

## EFFICIENCY OF TRAZODONE IN TREATMENT OF NOCTURIA IN MEN WITH BPH. RANDOMISED, PLACEBO-CONTROLLED STUDY.

### Introduction:

The nocturia is one of the most bothersome symptoms in men with LUTS and BPH.[1]

The nocturia defined as “the complaint that the individual has to wake at night one or more times to void”[2].

The impact of nocturia on Quality of Life is still underestimated. Recent studies have shown a significant negative impact of interrupted sleep due to nocturia on daily activities and quality of life (QoL) [3]. In addition, it has been shown that quality of sleep is significantly affected by the hours of undisturbed sleep (HUS), defined “as the time between going asleep and the first awakening (to void)”, and sleep diary.

Basically, urologists prescribe alpha-blockers and antimuscarinic drugs for treatment LUTS (including nocturia). Few studies have shown efficacy of selective serotonin reuptakes inhibitors (SSRI) in treatment of LUTS and overactive bladder (OAB). Admittedly, using of SSRI in men with LUTS due the BPH are restricted (risk of acute urinary retention (AUR)). However, there is one of SSRI with alpha-blockers activity – trazodone. We decided to conduct the randomized, placebo-controlled study of efficacy of trazodone in men with LUTS (including nocturia) and BPH.

### Study design:

120 patients participated in the study after written informed consent. All patients were evaluated (DRE, TRUS, PSA, urofloumetry, IPSS, QOL).

The mean age of patients was  $58 \pm 7$  years.

The mean QoL was  $3.9 \pm 1.4$ .

The mean prostate volume was  $48.8 \pm 12.7$  sm<sup>3</sup>.

The mean Qmax was  $8.2 \pm 3.3$  ml/sec.

The mean postvoiding residual urine (PVR) was  $45.2 \pm 23.4$  ml.

Also, patients filled sleep diary, as well as shown in the table.

Sleep diary		
Time of falling asleep:		Time of awakening in the morning:
No	Time of awakening	Voiding volume (ml)
1.		
2.		
3.		
4.		
Total time of sleep(in minutes):		
Number of awakenings:		
Mean voiding volume:		
Time of uninterrupted sleep (TUS) (in minutes):		

Time of uninterrupted sleep (TUS) = Total time of sleep/Number of awakenings.

The patients were equally (randomized) divided into two groups. Patients in both groups filled the sleep diary during three nights in succession.

The patients of the 1<sup>st</sup> group were receiving trazodone 150 mg one time a day (before going to bed) within a month.

The patients of the 2<sup>nd</sup> group were receiving placebo (in the same time) within a month.

After that, patients in both groups were filled the sleep diary and they were evaluated (TRUS, PVR, urofloumetry).

### Results:

	1 <sup>st</sup> group (trazodone)		2 <sup>nd</sup> group (placebo)	
	Before	After	Before	After
TUS (minutes)	88 + 23	183 + 37*	92 + 26	103 + 29
QoL	4.1 + 1.4	2.1 + 0.8	3.7 + 1.3	3.3 + 1.1
Qmax (ml/sec)	8.4 + 3.5	12.1 + 4.2*	8.0 + 3.2	7.8 + 3.1
PVR (ml)	45.0 + 22.4	26.4 + 18.1*	45.7 + 24.1	49.3 + 25.2
Voiding volume (ml)	121.7 + 44.2	212 + 54.7*	118 + 39.6	136 + 41.9

\*p<0.01

There weren't significantly complications in both groups.

### Conclusions:

This study has shown efficiency of trazodone in treatment of men with nocturia and BPH. But we need in double-blind, randomized, placebo-controlled studies.

### References

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<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>Yes</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Ethics Committee of Kuban State Medical University</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>