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COMPARISONS OF CLINICAL OUTCOME AND URODYNAMIC EFFECTS IN FEMALE OVERACTIVE BLADDER PATIENTS AFTER 3-MONTH VERSUS 6-MONTH SOLIFENACIN TREATMENT: A RANDOMIZED PROSPECTIVE STUDY.

Hypothesis / aims of study

It had been that the median time for a therapeutic response was 3 months [1]. We were interested whether prolonged antimuscarinic treatment can decrease the recurrence of significant OAB symptoms that need retreatment.

Study design, materials and methods

A prospective randomized controlled trial was performed in a tertiary referral center. Consecutive women with OAB symptoms were randomized assigned to receive solifenacin 5 mg once a day for 3 months or 6 months. Baseline characteristics, including urodynamic parameters, 20 min pad weights, 3-day bladder dairies, questionnaires and urine nerve growth factors, were compared. Recurrence-free interval was measured from the date of the first antimuscrinic dose to the date of documented OAB symptoms recurrence while received antimuscrinics retreatment, or last follow-up.

Results

A total of 182 women were analyzed. Ninety-one patients received 3 months therapy and 91 patients received 6 months therapy. Most baseline data were not statistical different between these two groups (Table 1). However, the recurrence-free interval did not differ between these two groups (Figure 1, Log rank test, P = 0.26). Multivariate analysis revealed that age and nocturia episodes were the sole two independent factors affecting recurrence-free interval. The intension-to-treat duration (i.e., 3 months versus 6 months) did not affect the recurrence-free interval (power = 0.67, Figure 1 and Table 2). After treatment, significant better improvements of NGF/Cre, Overactive Bladder Symptoms Score, Patient Perception of Bladder Condition, daytime frequency episodes, some King's Health Questionnaires subscores in the 6 months group, compared with the 3 months groups (Table 3).

Interpretation of results

Prolonged antimuscarinic treatment duration could improve some clinical parameters, but seemed not to have significant effect on the recurrence of OAB symptoms. In addition, only age and nocturia episodes affect the recurrence of OAB.

Concluding message

Prolonged antimuscarinic treatment has a better impact on OAB symptoms and health-related quality of life, but may not result in the decrease of the recurrence of OAB symptoms.

Table 1. Baseline characteristics and follow-up data of both groups who received different treatment durations of antimuscarinics for female OAB (n=182).

Variable	3 months (n=91)	6 months (n=91)	P†
Age (years)	59.2±13.7	60.0±12.8	0.74
Parity	1.5±1.4	2.8±1.4	0.44
NGF/Cre (pg/mg)	11.4±23.2	24.0±31.9	0.03
Recurrence free interval (weeks)	59.1±39.9	54.7±37.4	0.53
Follow-up interval (weeks)	64.9±41.0	57.0±38.9	0.31
Incomplete treatment cases	28 (31)	37 (41)	0.16
Pad weight (g)	12.6±27.6	22.9±38.6	0.04
Qmax (mL/s)	17.6±7.7	20.2±17.0	0.30
Voided volume (mL)	234±100	248±106	0.43
PVR (mL)	35±21	32±17	0.17
Strong desire (mL)	218±50	227±43	0.18
PdetQmax (cmH2O)	28±19	25±14	0.20
MUCP (cmH2O)	59±30	51±26	0.10
USS	2.0±1.1	2.1±1.0	0.91
OABSS	7.6±2.6	8.3±3.0	0.06
PPBC	3.8±1.4	3.9±1.2	0.99
UDI-6	6.3±3.4	7.1±3.9	0.19
IIQ-7	8.2±6.0	8.4±5.6	0.73
Nocturia episodes (72 h)	6.2±5.0	5.8±3.7	0.88
Urgency episodes (72 h)	11.8±13.5	11.6±13.0	0.80
Daytime frequency (72 h)	30.0±12.0	32.5±15.6	0.34
Incontinence episodes (72 h)	1.8±4.8	1.9±4.7	0.67
General health perceptions	56.9±20.5	56.7±18.7	0.96
Incontinence impact	52.6±31.6	51.5±31.7	0.78
Role limitation	43.5±31.5	43.9±30.0	0.95
Physical limitation	44.9±32.6	49.1±31.7	0.37
Social limitation	30.0±8.2	33.0±29.5	0.50

Personal relationships	25.7±30.2	18.8±28.4	0.13
Emotions	42.6±31.2	42.0±32.2	0.85
Sleep / energy	50.4±27.8	48.5±27.8	0.64
Severity measures	28.2±25.7	38.0±27.1	0.005

