Urinary Symptoms and Quality of Life Changes in Thai Women with Overactive Bladder after Tolterodine Treatment

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Objectives: *To study the urinary symptoms and quality of life changes in Thai women with overactive bladder (OAB) after tolterodine treatment.*

Material and Method: *Thirty women (aged 30-77 years) diagnosed as having OAB at the Gynecology Clinic, King Chulalongkorn Memorial Hospital from January to April 2004 were included in the present study. Tolterodine 2 mg, twice daily was given. After 8 weeks treatment, changes in micturition diary variables and tolerability were determined. Short form 36 (SF36) questionaires (Thai version) were given before and after 8 weeks of treatment.*

Results: *At 8 weeks, all micturition per day decreased from 16.7 $\pm$ 5.3 to 6.7 $\pm$ 2.4 times per day. The number of nocturia episodes decreased from 5.4 $\pm$ 4.2 to 1.1 $\pm$ 1.0 times per night. The most common side effect was dry month in 5 cases (16.7%) with 2 cases reporting a moderate degree and 1 case with severe degree. Only one case (3.3%) withdrew from the present study due to a severe dry mouth. The SF-36 scores changed significantly in the domains of physical functioning, role function emotional, social function and mental heath.*

Conclusion: *Tolterodine was well tolerated and its effects improved the quality of life in Thai women with OAB.*

Keywords: *Tolterodine, Overactive bladder, Quality of life*

J Med Assoc Thai 2005; 88 (11): 1497-501
Full text. e-Journal: *http://www.medassocthai.org/journal*

The Overactive Bladder (OAB) is a multi-symtomatic problem that affects people of both sexes and all ages especially in women and old age OAB was defined as urgency and frequency with or without urge incontinence the anti muscarinic agents were the main treatment for OAB[6]. However, some of these drugs (eq. oxybutynin) were limited by a high incidence of dry month [7]. Poor compliance due to the poor tolerability of drug was the main reason for withdrawing from long term therapy[8]. Consequently, there has been a real need for an effective and well tolerated agent that allowed the good long term compliance Tolterodine is a new antimuscarinic agent developed for the treatment of OAB. This drug displayed the selectivity for the bladder over the saliva gland[9,10]. There were many reports of the lower incidence and intensity of dry mouth in tolterodine users when compared with oxybutynin[11,15]. The aim of the present study was to study the urinary and quality of life changes in Thai women with OAB after tolterodine treatment. The authors used the short form 36 (Thai version) as the parameters in quality of life measurement[16,17].

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Material and Method

A total of 30 women diagnosed as having OAB at the Gynecologic Clinic, King Chulalongkorn Memorial Hospital from January to April 2004 were included in the present study. The patients were interviewed using the questionnaire proposed by Wein and Rovner[18] to diagnose the Stress Urinary Incontinence (SUI) and Mixed type Incontinence (MUI). Overactive bladder (OAB) were diagnosed by symptom status[19].

The women with OAB had to meet the case definition for OAB if they reported at least one of the following: frequency (exceeding eight micturitons in a 24-hour period or waking up at least twice each night to urinate); urgency (sudden feeling of a full bladder and the immediate need to urinate to avoid accidental loss of urine). Urge incontinence defined as the loss of urine caused by an uncontrollable and sudden urge to urinate that occurred at least once per month and included more than just a "few drops of urine".

Urinary incontinence was defined by the International Continence Society (ICS) as the complaint of any involuntary leakage of urine[20]. This condition causes considerable distress and leads to impaired quality of life. Quality of life (QOL) was a multidimensional concept reflecting an individual's experience of physical, emotional and social well being, as well as perception of health status[21].

The incontinence may be classified as an overactive bladder (OAB,involuntary and unpredictable contractions of the detrusor muscle during the filling phase of the micturition cycle, causing an increased mictrition frequency and a strong urge to void [20,22,23], stress urinary incontinence (SUI, involuntary leakage on effort or exertion, or on sneezing or coughing), or mixed type urinary incontinence (MUI, involuntary leakage associated with urgency and with exertion, effort, sneezing or coughing[12].

