



Psychometric assessment of female overactive bladder syndrome and antimuscarinics-related effects



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ABSTRACT

Objectives: To investigate the characteristics of psychological distress (PD), personality traits, and family support in women with overactive bladder syndrome (OAB), and the effects of antimuscarinic treatment. **Study design:** Women with and without OAB (age- and body mass index [BMI]-matched control group) were prospectively enrolled; they recorded bladder diaries, underwent urodynamic studies, and completed PD, personality traits, and filled family support questionnaires before and after antimuscarinic treatment. OAB women underwent treatment with tolterodine or solifenacin for 12 weeks. The control group completed questionnaires.

Main outcome measures: The differences in PD, personality traits, and family support scores between both groups, and the changes after antimuscarinic treatment in OAB women.

Results: Eighty-five women with OAB (tolterodine, $n=42$; solifenacin, $n=43$) and 65 without OAB completed the studies. Linear regression analysis with age and BMI adjustment revealed: coefficients of OAB were significant (all $P<0.05$) for somatic complaints (mean: 0.87 vs. 0.63, coefficient = 0.21), obsessive–compulsive symptoms (0.69 vs. 0.44, coefficient = 0.25), anxiety symptoms (0.42 vs. 0.27, coefficient = 0.14), General Symptom Index (GSI, 0.48 vs. 0.33, coefficient = 0.14), neuroticism (9.23 vs. 5.17, coefficient = 3.73), and extroversion–introversion (13.64 vs. 15.25, coefficient = -1.73). Anxiety symptoms (0.42 vs. 0.36) and GSI (0.48 vs. 0.39) improved after antimuscarinics (all $P<0.05$). High Overactive Bladder Symptom Score questionnaire score (coefficient = -0.39), low hostility score (coefficient = 2.11), and high additional symptoms score (coefficient = -1.46) were associated with good therapeutic effect (all $P<0.05$).

Conclusions: OAB women experience more PD, neuroticism, and introversion than asymptomatic women, and antimuscarinics could improve PD.

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1. Introduction

Overactive bladder syndrome (OAB) is characterized by urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence [1]. Myogenic, neurogenic, and peripheral autonomous theories have been considered as possible aetiologies of detrusor overactivity which is a frequent urodynamic finding in OAB patients [2]. However, the exact etiology of OAB is still obscure. Psychological causes have

been investigated, with conflicting results [3]. Numerous series demonstrated that patients with detrusor instability did not have more psychological disorder than patients with other types of incontinence [3–5]. Nonetheless, Zorn et al. [6] reported a strong association between depression and idiopathic urge incontinence.

Knowledge about the association of psychological distress (PD) and personality traits with OAB may be helpful for further research of OAB pathophysiology and for treating OAB patients. Thus, the primary objective of this study was to elucidate the characteristics of PD and personality traits in OAB women.

The detrusor muscle predominantly contains M2 and M3 muscarinic receptors, and M3 receptors are the most important for detrusor contraction. Nonetheless, all five muscarinic receptors have been identified in the brain. M1 and M2 receptors are considered to play a major role in memory and cognitive function

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[7]. Antimuscarinics are the mainstay treatment for OAB patients, and may penetrate the blood–brain barrier of OAB patients. The elderly are more likely to have blood–brain barrier impairment. Thus, antimuscarinics may result in central nervous system (CNS) adverse effects [7]. Common CNS adverse effects include headache, somnolence, and dizziness. Furthermore, cognitive impairment, confusion, memory loss, and depression have been reported during antimuscarinic treatment [7–9].

Tolterodine in extended release (ER) form shows a similar degree of selectivity for all muscarinic receptor subtypes and has a half-life of 8 h. Solifenacin has moderate selectivity for the M3 receptor over the M2 receptor and a half-life of 45–68 h. We previously reported similar therapeutic efficacy for tolterodine and solifenacin [10]. Several cases of memory loss and cognitive impairment during tolterodine treatment have been reported [7–9]. In contrast, antimuscarinics selective for M3 receptors (such as solifenacin) are considered to cause less CNS adverse effects [7,11]. Thus, the secondary objectives of this study were to investigate the effect of antimuscarinics on PD and personality traits; to elucidate which antimuscarinic is a better choice for OAB women (especially with concomitant PD); and to determine whether PD or personality traits can affect the therapeutic effect.

2. Methods

This clinical trial was a nonrandomised open-label study conducted from August 2008 through February 2010 at the Department of Obstetrics and Gynecology of National Taiwan University Hospital. The hospital's research and ethics committee approved the study protocol. Informed consent was obtained from each patient.

The screening visit was designated as visit 0, and the following inclusion criteria were used: (1) women at least 18 years old, who had at least a 3-month history of OAB symptoms, including urgency, urinary frequency, nocturia, or urge incontinence and (2) an average of ≥ 8 micturitions in 24 h. Eligibility was determined at visit 1, using the results recorded in the 3-day bladder diary prior to visit 1. Patients with previous bladder or urethral surgery, active urinary tract infections, history of psychotic disorder (such as schizophrenia) or possible neurogenic lesions were excluded from the study. Urodynamic studies were also performed for the enrolled OAB women before visit 1 and after 12 weeks of treatment.

