RESEARCH ARTICLE

A study of efficacy of new generation atypical antipsychotic (Lurasidone) across positive and negative symptom-domains in fresh cases of schizophrenia

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Background: Increasing antipsychotics have altered the course of schizophrenia. Few drugs have shown improvement in negative symptoms and cognitive deficits, compounded by intolerable side effects. Lurasidone is a relatively new entrant in the field of schizophrenia in the Indian context. This study evaluated the overall efficacy of Lurasidone across the whole spectrum of symptoms of schizophrenia and compared the degrees of improvement in the positive and negative domains.

Methods: This is a longitudinal observational study. PANSS was administered at baseline, after 1 month, and after 3 months. A total of 57 patients, diagnosed using ICD-10 criteria, were recruited from the psychiatry OPD of MVJ Medical College and Research Hospital. 7 patients dropped out due to intolerability. The remaining was followed up. Statistical analysis of the data was done using the Statistical Package for Social Sciences Software (SPSS). Using appropriate statistical methods, dimensional comparisons were made using the central tendencies like means with S.D for Lurasidone before and after treatment.

Results: In the positive scale of PANSS, the mean reduction of positive score at the end of 4 weeks was 6.13, at the end of 3 months the mean positive score was 10.900. Both scores were statistically significant. In the negative scale of PANSS, mean reduction of negative scores at the end of 4 weeks was 6.615, which were statistically significant; at the end of 3 months, the mean reduction on negative scores was 10.35 which were statistically significant.

Conclusion: The current study showed that Lurasidone has effect on both positive and negative symptoms of schizophrenia at week 4 and better efficacy at week 12. Overall results show better response to positive symptoms. However a longer follow up would help us study the influence of Lurasidone on the course of schizophrenia as well as response to individual domains and symptoms.

Key Words: *Lurasidone; Efficacy; Indian population; Schizophrenia*

INTRODUCTION

The management of schizophrenia has seen significant strides over the last decades, due to the increasing availability of a number of antipsychotics. Yet, the low efficacy in relation to the negative and cognitive symptoms of schizophrenia and the disturbing adverse reactions associated with current antipsychotics, reflect the need for better molecules targeting unexplored pathways.

Lurasidone is a relatively new entrant in the field of schizophrenia in the Indian context.

There are few systematic studies done in India, about the efficacy of Lurasidone. Hence this study is an attempt to evaluate the efficacy of the new generation antipsychotic Lurasidone, across various symptom domains of schizophrenia. Lurasidone is a newer atypical antipsychotic which is already FDA-approved for the treatment of schizophrenia [1].

Lurasidone is highly protein-bound (99.8%), with affinity for albumin and alpha-1-glycoprotein [2]. In trials that food can affect the absorption of Lurasidone, akin what can be seen with Ziprasidone, but possibly with a lower caloric threshold than necessary with Ziprasidone [3]. According to Meyer et al. [2] CYP3A4 is the primary metabolic pathway for Lurasidone and; Chiu et al. presented that this has implications regarding the use of Lurasidone in the presence of inducers and inhibitors of CYP3A4 [4]. Loebel et al. showed that Lurasidone was significantly superior to placebo in improving all five PANSS factor scores. Week 6 change scores were significantly compared with placebo among patients treated with 40, 80, and 120 mg/days on the PANSS positive factor, negative factor, disorganized thought, hostility, and depression/anxiety [5]. In a study by Cucchiaro et al. directly comparing Lurasidone 120 mg/day with another antipsychotic, Lurasidone"s efficacy among stable outpatients with schizophrenia was found to be similar to that of Ziprasidone 160 mg/day [6]. This is not a clinical trial and this medicine is not an experimental drug. It is already a fairly established medicine which is cleared for clinical usage across the world. The study involves only a clinical evaluation of this symptom response, without any invasive investigations or procedures. In that sense it's quite a safe study. A good number of schizophrenia patients would have been put on Lurasidone anyway, in routine practice by the senior psychiatrists of this department. This study is only a systematic scoring of the improvements in various symptoms and recording those observations in a methodical way, without subjecting the patients to any untested or unapproved treatments or without compromising the patients' wellbeing in anyway. This study is also a small attempt, using only safe, non-invasive, clinical evaluation methods to add to the weight of evidence as to whether Lurasidone is effective enough in treating schizophrenia patients in Indian settings.

Aims and objectives of the study

1. This study is designed to evaluate the overall efficacy of Lurasidone across the spectrum of symptoms of schizophrenia (positive and negative domains).

