e-ISSN: 0975-1556, p-ISSN:2820-2643
Available online on www.ijpcr.com
International Journal of Pharmaceutical and Clinical Research 2024; 16(5); 1455-1458

Original Research Article

Assessing the Effectiveness of Aripiprazole in Treating Schizophrenia within Bihar Population

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Received: 10-01-2024 / Revised: 12-02-2024 / Accepted: 17-03-2024
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Conflict of interest: Nil

Abstract:

Background and Objectives: During the past decade, there has been some progress in the pharmacotherapy of schizophrenia and schizoaffective disorder. Aripiprazole is recommended at a dose of between 10 and 15 mg/day in the treatment ofschizophrenia, with a dose range considered to be effective, between 10 and 30 mg/day. To study the efficacy and safety of Aripiprazole in low doses of 15 mg versus high doses of 30 mg in the treatment of Schizophrenia.

Methods: Total 60 new and old patients (who are not on any treatment) between 18-60 years of either gender who meet the diagnostic criteria as per DSM-IV classification for schizophrenia and schizoaffective disorder. Patients were randomly divided into 2 groups on single blind study criteria. Group-I: Aripiprazole 15 mg once a day, morning dose for 6 weeks. Group-II: Aripiprazole 30 mg once a day, morning dose for 6 weeks. Efficacy assessment included at baseline and at 6 weeksend study scoring on PANSS, EPRS and CGI.

Results: In both the groups aripiprazole showed the efficacy by improving the number of patients. In group-I, 20 patients has shown the improvement in overall scores of all scales. In group-II, 16 patients have shown the improvement in overall scores in different scales.

Conclusions: Aripiprazole is effective in schizophrenia and schizoaffective disorder, low doses of 15 mg is equally effectiveas high dose of 30 mg.

Keywords: Efficacy, Aripiprazole & Schizophrenia.

Introduction

Schizophrenia and schizoaffective disorder are quite common in young adult population, with high incidence rate of chronicity, morbidity and suicidal tendency. Both typical and atypical antipsychotic drugs are used for the treatment of schizophrenia. Schizoaffective disorder sharesclinical characteristics with schizophrenia and affective disorder, with patients experiencing concurrent manic, mixed, or depressive episodes during psychosis. [1,2] Aripiprazoleis anatypical antipsychotic that is reported to be effective in the treatment of schizophrenia. [3] Atypical or second-generation antipsychotics are said to differ from conventional or typical antipsychotics in terms of their effects on the positive and negative symptoms of schizophrenia and on cognition, and in terms of their adverse effect profiles [4]. Aripiprazoleis the prototype of a 'third generation' of antipsychotics – the so-called dopamine– serotonin-system stabilisers. It is claimed to be at least as effective as haloperidol in the treatment of positive and negative symptoms of schizophrenia, and it may cause fewer adverse effects. Aripiprazole is reported to be useful in all phases of schizophrenia, and to enhance cognitive function. [5] Aripiprazole is a quinolinone derivative with a high affinity for dopamine D_2 and D_3 receptors, and serotonin 5-HT_1A, 5-HT_2A and 5-HT_2B receptors. The mechanism of action of aripiprazole is not yet known, but evidence suggests that its efficacy in the treatment of the positive and negative symptoms of schizophrenia and its lower propensity for extra pyramidal symptoms (EPS) may be attributable to aripiprazole's partial agonist activity at dopamine D_2 receptors. At serotonin 5-HT_1A receptors, in vitro studies have shown that aripiprazole acts as a partial agonist whereas at serotonin 5-HT_2A receptors aripiprazoleis an antagonist. [6] The efficacy of aripiprazole has been demonstrated in patients with schizophrenia or schizoaffective disorder. In general, significant reductions from baseline in mean Positive and Negative Syndrome Scale total, positive and negative symptom scores, and Clinical Global Impression Severity of Illness scores were observed in patients with acute relapse of chronic schizophrenia or schizoaffective disorder receiving recommended (10 or 15 mg/day) or higher-than-recommended (20 or 30 mg/day) dosages of aripiprazole versus those receiving placebo in three well

controlled, short-term trials. Aripiprazole 10-30 mg/day was generally well tolerated. The tolerability profile of aripiprazole was broadly similar to that observed with placebo in a meta-analysis of short-term trials in patients with acute relapse of schizophrenia or schizoaffective disorder and in a 26-week trial in patients with chronic stable schizophrenia. [6]

Objectives: To study the efficacy of Aripiprazole in the treatment of Schizophrenia and to compare the efficacy and safety of Aripiprazole in low doses versus high doses ofin the treatment of Schizophrenia.