†By Wilcoxon rank-sum test. ‡Data were expressed as mean ± standard deviation or number (percentage). IIQ-7=Incontinence Impact Questionnaire-7; MUCP=maximum urethral closure pressure; NGF=nerve growth factors; OAB=overactive bladder syndrome; OABSS=Overactive Bladder Symptoms Scores; PdetQmax= detrusor pressure at Qmax; PPRC=Patient Perception of Bladder Condition Questionnaire; PVR=post-void residual; Qmax=maximum flow rate; UDI-6=Urinary Distress Inventory-6 Questionnaire, USS=Urgency Severity Scales Questionnaire.

Table 2. Cox proportional hazards regression analyses for predicting recurrence of OAB (n=182)

Variable	Univariate analysis	P	Multivariate analysis	P
Age	1.07 (1.03-1.12)	0.001	1.07 (1.03-1.12)	0.001
Parity	1.65 (1.25-2.17)	<0.001	-	-
Voided volume (mL)	0.995 (0.991-0.999)	0.02	-	-
Strong desire (mL)	0.990 (0.983-0.998)	0.01	-	-
MUCP (cmH2O)	0.981 (0.965-0.998)	0.03	-	-
OABSS	1.15 (0.99-1.33)	0.07	-	-
PBC	1.45 (1.05-2.01)	0.02	-	-
Nocturia episodes (72 h)	1.08 (1.02-1.13)	0.004	1.08 (1.02-1.13)	0.004
General health perceptions	1.01 (1.00-1.04)	0.08	-	-

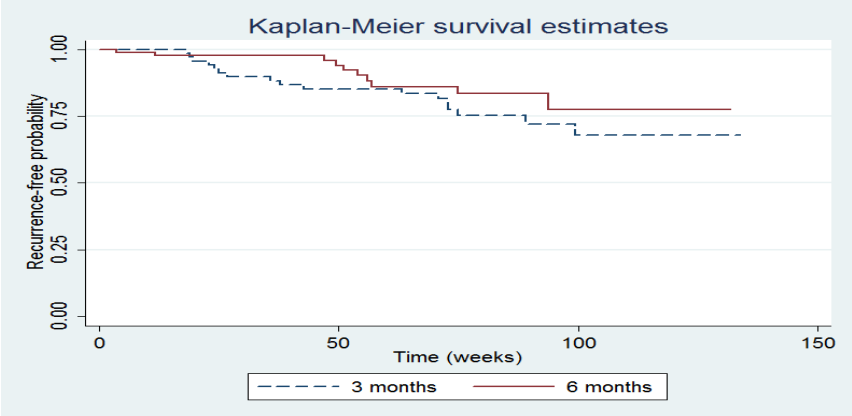
† By Wilcoxon rank-sum test. ‡Data were expressed as hazard ratio (95% confidence interval). The abbreviations were as Table 1. Only those with P<0.10 at univariate analysis were shown here.

Table 3. Comparisons of clinical outcome and urodynamic parameters before and after treatment

	Baseline			After 3 or 6 months' treatment		
Variable	3 months (n=63)	6 months (n=54)	P†	3 months (n=63)	6 months (n=54)	P†
NGF/Cre (pg/mg)	11.4±23.2	24.0±31.9	0.03	-4.0±24.7	-18.1±28.2	0.004
OABSS	7.7±2.7	8.2±2.8	0.18	-2.8±2.9	-4.5±4.2	0.01
PPBC	3.8±1.4	4.1±1.2	0.30	-1.3±1.5	-2.0±1.3	0.004
Daytime frequency (72 h)	30.2±13.1	34.8±17.2	0.14	-6.9±12.7	-12.7±15.4	0.03
Physical limitation	49.2±32.8	54.6±32.8	0.37	-20.0±32.6	-31.3±31.5	0.049
Social limitation	31.5±27.7	39.3±30.3	0.17	-14.6±29.6	-25.7±28.6	0.048
Severity measures	26.7±23.4	43.1±28.3	0.0007	-8.2±19.8	-28.5±32.0	0.0005

† By Wilcoxon rank-sum test. ‡Data were expressed as mean ± standard deviation. The abbreviations were as Table 1. Only those with P<0.05 at univariate analysis were shown here.

Figure 1 . Recurrence-free curves between the 3 months and 6 months treatment duration groups



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