

OBSERVATIONAL STUDY COMPARING THE SAFETY OF TYPICAL AND ATYPICAL ANTIPSYCHOTIC DRUGS IN PATIENTS AFFECTED BY DEMENTIA WITH BEHAVIOURAL AND PSYCHOLOGICAL SYMPTOMS OF DEMENTIA (BPSD)

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Background: Dementia is a clinical syndrome characterized by acquired loss of cognitive and emotional abilities, severe enough to interfere with daily functioning and quality of life. BPSD are a common feature in all dementias and their management should involve non-pharmacological measures when possible. If pharmacological therapy is deemed necessary the conventional and atypical antipsychotic drugs are commonly prescribed. Although antipsychotics are widely used to treat BPSD, little evidence supports their efficacy and, more importantly, there are concerns about the increased risk of cerebrovascular AdverseEvents (AEs) and mortality associated with their use. **Objectives:** 1. To evaluate whether the mortality and incidence of serious AEs (in particular cerebrovascular accidents, cardiac arrhythmias, extrapyramidal and metabolic disturbances) are significantly different in patients treated with typical or atypical antipsychotics. 2. To assess: - prevalence use of antipsychotics (typical and atypical), dosage and duration of antipsychotic treatment, reason and time of discontinuation of the antipsychotics, demographic and clinical characteristics influencing the appearance of AEs, incidence of AEs between patients treated with different typical and atypical antipsychotics, concomitant administration of other drugs and the risk of drug interactions. **Methods:** An observational cohort study is being carried out, in Regione Campania, in a sample of non-institutionalised patients affected by dementia and BPSD, treated with antipsychotics. All the patients will be followed till the end of the study or death and will be re-assessed every six months. All data are collected using an ad-hoc questionnaire and all AEs and clinical outcomes are carefully monitored. **Results:** Our preliminary data show that patients with dementia and BPSD are 334 (213 females; 63.5%). 103 (30.8%) patients are affected by mild dementia of the Alzheimer's type, 95 (28.4%) by vascular dementia, 61 (18.3%) by severe dementia of the Alzheimer's type. Agitation, aggression, hallucinations, delirium are the most common BPSD. At the time of enrolment, 46% of patients were receiving antihypertensive drugs, 34% cholesterol-lowering drugs, 16% antiinflammatory drugs and 4% nitrodilator and inotropic drugs. Most patients are treated with atypical antipsychotics; they result younger and of male gender than patients administered with conventional antipsychotics. The most frequently prescribed antipsychotics are quetiapine, risperidone, olanzapine. **Conclusions:** The results of this study will supply elements in the determination of the risk-benefit profile of conventional and atypical antipsychotic drugs in non-institutionalised patients affected by dementia and BPSD. These data should also reveal subpopulations at higher risk of developing AEs and suggest safer dosages and therapy duration profiles.