Methods and Materials

This study was conducted in department of Pharmacology and department of Psychiatry OPD at Darbhanga Medical College and Hospital Laheriasarai, Bihar. of either gender aged 18-60 years. This clinical research study was conducted to determine the efficacy and safety of aripiprazole in low dose (15 mg) versus high dose (30 mg)in a patient of schizophrenia and schizoaffective disorder.

This study comprised of all the new and old patients (who are not on any treatment) of age group between 18-60 years of either gender who meet the diagnostic criteria as per DSM-IV classification for schizophrenia and schizoaffective disorder and those patients and their relatives who are willing to give consent for the treatment were taken in the study.

Inclusion Criteria

All the new and old patients (who are not on any treatment) of either sex who met the diagnostic criteria as per DSM-IV classification for Schizophrenia or Schizoaffective disorder were taken in the study. (ii) Those patients and their relatives who are willing to give consent for the treatment.

Exclusion Criteria

Schizophrenic patients who are taking any antipsychotic drug treatment in last one month. (ii) If the subject is women who is pregnant or breast feeding or at risk of pregnancy during therapy. (iii) If the patient consume alcohol or have drug dependency in the last 6 months.(iv) If the patient is on ketoconazole carbamazepine, levodopa, dopamine agonist, diuretic therapy or is at risk of torsade-de-pointes. (v) Patient hypersensitive to antipsychotic drugs like aripiprazole. (vi) If the patient is suffering from hepatic, renal, metabolic or neurological disorders (Parkinson's disease or other movement disorders). (vii) ECG with long QT interval.

All the new and old patients of Schizophrenia and Schizoaffective disorder who met DSM-IV criteria and not treated by any antipsychotic drugs in past one month is to be taken on all OPD days. Prior written informed consent from each patient and their relative's enrolled in this study were taken. The patients who were already on treatment were excluded.

Total 60 patients were taken in the study. Each patient has undergone detailed Psychiatric and medical history with clinical examination. Efficacy assessment included at baseline and at 6 weeks end study scoring on PANSS (Positive and Negative Symptoms Scale), EPRS (Extrapyramidal Rating Scale) and CGI (Clinical Global Impression) was done.

These patients were randomly divided into 2 groups on single blind study criteria.

Group-I: Patients prescribed tablet Aripiprazole 15 mgonce a day, morning dose for 6 weeks.

Group-II: Patients prescribed tablet Aripiprazole 30 mg once a day, morning dose for 6 weeks.

Efficacy and safety data of aripiprazole was compared every week for 6 weeks by applying the 3 standard scales on the patients, these scales were PANNS, EPRS and CGI. Improvement was considered when reduction of >50% score on PANSS on 6^{th} week from baseline. When rating onCGI scale is in between 2-3 at 6 weeks of treatment, it shows the improvement. The analysis of efficacy and side effects of 15 mg versus 30 mg of Aripiprazole was compared on demographic, efficacy and safety profile by using appropriate statistical tests of significance.

