chosen 48 cases on Haloperidol, 44 cases on Chlorpromazine, 46 cases on Clozapine, 68 cases on Risperidone and 58 cases on Olanzapine.

Results: Total costs of long-term hospital treatment are lower for patients treated with novel neuroleptics.

Treatment with novel neuroleptics assures a better compliance, allowing patients to continue their previous activities, keeping them out from the hospital.

Assuring long-term cost-ef®ciency for patients on novel neuroleptics involves their selection using the following criteria: good social support, young age and fair chances to maintain their previous activities, to be sure they will not become a burden for society through repeated hospitalisations

P.2.08 Onset of action and effectiveness with olanzapine versus typical antipsychotic drugs in the treatment of inpatients with schizophrenia (EUROPA Study)

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Objective: To assess the time to onset of action and the effectiveness of olanzapine versus typical antipsychotic drugs (APS) in the treatment of schizophrenic in-patients in acute psychiatric units.

Method: Data were collected from a prospective, comparative, non-randomised, open, observational study of evaluable 904 inpatients with schizophrenia. Treatment was based on clinical criteria. Patients were followed-up during their entire hospital stay. Clinical status was measured through the Brief Psychiatric Rating Scale (BPRS), and Clinical Global Impression of Severity (CGI-S).

Safety was evaluated through the collection of spontaneous adverse events and a speci®c questionnaire for extrapyramidal symptoms (EPS).

Treatment-response was de®ned as according to the following criteria: Baseline-endpoint decrease in BPRS total score $\geq$40% plus an endpoint BPRS score $<$18 or an endpoint CGI score $\leq$3. Only patients who maintained the response until the end of the study are considered as responders.

Results: 483 patients received olanzapine as monotherapy or in combination with another antipsychotic (olanzapine group), and 421 received typical APS as monotherapy or in combination (control group). Patients in the control group were signi®cantly older and more severe at baseline according to BPRS total and CGI scores. Both treatment groups were similar in other relevant baseline variables, like gender, schizophrenia type and number of hospital admissions.

Response rate was 70.8% (335 patients) in olanzapine group compared to 58.4% (243 patients) in control group (Chi2 adjusted by type of schizophrenia, baseline CGI score, baseline BPRS score and evolution time; $P=0.002$). Regarding time to onset of action, olanzapine group showed a shorter time to response than the control group (Log-Rank test; $P=0.002$) in a 3 months period (only 2 patients, one in each group showed a longer time to response). Median time to response was 16 days for olanzapine (C.I. 95% [15; 19]) and 22 days for control group (C.I. 95% [19; 22]). As response was only to be in¯uenced by baseline CGI score as a risk factor (Logistic model with response status as dependent variable and treatment group, type of schizophrenia, baseline CGI and BPRS scores, evolution time; age, gender and treatment regime as independent variables; $P<0.001$; OR=0.74 with C.I. 95% [0.62±0.88]), it was included as a covariate in a Cox regression model to compare time to onset between both groups. Once again and under this covariate in¯uence, olanzapine was signi®cantly better than the control group (Chi2; $P=0.006$; RR=1.26 with C.I. 95% [1.07±1.49]) on decreasing time to onset of action.

Conclusions: Data showed that olanzapine was effective in a non-selected sample of acute hospitalised schizophrenic inpatients, and these results are consistent with previous controlled trials. In spite of the limitations of this study to detect time to response, data also suggested that patients in olanzapine group reached response in a lower time period.

P.2.09 Effectiveness and safety with olanzapine vs. typical antipsychotics on tranquillisation in schizophrenic in-patients (Study EUROPA)

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Objective: To assess the effectiveness of olanzapine in comparison with typical antipsychotics on tranquillisation of schizophrenic in-patients with acute psychotic symptoms.

Method: Data were collected in a comparative, naturalistic, open, non-randomised study on 904 schizophrenic in-patients (Study EUROPA). At the beginning of their hospitalisation, patients were included in the study with olanzapine or with typical antipsychotic (APS). Patients were not subjected to any experimental condition and were evaluated during all the hospitalisation period. To assess the effectiveness on tranquillisation, following items of the Brief Psychiatric Rating Scale (BPRS) were used: Anxiety, Tension, Hostility, Uncooperativeness and Excitement. Analysis was performed on patients with a baseline score $\geq$3 in these ®ve items. Tranquillisation assessment was de®ned as a higher than 50% decrease in these items. Treatment response was de®ned as BPRS total score decrease higher than $\geq$40% and ®nal BPRS total score $<$18 or ®nal CGI score $\leq$3. Tolerability was assessed

through a speci®c extrapyramidal symptoms (EPS) questionnaire.