2. To compare the degrees of improvement in positive and negative domains and determine in which group of symptoms, Lurasidone has higher efficacy.

METHODOLOGY

Source of data

Patients diagnosed with schizophrenia using ICD 10 criteria on Lurasidone treatment attended the psychiatry OPD at MVJMC and RH, which is a tertiary care referral hospital.

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Sample size

50 cases of schizophrenia patients will be assigned.

Age group

Patients diagnosed with schizophrenia using ICD 10 criteria on Lurasidone treatment attended the psychiatry OPD at MVJMC and RH, which is a tertiary care referral hospital.

Source of data

Patients diagnosed with schizophrenia using ICD 10 criteria on Lurasidone treatment attended the psychiatry OPD at MVJMC and RH, which is a tertiary care referral hospital.

Methods of collection of data (including sampling procedure if any):

Sampling procedure

• The cases will be recruited and the data will be collected over a period of 1 year and 10 months (Nov 2016–Sep 2018). Selection will be made in a serial consecutive way that consent to participate in the study.

• Permission was obtained from our college ethical committee.

Inclusion criteria

1. Newly diagnosed case of schizophrenia.

2. Age groups between 18-60 years are included for homogeneity.

3. Written Informed consent.

Exclusion criteria

1. Other psychiatric disorders will be excluded.

2. Patients with schizophrenia already receiving treatment.

3. Patients who would not show an adequate response when put on lurasidone, even after a sufficient amount of time (6 weeks) and adequate dose (60-120 mg) will be switched on other antipsychotics in the best interest of patients. They will be considered as dropouts from the study.

4. Patients suffering from severe and debilitating comorbid medical and surgical illness.

Instruments

Semi-structured pro forma will be used to record basic socio-demographic data.

Modified BG Prasad's socioeconomic status scale

Prasad's socioeconomic classification is widely used in Indian medical literature, it was proposed for the first time by Prasad on per capita income per month and then revised by him based on cost of living (Table 1) [7].

TABLE 1

The updated classification of social class-2016

Classification for 2016 PCI/month in rupees	Social class
I	6277 and above
II	3139 – 6276
III	1883 – 3138
IV	942 – 1882
V	Less than 942

Modified BG Prasad's socioeconomic status scale

Prasad's socioeconomic classification is widely used in Indian medical literature, it was proposed for the first time by Prasad on per capita income per month and then revised by him based on cost of living (Table 1) [7].
Modified BG Prasad's socioeconomic status scale

Positive and Negative Syndrome Scale (PANSS)

• The Positive and Negative Syndrome Scale (PANSS) is a psychiatric rating scale for measuring symptom severity in two categories, that is, positive and negative types in patients with schizophrenia.

• It was published in 1987 by Stanley Kay, Lewis Opler, and Abraham Fiszbain. It is widely used in evaluating the outcome of antipsychotic therapy [8].

• The PANSS is a relatively brief interview, requiring 45 to 50 minutes to administer.

• Both Positive and Negative scale contains 7 items each. Each item rated between a score of 1-7. Peralta and Cuesta reported on the inter-rater reliability of the PANSS in a sample of 100 consecutively admitted patients with schizophrenia. Positive and negative scales showed good inter-rater reliability: Interclass Correlation Coefficients (ICC) of 0.72 and 0.80, respectively [9].

Study design

• This is a longitudinal observational study.

• Minimum period of study for each patient is 3 months.

• PANSS will be administered at baseline, i.e., before starting the treatment, after 1 month and after 3 months.

Assessment at particular visits

First visit/Baseline assessment:

• Patients will be informed in detail about the purpose and requirements of the study.

• A thorough physical examination will be carried out including Body Mass Index (BMI) and recorded.

• Blood investigations are done; complete blood count, liver function test, renal function test, serum electrolytes, fasting and post prandial blood sugars, thyroid function test and ECG.

• Assessment of positive and negative symptoms of schizophrenia by applying PANSS.

Second visit/Second assessment:

• This will be done at the end of 1st month, it consists of

• Re-assessment of the severity of positive and negative symptoms of schizophrenia by applying PANSS.

• A thorough physical examination including Body Mass Index (BMI) will be carried out and recorded.

Third visit/Third assessment:

• This will be done at the end of 3rd month, it consists of

• Re-assessment of the severity of positive and negative symptoms of schizophrenia by applying PANSS.

• Treatment emergent adverse effects of Lurasidone are recorded as on the check list.

