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ASSESSMENT OF TRANSDERMAL OXYBUTYNIN IN OVERACTIVE BLADDER: NAIVE AND PREVIOUSLY TREATED PATIENTS

Hypothesis / aims of study

It has been reported that anticholinergic therapy for overactive bladder (OAB) appears to be more efficacious in patients with prior experience with these agents relative to treatment-naive patients (1). This may occur as a result of the significant placebo effect commonly observed in these trials. Large placebo responses may be attributed to changes induced by urinary diary keeping or behavior modifications, which are required by most clinical studies of OAB treatments. Nevertheless, large placebo responses have been reported more often with patients who have never received pharmacologic therapy. On the other hand, it also appears that treatment-naive patients may be more likely to discontinue therapy owing to dry mouth than are their experienced counterparts (1). This analysis assesses the impact of prior anticholinergic therapy on the response to and tolerability of transdermal oxybutynin, a new treatment for OAB.

Study design, materials and methods

Data from two 12-week placebo-controlled clinical studies of transdermal oxybutynin were examined (2,3). The first trial included 257 patients with OAB who received either transdermal oxybutynin 3.9 mg/d or placebo. Only 55 (22.2%) were taking an anticholinergic OAB medication at study entry. The second study enrolled 238 patients with OAB who were also given transdermal oxybutynin 3.9 mg/d or placebo; however, all patients in this study had responded positively to prior anticholinergic therapy.

Results

There were no significant differences in demographic characteristics in the 2 trials between patients treated with transdermal oxybutynin and those given placebo, other than their experience with antimuscarinic therapy at baseline.

Changes from baseline in urinary incontinence were similar in the groups receiving active treatment across trials 1 and 2 (median reduction in trial 1 was 19 episodes, and in trial 2 was 21 episodes, per week). Reductions in daily urinary frequency and increases in urinary void volume were also similar in these groups across the 2 trials. Interestingly, the median placebo response was similar among naive and experienced patients.

Transdermal oxybutynin was well tolerated in both trials; the incidence of anticholinergic adverse events in the treatment groups was similar to that of placebo in both trials. However, as in previous reports with oral agents, dry mouth was reported more frequently by treatment-naive patients.

Table. Anticholinergic Adverse Events Reported During the 12-Week Double-Blind Treatment Period

	Trial 1 (77.5% treatment-naive)		**Trial 2 (100% previously treated)**	
	Transdermal Oxybutynin (%)	**Placebo (%)**	**Transdermal Oxybutynin (%)**	**Placebo (%)**
Dry mouth	9.6	8.3	4.1	1.7
Dizziness	4	3.8	0.8	0.9
Somnolence	1.6	0.8	-	-
Nausea	1.6	5.3	2.5	0.9
Constipation	0.8	3.0	3.3	1.7
Palpitations	0.8	0	-	-
Abnormal Vision	0	1.5	2.5	0.9

Interpretation of results

Analysis of the results from these 2 clinical trials of transdermal oxybutynin shows that, contrary to previous reports on oral therapies for OAB, patients who had not had any prior experience with pharmacologic treatment for OAB were as responsive to transdermal oxybutynin as patients who had responded to prior anticholinergic medication. The response to placebo was also similar across the 2 trials. The incidence of dry mouth was low in both studies, being similar in patients who received transdermal oxybutynin and in those who were in the placebo groups. Similar to earlier reports with other anticholinergic therapies for OAB, dry mouth was reported even less by patients who had previously responded to anticholinergic treatment for OAB relative to patients with no such experience.

Concluding message

Transdermal oxybutynin therapy is likely to be effective in a wide range of patients with OAB, regardless of their treatment history. Both naive and previously treated patients are likely to experience similar efficacy when treated with transdermal oxybutynin. Transdermal oxybutynin is well tolerated. In particular, the incidence of dry mouth, the primary reported cause of discontinuation of this class of agents, does not differ significantly from that of placebo in naive as well as in experienced patients. As shown in previous trials with oral therapies, patients experienced with the use of similar therapies for OAB may be less likely to report anticholinergic adverse events.

References

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FUNDING: Watson Pharma