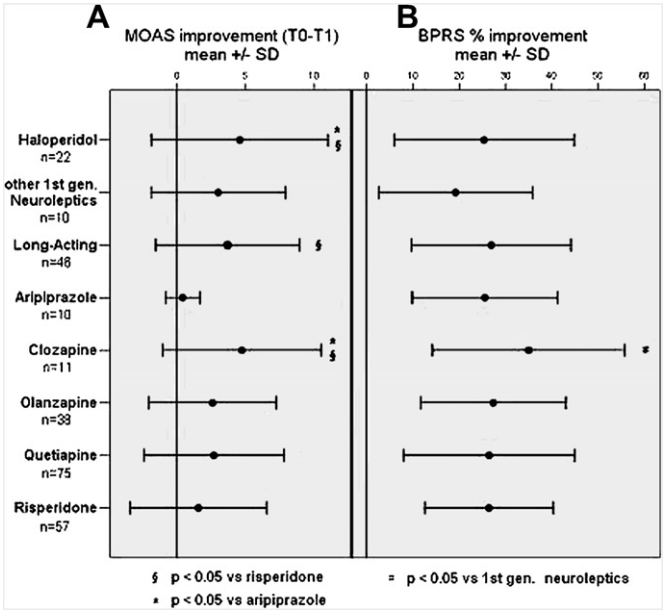
However, further researches are warranted to provide a better qualification of antipsychotic drugs on aggressive dimension



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P0258

Placebo-controlled clinical trials of new atypical antipsychotics in schizophrenia

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Background: Placebo-controlled (PC) Phase 3 trials are critical for the registration of new atypical antipsychotic medications (AAP) for schizophrenia but use of placebo when efficacious treatments exist has been questioned.

Objective: To investigate evidence for the use of placebo in clinical trials of schizophrenia via a meta-analysis of large, PC trials of new AAPs.

METHODS: Using the FDA Summary Basis of Approval reports, we examined outcome data from all Phase 3 clinical trials that evaluated investigational AAPs. Publications from peer-reviewed literature were also identified. The main outcome variables were: symptom improvement in individual treatment arms, clinical response, therapeutic failure.

Results: Meta-regression indicated a highly significant difference between improvement in the placebo and the active arm ($p<0.0001$). Effect size (ES) estimate for the placebo arm revealed that patients in this arm obtained a statistically significant but clinically negligible symptom reduction (Cohen d: ~0.15; $p<0.004$) while active-treated patients displayed a substantial symptom reduction (Cohen d: ~0.70; $p<0.0001$). Active treatments showed a highly significant ($p<0.001$) superiority vs. placebo in clinical response and therapeutic failure, with failure rates often exceeding the rate of clinical response. ESs for change varied substantially across trials, with an ES range of d=0.8 for the placebo and the active arms, respectively.

Conclusion: Variable ESs across studies support the view that placebo control has major importance in trials of new AAPs. However, efforts should focus on finding design alternatives and to minimize the risks of PC trials so that they may be conducted in ethically acceptable manner.

P0259

Antipsychotics in psychiatric inpatients: Naturalistic data on first vs. repeated episodes

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Antipsychotics are widely used in psychiatric patients for various indications, beside psychosis most often in mood disorders, BPSD in dementia and agitation. Official guidelines are based on RCT data which differ from naturalistic data on the use of antipsychotics in real-life clinical setting.

The aim of our cross-sectional naturalistic study of hospitalized psychiatric patients (n=310) was to get insight into prescription patterns for antipsychotics. We were especially interested in the class of antipsychotic, dose and combinations with other antipsychotics and other psychiatric drugs compared with diagnosis and number of hospitalizations. Structured data sheet was used to record data from medical records.

Results have confirmed the use of antipsychotics in variety of indications outside psychosis, especially mood disorders and agitation. Newer antipsychotics predominate although older antipsychotics have been used consistently in patients with longer illness duration and more hospitalizations (especially depot formulations), in acute agitation control as well as in acute mania and in combinations with atypical antipsychotics. Patients with first few hospitalizations are likely to receive antipsychotic therapy according to guidelines with atypical drugs in monotherapy. Equivalent doses for atypical antipsychotics although are usually higher then for typicals and lower for first hospitalizations.

The real-life use of antipsychotics is an important issue for different reasons including long-term treatment, burden of potential serious long-term side-effects as well as the quality of life in patients. Our data show that real-life uses of antipsychotics differ in some patient populations from recommended for various reasons that will be discussed.

P0260

Hospitalizations and compliance among schizophrenic patients in treatment with clozapine

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Objectives: Demostrate that clozapine decrease the number of hospitalizations, and improve the adherence to treatment.

The sample consisted of 36 schizophrenia patients who were in treatment with a typical and atypical neuroleptic and then had their medication changed to clozapine. We ascertained the number of inpatient hospitalizations before starting clozapine and compared this with the number of hospitalizations after starting clozapine. We also followed an age- and gender-matched comparison group of other schizophrenia patients who were at treatment approximately the same time. Results indicate that the mean number of rehospitalizations while on other neuroleptic was bigger than after the commencement of clozapine treatment. The decrease in hospitalization rate for the comparison group was also statistically significant. The pre-post change was much greater for the clozapine patients than comparison

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