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COMPARISON OF EFFICACY AND TOLERABILITY OF TWO SELECTIVE M3 RECEPTOR ANTAGONISTS SOLIFENACIN AND DARIFENACIN IN WOMEN WITH OVERACTIVE BLADDER – THE SOLIDAR STUDY

Introduction: To asses clinical efficacy and tolerance of solifenacin and darifenacin in women with OAB with urgency as primary end point. To estimate the impact of both anticholinergic drugs on quality of life of patients and to assess treatment outcome (objective and subjective improvement).

Methods: Multicentric, prospective, randomized, head to head, open label pilot study in 100 women with OAB. Patients were randomly assigned into two groups, 50 of them received solifenacine and the remaining 50 patients darifenacin. Study duration was 3 months, patients came to the office 1 and 3 months after inclusion in the study and they always filled out voiding diaries, urgency perception questionnaires as well as the Urogenital Distress Inventory (UDI) and Incontinence Impact Questionnaires (IIQ). At the end of the study all patients estimated the success of treatment on the basis of VAS scale.

Results: Only 77 patients were enrolled into study. Their average age was 54.8 years, and their BMI amounted to 27.6 kg/m2. The average duration of OAB symptoms and urge urinary incontinence was 86.0 and 46.5 months, respectively. 40 patients received solifenacin and remaining 37 patients darifenacin. Before treatment patients from both groups did not differ statistically significant in any of observed variables. 16 patients did not finish the study (8 solifenacin, 8 darifenacin), mainly due to side effects (8 patients). After 3 months of treatment we observed a significant improvement in severity, frequency and botherness of urgency in all patients, significantly improved were also other OAB symptoms (Table 1). Objective improvement after 1 months was greater in patients with solifenacin (p= 0.033), these patients also expereienced significantly less irritative symptoms (p= 0.034). There was no difference in subjective improvement score between both drugs. Quality of life was better after three months in both groups of patients and there was no significant difference between both drugs with this regard (p= 0.174). However, we observed a significantly higher objective improvement score (3.8 vs. 3.2, p= 0.047) as well as the subjective improvement VAS score (74.4 vs. 54.1, p= 0.010) in solifenacin group.
Patients receiving solifenacin used significantly less pads after three months (Figure 1). Common side effect with both drugs was dry mouth (32% of patients). In Figure 2 we are presenting the prevalence of different difficulties and side effects in the beginning of the study and after 3-month treatment. After 3-month treatment 65.6% of patients received the same dose of solifenacin (37.9% in darifenacin group), higher dose received 44.8 % patiens with darifenacin (12.5 % in solifenacin group).

Conclusions: Both anticholinergics significantly improved urgency as well as other OAB symptoms and thus significantly improved the quality of life of patients. These observations are, however, in accordance with literature [1]. Common side effect was dry mouth which developed or worsen in one third of patients. Objective and subjective treatment outcome were higher in patients receiving solifenacin, the reason for later probably being 3.5-times higher solifenacin concentration in urine as compared to darifenacin. We feel that a greater study population is needed to confirm our preliminary results.

Table 1: Effect of anticholinergics on OAB symptoms

URGENCY	**Before treatment**	**After treatment**	**P**
Severity (1-4)	3.1 ± 0.6	2.2 ± 0.9	<0.0005
Frequency	5.8 ± 12	4.0 ± 2.2	<0.0005
Botherness (VAS %)	73.0 ± 18	44.5± 26	<0.0005
Urinary Frequency	9.1±3.6;	7.1±2.8	< 0.0005
Nocturia	2.6±1.4	1.4±1.3	< 0.0005
Daytime UI	2.5±3.4	1.5±2.3	0.001
Night-timeUI	0.6±0.9	0.3±0.7	0.001
Number of pads	2.8±2.6	2.0±2.4	< 0.0005

Figure 1. Pad use during anticholinergic treatment

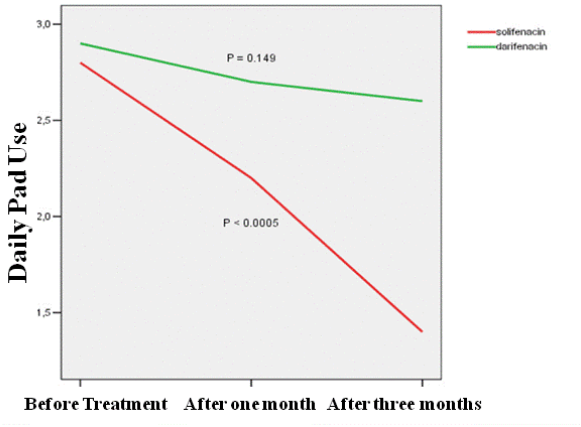
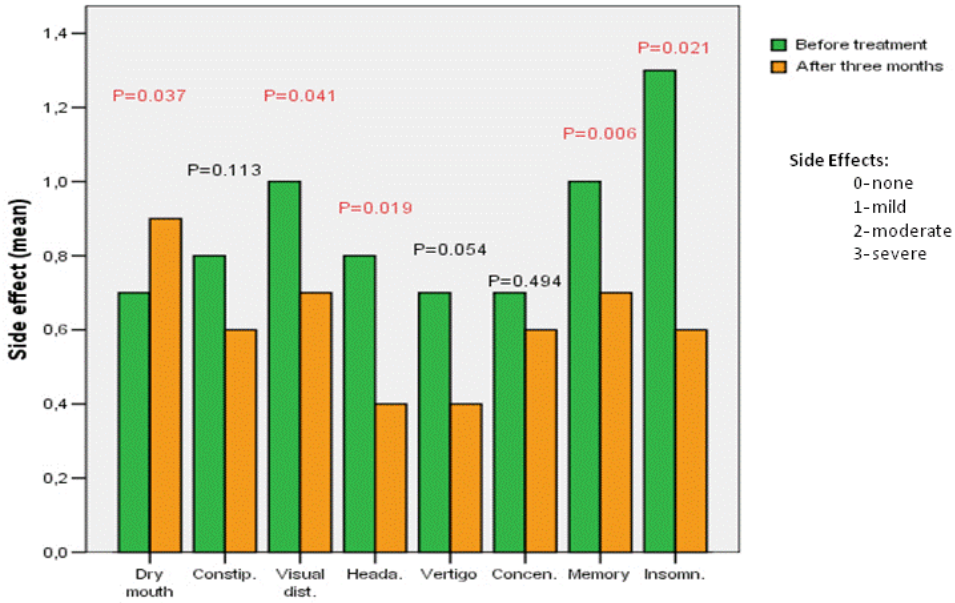


Figure 2. Prevalence of different difficulties and side effects at the beginning of the study and after 3-month treatment



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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Research was approved by the Ethical Committee at the Ministry of Health, Republic of Slovenia and by IRB at the University Clinical Centre Maribor.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**