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Original Research Article

TO EVALUATE EFFICACY AND COGNITIVE PROFILE OF AMISULPRIDE *PER SE* AND COMPARE IT AGAINST THAT OF OLANZPINE IN NEWLY DIAGNOSED SCHIZOPHRENIC PATIENTS.

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Abstract

Background & Methods: The aim of the study is to evaluate efficacy, safety and cognitive profile of amisulpride *per se* and compare it against that of olanzpine in newly diagnosed schizophrenic patients. The psychiatrist and further assessed on the ICD – 10 Criteria.

Results: During the study period change observed in BPRS score in amisulpride group was 15.75[SD:3.67] and in olanzapine group was 14.72 [SD:2.93]. This improvement was similar in both groups and was not statistically significant [p=0.56]. Scores in each visit for Token test [scores presented as mean of the scores in the test [SD] values]. [$p<0.05$]

Conclusion: Results of clinical study showed that amisulpride and olanzapine are having equal efficacy in terms of improvement of positive and negative symptoms of schizophrenia. Results were analysed by Mann Whitney U test for unpaired samples. Efficacy was assessed by Brief Psychiatry Rating Scale [BPRS].

Keywords: efficacy, cognitive, amisulpride, olanzpine & schizophrenic patients.
Study Design: Observational Study.

1. Introduction

Brief descriptions of what would probably regarded as schizophrenia are found in hindu ayurveda as long as 1400 BC and in the writings of the cappadocian physician Aretaeus in the first century A.D[1]. Written documents that identify Schizophrenia can be traced to the old Pharaonic Egypt, as far back as the second millennium before Christ. Depression, dementia, as well as thought disturbances that are typical in schizophrenia are described in detail in the Book of Hearts[2]. The Heart and the mind seem to have been synonymous in ancient Egypt. The physical illnesses were regarded as symptoms of the heart and the uterus and originating from the blood vessels or from purulence, fecal matter, a poison or demons.

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A number of psychological mechanisms have been implicated in the development and maintenance of schizophrenia[3]. Cognitive biases that have been identified in those with a diagnosis or those at risk, especially when under stress or in confusing situations, include excessive attention to potential threats, jumping to conclusions, making external attributions, impaired reasoning about social situations and mental states, difficulty distinguishing inner speech from speech from an external source, and difficulties with early visual processing and maintaining concentration[4]. Some cognitive features may reflect global neurocognitive deficits in memory, attention, problem-solving, executive function or social cognition, while others may be related to particular issues and experiences[5].Despite a common appearance of "blunted affect", recent findings indicate that many individuals diagnosed with schizophrenia are highly emotionally responsive, particularly to stressful or negative stimuli, and that such sensitivity may cause vulnerability to symptoms or to the disorder[6].Some evidence suggests that the content of delusional beliefs and psychotic experiences can reflect emotional causes of the disorder, and that how a person interprets such experiences can influence symptomology. Further evidence for the role of psychological mechanisms comes from the effects of therapies on symptoms of schizophrenia[7-9].

2. Material and Methods

The study subjects were newly diagnosed cases of schizophrenia diagnosed at The Psychiatric OPD, Amaltas Institute of Medical Sciences, Dewas by the psychiatrist and further assessed on the ICD – 10 Criteria on 50 cases 29 males & 21 females.

- Either before or after completing the examination procedure, observe the patient unobtrusively at rest (e.g., in the waiting room).
- The chair to be used in this examination should be a hard, firm one without arms.
- Ask the patient whether there is anything in his or her mouth (such as gum or candy) and, if so, to remove it.
- Ask about the *current* condition of the patient's teeth. Ask if he or she wears dentures.
- Ask whether teeth or dentures bother the patient *now*.
- Ask whether the patient notices any movements in his or her mouth, face, hands, or feet.
- If yes, ask the patient to describe them and to indicate to what extent they currently bother the patient or interfere with activities.

3. Result

Table 1: CHARACTERISTICS OF PATIENTS:

	Amisulpride	Olanzapine
Age [years]Mean[SD]	28.6± 4.51	30.3± 3.22
Gender [male/female]	15/10	14/11
Weight [kg]	50.1 ± 8.78	48.9 ±9.32
Duration of illness [weeks]	10.7 ±3.22	09.2 ± 3.54
Mean BPRS score	53.4± 5.69	56.6 ± 3.73

Characteristics of patients exposed to drugs [Categorical variables presented as absolute patient numbers and quantitative variables presented as mean [SD] values]

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Table 2: EFFICACY

Visit	Amisulpride group	Olanzapine group
1	53.4 ± 5.69	56.6 ±3.73
2	46.1 ± 5.72	48.3 ± 7.20
3	36.9 ± 6.81	41.2 ± 7.74
Mean Change from baseline	-15.8 ± 3.61	-15.3 ± 2.69

During the study period change observed in BPRS score in amisulpride group was 15.75[SD:3.67] and in olanzapine group was 14.72 [SD:2.93]. This improvement was similar in both groups and was not statistically significant [p=0.56].

Table 3: COGNITIVE ASSESSMENT

Token test	Amisulpride	Olanzapine
Visit 1	13.06±3.37	13.43±2.64
Visit 2	17.83±4.22	16.78± 1.37
Visit 3	21.33 ± 3.21	20.34± 3.45
Mean change	7.64 ±1.56	5.89 ± 2.09

Scores in each visit for Token test [scores presented as mean of the scores in the test [SD] values]. [$p<0.05$]

4. Discussion

The primary effectiveness variable used was Brief Psychiatric Rating Scale (BPRS) scale. This scale describes the patient condition by evaluating different positive and negative symptoms[10]. Present study showed that there was improvement in BPRS score both in amisulpride group and olanzapine group, but this improvement became significant from 2nd follow up onwards. Overall improvement was more in olanzapine than amisulpride. Also, the scores decreased significantly from baseline to the end follow up visit in both the study groups. This showed that both the drugs were quite effective in treating the symptoms of schizophrenia. But olanzapine seemed to be more effective than amisulpride in our study. It was observed that there were rapid decrease in BPRS after 4th week in both the groups favouring the use of both the drugs in treating schizophrenia[11].

Amisulpride, a substituted benzamide acting as an atypical antipsychotic was the main focus of study. It is endowed with potent antipsychotic property along with better side effect profile. Schizophrenia [a psychiatric disorder that manifests as abnormalities in perception or expression of reality] is a common psychiatric disorder affecting about 1 % population. The mainstay of treatment is pharmacotherapy with antipsychotic medications; these primarily work by suppressing dopamine activity[12]. These agents are divided into typical and atypical groups based on occurrence of extra pyramidal side effects with the former. Though atypical agents carry this advantage over typical agents, there is different set of side effects amongst atypical agents. This set includes weight gain, sedation, alteration of lipid profile etc. Basic reason of focus on side effect profile of these agents is that efficacy wise they are more or less equal.

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When secondary effectiveness variables were considered, in the present study it was seen that there were significant ($p < 0.001$) decrease in the Clinical Global Impression severity scale (CGI-S) and Clinical Global Impression Improvement scale (CGI-I), from baseline till end follow up in both the study groups and this decrease was more in case of olanzapine than amisulpride when both groups were compared to each other and became statistically significant at 8th and 12th week in case of CGI-S whereas statistical significance was seen only in end follow up visit in case of CGI-I[13].

5. Conclusion

Results of clinical study showed that amisulpride and olanzapine are having equal efficacy in terms of improvement of positive and negative symptoms of schizophrenia. Results were analysed by Mann Whitney U test for unpaired samples. Efficacy was assessed by Brief Psychiatry Rating Scale [BPRS].

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