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DOES THE NUMBER OF PREVIOUS VAGINAL DELIVERIES AFFECT OVERACTIVE BLADDER SYMPTOMS OR THEIR RESPONSE TO TREATMENT?

Hypothesis / aims of study

Childbirth, particularly vaginal delivery is a well established risk factor for stress urinary incontinence. A relationship between pregnancies and urge urinary incontinence has also been proposed for Asian populations [1,2], but little data is available for Caucasian women. Therefore, the present study has used the database of a previously published, large-scale observational study into the use of solifenacin in OAB patients [3] to explore associations between number of vaginal deliveries and OAB symptoms. As a secondary aim we have explored a possible association between deliveries and the therapeutic response to solifenacin. Finally, we also compared males and females with regard to OAB symptoms and therapeutic responses.

Study design, materials and methods

This study is a pre-planned secondary analysis of an open-label, observational study into the safety and efficacy of solifenacin in patients with OAB [3], which was performed as part of the post-marketing surveillance in Germany. 4450 Patients were evaluated who had received solifenacin treatment (5-10 mg) for 12-14 weeks by 1316 office-based urologists based upon their medical judgment. Ethnicity of patients in this study was largely Caucasians. Captured variables were episode frequencies of the classical OAB symptoms frequency, nocturia, urgency and incontinence and various validated OAB rating scales. Significance of differences was assessed by one-way analysis of variance with multiple comparison-corrected post-tests; a $p < 0.05$ was considered significant.

Results

Women with 0, 1, 2 or >2 vaginal deliveries represented 15% (n=673), 15% (n=694), 33% (n=1456) and 21% (n=894), respectively, of the study population, and 16% (n=713) of patients were male. All 5 groups exhibited rather similar baseline values with regard to age and OAB symptoms (figure 1) as well as various OAB rating scales (data not shown), but some small differences reached statistical significance with large patient numbers. Treatment responses to solifenacin were also very similar in all patient groups for OAB symptoms (figure 2) and various rating scales (data not shown).

Interpretation of results

Our baseline data from a largely Caucasian population did not confirm a relevant association between number of vaginal deliveries and intensity of various OAB symptoms. While one of the Asian studies was population-based [2], the difference between our and the previous findings is unlikely to be related to study design as the other Asian study recruited patients in a similar manner as our study [1]. Probably more important differences relate to ethnicity and the fact that the Asian studies used the presence of OAB as a categorical variable, whereas we have looked at the extent of OAB symptoms.

To the best of our knowledge no previous study has assessed the potential role of parity in the treatment responses to a muscarinic receptor antagonist in OAB patients. Our data indicate rather similar treatment responses irrespective of gender and number of vaginal deliveries.

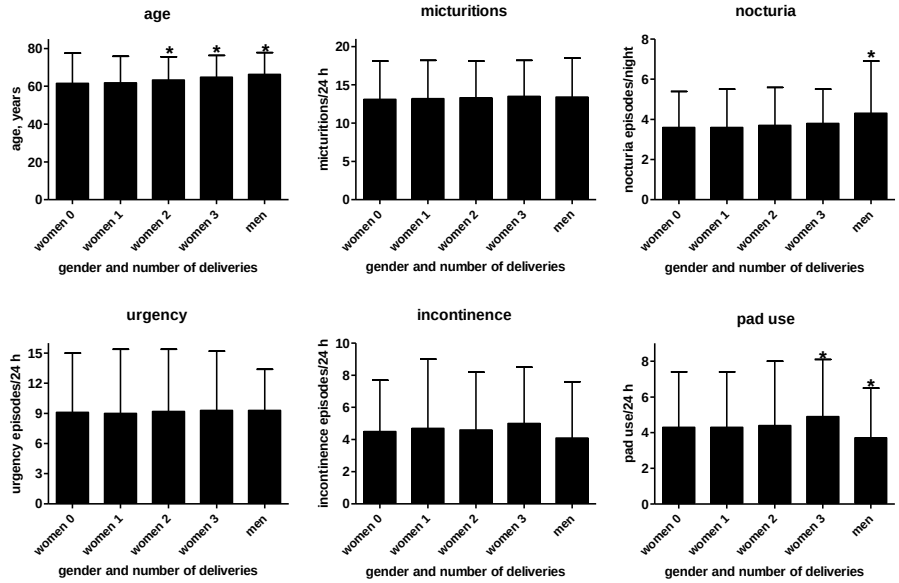

Figure 1: Age and OAB symptoms according to gender and number of vaginal deliveries (means ± SD).

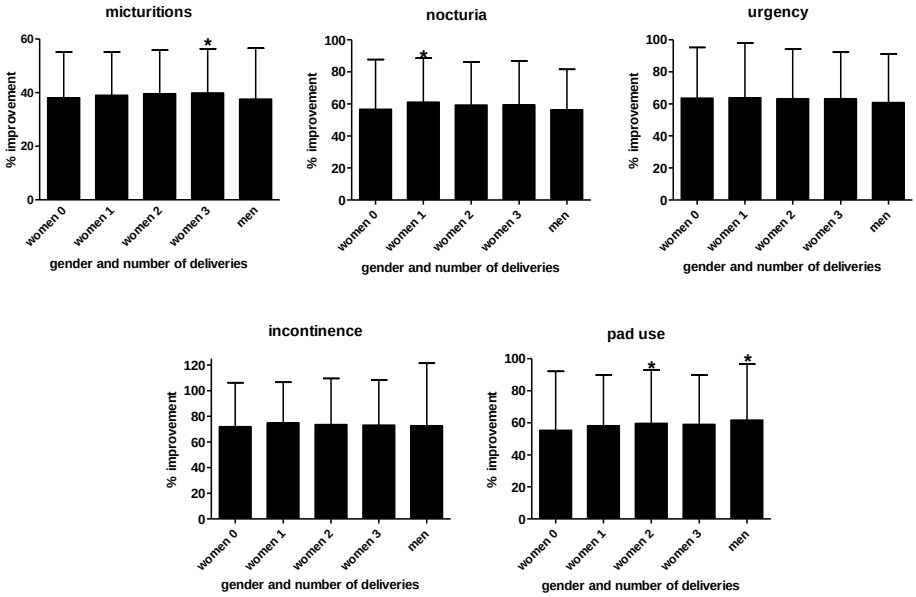

Figure 2: Treatment-induced improvements of OAB symptoms according to gender and number of vaginal deliveries (means ± SD).

Concluding message

At least in a Caucasian population, gender or number of vaginal deliveries do not exhibit pathophysiologically informative differences between groups. The muscarinic antagonist solifenacin appeared similarly effective in all groups irrespective of gender or number of vaginal deliveries.

References

1. Int Urogynecol J (2001) 12; 226-231
2. Neurourol Urodyn (2006) 25; 717-721
3. Drug Safety (2008) in press

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**At the time the study was performed in Germany, local regulations did not recommend ethical approval or trial registration for purely observational studies.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**