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Long-term Lurasidone Treatment is Not Associated with Clinically Significant Elevations of Prolactin- or Hyperprolactinaemia-related Adverse Events: a Post-HOC Analysis

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Introduction
Elevation of prolactin level is a known adverse effect of antipsychotics. Long-standing hyperprolactinaemia may inhibit reproductive function by impairing gonadal steroidogenesis and is associated with a number of adverse effects such as galactorrhoea, amenorrhoea, gynecomastia, impotence and decreased bone mineral density. Lurasidone is a recently approved atypical antipsychotic agent for the treatment of schizophrenia.
Aims/Objectives
To compare the incidence of treatment-emergent adverse events (TEAEs) related to hyperprolactinaemia in patients treated with lurasidone or active comparators.
Methods
Pooled data from two 52-week studies that evaluated the long-term safety and efficacy of lurasidone compared with quetiapine XR or risperidone in patients with schizophrenia were reviewed post-hoc for prolactin levels and TEAEs considered to be related to hyperprolactinaemia.
Results
Prolactin levels decreased marginally in the lurasidone group (median -8.00 pmol/L, N=624) and quetiapine XR group (median -17.39 pmol/L, N=85), and increased in the risperidone group (median 385.00 pmol/L, N=199) (LOCF). The incidence of markedly abnormally high prolactin values (≥5× upper limit of normal) was 2.0%, 1.4% and 4.0% in the three groups, respectively. The hyperprolactinaemia-related TEAEs breast mass, gynecomastia, breast enlargement, breast tenderness, hypogonadism, infertility, pituitary tumors and mammary gland tumors were absent from all groups. Low rates (≤2.5%) of galactorrhoea, amenorrhoea and erectile dysfunction were seen in the lurasidone and risperidone groups, while no TEAEs were recorded in the quetiapine XR group.
Conclusions
This post-hoc review shows that long-term treatment with lurasidone was not associated with a clinically significant increase in prolactin levels and the incidence of associated TEAEs was low.

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