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Original Research Article

Clinical efficacy and safety of lurasidone in schizophrenia: 8 week randomized double blind active controlled trial

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ABSTRACT

Background: Schizophrenia comprises a group of disorders with heterogeneous etiologies, it includes patients whose clinical presentations, treatment response, and courses of illness vary. This study was carried to study the clinical efficacy and safety of Lurasidone versus Risperidone on psychopathology and cognition in patients with first episode of schizophrenia.
Methods: Patients diagnosed with first episode of schizophrenia were enrolled in the study. Patients were randomized to 80 mg/d (n = 27) of Lurasidone or 6mg/d (n = 27) of Risperidone. Efficacy assessments included Positive and Negative Syndrome Scale (PANSS) scores, Schizophrenia cognition rating scale (SCoRS). IL-6 estimation was done and safety assessment was done using UKU side effect rating scale.
Results: During the eight weeks of study; significant improvement was observed in PANSS total and all its subscale scores with both Lurasidone and Risperidone. Mean change in PANSS scores were not significant between the groups (-32.93 vs -35.33 $p>0.05$). Mean change in SCoRS scores were significantly higher in Lurasidone group as compared to risperidone group (-8.43 vs -2.34, $p<0.001$). Significant reduction in the IL-6 levels with both the groups but mean change in IL-6 levels were not significant between the group (-10.47 vs -8.31, $p>0.05$). UKU side effect rating scores were significantly higher with Risperidone as compared to Lurasidone ($p<0.001$).
Conclusions: Lurasidone is as effective as Risperidone in improving psychopathology in patient of schizophrenia. Lurasidone proved more efficacious in improving cognition as compared to Risperidone. Both the treatment modalities are efficacious in lowering IL-6 levels. Lurasidone causes less adverse effects as compared to Risperidone.

Keywords: IL-6, Lurasidone, Positive and negative syndrome scale, Risperidone, Schizophrenia, SCoRS

INTRODUCTION

Schizophrenia comprises a group of disorders with heterogeneous etiologies, and it includes patients whose clinical presentations, treatment response, and courses of illness vary. Signs and symptoms are variable and include changes in perception, emotion, cognition, thinking, and behaviour. The lifetime prevalence of schizophrenia is about 1 percent.[1] The most widely used standardized criteria for diagnosing schizophrenia come from the world health organization's international statistical classification of diseases and related health problems, the ICD-10. Major symptoms seen in schizophrenia are positive, negative, disorganization and cognitive impairment. Various etiological hypotheses have been proposed for schizophrenia. There has been a growing

body of literature that suggests the role of genetic susceptibility, gestational and perinatal complications, intrauterine viral infections, immune, the endocrine and the nervous systems. All interact with each other through cytokines, hormones and neurotransmitters. Neurotransmitters like dopamine, serotonin, norepinephrine, GABA, glutamate, neuropeptides are involved in the pathogenesis of schizophrenia. During recent decades, evidence for the involvement of the immune system has accumulated.[2]

The human immune system is functionally divided into 'innate' and 'adaptive' immune responses. Both innate and adaptive systems have cellular and humoral components. T helper-1 (TH-1) system activates the cellular arm and the T helper-2 (TH-2) system activates the humoral arm of the adaptive immune system. 'Type-1' activating cytokines such as Interleukin-2 (IL-2), Interferon-γ (IFN-γ) and Tumor necrosis factor-β (TNF-β) produced by TH-1 cells. TH-2 or certain monocytes/macrophages (M2) produce mainly IL-4, IL-10, and IL-6 and transforming growth factor (TGF)-β.[3] The Th-1/Th-2 imbalance with overactivation of Th-2 immune response is associated with schizophrenia.[4] Increased levels of interleukin-6 (IL-6) and the activation of the IL-6 system in schizophrenia might be the result of the activation of type-2 monocytes/macrophages. IL-6 levels are increased in the patients of schizophrenia.[5]

Risperidone is an atypical or second-generation antipsychotic drug mainly used to treat schizophrenia.[6] Lurasidone is a newer atypical second-generation antipsychotic drug. Lurasidone acts as an antagonist on α1, α2A, α2C, D1, D2, 5HT2A, 5HT2C, 5HT7 receptors and a partial agonist at 5HT1A receptor. It has the high affinity for the 5HT7 and 5HT1A receptors, moderate affinity for α2C adrenergic receptors, weak affinity for α1 adrenergic and serotoninergic 5HT2C receptors and no affinity for histaminergic H1 or muscarinic M1 receptors.[7] It is a well-tolerated drug, less propensity to induce weight gain, sedation, and lipid-related adverse effect. Lurasidone 80 mg/day is approved dose for the treatment of schizophrenia.[8-10]

In animal studies, Lurasidone has been found to reverse dizocilpine-induced learning and memory impairment and was found to be superior to other antipsychotics, including risperidone, olanzapine, quetiapine, haloperidol, etc. in this regard. It has activity at several serotonin receptors that are involved in learning and memory, and unlike other antipsychotics, lacks any anticholinergic effects which are known to impair cognitive process and memory.[11-13]

Present study was conducted to study clinical efficacy of Lurasidone versus Risperidone on psychopathology and cognition in patients with first episode of schizophrenia and to study change in serum IL-6 level in both the groups.

