

RESEARCHES ON THE IMPROVEMENT OF QOL IN BOTH PATIENTS WITH OVERACTIVE BLADDER SYNDROME AND THEIR CAREGIVERS.

-COMPARISON BETWEEN PHARMACOTHERAPY ALONE AND COMBINATION OF PHARMACOTHERAPY, PHYSICO-THERAPY, AND EDUCATION OF BOTH PATIENT AND CAREGIVER.-

Hypothesis / aims of study

The prevalence of OAB in Japan is 12.4% older than 40 years old according to Survey by the Japan Neurogenic Bladder Society (1) . With the increase in the number of geriatric population, the number of overactive bladder (OAB) patients increases; the prevalence of OAB in older than 80 years is as high as 36.8%. Hence, there is huge number of geriatric patients with OAB requiring care. Such situation may result in poor quality of life for both patients and caregiver. Now, home-care service system has been widely distributed in Japan, and most of these services are reimbursed by Health Insurance System of Japanese Government. The objectives of this study are to compare the effects of pharmacotherapy (anti-cholinergic) only and combination of pharmacotherapy (anti-cholinergic) and interventions including pelvic floor exercise, bladder training, and life-style modifications using electric diary apparatus, on the QOL of both geriatric patients with OAB and their caregiver at their home.

Study design, materials and methods

Materials; Geriatric OAB patients older than 65 years old who are living in their original houses with OAB and their caregivers were included. Exclusion criteria were bladder stone, bladder or prostate cancer, urinary tract infection, urinary retention, past history of radiation, and people requiring help for urination.

After full informed consent was taken, 22 sets of OAB patients and their caregivers were included into this study.

Study Design; those 22 sets were randomly assigned into 2 groups (group A: only pharmacotherapy with Sorifenasin 5mg/day, and group B: combination of pharmacotherapy with Sorifenasin 5mg/day and interventions). The period of treatments were 4 weeks. For group A, handouts regarding OAB and urinary incontinence, brief textbooks were given. For group B, the following interventions with handouts were given.

Interventions; lifestyle modifications, and physical therapies (bladder training, and pelvic floor exercise) by therapists from home-care service system before, at 2 weeks, at 4 weeks, and after 2 weeks of pharmacotherapy.

Methods of evaluation for QOL and other factors; Independence of activity of daily living(ADL), Intelligence, and QOL of patients were evaluated using Barthel Index (BI) , ADL classification, Mini Mental State (MMS) and SF-36v2. QOL of caregivers were evaluated using Barden Index of Caregiver (BIC-11, and short version of Zarit's care-burden(J-ZBI-8. Patients' 24 hours' episodes of urgency, urinary frequency, voiding episodes, urinary incontinence episodes were evaluated using electric recording machine (2). Patients' OAB symptoms were evaluated using OABSS (3). Post-void residual urine volume was measured using a portable ultrasonography scanner. All of those parameters were evaluated before, at 2 weeks, at 4 weeks, and after 2 weeks of pharmacotherapy.

Data were expressed as mean \pm s.d.mean, and statistical analysis was made by paired t-test, and Man-Whitney's U-test.

Results

Mean age of patients in group A and B were 72.9 and 75.3 years old (NS). Background factors regarding OAB, BI, ADL classification, MMS and SF-36v2 were similar. Mean age of caregivers in group A and B were 62.0 and 61.4 years old (NS). In patients, total and each score of OABSS improved at 2, 4, and 6 weeks in Group B, but only total score of OABSS improved at 2, 4, and 6 weeks in Group A. Frequency of urination, and frequency of urgency improved at 2, 4 and 6 weeks in group B, but not in group A. In caregivers, J-ZBI-8 significantly improved at 2, and 4 weeks in group B, but not in group A. BIC-11 showed no improvement in either group (table).

Interpretation of results

Caregivers for elderly patients living in their own houses may usually show lower QOL. In this study, several interventions by therapists from home-care service system have possibility in improving QOL of caregivers for elderly people.

Concluding message

These results suggest that pharmacotherapy (anti-cholinergic) in combination with several interventions can improve QOL in not only geriatric patients with OAB but also their caregivers.

Change in J-ZBI-8, BIC-11 in caregivers

Group A (n=11)

		before	2 weeks	4 weeks	6 weeks
J-ZBI-8		12.5	13.3	14.2	14.8
BIC-11	Time burden	4.0	3.8	3.8	4.1
	Psychological burden	2.8	3.0	2.8	3.4
	Real burden	2.8	2.7	2.9	3.3
	Physical burden	3.2	3.5	3.6	3.5
	Service-related burden	1.4	2.3	1.9	2.2
	Overall burden	1.5	1.5	2.0	1.9

Group B (n=11)

		before	2 weeks	4 weeks	6 weeks
J-ZBI-8		10.5	9.5***	9.4**	11.0
BIC-11	Time burden	3.0	2.9	3.1	3.5
	Psychological burden	2.0	2.9	3.1	3.5
	Real burden	1.5	1.5	1.8	1.7
	Physical burden	1.8	1.8	1.8	1.7
	Service-related burden	1.4	1.5	1.2	1.5
	Overall burden	1.5	1.1	1.0	1.3

n=11, Mean, * : p<0.05, ** : p<0.01 (vs before, Wilcoxon's signed-ranks test)

References

1. BJU Int, 96: 1314-8, 2005
2. Urology, 69:570-571, 2007
3. Urology, 68:318-323, 2006

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethical Committee, University of Yamanashi, School of Medicine.
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes