

PROPIVERINE HYDROCHLORIDE IMPROVED CORRELATIVELY SUBJECTIVE QOL AND OBJECTIVE FINDINGS IN JAPANESE PATIENTS WITH URINARY FREQUENCY AND/OR INCONTINENCE

Hypothesis / aims of study

Propiverine hydrochloride is widely used as an anticholinergic drug for patients with urinary frequency and/or incontinence, and accumulated evidence has demonstrated its efficacy and safety. The present study was designed to investigate how urinary frequency and incontinence affect the patient's subjective QOL and whether an improvement in objective findings by medical treatment favorably affects his/her subjective QOL.

Study design, materials and methods

With informed consent in writing, a voiding diary with the KHQ and ICIQ-SF was delivered to 83 Japanese patients with urinary frequency and/or incontinence before and after treatment with propiverine hydrochloride 10 or 20 mg/day for 8 weeks. They had ≥ 8 or ≥ 3 episodes of urinary frequency in the daytime and at night, respectively, or ≥ 1 episode of urinary incontinence or urgency in a day.

Results

Sixty-eight patients (aged 18-84 yrs; mean: 68.6 yrs), i.e., 44 male and 24 female patients, completed the diary and the questionnaires. The numbers of cases of diseases observed in the present study were as follows: 30 cases of overactive bladder; 11 cases of neurogenic bladder; 16 cases of pollakisuria nervosa; 6 cases of nonbacterial chronic cystitis or chronic prostatitis; and 5 cases of other diseases.

Objective symptoms decreased significantly with respect to the mean frequency of urination and to the mean incidence of urinary incontinence both in daytime and at night (Table 1). The KHQ and ICIQ-SF scores improved significantly with respect to all domains except personal relationships in the KHQ (Tables 2 and 3). In the KHQ, furthermore, a significant Spearman rank correlation was found between a decreased incidence of urinary incontinence and an improvement in role limitations (Fig 1) and between a decreased incidence of urinary incontinence and an improvement in emotional problems (Fig 2). In the ICIQ-SF, in addition, a significant correlation was also found between a decreased incidence of urinary frequency and a subjective improvement in quantity of leakage, between a decreased incidence of urinary frequency and an improvement in subjective QOL scores (Fig 3), between a decreased incidence of urinary frequency and an improvement in the total ICIQ-SF score (Fig 4), and between a decreased incidence of urinary incontinence and an improvement in subjective QOL scores (Fig 5).

Thirty-two episodes of adverse reactions were observed in 27 cases, the incidence rates of which were as follows: 24.0% for digestive symptoms (17 events of dry mouth, 2 of constipation, and 1 of abdominal discomfort); 7.2% for urinary tract symptoms (5 events of difficulty in urination and 1 of urinary tract infection); and 6.0% for ocular symptoms (2 events of pain, 2 of dizziness, and 1 of poor eyesight). None of them was serious.

Interpretation of results

Medical treatment of urinary frequency and incontinence with propiverine hydrochloride significantly improved both subjective QOL and objective findings, with significant positive correlations between them.

Concluding message

These results suggest that an improvement in objective symptoms with propiverine hydrochloride favorably improves subjective QOL of the patient, and these results provide further evidence about the safety and efficacy of propiverine hydrochloride.

Table 1 Changes in objective symptoms before treatment 8 W of treatment

	before treatment	8 W of treatment
Frequency(daytime)	10.2 ± 4.5	7.9 ± 2.5*
(night)	2.1 ± 1.9	2.0 ± 1.1*
Incontinence(daytime)	1.5 ± 2.2	0.5 ± 1.3*
(night)	0.7 ± 1.5	0.3 ± 0.9*

N=35, mean ± SD, * p<0.01 vs before treatment by t-test

Table 3 Changes in ICIQ-SF score

Domain of ICIQ-SF	ICIQ-SF	
	before treatment	8 W
Total ICIQ-SF score	9.7 ± 4.4	4.8 ± 3.8**
QoL score	4.2 ± 2.8	1.8 ± 1.9**
Frequency of incontinence	2.9 ± 1.0	1.5 ± 1.4**
Quantity of leakage	2.7 ± 1.2	1.4 ± 0.9**

N=25, mean ± SD, **p<0.01 by Wilcoxon test

Table 2 Changes in KHQ score

Domain of KHQ	KHQ score	
	before treatment	8 W
General Health	49.3 ± 24.9	38.8 ± 21.9*
Incontinence impact	61.1 ± 31.4	33.2 ± 29.9**
Limitations		
Role	51.3 ± 37.0	23.1 ± 26.2**
Physical	47.6 ± 34.9	25.4 ± 29.3**
Social	35.4 ± 29.9	19.0 ± 27.9**
Emotional problems	49.3 ± 34.9	29.4 ± 29.6**
Sleep/Energy disturbance	39.3 ± 33.5	23.6 ± 27.3**
Severity measures	25.1 ± 20.6	16.1 ± 13.4**

N=36, mean ± SD, * p<0.05, **p<0.01 by Wilcoxon test

Fig1

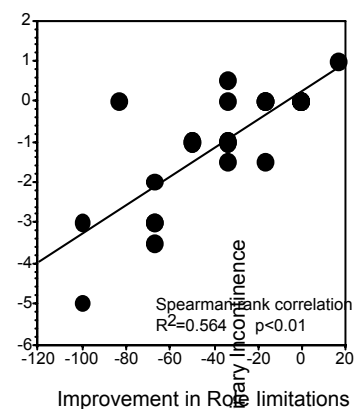


Fig 2

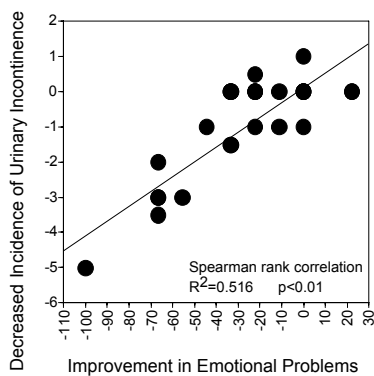


Fig 3

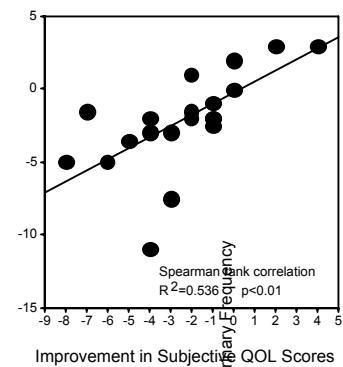


Fig 4

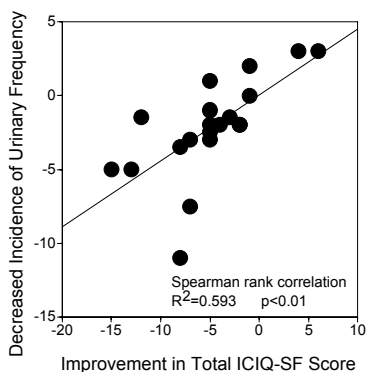


Fig 5