Results: In the global sample, 229 patients reported a baseline score ≥3 in the ®ve tranquillisation items. 110 received olanzapine in monotherapy or combined with antipsychotics (group olanzapine) and 119 received APS in monotherapy or combined (APS group). No signi®cant differences in baseline tranquillisation items scores were found between groups [Wilcoxon; ns]. Decrease in Anxiety score at the end of the study was signi®cantly higher for olanzapine (median 4, range: 3 to 6) than APS group (median 3, range: 0 to 6) [Wilcoxon; $P=0.002$]. No differences were found in the other items. Olanzapine group reported higher decreases in Anxiety, Tension, Hostility and Excitement scores than APS group, when baseline scores were ≥3 [Wilcoxon; $P\leq0.05$ in all cases]. This patients mean olanzapine dosage during the study period was 19 mg (range: 7.5 to 30 mg/day). Percentage of patients with treatment response in this 229 patients group was signi®cantly higher in olanzapine group than in APS group (73.1% versus 55.6%) [Chi^2; $P=0.006$]. EPS incidence during the treatment period was signi®cantly lower in olanzapine group than in APS group (17.3% versus 45.8%) [Chi^2; $P<0.0001$].

Conclusions: In this observational study, olanzapine has shown equal effectiveness than typical APS in schizophrenic in-patients tranquillisation. Olanzapine reported a higher response rate in Anxiety, Tension, Hostility and Excitement BPRS scale items than typical antipsychotics in a moderate-severe tranquillisation baseline score population.

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P.2.10 Rapid acting intramuscular olanzapine in acutely agitated schizophrenic patients

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Introduction: Agitation is a common component of schizophrenia that may present at a psychiatric emergency patient.

Oral medications are often not a treatment option due to lack of patient cooperation and relatively slow onset of action.

Method and material: An international double-blind study in acutely agitated patients with diagnosis of schizophrenia, schizophreniform disorder or schizoaffective disorder (DSM IV) was performed. Romania participated with 3 sites (Bucharest, Iasi and Timisoara) with a total amount of 84 patients. Patients were randomised to one of 6 treatment groups: four ®xed doses of olanzapine (2.5, 5, 7.5, 10 mg), haloperidol (7.5 mg) and placebo.

Results: IM olanzapine has a rapid onset of action, demonstrating superiority over IM haloperidol on the PANSS Excited Component.

Many patients with IM olanzapine have an effective response to the ®rst dose. The majority of patients treated with IM olanzapine responded to the ®rst injection and did not required a 2nd or 3rd injection.

Conclusions: IM olanzapine is one effective alternative treatment for agitation in patients with schizophrenia.

Rapid control of agitation protects both the patient and caregiver from potential injury.

P.2.11 Rapid acting intramuscular olanzapine vs. rapid acting intramuscular haloperidol and placebo-safety results

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Olanzapine is an effective atypical antipsychotic agent. It is both ef®cient and safe in oral administration. The psychiatric management of acutely psychotic patients often requires the use of IM injections. This study, double-blind, randomised, compared the safety of short acting intramuscular olanzapine vs. short acting haloperidol and placebo.

Material and method: Three sites from Romania were participating, from a total of 14 sites; 84 patients from a total of 282 entered the study. No statistical differences between the treatment groups in baseline characteristics (age, gender, baseline severity of illness ± PANSS Excited Component, BPRS).

Results: No patients in any treatment group were discontinued from the study due to an adverse event. One serious event was reported during the trial. For extrapyramidal symptoms BARNES Global Score and Simpson Angus Total Score were used.

Conclusions: IM olanzapine provides safe alleviation of agitation in patients with schizophrenia. IM olanzapine provides the advantages of treatment with an atypical antipsychotic, regarding safety, to patients who require rapid tranquilization.

P.2.12 Pros and cons of observational studies in the pharmacological treatment of schizophrenia: the Spanish experience with olanzapine

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Advocates of evidence-based medicine classify studies