

DARIFENACIN PROVIDES MEANINGFUL IMPROVEMENTS TO PATIENTS DISSATISFIED WITH OXYBUTYNYN OR TOLTERODINE THERAPY

Hypothesis / aims of study

OAB is chronic condition of multiple symptoms that increases with age and affects 12.8% of women (1) First-line pharmacotherapy for OAB is with antimuscarinic agents. Patients who are dissatisfied with one antimuscarinic agent may benefit from 'switching' to another antimuscarinic. The aim of this study was to determine whether patients dissatisfied with oxybutynin or tolterodine received benefits from darifenacin that were meaningful to patients and how these meaningful benefits correlate with other measures of treatment success, i.e., overall satisfaction with treatment benefit and interest in continuing therapy.

Study design, materials and methods

Patients (n=437) completing a 12-week open-label clinical study on the efficacy of darifenacin (2) were provided information at the last study visit about an opportunity to volunteer to participate in a phone interview to assess patient satisfaction with darifenacin treatment. To volunteer, patients had to contact a third party research agency. Informed consent was provided by 72 patients (16% of the clinical study population) who were interviewed within 2 weeks of their last visit by a trained moderator using a semi-structured interview guide. Interviews began with open-ended questions about patients' experiences during the study, followed by questions on overall and specific benefits from darifenacin using a 5-point Likert scale (1=not at all meaningful to 5=extremely meaningful). Patients were also asked about their interest in continuing therapy using a similar 5-point Likert scale. Bladder diary data and Patient Satisfaction with Treatment Benefits scores collected in the 12-week clinical study were analyzed for the interview population to compare changes in these parameters in subgroups of patients who did or did not report an overall meaningful benefit (using Wilcoxon's signed-rank test).

Results

87.5% of patients interviewed (63/72) reported receiving meaningful improvements in their overall bladder function from darifenacin therapy. Of these patients 87.3% (55/63) reported that the improvements were extremely or very meaningful.

Patient responses to specific questions on meaningful improvements (Table 1) provide additional insight into what patients found meaningful while being treated with darifenacin.

Table 1. Meaningful improvement ratings (mean score)

How meaningful* was your improvement in:	n=63
How often you felt urgency	4.24
The decrease in severity or strength of urgency	4.32
How often in a 24 hr period you experienced leaks and wetting accidents	4.38
Your ability to get a good night's sleep	4.45
Interruptions in your sleep	4.41

*Mean score based on 5-point Likert scale (1=not at all meaningful to 5=extremely meaningful)

Significant correlations between responses to questions on meaningful benefits and likelihood to continue therapy were observed (Table 2). Improvement in ability to get a good night's sleep and overall bladder function were most highly correlated with interest in continuing therapy. Interest in continuing therapy was assessed with a 5-point Likert scale (1=not at all interested to 5=extremely interested)

Table 2. Pearson's correlation coefficients between meaningful improvement mean and interest in continuing darifenacin therapy

Improvement in ability to get a good night' sleep	.572 **
Overall Bladder function	.542 **
Improvement in how often in a typical 24 hr time period you experienced leaks or wetting	.475 **
Decrease in the severity or strength of urgency during a typical 24 hr time period	.402 **
Fewer interruptions in your sleep	.384**
Improvement in how often in a typical 24 hr period that you felt urgency	.354 **
Improvement in how often you urinated in a typical 24 hr time period	.251 *

*sig at p-value<0.05; **sig at p-value<0.01

Patients who reported meaningful improvements from darifenacin scored significantly higher on overall satisfaction with treatment and interest in continuing therapy, two additional measures of treatment success from a patient's perspective (Table 3) included in this study.

Table 3. Patient satisfaction with treatment benefit and interest in continuing therapy among patients who did/did not report an overall improvement

	No overall meaningful improvement (Mean score)	Any meaningful overall improvement (Mean score)
	n=9	n=63
Overall satisfaction with treatment benefit	2.22	3.65*
Interest in continuing therapy	2.22	4.35*

*sig.at p-value<0.05

Interpretation of results

Using three different patient-centric measures of treatment success (meaningful improvement, overall patient satisfaction with therapy, and interest in continuing therapy), volunteers from a previous study with darifenacin, who were dissatisfied with tolterodine or oxybutynin, received meaningful improvements on several parameters. High levels of satisfaction with treatment benefits were also reported and the majority of patients showed great interest in continuing therapy with darifenacin.

Concluding message

OAB patients dissatisfied with a previous drug treatment may be successfully treated with an alternative therapy such as darifenacin.

References

1. Irwin DE. Eur Urol 2006;50:1306-15
2. Zinner N. Int J Clin Pract 2008;62(11):1664-74

<i>Specify source of funding or grant</i>	Procter & Gamble Pharmaceuticals and Novartis Pharmaceuticals
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	The interviews were not conducted as a clinical study so no ethical review board approval was sought. However, patients provided informed consent before being interviewed.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes