Research Article

Improved quality of life and overactive bladder symptoms score in cases of mainly irritative symptoms due to benign prostatic hyperplasia treated with tamsulosin plus solifenacin.

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Abstract
Benign prostatic hyperplasia (BPH) is the most common benign tumor among aging males. BPH is not a life-threatening condition but causes negatively impact patients' health-related quality of life its symptoms leads to sleep disruption, depression, anxiety, decreased mobility, increased falls, and causes problems in sexual activity[1, 2]. BPH is characterized by a spectrum of irritative and obstructive symptoms. Irritative symptoms include urinary urgency, frequency, nocturia, and incontinence. Obstructive symptoms include hesitancy, straining, slow stream, splitting or spraying, intermittent stream, and dribbling[3, 4].
Keywords: overactive bladder, irritative symptoms, prostatic hyperplasia

Introduction
Drug treatment for men suffering from LUTS due to BPH includes alpha 1 adrenergic blockers (α1-blockers), 5-α reductase inhibitors (5ARIs) or a combination of the both, anticholinergic agents, β3-adrenoceptor agonists, and phosphodiesterase type-5 inhibitors (PDE5i) have been investigated by recent studies for the treatment of BPH. α_1-Adrenergic blockers are the drug class of choice for treatment of voiding symptoms relating to BPH, while antimuscarinics are the drug class of choice for treatment of storage symptoms. Recent studies have reported that the add-on effect of anticholinergic to patients already on α-blockers was associated with significant efficacy and health-related quality of life benefits over α-blockers monotherapy in men with LUTS/BPH who had both irritative and voiding symptoms at baseline[5-7].

Patients and Methods
This study included 105 patients aged 45 or older suffering from mainly irritative symptoms due to BPH. This study designed for patients that are seeking medical advice in urology outpatient clinic, urology and nephrology center, Minia University Hospital.

We randomly divided 105 patients into 2 groups. The first group (n= 51) treated with 0.4 mg tamsulosin and the other group (n=54) treated with 0.4 mg tamsulosin plus 5 mg solifenacin, all administered once daily for 12 weeks. We obtained the quality of life questionnaire (table 1) and over-active bladder symptoms score questionnaire (table 2) and compared them.

Results
Out of 51 patients received 0.4 mg tamsulosin daily, only 48 patients had completed the study period as 3 patients were excluded from the study due to lost follow-up. The mean age of patients in this group was 63.25±5.1 years old (mean±SD). The quality of life was significantly improved by the administration of 0.4 mg tamsulosin. Significant improvements were observed in OABSS (table 3).

Out of 54 patients received tamsulosin 0.4 mg plus solifenacin 5 mg daily, only 49 patients had completed the study period as 5 patients were excluded from the study due to lost follow-up. The mean age of patients in this group was 63.4±5.69 years old

(mean±SD). The quality of life was significantly improved by the administration of 0.4 mg tamsulosin plus 5 mg solifenacin. Significant improvements were observed in OABSS (table 4).

By comparing the two groups we found that There is no significant difference between 2 groups before treatment but the quality of life score for patients after treatment with tamsulosin only is significantly greater than patients after treatment of tamsulosin plus solifenacin at significant level < 0.01 (table 5).

There is no significant difference in OABSS between 2 groups before treatment but OABSS for patients after treatment with tamsulosin only is Significant greater than patients after treatment of tamsulosin plus solifenacin at significant level <0.01(table 6).

Table 1: Quality of Life Due to Urinary Symptoms questionnaire

Quality of life due to urinary symptoms	Delighted	Pleased	Mostly satisfied	Mixed about equally satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Table 2: Overactive Bladder Symptom Score (OABSS)

Question	Frequency	score
How many times do you typically urinate from waking in the morning until sleeping at night?	≤ 7	0
	8-14	1
	≥ 15	2
How many times do you typically wake up urinate from sleeping at night until waking in the morning?	0	0
	1	1
	2	2
	≥ 3	3
How often do you have a sudden desire to urinate, which is difficult to defer?	Not at all	0
	Less than once a week	1
	Once a week or more	2
	About once a day	3
	2-4 times a day	4
	5 times a day or more	5
How often do you leak urine because you cannot defer the sudden desire to urinate?	Not at all	0
	Less than once a week	1
	Once a week or more	2
	About once a day	3
	2-4 times a day	4
	5 times a day or more	5

Table 3: Effect of tamsulosin only on group A.

