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FAVOURABLE EFFICACY AND TOLERABILITY WITH LONG-TERM SOLIFENACIN TREATMENT SUPPORT HIGH PATIENT PERSISTENCE

Hypothesis / aims of study

As defined by the International Continence Society, symptoms of overactive bladder (OAB) include urgency, with or without incontinence, usually with frequency and nocturia. Long-term therapies for OAB must be effective and well tolerated, as OAB is a chronic condition. Treatment compliance and persistence with antimuscarinic agents, the therapy of choice for OAB, has been generally unsatisfactory. In a recently reported prescription tracking analysis, less than 15% of patients treated with antimuscarinic agents remained on therapy at 1 year. Lack of efficacy, poor tolerability and cost were cited as likely reasons for the poor persistence [1]. Solifenacin succinate is a once-daily (od) oral antimuscarinic agent that has been evaluated for the treatment of OAB at both 5 mg (suggested starting dose) and 10 mg dosage strengths. In 12-week trials, solifenacin statistically significantly reduced urgency, incontinence, and frequency, the key symptoms of OAB [2, 3], and its use has been associated with low rates of dry mouth especially at the 5 mg dose. This abstract reports results from two clinical trials evaluating the efficacy, safety, and tolerability of solifenacin that were extended under a single protocol to provide long-term data on patient satisfaction and persistence of efficacy.

Study design, materials and methods

From a study population of 1802 eligible patients who completed the original double-blind, 12-week studies, 1637 (91%) agreed to continue with solifenacin treatment in the open-label extension. A 4-week treatment period with solifenacin 5 mg od was followed by 36 weeks of solifenacin treatment (5 mg od or 10 mg od), during which time adjustment between the two dosages was permitted only at study visits. Assessments at 4, 16, 28, and 40 weeks included 3-day micturition diaries and adverse event (AE) reporting.

Results

A total of 1329 patients (81%) remained in the extension study and completed the 40-week evaluation. The percentage reduction from baseline in mean number of micturitions per 24 hours improved from –21% at the end of the 12-week double-blind studies to –23% at the end of the open-label extension study. The percentage increase from baseline in mean volume voided per micturition improved from 28% at the end of the double-blind studies to 31% at the end of the open-label extension study. The reductions in urgency and incontinence episodes that were demonstrated in the double-blind studies were maintained through the extension study. Improvements in efficacy outcomes were associated with an efficacy rating of “satisfactory” by 74% of patients at the final assessment interview. A full 98% of patients rated solifenacin tolerability as “satisfactory/acceptable” at the last visit. In addition, dry mouth, the most common side effect reported during the open-label extension study was reported in 10% of patients while receiving the 5 mg od dose and in 17% of patients while receiving the 10 mg od dose; the rate of dry mouth in the total population was 21%. The discontinuation rate did not appear to be dose related, as discontinuations due to AEs occurred in 39 patients (2.4%) taking solifenacin 5 mg od and in 38 patients (3.4%) taking solifenacin 10 mg od.

Interpretation of results

The high patient satisfaction associated with solifenacin treatment of OAB in long-term studies is likely due to the combination of efficacy and tolerability provided by this antimuscarinic agent. Solifenacin may therefore offer the advantage of high patient persistence with therapy for this chronic condition.

Concluding message

The balance of efficacy and tolerability demonstrated with solifenacin may contribute to long-term persistence on therapy.

References

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