• A thorough physical examination including body mass index, will be carried out and recorded.

Statistical method used

Statistical analysis of the data will be done using the Statistical Package for Social Sciences Software (SPSS) or any other modern suitable software. Using appropriate statistical methods, dimensional comparisons will be made using the central tendencies like the means with S.D for Lurasidone before and after treatment. T-test will be applied for finding out the significance of 'p' values where appropriate.

RESULTS

57 patients fulfilling the inclusion criteria were approached for the current study, 50 were able to complete the study the rest 7 subjects dropped out due to intolerability of lurasidone. Out of 57 of study population, 35 were males

(61.4%), 22 were females (38.6%)

The participants were 20 to 49 years of age. Majority of age group were 20 to 29 years (71.93%), whereas 30 to 39 years was 24.56% and 40 to 49 years was 3.51% (Table 2).

TABLE 2

Distribution of the study participants according to age group

Age group	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
20-29 Years	24 (68.6%)	17 (77.3%)	41 (71.9%)
30-39 Years	9 (25.7%)	5 (22.7%)	14 (24.6%)
40-49 Years	2 (5.7%)	0	2 (3.5%)

Total 6 (10.53%) were educated till primary school (0 to 7); 25 (43.86%) were educated up to secondary school (8 to 10); 22 (38.6%) were educated till PUC or intermediate; 4 (7.02%) were graduates (Table 3).

TABLE 3

Educational status of the study participants

Education	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Primary (0-7)	3 (8.6%)	3 (13.6%)	6 (10.5%)
Secondary (8-10)	19 (54.3%)	6 (27.3%)	25 (43.9%)
Intermediate/ PUC	10 (28.6%)	12 (54.5%)	22 (38.6%)
Graduate	3 (8.6%)	1 (4.5%)	4 (7.0%)

Table 4 shows the distribution of the study participants according to their occupation, which includes unemployed/housewife, unskilled workers, semiskilled workers, skilled workers, clerical/shop owners, and semi-professional. Majority of 16 (28.1%) were skilled workers; 15 (26.3%) were semiskilled workers; 10 (17.5%) were unemployed/housewife; 7 (12.3%) were unskilled workers; 6 (10.5%) were clerical/shop owners and 3 (5.3%) were semiprofessional.

TABLE 4

Distribution of the study participants according to their occupation

Occupation	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Unemployed/ Housewife	0	10 (45.5%)	10 (17.5%)
Unskilled worker	4 (11.4%)	3 (13.6%)	7 (12.3%)
Semiskilled worker	12 (34.3%)	3 (13.6%)	15 (26.3%)
Skilled worker	12 (34.3%)	4 (18.2%)	16 (28.1%)
Clerical, Shopowner	5 (14.3%)	1 (4.5%)	6 (10.5%)
Semi professional	2 (5.7%)	1 (4.5%)	3 (5.3%)

The sample was categorized in to various socio-economic groups based on the Modified B.G. Prasad's classification. Table 5 depicts the distribution of the study participants according to their socio-economic status by modified B.G. Prasad's classification. Out of which 6 (10.5%) were of Class 2; 14 (24.6%) were of Class 3, a majority of about 20 (40.4%) belonged to Class 4 and Class 5 consisted of 14 (24.6%), there was no patient from class 1 socio-economic status.

TABLE 5

Distribution of the study participants according to their socio-economic status

Socio-economic status	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Class 2	4 (11.4%)	2 (9.1%)	6 (10.5%)
Class 3	9 (25.7%)	5 (22.7%)	14 (24.6%)
Class 4	16 (45.7%)	7 (31.8%)	23 (40.4%)
Class 5	6 (17.1%)	8 (36.4%)	14 (24.6%)

Table 6 shows the distribution of study participants according to their area of residence. Rural study participants consisted of 24 males and 14 females, a total of about 38 (66.7%). Urban study participants consisted of 11 males and 8 females, a total of about 19 (33.3%).

TABLE 6

Distribution of the study participants according to their area of residence

Area of residence	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Rural	24 (68.6%)	14 (63.6%)	38 (66.7%)
Urban	11 (31.4%)	8 (36.4%)	19 (33.3%)

Table 7 shows distribution of the study participants according to their marital status. Of which 9 males and 10 females are Single (unmarried, divorced, widowed), which is about 19 (33.3%) of the total study population. 26 males and 12 females were married, which is about 38 (66.7%) of the total study population.

