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EXTENDED RELEASE FORMULATIONS OF OXYBUTYNIN AND TOLTERODINE FOR THE TREATMENT OF OVERACTIVE BLADDER: A GERMAN HEALTH ECONOMIC ANALYSIS

Hypothesis / aims of study

This pharmacoeconomic analysis addresses the cost-effectiveness of the extended release formulation of oxybutynin (XL) relative to long-acting tolterodine (LA) for the treatment of overactive bladder (OAB) in Germany.

Study design, materials and methods

A previously validated state-transition model was used to assess and compare the health economic outcomes over the course of one year. Effectiveness and persistence data were derived from the OPERA trial, a 3-month randomized double-blind trial comparing oxybutynin XL 10mg qd to tolterodine LA 4mg qd in female patients suffering from OAB symptoms. 96.1% of the enrolled patients had more than 21 total urinary incontinence episodes (TUI) per week at baseline. In this trial, oxybutynin XL was shown to be more effective than tolterodine LA in reducing micturition frequency and had superior outcomes at all visits for other endpoints such as mean urge urinary incontinence episodes and mean total incontinence episodes, with similar rates of dry mouth and other adverse events. For the model, five disease severity states were defined by the number of TUI episodes per week: TUI=0 (complete continence), TUI=1-6, TUI=7-21, TUI=22-42, and TUI>42. Severity-specific cost profiles for urinary incontinence were developed for Germany, and are reported in 2003 Euros. Only direct costs were included in this analysis, and these were limited to drug treatment, doctor visits, and pad or protection use. Daily treatment costs were assumed to be equal for both drugs. It was assumed in the model that after 3 months, the duration of the OPERA trial, patients discontinuing drug treatment would return to their baseline severity.

Results

After one year, total costs with oxybutynin XL are expected to be \in 26 lower per patient compared to tolterodine LA, with 4.6 more patients per 100 treated attaining complete continence, defined as not having any incontinence episodes (18.1% versus 13.5%) in the last two weeks of the one-year modeling period. Patients on oxybutynin XL will also have the benefit of almost 11 additional incontinence free days (129.6 versus 119.0), and 17 fewer incontinence episodes over the course of the year (955.4 versus 972.5). Proportion of patients still on treatment in the last two weeks of the year was slightly lower with oxybutynin XL (73.5% versus 76.0%). Sensitivity analyses demonstrated that oxybutynin XL's advantage was maintained over wide ranges of inputs, and outcomes were similar if analyses were limited to only 3 months, the duration of the OPERA trial.

Interpretation of results

Results suggest that oxybutynin XL is the better treatment for female patients suffering from overactive bladder in Germany. This analysis was based on the only randomized, doubleblind, head-to-head trial of the two extended-release formulations. Further research is needed in order to evaluate these new anticholinergic agents in real practice settings.

Concluding message

These analyses showed, based on clinical trial data, that at price parity oxybutynin XL is the dominant treatment leading to better health outcomes and lower total costs compared to tolterodine LA over a one-year period.

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