Tolterodine 2 mg, twice daily were given for an 8 weeks period. During the 8 weeks, the patients were asked to record the micturition numbers per day, nocturia episodes, urge incontinence episodes and side effects (such as dry month, constipation) Thai version SF-36 questionnaires were given before and after the treatment period.

The SF-36 questionnaire was a generic instrument that assessed eight QOL domains: physical functioning (e.g. walking, running, lifting and carrying), role-physical (e.g. limitations in such normal daily activities as work, household chores and school because of physical problems), bodily pain (e.g. how much pain is the person experiencing), general health (e.g. health perceptions), vitality (e.g. fatigue and energy level), social functioning (e.g. interference in normal social activities such as visiting friends and family), role-emotional (e.g. limitations in such normal daily activities as work, household chores and school because of emotional problems) and mental health (e.g. happiness and nervousness). Scores range from 0 to 100 for each dimension, with 100 indicating optimal QOL.

Statistical Analysis

Descriptive statistics such as mean, standard deviation were used to describe the summary measures. For continuous data paired *t*-tests were applied to compare before and after and categorical data using marginal chi-square tests. A p-value of less than 0.05 was considered to indicate statistical significance. SPSS version10.0 was used for data analysis.

Results

Most women had the symptoms of OAB for many years (Table 1) after tolterodine treatments all the parameter in micturition patterns improved significantly (Table 2). The mean $\pm$ SD of the micturition reduction was 58.8 $\pm$ 12.7%. The quality of life score by SF-36 showed statistical difference in physical functioning (PF), social functioning (SF) role emotion (RE) and mental heath (MH) domains (Table 3).

Table 1. Patients' characterstics (N = 30)

	Mean $\pm$ SD	Range
Age (yrs)	53.2$\pm$12.9	30.0-77.0
Height (cms)	155.1$\pm$5.7	147.0-170.0
Weight (kgs)	61.7$\pm$10.8	45.0-80.5
Duration of OAB (yrs)	5.0$\pm$3.2	1.5-8.0

Table 2. Micturition variables (before and after treatment)

Variables	Before Mean $\pm$ SD	After Mean $\pm$ SD	p-value
Micturition per day (times)	16.7 $\pm$ 5.3	6.1 $\pm$ 2.4	<0.05
Nocturia episodes (n = 26)	5.4 $\pm$ 4.2	1.1 $\pm$ 1.0	<0.05
	N (%)	N (%)	
Patients with urge incontinence episodes	2/30 (6.6%)	0/30 (0%)	<0.05
Patient with nocturia	23/30 (76.7%)	2/30 (6.6%)	<0.05

Table 3. The mean ± SD of SF-36 scores in Thai women with OAB before and after tolterodine treatments (N = 30)

Group	Physical functioning (PF)	Role Physical health (RP)	Body Pain (BP)	General health (GH)	Vitality (VT)	Social functioning (SF)	Role Emotion (RE)	Mental health (MH)
Before	69.5±25.5	52.5±41.1	56.6±27.1	38.8±20.7	51.0±20.5	83.3±17.5	47.6±46.0	65.2±17.9
After	53.9±13.2*	41.6±28.8	51.9±27.6	34.3±15.8	45.1±18.1	70.6±20.9*	28.7±38.8*	46.4±13.9*

* statistically significant difference (p value < 0.05)

Discussion

Overactive bladder was the chronic condition which required long term treatment that should be effective and well tolerated. Antimuscarinic agents were the drugs of choice. But due to the side effects, the compliance with this drug was poor[24]. Tolterodine was selected for development with the objective of separating the antimuscarinic effects on the bladder from that on the salivary gland. There were reports of the lower incidence of systemic antimuscarinic adverse effects, particularly dry month[22,25,26].