TABLE 7

Distribution of the study participants according to their marital status

Marital status	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Single (unmarried/ divorced/widowed)	9 (25.7%)	10 (45.5%)	19 (33.3%)
Married	26 (74.3%)	12 (54.5%)	38 (66.7%)

Table 8 depicts the distribution of study participants according to the type of family. Our study consists of 17 (29.8%) participants belonging to the joint family and nearly 70% of the study participants belong to the nuclear family.

TABLE 8

Distribution of the study participants according to the type of family

Family type	Male N=35 (%)	Female N=22 (%)	Total N=57 (%)
Joint	11 (31.4%)	6 (27.3%)	17 (29.8%)
Nuclear	24 (68.6%)	16 (72.7%)	40 (70.2%)

In this present study, at the first visit, that is, before giving Lurasidone at baseline, there were 57 participants. There were a significant improvement in the positive scale from the first visit to the second visit i.e., there was improvement in positive scale after giving the Lurasidone. The mean score at the first visit was 26.519, the mean score at the end of 2nd visit was 17.000, and the mean at the end of 3rd visit was 10.900 (Table 9).

There is a significant improvement in the negative syndrome scale after administration of the Lurasidone. The mean negative syndrome scale score at the end of 1st visit was 23.250, whereas after treatment with Lurasidone for one month, i.e. At the second visit it was 16.635 and at the 3rd visit it was 12.900 (Table 10).

At baseline, the positive scale was higher compared to the negative scale in the study participants. After administration of lurasidone, both scales had similar improvement, i.e., Lurasidone had equal effect on both the positive as well as negative scale. Mean positive scale score at the end of 1st visit was 26.509 and mean negative syndrome scale score at the end of 1st visit was 23.351, whereas mean positive scale score on 2nd visit was 17.000 and mean negative syndrome scale score on 2nd visit 16.635 and Mean positive scale score at the end of 3rd visit was 10.900, mean negative syndrome scale score at the end of 3rd visit was 12.900 (Table 11).

The mean scores of both positive and negative symptom scales have decreased over 3 visits as shown in Figure 1. It shows that there is an improvement in both positive and negative symptom scales with the administration of Lurasidone.

Composite scores were calculated by subtracting the negative symptom score from the positive symptom score. It ranges from -42 to +42. It shows the predominance of one syndrome in relation to the other.

The predominantly positive score gradually decreased over the 3 visits, whereas the predominantly negative scores gradually increased over the 3 visits as shown in Figure 2.

TABLE 9

Association between positive scales at different visits

Sl no	Positive scale at different visits	Mean	N	Std. Deviation	Std. Error mean	T value *	Df	P value
1	1st visit	26.519	52	0.9391	0.1302	43.503	51	0.0001
	2nd visit	17.000	52	1.0479	0.1453			
2	1st visit	26.560	50	0.9293	0.1314	74.858	49	0.0001
	3rd visit	10.900	50	1.1473	0.1623			
3	2nd visit	16.900	50	0.9313	0.1317	35.496	49	0.0001
	3rd visit	10.900	50	1.1473	0.1623			

Note: *paired `t' test was used to test the association between different quantitative variables. At 95% CI, a probability value (P value) of ≤ 0.05 was considered as statistically significant.

TABLE 10

Association between negative scales at different visits

Sl. No	Negative scale at different visits	Mean	N	Std. Deviation	Std. Error mean	T Value	Df	P Value
3rd visit	1st Visit	23.250	52	2.4565	0.3407	19.095	51	0.0001
3rd visit	2nd Visit	16.635	52	1.0484	0.1454			
3rd visit	1st Visit	23.220	50	2.4932	0.3526	28.787	49	0.0001
3rd visit	3rd Visit	12.900	50	0.8144	0.1152			
3rd visit	2nd Visit	16.560	50	0.9930	0.1404	20.888	49	0.0001
3rd visit	3rd Visit	12.900	50	0.8144	0.1152			

TABLE 11

Association between positive and negative scales at different visits

Sl. No	Scales at different visits	Mean	N	Std. Deviation	Std. Error mean	T Value	Df	P Value
1	Positive scale on 1st visit	26.509	57	0.9087	0.1204	9.039	56	0.000
	Negative scale on 1st visit	23.351	57	2.3867	0.3161			
2	Positive scale on 2nd visit	17.000	52	1.0479	0.1453	1.827	51	0.074
	Negative scale on 2nd visit	16.635	52	1.0484	0.1454			
3	Positive scale on 3rd visit	10.900	50	1.1473	0.1623	-9.707	49	0.000
	Negative scale on 3rd visit	12.900	50	0.8144	0.1152			