	Before (Mean ± SD)	After (Mean ± SD)	P value
(1) Quality of Life	4.36±0.52	2.30±0.50	< 0.001
(2)OABSS	11.63±1.475	7.87±1.555	< 0.001*

Table 4: Effect of tamsulosin plus solifenacin on group B.

	Before (Mean ± SD)	After (Mean ± SD)	P value
(1) Quality of Life	4.37±0.485	1.29±0.498	**< 0.001**
(2) OABSS	11.43±1.458	5.00±1.064	**< 0.001***

Table 5: comparison between the change in QOl in group A and group B.

		Mean Rank	P-value
Quality of Life (Before)	**Tamsulosin Only**	100.37	0.970
	Tamsulosin plus Solifenacin.	100.63	
Quality of Life (After)	**Tamsulosin Only**	138.98	0.000
	Tamsulosin plus Solifenacin.	62.02	

Table 6: comparison between the change in OABSS in group A and group B.

		Mean Rank	P value
OABSS (Before)	**Tamsulosin Only**	103.78	0.414
	Tamsulosin plus Solifenacin.	97.22	
OABSS (After)	**Tamsulosin Only**	145.03	0.000
	Tamsulosin plus Solifenacin.	55.98	

Discussion

The reduction in urinary symptoms was associated with an improvement in the QOL of patients. Regarding our study, in group (A) patients with Tamsulosin 0.4 mg only there was improving in the QOL (question 8 of IPSS) from a mean ± SD of 4.36 ± 0.52 to 2.30±0.50 after 12 weeks, The mean change in IPSS-QoL score from baseline to endpoint was (2 points). This improvement was statistically significant (p-value< 0.001) and also was in agreement with Chapple et al., (2005), (1.3 points; p= 0.0005)[8,9].

Regarding our study`s results of group (B) patients with combination therapy, There was improving in QOL from a mean ± SD of 4.37±0.485 to 1.29±0.498.

This improvement was statistically significant (p-value < 0.001) and in agreement with van Kerrebroeck et al., (2013), who found that the Change from baseline to endpoint in the QOL due to urinary symptoms with a combination of solifenacin 6 mg plus tamsulosin OCAS 0.4 mg was (_1.3). Significant improvements in IPSS QoL score was reported (p < 0.001). Our study on Egyptian patients with highly statistically significant differences more than that in the NEPTUNE, which is explained by the tendency of our patients to the medical treatment rather than other invasive interferences making them highly sensitive to any positive effects on their life[10,11].

In our study, combination therapy was associated with significant additional benefits (P-value < 0.001) in QOL when compared with monotherapy with tamsulosin OCAS 0.4 mg these result in agreement with van Kerrebroeck et al., (2013) who stated significant improvements in IPSS QoL score with combination

therapy compared with tamsulosin OCAS ($p < 0.05$)[10].

Regarding overactive bladder symptom score (OABSS), in our study the combination therapy with the group (B) proved to be an effective treatment because of a statistically significant difference (p-value < 0.001), as OABSS, showed significant improvement from a mean ± SD of 11.43±1.458 to 5.00±1.064 after 3 months, these results were in agreement with Masumori et al., (2010), and Yamaguchi et al., (2011). Who found also a significant improvement by addition of solifenacin to tamsulosin as an improvement from 8.0±2.5 before addition of solifenacin to 4.8±2.6 after 12 weeks of adding solifenacin[12]. In ASSIST study, OABSS also Changes from baseline to end of treatment was statistically significant in cases treated with tamsulosin 0.4 mg plus solifenacin 5mg (p-value < 0.001)[13,14].

Conclusion

Our study concluded that the combination of solifenacin plus tamsulosin was associated with a benefit on QOL and OABSS in patients with mainly irritative symptoms due to benign prostatic hyperplasia when compared with tamsulosin only.

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