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EVALUATION OF THE EFFECTIVENESS, PERSISTENCE, AND TOLERABILITY OF TRANSDERMAL OXYBUTYNIN IN PATIENTS WITH OVERACTIVE BLADDER SYNDROME. A RETROSPECTIVE OBSERVATIONAL STUDY.

Hypothesis/aims of study
The efficacy of anticholinergic treatment in controlling urinary frequency and urgency in patients with overactive bladder syndrome (OAB) has been clearly demonstrated in clinical trials, although one of the primary concerns surrounding its use is the high rate of drop-outs (61.7% - 90.1%) (1-3). Factors associated with the use of treatment in routine clinical practice limit the generalization of these results. The aim of this study was to determine changes in symptoms of patients with OAB treated with transdermal oxybutynin (OXY-TDS), and persistence and tolerability at 12 months.

Study design, materials and methods
Observational, multicenter, retrospective study to evaluate the effectiveness of OXY-TDS after 12 months of treatment in 105 patients with a diagnosis of OAB in routine clinical practice. Effectiveness was evaluated by the detection of clinical changes between baseline (pre-) and 12 months (post-) in bladder diary, in urgency visual analogue scale (VAS), in International Consultation on Incontinence Questionnaire (ICIQ-SF), and in Overactive Bladder Awareness Tool (OAB-V8). Persistence was measured by the percentage of patients who did not discontinue treatment during the observational period. The sample size was based on an alpha risk of 5% and a statistical power of 80% for comparing 24-hour urinary frequency pre- and post-treatment with OXY-TDS. A minimum of 118 subjects was estimated to be necessary for detecting statistically significant differences of around 10% between baseline and end of treatment. A baseline urinary frequency of 11 was assumed, with a standard deviation of 4.

Results
In total, 92.4% of patients were women aged 59.4 ± 11.8 years with a history of OAB of 4.18 ± 5.0 years. Persistence at 12 months was 55.2% (n=58). Reasons for discontinuation were adverse reactions (40.9%) and lack of clinical response (38.7%). Effectiveness was evaluated in 47 patients. According to bladder diary, improvement was observed in 24-hour frequency (-2.6 voids/24 h, [95% CI: -3.50; -1.80, p <0.001]), nocturia (-0.9 voids [95% CI: -1.12; -0.45, p<0.001]), urgency (-4.70 episodes/day [95% CI: -6.05; -3.55, p<0.001]), and urge urinary incontinence (-1.9 episodes/day [95% CI: -2.85; -1.30, p<0.001]). A total of 70.2% of patients had >4 episodes of urgency/day at baseline, while at 12 months this figure fell to 4.2% of the study population (p<0.001). Improvement was also seen in VAS (-4.50 points [95% CI: -5.50; -4.00, p<0.001]) and in ICIQ-SF (-8 points [95% CI: -10.0; -6.5, p= 0.000]) and in OAB-V8 (-13.50 points [95% CI: -16.0; -11.5, p=0.000]). Only 14.3% of patients presented a systemic adverse effect (5.7% dry mouth). Local adverse reactions at the site of application were observed in 27.6% of patients (pruritus, erythema, irritation). Only 2 patients presented an adverse effect classified as severe.

Interpretation of results
The results of this study show an advantage for OXY-TDS compared to other anticholinergics in the treatment of patients with OAB.

Concluding message
OXY-TDS was an effective therapeutic option in patients with OAB. Persistence was better than with other treatments (anticholinergics and beta-3 agonists), and the incidence of systemic adverse effects, including dry mouth, was low.

Table 1. Changes from pre- to post- treatment in bladder diary after 12 months of OXY-TDS treatment

Bladder diary	Change [95% CI]	P value	Pre – treatment (n)	Post – treatment (n)
Daytime urinary frequency (episodes/day)*	-1.7 (-2.55;-1.15)	< 0.001	47	46
Nocturia (episodes/day)*	-0.9 (-1.12;-0.45)	< 0.001	47	44
24-hour frequency (episodes/day)*	-2.6 (-3.50;-1.80)	< 0.001	47	47
Maximum daytime voided volume (ml)*	63.3 (19.95;105.85)	0.006	38	39
Maximum nocturnal voided volume (ml)	-16.2 (-81.65;48.35)	0.651	38	39
Average voided volume (ml)	0.8 (-22.30; 20.70)	0.976	5	5

Urgency (episodes/day)	-4.7 (-6.05;-3.55)	< 0.001	47	47
Degree of urgency *	-1.4 (-1.85; -0.85)	< 0.001	47	44
Urge urinary incontinence (episodes/day)*	-1.9 (-2.85; -1.30)	< 0.001	46	43
Stress urinary incontinence (episodes/day)*	0.0 (-0.85; 0.00)	0.007	47	47
Pad changes (no./day)*	-2.2 (-2.80; -1.50)	< 0.001	40	45
Liquid intake / 24 h (ml)	15.8 (-134.15; 179.95)	0.698	38	38
24 hour urine production (ml)	115.9 (0.00; 223.35)	0.054**	38	39
Nocturnal urine volume (ml)	-30.9 (-107.50; 34.20)	0.51	37	38

P-values from Student's t-test, Wilcoxon signed rank test*, Change: mean difference, or Hodges-Lehman estimator of location shift*. **Wilcoxon test p-value (p= 0.047)

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Disclosures

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