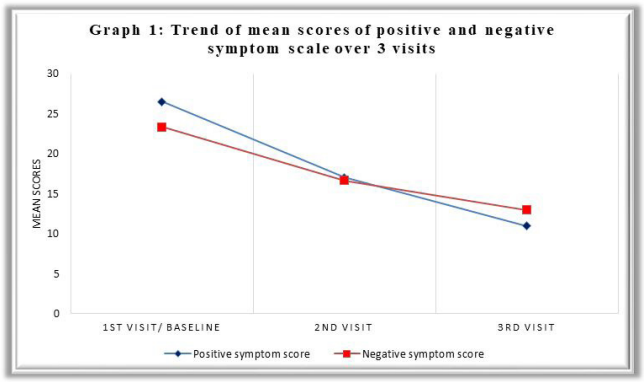

Figure 1) *Trend of mean scores of positive and negative symptom scale over 3 visits*

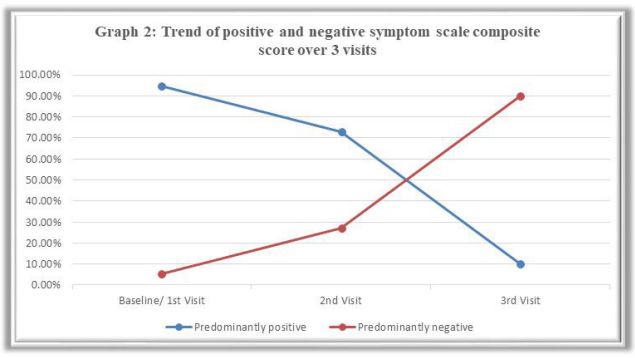

Figure 2) *Trend of positive and negative symptom scale composite score over 3 visits*

DISCUSSION

This study attempted to evaluate the overall efficacy of Lurasidone across a spectrum of symptoms of schizophrenia. It also tried to evaluate which symptom domain-positive or negative-Lurasidone had a higher impact in terms of resolution.

Discussion of methodology

Study design: This is a hospital based, prospective longitudinal observational study. Most of the other studies, which have evaluated the efficacy of Lurasidone have used a randomized, placebo controlled methods. This could not be done at our center since we wished to view the data in a naturalistic manner and a limitation of trained personnel. Observer bias is usually encountered in such studies, this was partly controlled for at two levels. At the primary investigator level, by being aware of it, and an additional evaluation by a consultant was done. Patients attending the OPD services, diagnosed with schizophrenia based on the ICD-10 criteria, who were drug naive, were serially inducted into the study. Patients were diagnosed by a consultant, who was then referred to the primary investigator for assessment. Patients having other comorbid psychiatric disorders were excluded. Patients were assessed for PANSS at 3 points in time-baseline, at the end of 1 month, and at the end of 3 months. Lurasidone showed its maximum effect at the end of 3 weeks in trials conducted by Meyer et al. [10] therefore patients were reassessed at the end of 1 month/4 weeks and another evaluation at the end of 3 months was done to see if the effects attained were sustained, and if there was any change in tolerability. Similar exercise was done in studies conducted by Loebel [11]. In the initial studies conducted by Meyer and Cucchiaro, et al. effects were studied for much shorter duration ranging from 1 week to 3 weeks [10]. Patients were started on Lurasidone at 40 mg and titrated up to 60 mg to 120 mg depending on response and tolerability. Lurasidone is an atypical antipsychotic which has been approved for the treatment of schizophrenia at doses of 40 to 80 mg. Higher doses were not found efficacious according to citrome [12]. However, few patients showed partial response at 80 mg and were able to tolerate the doses, in which the dose was increased to 120 mg. It is possible to assume that these patients had a variable rate of metabolism of the drug and therefore required a higher dose. A similar effect is seen in the study of other antipsychotics like Risperidone by Feng et al. [13] patients were ensured that they were not on any medication which may have induced its metabolism. Lurasidone is highly protein bound, and increased absorption is seen with a specified caloric intake, similar but known to be less than that required for Ziprasidone. Since this observation was carried out on OPD basis, patients' nutrition and other factors affecting the pharmacokinetics could not be accounted for this, it has been regarded as a limitation for the study and could explain the need for higher than recommended doses of Lurasidone. No specific studies have been done in separate ethnic group; most of the studies were done on Caucasian and Japanese populations. No specific studies are available on Indian population; as far as concerned, this is the first study in India, studying the efficacy of Lurasidone on this population. Further studies may throw light on issues related to psycho-pharmaco-genomics and variance in this population.