METHODS

This was an eight weeks randomized double blind active controlled parallel group study. The study was approved by the Institutional Ethics Committee of King George's Medical University, UP., Lucknow {Ref.code: 81st ECM II-B Thesis/P15} Old and new patients, with acute exacerbation of schizophrenia (first episode) diagnosed as per ICD-10 DCR criteria, total duration of illness less than two years, age between 18 to 50 years, PANSS scores in between 80-120 and not on any antipsychotic for last three months, attending the adult psychiatry OPD of King George's Medical University with the reliable informant were recruited in the study

Positive and Negative Syndrome Scale (PANSS) score <80 or >120; presence of any other major psychiatric disorder, except nicotine dependence; at risk for harm to self or others; established treatment resistance for schizophrenia; pregnant and lactating females; clinical situations requiring drugs which are CYP3A4/2D6 inhibitors or inducers; clinical situations requiring alternative drugs or interventions e.g. injectable antipsychotics, ECTs, change of therapy etc., or worsening of symptoms; having any major medical/surgical illness or any clinically significant abnormality in baseline investigations; on any other concomitant drugs that might alter serum interleukin levels were excluded from study.

Patients were allocated to either group A or B by computer aided block randomization. As the study was double blind, similar coloured capsules were filled with the drugs and coded as group A and group B by the chief supervisor. Codes were broken at the end of the study. Patients in group A were given Lurasidone and patients in group B were given Risperidone. Lurasidone was administered at a starting dose of 40 mg h.s. for 3 days and subsequently continued as 40 mg b.d. for 8 weeks. Risperidone was administered at a starting dose of 3 mg h.s. for 3 days and subsequently continued as 3 mg b.d. for 8 weeks. Compliance was ensured with help of caregiver and by physical verification of number of capsules acquired by investigator and consumed on each visit.

Rescue medications used in the study were Lorazepam (2-6 mg/day) for managing anxiety, agitation and insomnia; Zolpidem (5-10 mg/day) for managing insomnia; Trihexyphenidyl (2-10 mg/day) for managing extrapyramidal symptoms (EPS) Patients were monitored for clinical effectiveness and safety at 4 and 8 week of therapy. 4 ml of blood was collected at baseline and after 8 weeks of therapy each for serum IL-6 estimation.

Measures

Clinical efficacy in terms of psychopathology was assessed using Positive and Negative Symptom Scale

(PANSS).[14] The Schizophrenia Cognition Rating Scale (SCoRS) was used to assess cognition.[15]

To see the effect of both the drugs on serum IL-6 levels estimation of IL-6 was done by sandwich ELISA. Safety assessment was done by Udvalgfor Kliniske Undersogelser (UKU) Side Effect Rating Scale and measurement of weight to see for gain in weight. Body weight was taken at baseline and after 8 weeks of therapy.

Data analysis

Categorical variables are presented in number and percentage (%) and continuous variables are presented as mean±SD. Quantitative variables have been compared using unpaired t-test/Mann-Whitney Test between two groups. Paired t-test and Wilcoxon matched pair (Z) test within the group. Qualitative variables were compared using Chi-Square test/Fisher's exact test as appropriate. A p-value of <0.05 was considered statistically significant.

RESULTS

Participants were screened and enrolled in the study as depicted in Table 1. Finally, fifty-four patients, twenty-seven in each group completed the study and all the statistical analyses were performed on these fifty-four patients.

Table 1: Patients enrolled in the study.

Sr. no	Total no of patient screened	93
1.	Patient not fulfilling selection criteria	30
2.	Patient not fulfilling inclusion criteria	24
	Not fulfilled diagnostic criteria of schizophrenia	5
	Age >50 years	1
	Received antipsychotic treatment in past 3 month	13
	Duration more than 2 year	3
	Unreliable informant	2
3.	Patient excluded on exclusion criteria	6
	Cannabis dependence	3
	PANSS score > 120	1
	Presence of any other major psychiatric disorder (Obsessive-compulsive disorder)	2
4.	Dropout patient	9
	Required hospitalization and injectable antipsychotic	1
	Severe side effect	1
	Lost to follow up	7
5.	Total number of patients included	54
	Group A	27
	Group B	27

Table 2: Frequency distribution of socio-demographic characteristics of two groups.

