P02.317

OLANZAPINE VERSUS RISPERIDONE: A PROSPECTIVE COMPARISON OF CLINICAL AND ECONOMIC OUTCOMES IN SCHIZOPHRENIA

E.T. Edgell[1], W. Scott Andersen[1], B.M. Johnstone[1], B. Dulisse[1], D. Revicki[2], A. Breier[1], S. Gavart[1]*. [1]*Eli Lilly and Company, Indianapolis;* [2]*Medtap International, Bethesda, USA*

Objective: To compare the clinical and economic outcomes associated with olanzapine and risperidone treatment for schizophrenia.

Methods: An international, double-blind, prospective study was conducted. To facilitate economic comparisons our sample was restricted to patients enrolled in US sites. One-hundred and fifty patients were randomized to therapy with either olanzapine 10 to 20 mg/day (n = 75) or risperidone 4 to 12 mg/day (n = 75) for a maximum of 28 weeks. In addition to safety and efficacy, use of health services was assessed at baseline and prospectively, at 8 week intervals and study completion. Clinically important response, maintenance of response, EPS rates, and median total, non-medication, and medication costs were compared between treatment groups.

Results: Olanzapine-treated patients were more likely to maintain response compared to risperidone-treated patients (p = 0.048). In addition, a smaller proportion of olanzapine-treated patients required anticholinergic therapy compared with risperidone-treated patients (25.3% vs. 45.3%; p = 0.016). Total per patient medical costs were $2,843 (36%) lower in the olanzapine treatment group than in the risperidone treatment group (p = 0.342). Medication costs were significantly higher for olanzapine-treated patients ($2,513 vs. $1,581; p < 0.001), but this difference was offset by a reduction of $3,774 (52%) in non-medication costs for olanzapine-treated patients in comparison to risperidone-treated patients ($3,516 vs. $7,291, p = 0.083).

Conclusions: In this study olanzapine-treated patients experienced clinical improvements that translated into savings in cost of care for both inpatient and outpatient services. These savings offset the difference in medication acquisition cost between olanzapine and risperidone.

P02.318

GLOBAL INDEX OF SAFETY (GIS): A NEW INSTRUMENT TO ASSESS DRUG SAFETY: APPLICATION TO A PROSPECTIVE PHARMACOEPIDEMIOLOGICAL STUDY (EFESO)

J.A. Sacristán[1], J.C. Gómez[1], X. Badia[2], P. Kind[3], S. Gavart[4]*. *The EFESO Study Group;* [1]*Clinical Research Department, Lilly S.A. Madrid;* [2]*Public Health Institute of Catalonia, Spain*
[3]*Center for Health Economics, University of York;* [4]*Eli Lilly & Company, Windlesham, UK*

Objective: Develop a weighted, global index of safety (GIS) and compare the safety profiles of olanzapine-treated patients and patients treated with other antipsychotics using data from an observational prospective pharmacoepidemiological study (EFESO).

Methods: A total of 194 psychiatrists rated through a survey the severity (from 1 insignificant, to 5 extremely severe) of the most common adverse events (AE) that occur with antipsychotic treatment. The severity scores were then applied to the AE occurring in the 2,949 EFESO patients resulting in per-patient scores. A GIS was calculated for every group of patients receiving the same treatment by averaging the per-patient scores. The GIS was compared between the olanzapine-treated patients and a control group (composed of patients treated with all other antipsychotics) as well as with patients treated specifically with risperidone and haloperidol.

Results: The GIS calculated from the control group (4.3) was 72% higher (worse score) than that calculated for the olanzapine-treated patients (2.5) (p < 0.001). The GIS for the risperidone- (3.6) and haloperidol- (6.0) treated patients were 44% and 140% higher than that calculated for the olanzapine-treated patients (p < 0.001).

Conclusion: The GIS is a new instrument that produces a single, weighted score facilitating the safety comparison of antipsychotic treatments in terms of both AE frequency and severity. Application of the GIS in the EFESO study showed that olanzapine-treated patients had a significant better (lower) safety index compared to the patients in the control group and compared specifically to risperidone- and haloperidol-treated patients.

P02.319

ANTIPSYCHOTIC TREATMENT, ADVERSE EVENTS AND HEALTH-RELATED QUALITY OF LIFE

X. Badia[1], A. Casado[1], J.A. Sacristán[2], J.C. Gómez[2], K.J. Gregor[1], S. Gavart[3]*. *The EFESO Study Group;* [1]*Public Health Institute of Catalonia, Barcelona;* [2]*Clinical Research Department Lilly S. A., Madrid, Spain*
[3]*Eli Lilly and Company, UK*

Objective: Investigate the relationship between adverse events and health-related quality of life (HRQoL) in patients receiving antipsychotics for schizophrenia.

Methods: The analyses included a subset of patients from a large 6-month, prospective, observational study of outpatients receiving antipsychotics for schizophrenia. The analyses included the most commonly (>1%) recorded adverse events. The HRQoL was evaluated using the EQ-5D Index (EQ-I) and Visual Analog Scale (VAS).

Results: The analyses included 2,128 olanzapine-, 417 risperidone-, and 112 haloperidol-treated patients. The most common (>1%) adverse events were: tremor, hypokinesia/akinesia, rigidity, akithesia, dystonia, dyskinesia, weight gain, and somnolence. Compared to olanzapine-treated patients, haloperidol-treated patients had significantly higher incidences for 5 of the extrapyramidal symptoms and risperidone-treated patients had significantly higher incidences for 4 of the extrapyramidal symptoms. Risperidone- and haloperidol-treated patients were significantly more likely than olanzapine-treated patients to experience multiple extrapyramidal symptoms. Olanzapine patients were significantly more likely to experience weight gain compared to risperidone and haloperidol patients. Regression models indicated that akathisia, hypokinesia/akinesia, and the total number of extrapyramidal symptoms were significantly associated with decreases in the EQ-I and VAS scores from baseline to the 6-month end-point. Weight gain and somnolence were not significantly associated with EQ-I or VAS score changes from baseline to the 6-month end-point.

Conclusions: The results demonstrated an inverse relationship between adverse events and HRQoL in patients treated with antipsychotics for schizophrenia. Akathisia, hypokinesia/akinesia, and number of extrapyramidal symptoms had a significant impact on HRQoL. The relationship between weight gain or somnolence with HRQoL was not significant.

https://doi.org/10.1016/S0924-9338(00)94726-6 Published online by Cambridge University Press