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The Cohort Observational Study of Clozapine on Schizoaffective Disorder For Their Adverse Effects

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Abstract: *Schizophrenia has been observed in closed indoor people. There was improvement with antipsychotics for positive symptoms. Clozapine is newly discovered antipsychotic, with the improvement for positive and negative symptoms. Observed there were certain adverse effects like agranulocytosis. Hence there should be certain vision on treatment.*

I. Introduction

Clozapine was synthesized in 1958 by Wander AG, a Swiss pharmaceutical company, as tricyclic antidepressant imipramine[1]. In 1972, clozapine was released in Switzerland and Austria as Leponex[2]. Two years later it was released in West Germany, and Finland in 1975. Early testing was performed in the United States around the same time[2]. In 20th century, reports of agranulocytosis leading to death in some clozapine-treated patients, clozapine was voluntarily withdrawn by the manufacturer[3]. Clozapine fell out of favor for more than a decade despite unclear reasons for the agranulocytosis which occurred in Finland, the rate of which was 20 times higher[4] than had been reported in any other country. However, when studies demonstrated that clozapine was more effective against treatment-resistant schizophrenia than other antipsychotics, the FDA and health authorities in most other countries approved its use only for treatment-resistant schizophrenia, and required Restricted Distribution, a Patient Registry and regular hematological monitoring to detect granulocytopenia, before agranulocytosis develops. In December 2002, clozapine was approved in the US for reducing the risk of suicide in schizophrenic or schizoaffective patients judged to be at chronic risk for suicidal behavior[4]. In 2005 FDA approved criteria to allow reduced blood monitoring frequency[4]. In 2015 the individual manufacturer Patient Registries were consolidated by FDA request into a single shared Patient Registry Called The Clozapine REMS Registry[5].

II. Meterial And Methods

It is comparative, open labeled, cohort study conducted in regional center, Bhaskar Medical college, yenkapally village, moinabad mandal, Hyderabad, Telagana. It was conducted from jan 2016 to june 2016. It was conducted between two groups of patients taken Clozapine 40mg, 20 patients taken pills 6months period without adverse effects and at least 3months period (20 patients). It was compared incidence of adverse effects between two groups , incidence of Clozapine 40mg, taken at bed time for 3months and 6months.it was told to visit for fever /chest pain. Blood pressure should monitored at lying down, sitting, and standing postures The investigations conducted are total white blood cell count, total Nuetrophil count, Percentage of nuetrophils, Fasting blood sugar(FBS). These are conducted at the time of beginning of study, observed any adverse effects like fever/chest pain, at 3months and 6months. Any serious adverse event is there, ask the patient to stop taking pill and the immediately visit the hospital. Two groups are compared by paired t-test, standard deviation and P-value.

III. Results

Patients are taken as 3 groups one at the time of beginning of study, another group at 3 months, 6months, Paired t-test perfomed, p- value taken as acceptable.

Parameter	Beginning Mean± SD	3months Mean± SD	6months Mean± SD	p-value
Number of patients	40	20	20	
Blood Pressure	102± 5 mm of Hg	70± 4 mm of Hg	60± 5mm of Hg	0.05*
Fever	98.6^0F	98.6^0F	98.6^0F	
Tardive dyskinesia	nil	Dystonia	Dystonia	
Chest pain	nil	nil	+tive in 1	

Table 1:*p.value <0.05 is acceptable

Parameter	Beginning	3months	6months	

	Mean± SD	Mean± SD	Mean± SD	p-value
Number of patients	40	20	20	
WBC	11,400± 250 cells/dl	6,000 ± 220cells/dl	4,500 ± 225 cells/dl	0.01*
Nuetrophils	8,500± 125cells/dl	4,800 ± 110cells/dl	6000 ± 120 cells/dl	0.02*
% Nuetrophils	75± 20%	78± 18%	66± 10%	
RBS(mg/dl)	120± 23 mg/dl	160± 35mg/dl	180± 27mg/dl	0.05*

Table 2:*P-value <0.05 is acceptable

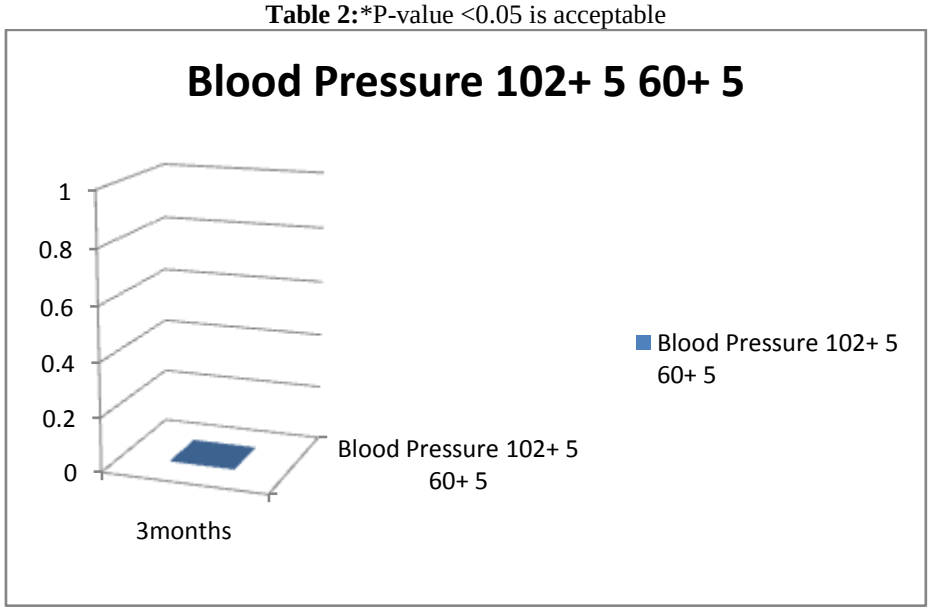

Chart 1: Blood pressure at 3months

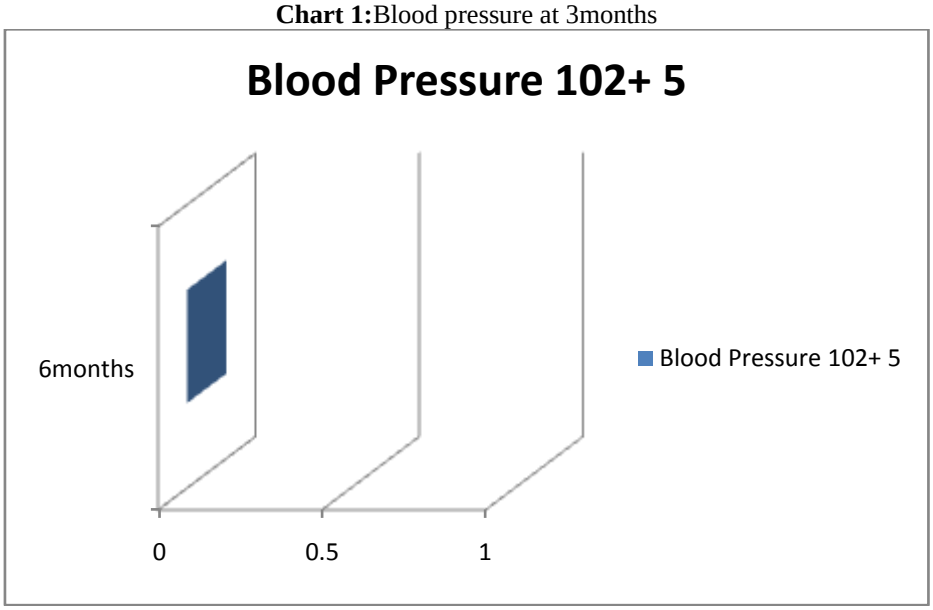

Chart:2 Blood Pressure at 6months

IV. Discussion

Clozapine, sold under the brand name Clozaril among others, is an atypical antipsychotic medication.[1] It is mainly used for schizophrenia that does not improve following the use of other antipsychotic medications. In those with schizophrenia and schizoaffective disorder it may decrease the rate of suicidal behavior.[1] It is possibly more effective than typical antipsychotics and in those who are treatment resistant.[3][4] It is taken by

mouth. Among normal blood pressure patients, after giving treatment for 3 months they were shown decrease in blood pressure. It was observed in considerable amount among patients shown in chart 1& table 1. It was less with other drugs[]. Here it is associated with other adverse effects like carditis. It has not came back to normal in 2-3hours. So patient has taken precaution to lie down in bed. Later it decreased. Random blood sugar levels were increased in 3months period &6months. Total white blood cell count, granulocyte count decreased considerably from 3months to 6months period. This indicate initial stages of agranulocytosis was observed. Treatment continued on the bases of conservative management. There was improvement in granulocyte count within 6months for them decreased at 3months.

V. Conclusion

There were decrease in negative symptoms better than other antipsycotics, still there were adverse effects like hyperglycemia, and decreased nuetrophil count. There may be improvement[2] in positive symptoms. Hence it can be recommended to take the drug.

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