		Lurasidone (80 mg) (N=27)	Risperidone (6 mg) (N=27)	χ^2 / Fisher value	p-value
Age group (years)	18-35	18(66.7%)	19(70.4%)	0.086	0.770
	36-50	9(33.3%)	8(29.6%)		
	Mean±SD	31.11±8.57	31.04±8.86		
Gender	Male	20(74.1%)	15(55.6%)	2.030	0.154
	Female	7(25.9%)	12(44.4%)		
Marital status	Married	17(63%)	16(59.3%)	0.078	0.780
	Unmarried	10(37%)	11(40.7%)		
Religion	Hindu	23(85.2%)	24(88.9%)	-	1.000
	Muslim	4(14.8%)	3(11.1%)		
Education	Illiterate	8(29.6%)	7(25.9%)	2.603	0.626
	Primary School	9(33.3%)	13(48.1%)		
	High School	4(14.8%)	2(7.4%)		
	Intermediate	3(11.1%)	1(3.7%)		
	Graduate	3(11.1%)	4(14.8%)		
Family type	Nuclear	18(66.7%)	11(40.7%)	3.650	0.052
	Joint	9(33.3%)	16(59.3%)		
Occupation	Farmer	3(11.1%)	0(0)	4.377	0.350
	Labour	7(25.9%)	7(25.9%)		
	Housewife	4(14.8%)	8(29.6%)		
	Unemployed	12(44.4%)	11(40.7%)		
	Service	1(3.7%)	1(3.7%)		

Chi-square (χ^2) test and fisher value test

Sample characteristics

After selection and allocation to either group, details of the patients regarding identification data, demographic profile and clinical variables were recorded on the semi-structured proforma. Both the groups were comparable on all these variables and no significant difference was found as depicted in Table 2.

Psychopathology

Psychopathology was assessed by using the Positive and Negative Syndrome Scale (PANSS). The subscale and total PANSS of both the groups over the periods are summarized in Table 3. In Lurasidone group within the group comparison shows significant decline in positive symptom, negative symptom, general psychopathology and total PANSS scores as compared to baseline after 4 weeks of therapy and after 8 weeks of therapy {p<0.001 Wilcoxon matched pair (Z) test, for all the subscales and total PANSS scores}. In Risperidone group within the group comparison significant decline in positive symptom, negative symptom, general psychopathology and total PANSS scores as compared to baseline after 4 weeks of therapy and after 8 weeks of therapy {p<0.001, Wilcoxon matched pair (Z) test, for all the subscales and total PANSS scores). When decline in mean score at 4 weeks and 8 weeks(Lurasidone Vs Risperidone) was compared statistically, there was no significant difference between the groups (p>0.05, by Mann-Whitney U test for all the subscales and total PANSS scores).

Table 3: Pre and post-treatment (mean±SD) of different scores of both the groups.

Scales (N 27)	0 weeks	4 weeks	p-value (0-4 weeks)	Mean change from0-4 weeks	8 weeks	p-value (0-8 weeks)	Mean change from0-8 weeks
Positive symptom scale score							
Lurasidone(80mg)	23.81±2.96	18.15±1.54	<0.001*	-5.67±3.56	13.56±1.76	<0.001*	-10.26±3.74
Risperidone(6mg)	23.96±3.26	18.19±1.18	<0.001*	-5.78±2.90	12.85±1.79	<0.001*	-11.11±3.77
p-value(between the groups)	0.862	-	-	0.683	-	-	0.419
Negative symptom scale score							
Lurasidone(80 mg)	24.56±2.61	19.30±2.05	<0.001*	-5.26±2.99	15.63±1.42	<0.001*	-8.93±2.88
Risperidone(6 mg)	24.37±3.52	19.37±3.13	<0.001*	-5.00±3.14	15.70±2.51	<0.001*	-8.67±3.95
p-value(between the groups)	0.827	-	-	0.619	-	-	0.481
General psychopathology symptom scores							
Lurasidone(80 mg)	44.56±3.78	37.15±3.07	<0.001*	-7.41±4.69	30.59±2.24	<0.001*	-13.96±4.42
Risperidone(6 mg)	44.07±3.35	37.67±7.10	<0.001*	-6.41±8.14	29.33±1.66	<0.001*	-14.74±3.69
p-value(between the groups)	0.622	-	-	0.828	-	-	0.366
Total PANSS scores							
Lurasidone(80 mg)	92.85±6.401	74.67±5.54	<0.001*	-18.19±8.84	59.93±3.86	<0.001*	-32.93±8.23
Risperidone(6 mg)	92.30±4.598	73.11±6.09	<0.001*	-19.19±6.41	56.96±3.31	<0.001*	-35.33±4.72
p-value(between the groups)	0.716	-	-	0.425	-	-	0.117
SCoRS scores							
Lurasidone(80 mg)	40.86±9.24	37.24±7.18	<0.001*	-3.63±3.15	32.43±6.97	<0.001*	-8.43±3.80
Risperidone(6 mg)	39.57±9.26	38.60±8.95	0.018*	-0.97±2.51	37.23±9.41	0.010*	-2.34±4.13
p-value(between the groups)	0.672	-	-	0.001*	-	-	<0.001*

