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## Comparative Efficacy, Safety and Cost Analysis of Amisulpride vs Olanzapine for Treatment of Schizophrenia

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**Abstract-** Schizophrenia is a psychiatric disorder associated with a range of psychological, behavioural and cognitive problems especially. Nowadays, atypical antipsychotics are the mainstay for the treatment of schizophrenia. Among them amisulpride and olanzapine are the most commonly used atypical antipsychotics. The objective of this study is to compare the efficacy, safety and cost analysis of amisulpride vs olanzapine for the treatment of schizophrenia. It is a double blind, randomised control clinical trial conducted over a period of 12 weeks. A total of 90 patients were included which were randomly divided into two groups. Group A consisting of 39 patients who received amisulpride tablet (400mg/day) and group B consisting of 38 patients received olanzapine tablet (10mg/day). The brief psychiatric rating scale (BPRS) was taken as main evaluation parameter for the effectiveness of treatment.

**Keywords:** schizophrenia, amisulpride, olanzapine, atypical antipsychotics.

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**Abstract-** Schizophrenia is a psychiatric disorder associated with a range of psychological, behavioural and cognitive problems especially. Nowadays, atypical antipsychotics are the mainstay for the treatment of schizophrenia. Among them amisulpride and olanzapine are the most commonly used atypical antipsychotics. The objective of this study is to compare the efficacy, safety and cost analysis of amisulpride vs olanzapine for the treatment of schizophrenia. It is a double blind, randomised control clinical trial conducted over a period of 12 weeks. A total of 90 patients were included which were randomly divided into two groups. Group A consisting of 39 patients who received amisulpride tablet (400mg/day) and group B consisting of 38 patients received olanzapine tablet (10mg/day). The brief psychiatric rating scale (BPRS) was taken as main evaluation parameter for the effectiveness of treatment. The cost for each line of treatment was also calculated at the end of 12 weeks. Both drugs show equivalent efficacy in improving psychotic symptoms on BPRS scale. In both groups no major adverse effect was seen except that olanzapine group showed significant weight gain. Amisulpride treatment is more expensive as compared to olanzapine treatment. Olanzapine should be used for poor Indian patients whereas amisulpride should be preferred in patients who can afford the treatment or having any kind of co-morbid condition for treatment of schizophrenia in Indian population

**Keywords:** schizophrenia, amisulpride, olanzapine, atypical antipsychotics.

## I. INTRODUCTION

Schizophrenia<sup>1</sup> is a chronic psychiatric disease characterised by variety of symptoms such as hallucinations, delusions, altered speech, cognitive decline and impairment in perception of reality. It is a chronic disease but with early onset which significantly decreases the quality of life and productivity of patients. Prevalence of schizophrenia worldwide<sup>2</sup> is approximately 24 million people and in India it affects more than 3 million people. The prognosis of disease is

generally not good. Typical and atypical antipsychotics are used for the treatment of disease. Typical antipsychotics have low efficacy for treatment of symptoms and also have a lot of adverse effect therefore, atypical antipsychotics are preferred nowadays over typical antipsychotics. Amisulpride and olanzapine are among the most commonly used antipsychotics<sup>3</sup>. Amisulpride is a relatively new drug in India as compared to olanzapine.

Both drugs work by blocking different group of receptors. Amisulpride has affinity for D2 and D3 dopamine receptors<sup>4</sup> which helps in relief of both positive and negative symptoms with less extrapyramidal symptoms whereas olanzapine has affinity for 5HT2 and D2 dopamine receptors<sup>5</sup> which helps in improving psychotic symptoms.

We have conducted a 12 week double blind, randomised clinical trial to compare the efficacy<sup>6</sup>, safety and cost of the amisulpride and olanzapine for treatment of schizophrenia. As cost of treatment is an important factor in India, we have done the cost analysis of both the treatments to help determine the treatment of choice for patients of schizophrenia.

## II. METHODOLOGY

This was a double blind randomised clinical trial conducted in the medicine department of Pacific Medical College and Hospital. The study was conducted according to good clinical practice guidelines (ICMR)<sup>7</sup>. The informed consent was taken from each patient. Patient inclusion criteria includes all diagnosed cases of schizophrenia according to ICD - 10<sup>8</sup> guidelines between age of 18 to 60 years. Exclusion criteria includes all pregnant and lactating women and patients with any co-morbidity. A total of 90 patients of schizophrenia were included in the study. These patients were randomly divided into 2 groups - group A (39 patients) and group B (38 patients). Group A patients received tablet amisulpride 400 mg/ day whereas group B patients received tablet olanzapine 10 mg / day for 12 weeks. Follow up visits were done at the end of 4th, 8th and 12th weeks. The efficacy of the drug was assessed using the change in the value of BPRS<sup>9</sup> score from the baseline. The safety profile of both the

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drugs was assessed by reporting any adverse event, involuntary movement, change in behaviour or weight gain. The cost of the treatment was calculated by adding the cost of medication given per day for 12 weeks. SPSS software was used for statistical analysis. For comparison of means in two groups we used unpaired student t test and for comparison of mean in a single group we used paired student t test. Repeated measures analysis of variance (ANOVA) test was used for comparison of means of different parameters. P-value was obtained to determine the statistical significance. P - value < 0.05 was taken as significant.