Fixed dose regimen was followed. Dosages used were comparable with other studies done by Nakamura et al. and Allena et al. [14]. However, in the studies mentioned, patient populations were already on some form of antipsychotic, and were changed to Lurasidone for study. It can also be inferred that the chronicity of illness in the studies mentioned could have affected the results in terms of response and severity of negative symptoms. This disparity was not seen in our study and our sample, despite being drug naïve, we had found similar response rates to other studies, for both positive and negative symptoms. Therefore, Lurasidone can be understood to be efficacious at both initial and chronic stages of schizophrenia. Response is defined as more than or equal to a 20% reduction in the PANSS scores. Similar response rate has been used for positive symptom domain and negative symptom domain. Our method of calculating response corresponds with other studies like Loebel, et al. which have evaluated Lurasidone and other antipsychotics for efficacy [11]. Along with PANSS, a complete physical examination and checklist for side effects of Lurasidone was done. A total of 57 patients were evaluated for this study.

Discussion of results

A semistructured proforma based on BG Prasad's socio-economic classification was used to record the socio-demographic data. Prasad's socioeconomic classification is widely used in Indian medical literature. It was proposed for the first time by Prasad on per capita income per month and then revised by him based on cost of living [2]. Our study population consisted mostly of subjects from rural backgrounds, educated up to secondary high school and was unemployed at the time of study. 66.7% of the participants were from rural areas, 43.86% were educated up to secondary school. As such, the population had lesser demanding jobs cognitively, and may have a higher load of negative symptoms, either primary or secondary, but could have been reported far less than the case. A distinction between primary and secondary negative symptoms cannot be made using the PANSS scale and this is one of the limitations of the study. The reduction in positive and negative scores corroborated with those of other studies, but there may have been a slightly higher response considering the unique socio-economic background of the population. This response could not be brought out by our study protocol.

The current study showed that Lurasidone has an effect on both positive and negative symptoms of schizophrenia at week 4 and better efficacy at week 12. The mean positive score at baseline was 26.519. The early improvement rate in study group was estimated based on the mean reduction of positive score on PANSS from baseline to 1 month. In positive scale of PANSS, mean reduction of positive score at the end of 4 week was 6.13 which were statistically significant. At the end of 3 months the mean positive score was 10.900, there was a mean reduction of 10 on positive score on PANSS which was statistically significant. The mean negative score at baseline was 23.250. The early improvement rate in group was estimated based on the mean reduction of negative score on PANSS from baseline to 1 month. In negative scale of PANSS, mean reduction of negative score at the end of 4 week was 6.615 which were statistically significant; at the end of 3 months the mean reduction on negative score was 10.35 which were statistically significant.

Our results were similar to previous studies done by Nakamura et al. and Loebel et al. who concluded that treatment with Lurasidone was associated with statistically significant and greater improvement than placebo on the primary efficacy measure [14,11]. PANSS total score showed a similar pattern of statistically significant early and sustained improvement with Lurasidone. Compared to other studies, our results indicate a significant reduction in positive domain scores at the end of 1st month and a significant reduction in negative domain at the end of 3rd month, while other studies have reported a statistically significant response at 6 weeks and 12 weeks, but our study did not have an intermediate assessment point between the end of 1st month and the end of 3rd month. Overall reduction in PANSS score was similar to other studies mentioned above, but a higher response to positive than negative symptoms was noted. However, a longer follow-up would help us study the influence of Lurasidone on the course of schizophrenia as well as the response to individual domains and symptoms.

CONCLUSION

This study attempted to evaluate the overall efficacy of Lurasidone across a spectrum of symptoms of schizophrenia. It also tried to evaluate which symptom domain, positive or negative Lurasidone had a higher impact in terms of resolution. The current study showed that Lurasidone affects both positive and negative symptoms of schizophrenia at week 4 and better efficacy at week 12. Overall reduction in PANSS score was similar to other studies done in the past, but a higher response to positive than negative symptoms was noted. However, a longer follow-up would help us study the influence of Lurasidone on the course of schizophrenia as well as the response to individual domains and symptoms.

FUNDING

No funding sources.

CONFLICT OF INTEREST

None declined.

ETHICAL APPROVAL

The study was approved by the ethical committee.

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