Urodynamic studies were performed with the women in a seated position using a Life-Tech six-channel monitor with computer analysis and the Urolab/Urovision System V (Houston, Texas, USA). These studies included uroflowmetry, filling cystometry (at an infusion rate of 60 mL/min with 35°C distilled water), voiding cystometry, and stress urethral pressure profiles (with a strong-desire volume of distilled water in the bladder).

Interim analyses for age and body mass index (BMI) distribution of the enrolled OAB patients were performed to determine the number of age- and BMI-matched controls required. Women without OAB symptoms and history of psychotic disorder (such as schizophrenia) were invited to participate as the control group.

Solifenacin became available at our hospital after March 2009. Thus, the women who enrolled before March 2009 were treated with tolterodine ER 4 mg, and those who enrolled after March 2009 were treated with solifenacin 5 mg; the dose was taken once a day for 12 weeks. Patients were followed up at week 4 (visit 2), week 8 (visit 3), and week 12 (visit 4).

At visit 1 and visit 4, all of the women with OAB were asked to complete a validated Chinese version of the Overactive Bladder Symptom Score questionnaire (OABSS) [12]; the short form of the Incontinence Impact Questionnaire (IIQ-7) [13,14]; Brief Symptom Rating Scale (BSRS) [15,16]; Maudsley Personality Inventory (MPI) [17]; and Adaptability, Partnership, Growth, Affection, and Resolve

(APGAR) questionnaires [18]. Women in the control group were requested to complete the above questionnaires. The OABSS is used to assess the severity of OAB symptoms [12]. The IIQ-7 is used to assess health-related quality of life [13,14]. A reduction of the IIQ-7 score indicates a positive response to OAB treatment [14].

The BSRS includes the following dimensions of psychopathology: somatic symptoms, obsessive–compulsive symptoms, interpersonal sensitivity, depressive symptoms, anxiety symptoms, hostility, phobic–anxiety, and paranoid tendency. Additional symptoms include vegetative and other clinical indicators [15,16]. The BSRS is composed of 30 items rated on the basis of degree of distress caused by that item over the past week [16]. Each dimension is assessed by several questions with a 5-point Likert scale (0–4 points). The severity of a psychopathologic factor is expressed with an index calculated as the sum of scores divided by the number of questions in that specific dimension. The General Symptom Index (GSI), a mean score of all BSRS items, represents the global severity of PD, and a higher GSI indicates more severe PD. The BSRS has been reported to be a reliable and valid psychiatric self-rating scale for use in psychosomatic research [19].

To identify subjects with clinically pathological mood/anxiety scores, an adjusted *T* score of mood/anxiety symptom dimensions in the BSRS was applied. A total of 4600 consecutive participants in a health screening program in our hospital who had filled the BSRS served as the reference group [20]. These subjects were grossly representative of the hospital's catchment population. After adjustment by age and sex standardization, the mean score of the mood/anxiety sub-scale of the BSRS in the reference group was defined to be 50, and the standard deviation was set at 10. The clinically pathological score of the mood/anxiety sub-scale was arbitrarily defined as the OAB subject's sub-scale score greater than the mean score of the reference group by two standard deviations ($>$ adjusted *T* score of 70).

The shortened version of the MPI (30 items) is used to assess personality traits and to measure subscales of neuroticism stability and extroversion–introversion [17]. The psychometric properties of the Chinese version of the MPI have been reported [21]. A higher score on this inventory indicates a higher level of neuroticism or extroversion.

The APGAR score (five items) is used to measure the perceived family support in the domains of adaptation, partnership, growth, affection, and resolve [18]. Each item is designed to describe the frequency of feeling satisfied with one domain of family functioning, and a higher score indicates better family support.

In this study, therapeutic effect was defined as the change of the OABSS score from baseline. OAB is considered to improve if there is a reduction in the OABSS score of ≥ 3 from baseline after 12 weeks of antimuscarinic treatment [22].

Stata v.8 software (StataCorp, College Station, TX, USA) was used for statistical analyses. Wilcoxon rank-sum and signed-rank tests were used as the statistical methods where appropriate. We performed multivariate backward stepwise linear regression analysis by including variables of age, body mass index, baseline OABSS score, baseline IIQ-7 score, solifenacin or tolterodine treatment, all BSRS dimensions, personality traits, and familial APGAR score, with a cut-off point of $P < 0.05$ to analyze the effect of variables on therapeutic effect (i.e. the change of OABSS scores). The power to test the quality of means was calculated from the means, standard deviations, and numbers of the variables of the two groups.

3. Results

Fig. 1 shows the flowchart of the OAB women. Eighty-five women with OAB (tolterodine, $n = 42$; solifenacin, $n = 43$) and 65 without OAB completed the studies. Baseline characteristics such

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