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Asenapine in the Clinical Management of Mania: From Randomized Clinical Trials to Everyday Practice

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Introduction

Available literature on asenapine (ASE), a new second-generation antipsychotic, consists of several randomized clinical trials (RCTs) in highly selected populations. Real-world, observational studies from acute inpatient settings are still lacking.

Objectives

In a group of subjects treated with ASE (A) and an ASE-naïve control population (B):

1) evaluation of differences in Length of Stay (LoS)

2) re-hospitalization during the following 6 months

Aims

To highlight differences between clinical trials and real-world data.

Methods

Clinical data were collected over 2 years from 20 inpatients who met DSM-IV-TR criteria for manic episodes (ME) treated with ASE and from a control population matched for age, gender and diagnosis who underwent conventional treatments in the same setting.

Results

LoS was 17.9 (SD ±9.0) days for group A and 14.7 (SD ±12.7) days for group B; the result of the Kruskal-Wallis test showed no significant differences ($?^2$=2.199, p=0.138). In spite of a high discontinuation rate, only 17.7% of patients in group A were re-hospitalized in the following 6 months compared to 41.2% of those in group B (RR=0.43, 95% CI: 0.13-1.39).

Conclusions

In RCTs, ASE emerges as an effective compound for the treatment of MEs in highly selected populations that differ substantially from real-world clinical practice. However, on the basis of our results, ASE doesn't appear to offer specific advantages in the clinical management of acute inpatients. In this presentation, the importance of poly-psychopharmacology, adherence and co-morbidity will be discussed to highlight the need for larger, multi-centre, observational studies with adequate follow-up in real-world settings.

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