Cognition

Cognition was assessed by using schizophrenia cognition rating scale (SCoRS). SCoRS scores of both the group were summarised in Table 3. In Lurasidone group within the group comparison shows significant decline in SCoRS as compared to baseline after 4 weeks and 8weeks of therapy {p<0.001, Wilcoxon matched pair (Z) test}. In Risperidone group within the group comparison, significant decline in SCoRS as compared to baseline after 4 weeks of therapy {p=.018, Wilcoxon matched pair (Z) test} and also declined significantly after 8 weeks of therapy {p=.010, Wilcoxon matched pair (Z) test} when compared to baseline. When decline in mean score at 4

weeks and 8 weeks (Lurasidone Vs Risperidone) was compared statistically, there was a significant decline in Lurasidone group as compared to Risperidone group (p=0.001, Mann-Whitney U test).

Immunological outcomes

Owing to resource constraint, IL-6 level was assessed in 20 patients of each group and not the entire sample. Of this post intervention sample of one patient from group B was hemolysed so discarded. Hence, IL-6 level was measured in 20 patients of group A and in 19 patients of group B

The serum IL-6 levels of two groups over the periods are summarized in Table 4. There was significant decrease in serum IL-6 levels in Lurasidone group as compared to baseline after 8 weeks of therapy (p=0.002, paired t test).

Also there was significant decrease in serum IL-6 levels in Risperidone group as compared to baseline after 8 weeks of therapy (p=0.038, paired t test). When decline in mean score was compared statistically between the groups, there was no significant difference between the groups (p>0.05, unpaired t test).

Table 4: Pre and post-treatment (mean±SD) of IL-6 levels of patients of both the groups.

Scales	0 weeks	8 weeks	p-value (0-8 weeks)	Mean change from0-8 weeks
IL-6 levels (pg/nl)				
Lurasidone(80 mg) (N 20)	138.17±15.56	127.7±21.67	0.002*	-10.47±12.79
Risperidone(6 mg)(N 19)	133.46±19.47	125.16±19.43	0.038*	-8.31±16.19
p value(between the groups)	0.408	0.702	-	0.646

Table 5: Comparison of different subscales of UKU side effect rating scale scores between the groups at 4 weeks and 8 weeks.

Groups (N 27)	Periods		p-value (4-8 weeks)
	4 weeks	8 weeks	
Psychic side effect scores			
Lurasidone(80mg)	4.07±1.27	6.04±1.91	<0.001*
Risperidone(6mg)	8.30±2.16	12.41±2.19	<0.001*
p-value(between the groups)	<0.001*	<0.001*	-
Neurological side effect scores			
Lurasidone(80mg)	1.04±0.81	1.30±1.20	0.020
Risperidone(6mg)	2.81±1.11	4.00±.96	<0.001*
p-value(between the groups)	<0.001*	<0.001*	-
Autonomic side effect scores			
Lurasidone(80mg)	0.56±69	0.59±.75	0.564
Risperidone(6mg)	2.48±1.53	3.48±1.67	<0.001*
p-value(between the groups)	<0.001*	<0.001*	-
Others side effect scores			
Lurasidone(80mg)	2.33±.92	2.74±.81	0.004
Risperidone(6mg)	3.44±.85	4.33±.92	<0.001*
p-value(between the groups)	<0.001*	<0.001*	-

Table 6: Pre and post-treatment (mean±SD) weight of patients of both the groups.

