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### **A PROSPECTIVE, MULTICENTER, OBSERVATIONAL STUDY TO ESTIMATE THE DRY MOUTH IN OVERACTIVE BLADDER PATIENTS TREATED WITH SOLILFENACIN**

#### Hypothesis / aims of study

Dry mouth is the most common side effect of antimuscarinic agents. This study was to evaluate the change of dry mouth after antimuscarinic treatment and the effect of dry mouth on the drug efficacy in overactive bladder (OAB) patients.

#### Study design, materials and methods

This is a prospective, multicenter, observational study of solifenacin in 331 patients for 8 weeks. Patients aged 20 years older with OAB symptom for more than 3 months and total score of overactive bladder symptom score (OABSS)  $\geq 3$ , and urgency score  $\geq 2$  were enrolled. Primary endpoints were the changes of dry mouth according to the baseline dry mouth status [non dry mouth group(NDG) versus dry mouth group(DG)] using Xerostomia inventory (XI), and the effect of dry mouth on the drug efficacy with OABSS. The definition of dry mouth development or aggravation was that mean XI scores change at least + 6 than the baseline score.

#### Results

The mean change of XI score increased 2.8 in total patients. NDG had a significantly increased in XI score than DG (+4.0 vs. +1.9,  $p = 0.015$ ). The mean change of OABSS decreased by 3.2 in total group. It was not statistically different in both groups (-3.4 vs. -3.0,  $p = 0.578$ ). The dry mouth aggravated in 71 patients (29.2%) (NDG 30.1% and DG 27.1%). Dry mouth was mainly mild or moderate in severity, and only ten patients (3%) stopped medication due to dry mouth.

#### Interpretation of results

The severity of the dry mouth increased, and the symptoms of OAB were also significantly improved. In the NDG, total XI score and VAS of dry mouth were significantly decreased by 8 weeks compared with DG, but the OABSS was significantly improved in the patients regardless of presence of dry mouth before the solifenacin treatment. Dry mouth was mainly mild or moderate in severity.

#### Concluding message

Dry mouth occurred or aggravated in about 30% of OAB patients regardless of presence of dry mouth before the solifenacin treatment. OAB symptoms were well-relieved and there was no influence of dry mouth to drug efficacy.

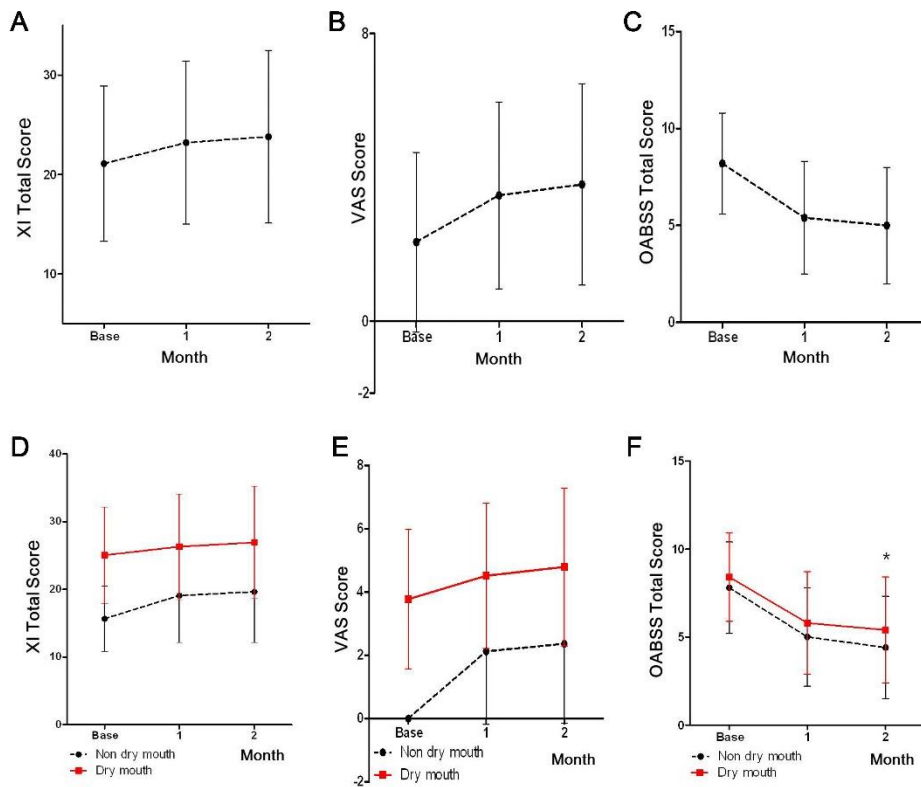


Figure 1. (A) Mean  $\pm$  SD changes in the XI total score in total patients (B) Mean  $\pm$  SD changes in the VAS score in total patients (C) Mean  $\pm$  SD changes in the OABSS total score in total patients. (D) Mean  $\pm$  SD changes in the XI total score between non dry mouth group and dry mouth group (E) Mean  $\pm$  SD changes in the VAS score between non dry mouth group and dry mouth group (F) Mean  $\pm$  SD changes in the OABSS total score between non dry mouth group and dry mouth group.

Disclosures

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