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SANTANIELLO F[1], VIANELLO A [1], COSTANTINI E[1], ZUCCHI A[1], TASCINI M C[1], GIANNANTONI A [1], PORENA M[1]
1. DEPARTMENT OF UROLOGY. UNIVERSITY OF PERUGIA

EFFICACY AND TOLERABILITY OF SOLIFENACIN 5 MG ONCE DAILY IN THE TREATMENT OF OAB SYNDROME

Hypothesis / aims of study

The prevalence of overactive bladder (OAB) is approximately 16% in the general population.
OAB worsens Quality of Life and although antimuscarinic agents are efficacious, compliance is very low.
Solifenacin succinate, a new oral antimuscarinic agent designed for treating OAB, has a suggested starting dose of 5 mg once daily.
The present study evaluated the efficacy and tolerability of solifenacin 5 mg once daily in the treatment of patient with OAB, in a short-term follow up.

Study design, materials and methods

22 patients (15 F and 7M, all over 18 years old) referring symptoms of OAB were recruited to the study.
6 patients were previously treated with oxybutynin, and 4 with tolterodine without any success.
Urinary symptoms had been present for at least 6 months. Urinary incontinence was present in 5 cases.
All patients provided a detailed history, underwent a clinical examination and replied to a standard questionnaire regarding to daytime and night-time urinary frequency, number of episodes of urgency and urinary incontinence per day. Visual Analogic scale (VAS score 1-10) was used to assess patients satisfaction to treatment.
Urodynamics was performed in 10 patients. Uninhibited detrusor contractions threshold and Maximum pressure (UDC threshold, UDC pMax) and Maximum cystometric capacity (MCC) were accurately recorded.
Treatment consisted of solifenacin 5 mg once a day for at least one month. Patients were asked to assess treatment subjectively. After at least 1 month's therapy patients replied to the urinary symptoms questionnaire and VAS examination . All local or systemic side effects were recorded.

Results

Mean follow up was 45 $\pm$ 15.6 days . A clinical improvement was detected in 20 patients (90.9%).
A significant difference emerged in frequency of all clinical variables before and after a mean of 45 days' treatment.
No patient could achieve complete urinary continence after treatment.
The most common treatment-related adverse events were dry mouth and constipation observed in 36.3% and in 18.18% of patients respectively. Four patients stopped treatment because of side effects and four other patients because of scarse response to treatment.

Table 1: Clinical results

	Before treatment	After treatment	P
Daytime urinary frequency	5.91 $\pm$ 1.69	3.32 $\pm$ 1.83	< 0.0001
Night time urinary frequency	3.73 $\pm$ 1.16	1.73 $\pm$ 1.20	< 0.0001
Urgency (n°episodes/ day)	3.36 $\pm$ 0.9	1.5 $\pm$ 1.33	< 0.0001
Urinary incontinence (episodes/day)	0.64 $\pm$ 0.0	0.36 $\pm$ 0.0	N.S

No significant difference emerged in urodynamic parameters.
The VAS scores were over 5 in 62.4% of patients and under 5 in 37.6%.

Table 2: Urodynamic results

	Before treatment	After treatment	P
UDC threshold	158.86 $\pm$ 63.38	155.14 $\pm$ 119.32	N.S
UDC pMax	39.71 $\pm$ 14.71	42.57 $\pm$ 38.10	N.S
MCC	299.14 $\pm$ 113.28	330.57 $\pm$ 171.90	0.08

Interpretation of results

The results of the study show that solifenacin 5 mg once daily is effective in reducing OAB symptoms in about 90% of patients, in a short term follow up.
Overall, patients' satisfaction, as expressed by VAS score, is good. On urodynamic point of view, only maximum cystometric capacity improves after treatment, even if not significantly.
This can explain patients symptoms amelioration, despite of the persistence of urinary incontinence episodes in five of them, as sustained by uninhibited detrusor contractions.

The rate of adverse events related to the drug is small and caused stop of treatment only in 4 patients.

Concluding message

Thus, we can conclude that Solifenacin 5 mg once daily is safe and effective in the short term treatment of OAB.

FUNDING: NONE
DISCLOSURES: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study was approved by the REGIONAL ETHICS COMMITTEE and followed the Declaration of Helsinki Informed consent was not obtained from the patients.