in the 2 groups before and after therapy

IIQ score	Group I (N=30)	Group II (N=30)	P value
At baseline			
Range	7-20	7-19	0.261
Mean	12.77	11.77	
SD	3.86	2.9	
At 3 months of therapy			
Range	4-14	4-15	0.88
Mean	8.07	8.17	
SD	2.18	2.89	
At 6 months of therapy			
Range	3-8	3-9	0.076
Mean	5.33	4.67	
SD	1.42	1.35	
P value between baseline and 6 months			
	<0.001	<0.001	

Table 2. Urodynamic findings in 2 groups before and after therapy

Urodynamic parameter	Group I (N=30)	Group II (N=30)	P value
AT BASELINE			
<b>Detrusor overactivity</b>	21	22	0.56
Q max			
Range	19.3-41.3	20.1-43.2	0.81
Mean	31.88	32.28	
SD	6.68	5.80	
T void in seconds			
Range	26.2-51	27.3-50	0.23
Mean	33.89	32.03	
SD	6.67	5.08	
AT 6 MONTHS OF THERAPY			
<b>Detrusor overactivity</b>	1	2	0.45
Q max			
Range	15.1-25.8	15.6-26.4	0.265
Mean	19.60	18.62	
SD	3.53	3.21	
T void in seconds			
Range	30.2-52.1	31.8-52.1	<0.001 (Significant)
Mean	42.91	36.84	
SD	6.47	3.78	

## Results

Table 3. Adverse effects of drug in 2 groups

SNO	Adverse effects	Solifenacin (n = 30)		Tolterodine (n = 30)	
		3rd month	6th month	3rd month	6th month
1	Dry mouth	1	0	2	7
2	Dry Eyes	0	3	0	0
3	Constipation	1	4	2	4
4	Palpitation	0	0	0	2
5	Postural Hypotension	0	1	0	0

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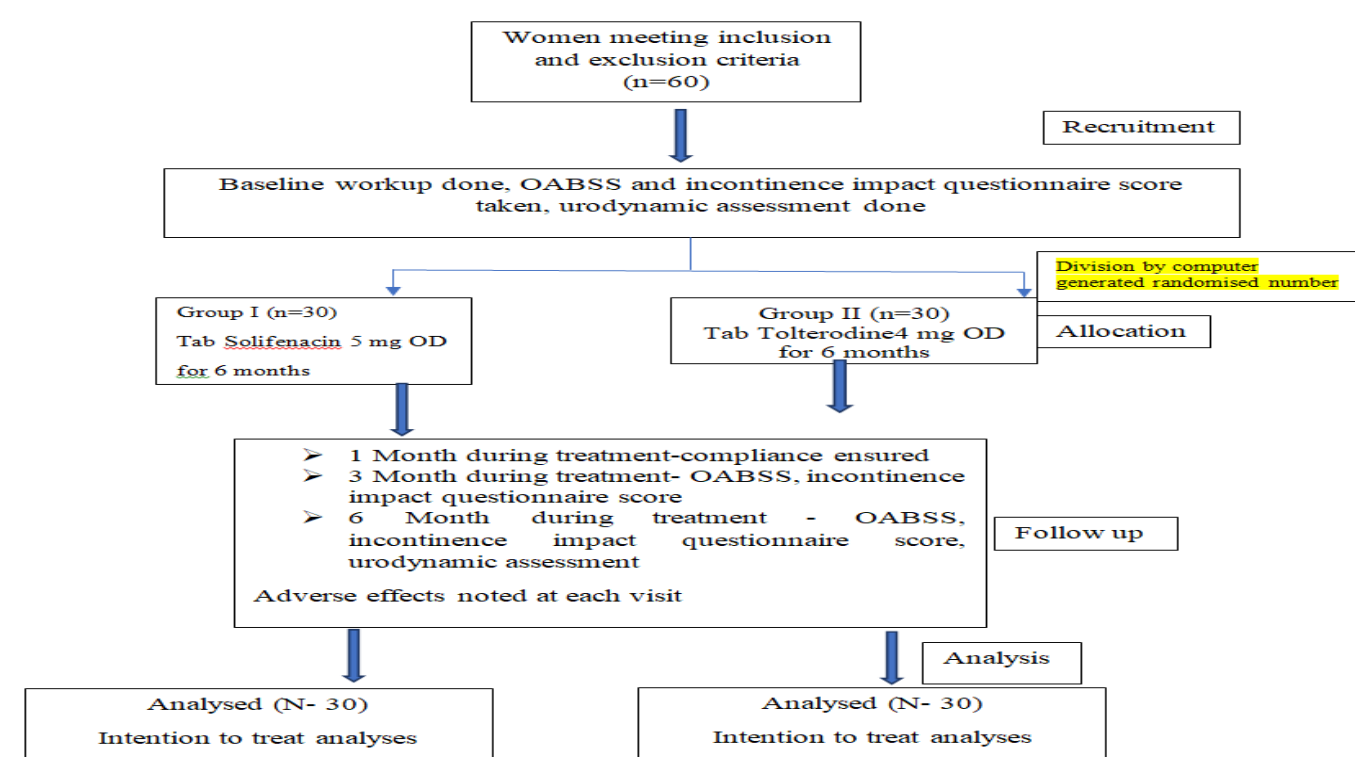
## Discussion

### Characteristics of women (N = 60)

S NO	Characteristic	Group I (N = 30)		Group II (N = 30)		P value
1	Age	Range (years)	Mean (years)	Range (years)	Mean (years)	0.872 NS
		25-65	42.5±9.81	25-75	42.07±10.79	
2	Married women	No	%	No	%	0.325 NS
		28	93.33	27	90	
3	Women with parity >1	No	%	No	%	0.56 NS
		27	90	23	76.6	
4	Mean BMI Kg/m <sup>2</sup>	24.79±3		24.07±2.61		0.325 NS
5	Mean creatinine value	0.83±0.21		0.86±0.21		0.42 NS

### Symptomatology of women (N = 60)

S no	Symptom	Group I (N = 30)			Group II (N = 30)			P value
1	frequency	NO	%	Mean duration (months)	No	%	Mean duration (months)	0.404
2	Urgency	30	100	7.9±2.09	30	100	7.33±3.07	0.234
3	Nocturia	21	70	7.97±2.39	25	83.3	7.1±3.16	0.451
4	Urge incontinence	27	90	4.05±2.82	30	100	3.48±2.26	0.867



## Conclusions

Both, solifenacin and tolterodine are effective for OABS with solifenacin showing higher increase in T Void and higher reduction in OABS score.

## References

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2. Bo K, Frawley HC, Haylen BT, Abramov Y, Almeida FG, Berghmans B, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Int Urogynecology J. 2017;28(2):191-213.