

OAB PATIENT SATISFACTION AND IMPROVED PERCEPTION OF BLADDER CONDITION WITH DARIFENACIN

Hypothesis / aims of study

Patients dissatisfied with one anti-muscarinic therapy for OAB may benefit from an alternative therapy. In evaluating the efficacy of the alternative therapy it is important to measure patient satisfaction with treatment benefit and patient perception of improvement in bladder condition resulting because these measures are indicative of successful treatment from the patient's point of view and can be predictive of patients' persistence with therapy.

Here we evaluate patient-reported outcomes, together with bladder diary parameters, during treatment with darifenacin (DAR), a selective M₃ receptor antagonist, in patients who expressed dissatisfaction with prior treatment with extended-release (ER) oxybutynin (OXY) or tolterodine (TOL).

Study design, materials and methods

This was a 12-week, open-label study of DAR treatment in DAR-naïve adults (≥18 years), with OAB symptoms for ≥6 months, who expressed dissatisfaction with prior OXY-ER or TOL-ER treatment (received for ≥ 1 week within last 12 months). Following a 2-week screening period and 1-week baseline, patients received DAR 7.5mg once daily (o.d.) for 2 weeks, then were offered up-titration to 15 mg o.d., with stable dose thereafter. The primary efficacy variable was the change from baseline to Week 12 of darifenacin treatment (or last visit) in the Patient's Perception of Bladder Condition (PPBC) [1]. Data were analyzed using two-sided Wilcoxon's signed rank test and the last observation carried forward (LOCF) method. Efficacy was also evaluated from bladder diary data as the change from baseline to Week 12 for micturition frequency and number of urgency and urge urinary incontinence (UUIE) episodes. The Patient Satisfaction with Bladder Treatment (PSTB) questionnaire, a new patient-reported outcome tool not yet validated, was explored in this study to better understand treatment satisfaction with improvement in symptoms among patients with OAB. Adverse events (AEs) were also recorded and summarized using frequencies and proportions.

Results

500 patients enrolled, 497 were treated (84.1% women) and 437 completed the study. Efficacy results are summarized in Table 1 (see next page).

Of the 473 respondents to the PSTB questionnaire, 405 (85.6%) patients were satisfied with DAR treatment and 68 (14.4%) were not satisfied. Satisfaction rates did not differ significantly between patients previously treated with OXY-ER (84.1%) or TOL-ER (86.8%).

The most common AEs were dry mouth (20.1% patients) and constipation (14.1% patients), infrequently leading to discontinuation (1.6% and 0.8% patients, respectively).

Table. Influence of up to 12 weeks of DAR 7.5/15 mg treatment on PPBC and OAB symptoms

		Previous treatment			All patients (N=497)
		OXY ER (N=218)	TOL (N=279)	ER	
PPBC	Patients, n	214	275		489
	Baseline	5.0	4.0		4.0
	12 weeks/last visit	3.0	3.0		3.0
	Change, absolute*	-1.0	-1.0		-1.0
Micturitions/day	Patients, n	208	274		482
	Baseline	10.2	10.4		10.2
	12 weeks/last visit	8.4	8.2		8.2
	Change, absolute*(%)	-1.8 (-17.4%)	-2.2 (-21.2%)		-2.0 (-19.5%)
Urgency episodes/week	Patients, n	208	274		482
	Baseline	5.6	5.6		5.6
	12 weeks/last visit	2.2	1.8		1.8
	Change, absolute* (%)	-2.6 (-55.5%)	-3.0 (-64.0%)		-2.8 (-61.6%)
UUI episodes/week	Patients, n	175	227		402
	Baseline	11.2	11.2		11.2
	12 weeks/last visit	2.8	1.4		1.4
	Change, absolute*(%)	-8.4 (-83.3%)	-8.4 (-88.0%)		-8.4 (-85.7%)

N=Intent-To-Treat population

All results shown as median values; *p<0.0001 for change from baseline, Wilcoxon signed rank test

Interpretation of results

Among patients who were dissatisfied with previous anti-muscarinic therapy, significant improvements from baseline in PPBC scores and the key OAB symptoms of micturition frequency, urgency episodes and UUI resulted from treatment with DAR 7.5/15 mg o.d. for up to 12 weeks.

Improvements in PPBC scores were associated with highly significant improvement in diary parameters.

All improvements were comparable for patients previously treated with OXY-ER or TOL-ER.

The majority of patients expressing dissatisfaction with prior antimuscarinic therapies reported treatment satisfaction with darifenacin (85.6%).

Concluding message

Patients previously dissatisfied with therapy for OAB and treated with DAR 7.5/15 mg o.d. reported significant improvements in their perception of their bladder condition and a high level of treatment satisfaction. DAR 7.5/15 mg o.d. should be considered as an effective alternative therapy for these patients since there is a high likelihood of treatment satisfaction that may result in better persistence with therapy.

References

1. Eur Urol 2006;49(6):1079-86.

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What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Quorum Central IRB, Seattle, WA, USA
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Was informed consent obtained from the patients?	Yes