Evaluation of Clozapine Interchangeability in a Canadian Outpatient Population
Silvia Alessi-Severini1, Patricia Honcharik1, Karleen Simpson1, Michael Eleff2 and David Collins1
Faculty Pharmacy1 and Department of Psychiatry, Faculty of Medicine2
University of Manitoba, Winnipeg, Manitoba, Canada

RESULTS

The medical records of all outpatients attending the Health Sciences Centre psychiatric clinics in Winnipeg (MB) were reviewed retrospectively. Those patients who had been stable on the same dose of clozapine for at least 2 months prior to the formulation switch were included in the study. Data collected in the six months before and after the interchangeability switch included dose regimens, number of physician/therapist’s visits, number of hospitalizations/ER visits, physician’s notes on patient’s progress, information on adverse events and co-medication regimens. Statistical analysis by paired t-test (p=0.05) was conducted for the numerical measures available before and after the switch.

BACKGROUND

Generic substitution is one of the cost containment strategies most widely used by drug plans. The consequent formulation switch is often anticipated by physicians and patients with apprehension, especially when it involves “critical dose” drugs. The first generic alternative of clozapine (Gen-Clozapine) became available on the Canadian market in February 2003 and was listed in the Manitoba Formulary as interchangeable with the brand name product (Clozaril) effective September 15, 2003. The interchangeability switch primarily affected psychiatric outpatients who are clients of the government-sponsored drug programs.

OBJECTIVE

To determine if the “forced” generic substitution of clozapine caused any significant treatment change in a Canadian outpatient population.

METHODS

The medical records of all outpatients attending the Health Sciences Centre psychiatric clinics in Winnipeg (MB) were reviewed retrospectively. Those patients who had been stable on the same dose of clozapine for at least 2 months prior to the formulation switch were included in the study. Data collected in the six months before and after the interchangeability switch included dose regimens, number of physician/therapist’s visits, number of hospitalizations/ER visits, physician’s notes on patient’s progress, information on adverse events and co-medication regimens. Statistical analysis by paired t-test (p=0.05) was conducted for the numerical measures available before and after the switch.

DISCUSSION

Clozapine doses at the time of the switch were not significantly different from the doses recorded at 2 months, 4 months and 6 months post-switch. Similarly, no significant changes were observed in the other measured parameters and no increase in any of the most commonly reported adverse events (including WBC/ANC counts) was detected. In these patients no evidence of psychiatric decompensation was reported that could have been directly attributed to the switch from brand-name to generic clozapine.

CONCLUSION

It is important to evaluate the consequences that administrative decisions might have in the clinical setting. In this population, the clozapine interchangeability switch did not seem to have negatively impacted patients’ treatment.