Results and Discussion

In this study mean age group of patients were 27-32 years, it means young age group is most commonly affected. As given in the table, there was no statistical significant difference observed among the two groups for patient's age, gender, marital status and geographical parameters ofrural and urban factors. (Table-1)

Total number of patients were 60, number of drop-out patients were 12, so 8 out of 60 patients (13%) didn't completed the study, they didn't follow-up. Total 4 out of the 60 (7%) In group-I total number of patients was 26 out of which 20 (77%) patients showed improvement and in group-II 16(73%) patients out of 22 patients showed improvement. The number of improved patients shown by effectiveness of drug reflects the efficacy of Aripiprazole. In both the groups aripiprazole showed the efficacy by improving the number of patients. In group-I 20 patients has shown the improvement in overall scores of all scales. In group-II 16 patients has shown the improvement in overall scores in different scales. In group-I total number of improved patients on PANSS positive scale was 18 patients (69%) out of 26 and in group-II 12 (55%) patients out of 22 were improved. Both groups showed significantly greater improvement in reduction on the PANSS positive scale from baseline to the end study. On PANSS negative symptom scale 16 patients (62%) out of 26

were improved in group-I and in group-II 16 patients (72%) out of 22 patients were improved. Both groups showed significantly greater improvement in negative symptoms as measured by the PANSS negative symptoms scale. More than 66% of patients showed efficacy for the aripiprazole in both the groups. On GPS scale in group-I 15 patients (58%) out of 26 were improved and in group-II 15 patients (68%) out of 22 were improved. Patients receiving aripiprazole 15 mg or 30 mg hasexperienced significant reduction from baseline to 6th weekwith a clinical improvement on GPS scale. .

On CGI scale in group-I, 20 patients (77%) out of 26 were improved and in group-II, 15 patients (68%) out of 22 were improved. In group-I CGI score at baseline is 5.7 and it goesdown by 3.6 at the end of 6th week. In group-II CGI score atbaseline is 6.1 and it goes down by 3.6 at the end of 6th week. In both the groups the improvement in CGI from baseline to 6th week score is 2.7 which is quite good improvement. Aripiprazole has shown improvement in 35 patients out of 48 patients after completion of 6 weeks study. No significant difference of improvement was found on age, gender, type and duration of illness between 15mg or 30 mg dose of Aripiprazole.

Average score of overall efficacy, positive and negative symptoms and average mean score of positive and negative symptoms

Groups	**Overall Efficacy**		**Total patients**
	Effective	**Not-effective**	
Group-I (15 mg)	20	6	26
Group-II (30 mg)	16	6	22
Average score in positive symptoms			
Group-I (15 mg)	18	08	26
Group-II (30 mg)	12	10	22
Average score in negative symptoms			
Group-I (15 mg)	16	10	26
Group-II (30 mg)	16	06	22
Average mean score of positive symptoms			
		Group-I (15 mg)	**Group-II (30 mg)**
Total no. of improved patients		18	12
Baseline		82	90
At 6 weeks		38	42
Average mean score of negative symptoms			
Total no. of improved patients		16	16
Baseline		70	86
At 6 weeks		36	40

$P<0.05$

Table 1: General Psychopathological Scale (GPS), PANSSand CGI Scales

Demo Parameters	graphic profile Group-I (Low dose 15mg)	Symptoms		Baseline	6th week
				Baseline	6th week
		Group-II (High dose 30 mg)	GPS	50	34
				48	32
			PANSS	Mean	score
Age (mean)	32 Years	27 Years	Positive	39	21
				40	21
			Negative	34	18
				35	16
Gender Males Females	22 08	Total		73	39
				75	37
		19	CGI	mean	score
		11	Group-I (15	5.7	
			3.6	1	2.7

		mg)		
Marital status Married Unmarried	12 18	Group-II (30 mg) 10 20	6.1 1	3.6 2.7

Conclusion

There was no statistically significant difference between two groups, aripiprazole there is high incidence of side effects due to which it results in low efficacy. It means low dose is equallyeffective as high dose. On comparison of total PANSS score of both the groups there is>50% improvement in symptoms of patients from baseline to 6 week of study. The result also shows theimprovement in PANSS positive and negative scale score which is also reduced by >50%. Improvements in GPS scale score >50% shows the efficacy of aripiprazole in both the groups. CGI >2.7 (=2 is much improved) improvement in score shows the efficacy of aripiprazole in both the groups.To recommend, it would be advisable to use aripiprazole inlow doses to prevent the side effects, by using low doses the cost of the treatment is also low

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