

## MINIMAL CHANGE OF NOCTURNAL FREQUENCY AFFECTING THE QUALITY OF LIFE

### Hypothesis / aims of study

It is well known that nocturia is a bothersome symptom that affects the quality of life (QoL) (1). However, it is not known how much of a decrease in nocturnal frequency is needed to improve the QoL. We determined the minimal change in nocturnal frequency affecting the QoL of patients with nocturia.

### Study design, materials and methods

A total of 87 patients with BPH and nocturia were treated with  $\alpha$ -blocker and desmopressin for 8 weeks. Considering that the minimal clinically important change (MCIC) is different according to the baseline value, we divided the patients into two groups (group I, II). Group I had mild to moderate nocturia with voiding <4 times per night, and Group II had severe nocturia with voiding  $\geq$ 4 times per night. Voiding diaries and King's Health Questionnaires (KHQs) were evaluated before and after treatment. To determine the minimal change in nocturia affecting the QoL, statistical analysis was performed with the change in KHQ score according to decreased times of nocturnal frequency.

### Results

Group I and II had 35 (mean age: 65.6years) and 52 (mean age: 73.3years) patients, respectively (Table 1). In group I (nocturia<4 times/night), KHQ sleep/energy domain scores in patients with decrease in nocturnal frequency $\geq$ 1 time/night after treatment were more improved than those in patients with decrease in nocturnal frequency<1 time/night (ANOVA test,  $p<0.05$ , Table 2). In group II (nocturia $\geq$ 4 times/night), KHQ sleep/energy domain scores in patients with decrease in nocturnal frequency $\geq$ 2 times/night were more improved than those in patients with decrease in nocturnal frequency<2 times/night (ANOVA test,  $p<0.05$ , Table 2).

### Interpretation of results

MCIC has been proposed to refer to the smallest difference in domain of interest which patients perceive as beneficial and which would mandate a change in the patient's management. However there are several practical problems in estimating the MCIC. The estimated magnitude varies depending on the distribution index and multiple potential anchors, the direction of change, starting point (baseline value).

Therefore Homma and Koyama (2) defined the MCIC of incontinence frequency as a minimum value of change of incontinence frequency in overactive bladder patients with apparent improvement in the QoL scores. They analyzed the patient as an one group. However the patients had different starting point in symptom degree varying from minor to severe. In our study, to define the minimal change of nocturnal frequency affecting the QoL, we divided the patients into two groups (Group I who had minor to moderate nocturia of less than 4 times/night, Group II who had severe nocturia of 4 or more times/night) and the domain scores of two groups were significantly different (Student's t-test,  $p<0.05$ ).

The minimal decrease in nocturnal frequency associated with a statistically significant improvement in KHQ sleep/energy domain scores was 1 time in group I and 2 times in group II.

### Concluding message

These data show that decrease in nocturia of at least 1 time in patients with mild to moderate nocturia (<4 times/night) and 2 times in patients with severe nocturia ( $\geq$ 4 times/night) are needed to improve the QoL.

Table 1. Characteristics of the patients in each group

	Group I (nocturia<4)	Group II (Nocturia $\geq$ 4)	p-value
No. of patients	35	52	
Age	65.6 $\pm$ 9.7	73.3 $\pm$ 11.3	0.002
No. of nocturia	2.5 $\pm$ 0.7	5.3 $\pm$ 1.3	0.000
Sleep/energy domain score	31.4 $\pm$ 23.5	57.4 $\pm$ 21.5	0.000

Table 2. The changes of KHQ sleep/energy domain score according to the number of decrease in nocturia

	The decrease in nocturia episodes	No. of patients	The decrease in sleep/energy domain score	p-value
nocturia<4	$\leq$ 0	8	-2.1 $\pm$ 16.5	<0.05*
	1	11	24.2 $\pm$ 30.2	
	2	10	23.3 $\pm$ 31.6	
	3	6	27.8 $\pm$ 13.6	

≤0	7	2.4±15.0	
1	14	6.0±15.5	
nocturia≥2	13	19.2±17.8	<0.05 <sup>†</sup>
3	10	23.3±16.1	
≥4	8	22.9±8.6	
Total	87	16.3±21.7	

KHQ: King's Health Questionnaire. <sup>\*</sup>: number of decrease in nocturia ≤0 vs 1, 2, 3. <sup>†</sup>: number of decrease in nocturia 0, 1 vs 2, 3, ≥4

#### References

1. Urology (2006) 67; 713-718
2. Neurourol Urodyn (2006) 25; 228-235

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<b><i>Is this a clinical trial?</i></b>	<b>No</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>Kangdon Sacred Heart Hospital IRB</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>