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## VALIDITY OF THE EIGHT-ITEM PATIENT-RATED SEVERITY OF OVERACTIVE BLADDER SYMPTOM BOTHER SCALE (OAB-V8) IN PREDICTING CHANGES IN HEALTH-RELATED QUALITY-OF-LIFE IN SUBJECTS WITH OVERACTIVE BLADDER

### Hypothesis / aims of study

Overactive bladder (OAB) is a disorder affecting seriously the quality of life of subjects with this health condition<sup>1</sup>. Self-administered health instruments may help clinicians to better understand the seriousness of the disorder helping in the suitable management of subjects. The OABq-SF is the abridged version of the OAB questionnaire which is able to capture both severity of symptoms bother and related quality of life in subjects with OAB<sup>2</sup>. The Spanish version of such instrument has been recently validated linguistically and psychometrically as well. The eight-item patient-rated severity of OAB symptom bothers scale (OAB-V8) is used to both screen for possible subjects with OAB and also, in those with this condition, to value the degree of patients symptoms bother, from mild to severe intensity of symptoms<sup>3</sup>. The aim of this research was to explore the ability (validity) of the OAV-V8 screening scale to predict changes in patient's Health-related Quality-of-Life (HRQoL) and severity of symptoms bother in subjects with symptomatic OAB treated with antimuscarinic drugs in routine medical practice in clinics of Urology.

### Study design, materials and methods

A longitudinal, prospective, observational study was designed. Patients of both genders, above 18 years old, diagnosed of OAB according with standard criteria and a score  $\geq 8$  in the patient-rated severity of bother symptoms OAB-V8 scale were enrolled in this study. Patients also had to be able of understanding and filling-in Patient-Reported-Outcomes instruments written in Spanish. The culturally adapted Spanish version of OABq-SF was administered on two occasions 3 months apart to a set of patients who were recruited consecutively at clinics of Urology all over the country and was prescribed a treatment with an antimuscarinic drug according with usual practice. Patients were compared in the two dimensions comprised in the OABq-SF: symptom bother and HRQoL. For validity of the OAB-V8 scale testing purposes, baseline scores in such scale were included in multivariate regression models a long with changes in the dimensions of the OABq-SF and baseline age, symptoms duration, age at the initiation of symptoms, body mass index and generic HRQoL assessed with the EQ-5D as covariates.

### Results

The study enrolled a total of 246 OAB patients, with a mean age of 57.7 years. 76% of enrolled subjects were women, 99% Caucasian, 37% active workers and 36% with primary schooling. Patients were enrolled in 18 urological clinics distributed all over the country according with their population density. OAB-V8 scores significantly correlated (Pearson's r coefficient) with OABq-SF domains; +0.790 and -0.659 for symptom bother and HRQoL domains, respectively ( $p < 0.001$  in both cases) indicating a possible association. Multivariate regression models showed OAB-V8 baseline score to be able as predicting changes in both domains of the OABq-SF;  $R^2 = 0.212$  and  $0.162$  in severity of symptom bother and HRQoL, respectively. OAB-V8 coefficients were significant in the two models with  $\beta$  coefficients of  $0.421$  ( $p < 0.001$ ) and  $0.340$  ( $p < 0.001$ ), respectively.

### Interpretation of results

Results provided in this study showed that changes in HRQoL and severity of symptoms bother after a course of an antimuscarinic drug for three-months in patients with OAB treated in routine medical practice are related with baseline scoring in the screening OAB-V8 scale; the most the severe the symptoms are at baseline, the highest the associated change in HRQoL and severity of symptoms bother are. Thus, the OAB-V8 PRO instrument could be used in routine medical practice in urology settings to screen for possible OAB patients, but also to anticipate changes in patients HRQoL that are to be treated with an antimuscarinic drug.

### Concluding message

The OAB-V8 scale provided evidence of predictive validity of self-assessment quality-of-life and severity of symptoms bother changes in patient with OAB treated with antimuscarinic drugs in routine medical practice.

### References

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<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes