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Original Research Article

Investing the Efficacy of Amisulpride for Schizophrenia Treatment

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Abstract:

Background: The study was performed at the Department of Pharmacology in collaboration with Department of Psychiatry, at DMCH Darbhanga. The maximum numbers of patients in were in reproductive age group that is in between 20 to 49 years. The mean age in Amisulpride group was 33.26(±10.23) years while in Olanzapine group it was 31.25 (±12.22) years. Schizophrenia was more common (80%) in younger (20-49years) age group. In our study the male /female ratio was 1.7. Our study supports the notion that Schizophrenia is more common in Married and Urban population. Only one patient from Olanzapine Group suffered Extrapyramidal symptoms of moderate severity requiring withdrawal from study.2 patients from Olanzapine group and 1 patient from Amisulpride group had Tremors and Akathesia of mild severity. There was no emergence of Extrapyramidal symptoms in rest of the patients (p>.05) Only one patient from Olanzapine Group suffered Extrapyramidal symptoms of moderate severity requiring withdrawal from study.2 patients from Olanzapine group and 1 patient from Amisulpride group had Tremors and Akathesia of mild severity. There was no emergence of Extrapyramidal symptoms in rest of the patients (p>.05).

Keywords: Efficacy, Amisulpride, Olanzapine & Schizophrenia.

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Introduction

Schizophrenia is the term for a group of disorders marked by chronicity, impaired behavioral function, and disturbances of thinking and affect. [1] Eugene Bleuler (1857 to 1939) was a Swiss psychiatrist generally credited for coining the term schizophrenia, of which he described primary symptoms of abnormal associations, abnormal affect, autistic behavior, and ambivalence the four A's. Schizophrenia is a severe mental disorder which accounts for much suffering of those affected andtheir families, in addition to a cost to society estimated as 1.1% of the total burden of disease (in terms of DALYs –disability adjusted life-years) and 2.8% of the total YLDs (years lived with disability) (Mental health policy and service development) [2 , 3] In India, for a population of nearly one billion people, there are an estimated four million people with schizophrenia, with different degrees of impact on some 25 million family members. (Mental health policy and service development) [4, 5] Life expectancy is also decreased as compared to the general population, not only due to suicide but inparticular due to cardiovascular disease.

Material and Method

The study was performed at the Department of Pharmacology in collaboration with Department of Psychiatry, at Darbhanga Medical College and Hospital Darbhanga Laheriasarai, Bihar. . Here patients were offered outpatients consultation and hospital admission when necessary.

Selection of Cases

The participants were of at least 18 years of age and below 60 years who had provided written informed consent before any study procedure was initiated.

Inclusion Criteria

- DSM –IV criteria for schizophrenia.
- Patient should not require hospitalization
- There should not be any past history or physical disorder that would likely to deteriorate duringparticipation
- There should be no abnormal lipid profile, ECG, abnormal blood glucose levels or abnormal BMI that would suggest deterioration during treatment.
- Should be able to communicate in Hindi/English.

Exclusion Criteria

- Patients requiring ECT or hospitalization.
- Patients with hypertension, Cardiac Disorder
- Pregnant /Nursing females.

- Patients with suicidal tendency.
- Unable to provide informed consent.

This study was carried out from March 2007 to September2009.This study was Double Blind. Drugs were provided to me in SEALED WHITE OPAQUE PAPER ENVELOPES labeled either as "A" or "1". The patients were RANDOMIZED either to receive drug A or drug 1 as per.

Results

Table 1: Demographic data

AGE	Amisulpiride	Olanzapine	Total	Percentage
< 20	2	1	3	5%
20-29	8	7	15	25%
30-39	8	11	19	31.7%
40-49	8	6	14	23.3%
50-59	3	4	7	11.7%
60-69	1	1	2	3.3%
TOTAL	30	30	60	100%

The maximum number of patients in was in reproductive age group that is in between 20 to 49 years. The mean age in Amisulpride group was 33.26(±10.23) years while in Olanzapine group it was 31.25 (±12.22) years.

Table 2: locality wise distribution

	Amisulpiride	Olanzapine	Total
Urban	18	20	38 (63.3%)
Rural	12	10	22 (36.7%)
	30	30	60

Table 3: Distribution according to durationof illness

Duration	Amisulpiride	Olanzapine	Total
< 1 Year	6	4	10
1-4 Year	20	21	41
5-9 Year	4	5	9
Total	30	30	60

16.6% of patients presented with duration of disease less than 1 year. Rest all patients had a chronic History with mean duration of illness of 1.4 (±1.32) years.

Table 4: Dropout rate

	Amisulpirid	Olanzapine
No. of Patients Lost to Followup	7	5
No. of Patients Lost due to Adverse Effects:	2	1

Total 12 patients (n=60) were lost to follow up, 05 from the Olanzapine group and 07 patients from the Amisulpiride group. The reason could not be determined since these patients never turned up to the Psychiatry OPD. One patient from the Olanzapine group suffered from severe Tremors and Akathesia during the 2ND week of trial period so was withdrawn from study and started on anticholinergic medication. 02 female patients in the Amisulpiride group complained of delayed menses on 30TH day follow up. They were referred to Gynaecologist and discontinued from the trial.

Hence Overall dropout rate in our study was 25%.

Use of sedative:

13 patients in Amisulpride group and 10 patients in Olanzapine group were prescribed Tab. Alprazolam 0.25mg on 15th day of study. 6 patients in Olanzapine group required to continue the medication throughout study while rest discontinued Tab. Alprazolam on subsequent visit. Only 03 patients in the Amisulpride group discontinued the sedative while rest all continued thedrug.

Discussion

In this Double blind Randomized Study final analysis was done in 21 patients from the Amisulpride groupand 24 in Olanzapine group. [6] All the patients were initially given Olanzapine 5mgand Amisulpride 100 mg in opaque sealed envelopes. 3 patients (12.5%) from Olanzapine group and 2 patients in Amisulpride group (9.5%) showed improvement at the initial dose. [7] they showed more than 10% reduction in BPRS and CGI scores on the first follow up. For rest of the patients the dose was doubled by providing 2 envelopes since 15th day. That is 21 patients in Olanzapine group and 19 patients in

Amisulpride group received double dose (10mg Olanzapine and 200mg Amisulpride) for rest ofthe study duration. [8,9] Both the drugs were equally efficacious when these drugs were compared on Physician administered CGI scale with a mean change in Severity scores of 2.095(±.831) in Amisulpride Group and 2.125(±0.68) in Olanzapine group. The improvement in scores were comparable in both the groups. [10]

Conclusion

Schizophrenia was more common (80%) in younger (20-49years) age group. In our study the male /female ratio was 1.7. Our study supports the notion that Schizophrenia is more common in Married and Urban population. Only one patient from Olanzapine Group suffered Extrapyramidal symptoms of moderate severity requiring withdrawal from study.2 patients from Olanzapine group and 1 patient from Amisulpride group had Tremors and Akathesia of mild severity. There was no emergence of Extrapyramidal symptoms in rest of the patients (p>.05)

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