### III. RESULTS

A total of 90 patients were included in the study (45 in each group) with baseline parameters as shown in table 1. Out of these 90 patients only 77 (39 in group A and 38 in group B) completed the study (table 2). 3 patients in group A and 2 patients in group B left the study due to unknown reason. 2 patients in group A and 3 patients in group B left the study due to lack of efficacy of treatment and 1 patient in each group left study due to some other reason. 1 patient died in group B during the course of study.

*Table 1:* Baseline parameters

	Group A	Group B
Age (mean)	32 years.	33 years
Gender (Male/female)	20/19	20/18
Duration of disease	11.0 years	10.5 years
Weight (mean)	53.5 kg	52.9 kg
Mean BPRS score	56.5.	57.5.

*Table 2:* Study follow up

	Group A	Group B
Total patients randomised	45	45
Patients Completed study	39	38
Patients left study	6	7
Left due to unknown reason	3	2
Left due to lack of efficacy	2	3
Death	0	1
Others	1	1

During the study the BPRS score was collected at the end of 4th, 8th and 12th week (table 3). The mean change in BPRS score in group A was 16.80 and in group B was 15.5. The efficacy of both the drugs was comparable and the difference is not statistically significant.

Table 3: The BPRS score

BPRS score	Group A	Group B
Baseline bprs socre	56.5	57.5
4th week bprs score	48.1	50.3
8th week bprs score	40.1	42.2
12th week bprs score	33.9	35.4

No major adverse effect was seen and only minor adverse effects was see in both line of drugs. Both drugs are comparable in terms of safety profile except that their is significant weight gain seen in olanzapine group. Amisulpride treatment can cost upto 3000 to 3500 INR whereas olanzapine treatment can cost between 800 to 900 INR for 12 weeks of treatment per patient. Amisulpride treatment is more expensive than olanzapine treatment.

#### IV. DISCUSSION

Most of the studies for the use of both these drugs in schizophrenia patients are conducted on western population. Still very few studies are done for the use of these drugs on Indian population therefore we have done a study which is primarily focused on Indian population<sup>10</sup>. We have compared efficacy, safety and cost of amisulpride and olanzapine for treatment of schizophrenia. Both these drugs are comparable in terms of efficacy. We used BPRS score as the main evaluation parameters for efficacy. Both these drugs also shows an equal improvement in symptoms of disease however both the drugs are helpful in improving positive symptoms more than the negative symptoms. Amisulpride is also helpful in improving the cognitive functions of the brain. No major adverse was seen with both drugs during the Course of treatment except weight gain which is a typical feature of all antipsychotics. However olanzapine group showed much more weight gain than amisulpride group. Difference in weight gain is due to the different receptors that both drugs target. Amisulpride has selective affinity for D2 and D3 dopaminergic receptors on the other hand olanzapine also has affinity for 5HT2 receptors. These drugs can increase the risk of hypertension, diabetes, obesity and cardiovascular disease in later part of life therefore olanzapine should be given carefully in patients having any kind of co-morbidity or obesity. In terms of cost amisulpride is more expensive than olanzapine treatment. Till now most of the studies are conducted in western counties whereas for poor parents in India cost of the treatment and affordability is a major issue. Therefore while deciding the deciding the treatment of choice for schizophrenia patients in India

cost of the treatment should also be. Considered along with efficacy and safety of drug. This study will help in deciding the treatment of choice for schizophrenia patients in Indian population. In general Olanzapine can be given to patients who do not have any kind of co-morbid condition whereas amisulpride should be preferred in patients who can afford the treatment or having any kind of co- morbid condition.

#### V. CONCLUSION

Both Amisulpride and olanzapine are comparable in terms of efficacy and safety profile except that there is significant weight gain seen with olanzapine. To conclude, olanzapine can be used in the patients who are not having any co-morbid condition whereas amisulpride should be preferred in patients who can afford it or having any kind of co-morbid condition for treatment of shizophrenia in indian population

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