



ORIGINAL ARTICLE

The translation and validation of Chinese overactive bladder symptom score for assessing overactive bladder syndrome and response to solifenacin treatment



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Received 3 March 2012; received in revised form 26 July 2012; accepted 30 July 2012

KEYWORDS

antimuscarinics;
detrusor overactivity;
incontinence;
overactive bladder;
symptom score;
voiding diary

Background/Purpose: Overactive bladder symptom score (OABSS) was developed by a Japanese urologist and is widely used in Asian countries. The aim of this study was to develop and validate a Chinese OABSS for assessing overactive bladder (OAB) and treatment outcome after solifenacin. **Methods:** The Chinese OABSS was developed by linguistic validation of the original version. Its reliability and validity, and correlations with a three-day bladder diary were tested. Patients answered the Chinese OABSS at enrollment and repeated the questionnaire after a non-treatment period of 2 weeks, and at 4 and 12 weeks after solifenacin (5 mg/day). Patients also

Conflicts of interest: The authors have no conflicts of interest relevant to this article.

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completed a three-day bladder diary and forms including patient perception of bladder condition, International Prostatic Symptom Score and quality of life index at each study visit (for a total of four visits). An analysis was conducted to evaluate the reliability and validity of the Chinese OABSS and the correlations with a three-day bladder diary and a patient perception of bladder condition, respectively.

Results: A total of 60 patients with OAB, including 31 OAB wet and 29 OAB dry, were enrolled. The test–retest reliability of Chinese OABSS was moderate to good with weighted kappa coefficients of 0.515–0.721 for each symptom score and 0.610 for total symptom score. Forty-eight (80%) patients completed the responsiveness study and were followed-up at all time points. Patients' OAB symptoms improved significantly from baseline to 3 months after solifenacin treatment. The changes in OABSS decreased gradually with time within the three months of solifenacin treatment.

Conclusion: The Chinese OABSS has been validated as a reliable instrument for assessing OAB. Solifenacin 5 mg once daily improved urgency and other symptoms of OAB including frequency, urge incontinence, OABSS and International Prostatic Symptom Score. The adverse effects were acceptable and became less significant with time in the three months of treatment.

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Introduction

Overactive bladder (OAB) is defined as a symptom syndrome of urinary urgency, with or without urgency incontinence, usually with urinary frequency and nocturia, in the absence of infection or other obvious pathological features.¹ OAB is highly prevalent and affects physical and mental health, activities of daily life and the quality of life (QoL) of patients, interfering with daily activities, travel and sleep/vitality.² Epidemiological studies have demonstrated that OAB is found at frequencies of 12.4–53.1%, depending on the target population and definition of OAB.^{3,4} OAB is highly prevalent in Asia too. The prevalence ranges from 8.0% in China to 28.4% in Korea.^{5,6}

Homma et al published the OAB symptom score (OABSS) in 2006.⁷ This is a single symptom score that employs a self-report questionnaire to quantify OAB symptoms. The authors selected four symptoms—daytime frequency, nighttime frequency, urgency and urgency incontinence—for the questionnaire.⁷ The OABSS is highly sensitive to treatment-related changes in OAB symptoms. Its simplicity and dependability mean that the OABSS can be an alternative to a bladder diary for symptom and efficacy assessment in daily clinical practice.⁸

OABSS evaluates symptoms from the patient's viewpoint and does not require diary recording. Its responsiveness to treatment was confirmed in Japanese patients.⁸ OABSS has an advantage over other scales for OAB symptoms, but it has also one concern in that it was developed using Japanese language and validated based on Japanese patient data only. In order to use the OABSS outside Japan, it needs to be translated into the local language and validated based on local patient data.

The present study (the Reproducibility Study of OABSS and Its Response to Treatment or RESORT) consisted two parts in order to validate a traditional Chinese version of OABSS with Taiwanese patients:

- The reproducibility study that evaluated the reliability and validity of the Chinese OABSS and correlations with other measures of OAB including a three-day bladder diary and a patient perception of bladder condition measure (PPBC).

- The responsiveness study compared the Chinese OABSS scores before and after pharmacotherapy with an antimuscarinic agent, Solifenacin (5 mg/day).

The aim of this study was to demonstrate the therapeutic efficacy of solifenacin assessed by this newly-validated Chinese OABSS.

Materials and methods

Translation of the Chinese OABSS

A standard linguistic validation process was conducted to ensure conceptual equivalence between the Chinese translations and the original OABSS using the methods described by Acquadro et al.⁹ The Taiwan Continence Society commenced linguistic validation and other elements of the production of a Chinese version of the OABSS. The process involved forward- and back-translation, and review by urologists and gynecologists in expert meetings.

Part one: The reproducibility study

A total of 60 consecutive patients with OAB were enrolled from urological or urogynecological outpatient clinics in this prospective, multicenter study in Taiwan. A brief protocol including the study calendar and inclusion/exclusion criteria for enrolling patients is given in [Supplement 1](#). Patients answered the Chinese OABSS at enrollment and repeated the questionnaire after a non-treatment period of two weeks.

Part two: The responsiveness study

Patients answered the questionnaire again four and 12 weeks after pharmacological treatment with the anti-muscarinic agent solifenacin (5 mg/day). Patients also completed a three-day bladder diary and a PPBC at each study visit (for a total of four visits). Patients were also requested to report their International Prostatic Symptom

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