SEROQUEL® and Diabetes: What We Know

SEROQUEL is an atypical that has had over 7.8 million patient exposures worldwide since its approval in 1997.

To date, the available data has not established a causal link between diabetes and SEROQUEL.

- In clinical trials, SEROQUEL has shown ***no difference*** in mean change of random glucose measurements compared to either placebo or other antipsychotics.
- In patients taking SEROQUEL, post-marketing reports of diabetes or diabetes-related events are ***very rare* (<0.01%)**. These reports were confounded by pre-existing or co-existing risk factors and/or had limited information.
- The results of retrospective epidemiology studies of SEROQUEL and diabetes have been ***inconsistent and inconclusive.*** [Data on file, DA-SER-XXX]
- Many patients with psychiatric illness have other characteristics that may contribute to metabolic abnormalities. [ADA 2004, Meyer 2003]

Some Medical Issues in Schizophrenia and Bipolar Disorder

Factor	Prevalence in Schizophrenia (%)	Prevalence in Bipolar Disorder (%)	Prevalence in General Population (%)
Smoking	73[1]	35*-55[3,4]	25[1]
Obesity (BMI ≥ 30)	18[2]	30[2]	33[1]
Diabetes Mellitus	13[2]	26[2]	7.0

*For mania.

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2. Regenold WT, Thapar RK, Marano C, et al. *J Affect Disord.* 2002;70:19-26.
3. Grant BF, Hasin DS, Chou P, Stinson FS, Dawson DA. *Arch Gen Psychiatry.* 2004;61:1107-1115.
4. Ucok A, Polat A, Bodkurt O, and Meteris H. *Psychiatry Clin Neurosci.* 2004;58:434–437

Warning Statement From Prescribing Information for SEROQUEL

Hyperglycemia and Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including SEROQUEL. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

REFERENCES

American Diabetes Association, American Psychiatric Association, American Association of Clinical Endocrinologists, North American Association for the Study of Obesity. Consensus development conference on antipsychotic drugs and obesity and diabetes. *Diabetes Care.* 2004;27:596-601.

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Seroquel® quetiapine fumarate