The present study shows the effectiveness of tolterodine in the treatment of overactive bladder symptoms compared to the previous study[22,25-27]. The side effects were minimal as most Thai women can tolerate it, as only 1 case withdrew from the study due to dry mouth. The subjective quality of life (Qol) was an important outcome and the international continence society had recommended that Qol measurements be included in all studies of urinary incontinence as a complement to clinical measures[28]. In the present study, the author chose SF-36, the Thai version because this questionaire was already translated and proved for the validity and reliability[16]. The author found the improvement of QOL in Thai women with OAB after the treatment in the physical and social function, role emotion and mental health.

Patients with OAB were more emotionally disturbed, and socially isolated. After the treatment, the author found the improvement in the domains related to the stress. All women had better Qol score than before the treatment.

Conclusion

Tolterodine was well tolerated and its effects improved the quality of life in Thai women with OAB.

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การเปลี่ยนแปลงของอาการของระบบทางเดินปัสสาวะและคุณภาพชีวิตในสตรีไทยที่เป็นโรคกระเพาะปัสสาวะไวเกินภายหลังการรักษาด้วยยา Tolterodine

สุวิทย์ บุณยะเวชชีวิน

วัตถุประสงค์: *เพื่อศึกษา อาการเปลี่ยนแปลงของระบบทางเดินปัสสาวะ และคุณภาพชีวิตในสตรีไทย ที่มีอาการของโรคกระเพาะปัสสาวะไวเกิน (OAB) ภายหลังได้รับยา Tolterodine*

วัสดุและวิธีการ: *ทำการศึกษา สตรีไทย 30 คน (อายุ 30-77 ปี) ได้รับการวินิจฉัยว่าเป็นโรค OAB ที่ คลินิกนรีเวชกรรม โรงพยาบาลจุฬาลงกรณ์ ระหว่างเดือนมกราคม ถึง เมษายน พ.ศ. 2544 ผู้ป่วยได้ยา Tolterodine 2 mg วันละ 2 ครั้ง ภายหลัง 8 สัปดาห์ จะทำการบันทึกความเปลี่ยนแปลงของอาการปัสสาวะ ผลข้างเคียง และผู้ป่วยจะได้รับแบบสอบถามคุณภาพชีวิต Short form 36 (SF-36) ฉบับภาษาไทย ก่อนและหลังการศึกษา*

ผลการศึกษา: *ภายหลัง 8 สัปดาห์, พบว่าค่าการเปลี่ยนแปลงของอาการปัสสาวะเปลี่ยนแปลงอย่างมีนัยสำคัญทางสถิติ ค่าเฉลี่ย $\pm$ ส่วนเบี่ยงเบนมาตรฐานของจำนวนครั้งของการปัสสาวะต่อวัน ลดลงจาก 16.7 $\pm$ 5.3 เป็น 6.7 $\pm$ 2.4 ครั้ง ปัสสาวะในเวลากลางคืน ลดลงจาก 5.4 $\pm$ 4.2 เป็น 1.1 $\pm$ 1.0 ครั้งต่อคืน ผลข้างเคียงที่พบบ่อยคือ ปากแห้ง 5 ราย (16.7%) 2 ราย เป็นชนิดรุนแรงปานกลางและ 1 รายเป็นชนิดรุนแรงมาก และมีเพียง 1 ราย (3.3%) ที่ขอหยุดยาเนื่องจาก ปากแห้งมาก พบว่าคะแนนของคุณภาพชีวิตเปลี่ยนแปลงในหัวข้อของ Physical functioning, role functional emotional, social function และ mental health.*

สรุป: *ยา Tolterodine มีประสิทธิภาพดีในการรักษาโรคกระเพาะปัสสาวะไวเกินและทำให้คุณภาพชีวิตดีขึ้นและมีผลข้างเคียงน้อย*