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Branded and generic drugs in general practice: findings after switching to generic olanzapine

Domenico Italiano(1), E Spina(2)
(1) Italian College of General Practitioners, Messina, Italy
(2) Department of Clinical and Experimental Medicine, University of Messina, Italy

Corresponding author: Dr Domenico Italiano, Italian College of General Practitioners, Messina, Italy. E-mail: domenicoitaliano@hotmail.com

Background and Aim: Several reports of loss of efficacy or adverse effects have been described after generic substitution in general practice. To date, studies comparing serum drug levels in patients switched to generic antipsychotics in a standard clinical setting are lacking. The aim of this study was to investigate if switching to generic olanzapine is associated with differences in its serum concentrations and therapeutic response.
Methods: Pre- and post-switching serum olanzapine concentrations were compared in schizophrenic outpatients who were switched from a chronic treatment with branded olanzapine to the same dose of its generic alternative. The Positive and Negative Syndrome Scale (PANSS) was concurrently administered to assess modifications in schizophrenia symptom control.
Results: A total of 25 patients (13 females and 12 males, mean age 41.2 + 12.8 years) concluded the study. Mean olanzapine dose was 12.2 + 5.4 mg/day. The mean olanzapine serum concentrations decreased from 27.7 + 14.4 ng/mL during treatment with the branded formulation, to 22.6 + 12.3 ng/mL after the switching to the generic formulation ($P < 0.01$). Total PANSS scores did not significantly change after switching from branded to generic formulation (49.6 + 8.3 vs 48.6 + 9.5, $P = 0.777$). No patient exhibited disease relapse or required dose adjustment after switching.
Conclusions: Significantly lower serum olanzapine concentrations were found after switching from branded to generic olanzapine. Although these modifications did not significantly impair schizophrenia symptoms control, it can not be excluded that a longer exposure to lower olanzapine serum concentrations may result in relapse of schizophrenic symptoms.