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EFFICACY OF INHALED LOXAPINE FOR THE ACUTE TREATMENT OF AGITATION IN PATIENTS WITH SCHIZOPHRENIA OR BIPOLAR DISORDER: IS IT INFLUENCED BY BASELINE AGITATION SEVERITY?

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Introduction: Agitation is a common problem in schizophrenia and bipolar disorder, often requiring drug therapy in an acute care setting. Experts in behavioral emergencies consider speed of onset as an important factor in choosing a treatment. One Phase 2 and two Phase 3 clinical trials were conducted to assess the efficacy of treating agitation with inhaled loxapine.

Objectives: To determine if baseline severity of agitation influenced patient outcome.

Methods: All trials were multi-center, randomized, double blind, parallel group, placebo controlled. Two doses of inhaled loxapine, 10 mg and 5 mg, were tested. Study subjects were agitated patients with schizophrenia or bipolar disorder who provided informed consent. At baseline, subjects were required to have a minimum total score of 14 for the five items of the PANSS Excited Component (PEC). The primary endpoint was the change in the PEC total score at 2 hrs. This meta analysis compared the efficacy of inhaled loxapine across the 3 studies in subjects with PEC ≥ 20 (88 patients, more severely agitated; MSA) to those with PEC ≤15 (90 patients, less severely agitated; LSA).

Results: In the 10 mg dose group, the mean PEC change from baseline for the MSA group was 10.5 while for the LSA subjects was 6.6. This represents a 50% change from baseline for the MSA subjects and a 45% change for the LSA subjects.

Conclusion: Inhaled loxapine has as good as or better effects in reducing agitation in more agitated patients as it does in less agitated patients.

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