Scales (N 27)	0 weeks	8 weeks	p-value (0-8 weeks)	Mean change from0-8 weeks
Weight (kg)				
Lurasidone(80 mg)	57.30±9.03	57.07±8.92	0.043*	-0.22±.0.54
Risperidone(6 mg)	55.26±8.68	56.63±8.79	<0.001*	+1.37±0.73
p value(between the groups)	0.402	0.854	-	<0.001*

Safety assessment

The scores for occurrence of psychic, neurological, autonomic and other side effects as per UKU side effect rating scale are summarized in Table 5. Psychic, neurological, autonomic and other side effects as per UKU side effect rating scale scores were present in both the groups after 4 weeks of therapy; significantly more in Risperidone(6mg) as compared to Lurasidone(80mg) ($p<0.001$, Mann-Whitney U test). Within the group comparison after 8 week of both treatments, there was significantly increase in side effects [Wilcoxon matched pair (Z) test], When compared statistically between the groups, psychic, neurological, autonomic and other side effects were significantly higher in Risperidone group as compared to Lurasidone group ($p<0.001$, Mann-Whitney U test) after 8 weeks of therapy.

The weight of the patients in both the groups is summarized in Table 6. There was a statistical difference ($p<0.001$, unpaired t test), when the difference in mean scores was compared between the group, In Risperidone group, there was significant increase in weight from baseline after 8 weeks of therapy ($p<0.001$, paired t test). In Lurasidone group, there was a significant loss in weight as compared to baseline after 8 weeks of therapy ($p=0.043$, paired t test).

DISCUSSION

In this study, a total of ninety-three patients were screened, out of which, thirty patients did not fulfill selection criteria. Thus, remaining sixty-three patients were allotted to either A (Lurasidone, at a starting dose of 40 mg h.s. for 3 days and subsequently continued as 40 mg b.d. for 8 weeks) or B (Risperidone, at a starting dose of 3 mg h.s. for 3 days and subsequently continued as 3 mg b.d. for 8 weeks) by computer aided block randomization.[16] Block randomization is a commonly used technique in clinical trial design to reduce bias and achieve balance in the allocation of participants to treatment arms, especially when the sample size is small. In this way, group A included thirty-two and group B included thirty-one patients. Five patients from group A and four from group B dropped out from the study.

Psychopathology

In this study, both the groups showed statistically significant improvement in psychopathology i.e., reduction of PANSS scores over the 8 weeks treatment. Reduction in PANSS score has been observed in total scores as well as in all the three subscales i.e., positive, negative and general psychopathology scores.

As evident, it implies that both the treatment arms (Lurasidone and risperidone) are effective and comparable in improving symptomatology. In one study, short term placebo controlled trial of clinical efficacy of Lurasidone, showed that mean difference in positive symptom was -8.4 at 6 weeks (in our study -10.26 at 8 wks), mean difference in Negative symptom was -5.2 at 6 weeks (in our study -8.93 at 8 wks) and mean difference in Total PANSS was -22.6 at 6 weeks (in our study-32.93 at 8 weeks).[17]

Lurasidone was as effective as risperidone in improving clinical condition as measured by PANSS. Same findings were mentioned in one study conducted by Citrome et al, in the year 2012.[18] One meta-analysis was conducted on randomized, controlled trials of 15 antipsychotic agents used for the treatment of schizophrenia showed that there were relatively small differences in terms of clinical efficacy, but there were substantial differences in side effects.[19] The results of the present study are similar with this meta-analysis.

Cognition

Diminished cognitive abilities is one of the most debilitating features of schizophrenia. The cognitive defects are also highly correlated with the measures of functional outcome.[20,21] In our study, we used the Schizophrenia Cognition Rating Scale.[22] At the baseline, Mean±SD SCoRS scores were compared statistically there was no significant difference ($p>0.05$), both the groups were comparable. Over the course of treatment, at 4 and 8 weeks, fall was more with Lurasidone than risperidone. In both the groups, the scores declined significantly after 4 and 8 weeks therapy ($p<0.05$) as compared to baseline. When a decline in mean score from 0-4 weeks was compared there was a significant difference between the groups ($p=0.001$, Mann-Whitney U test). Also, when decline in mean score from 0-8 weeks was compared there was a significant difference between the groups ($p<0.001$, Mann-Whitney U test). In one study, there was an improvement in visual learning, working memory, reasoning/problem solving, and social cognition in subjects who received 80 mg of Lurasidone.[23] Similarly in our study, in patients who received Lurasidone; there was a significant improvement in Schizophrenia cognition rating scale after 8 weeks of therapy.

Immunological factor

Owing to resource constraint, IL-6 level was assessed in 20 patients of each group and not the entire sample. Of this post intervention sample of one patient from group B was hemolyzed so discarded. Hence, IL-6 level was measured in 20 patients of group A and in 19 patients of group B. At baseline, the Mean±SD Serum IL-6 levels were When compared statistically there was no significant difference ($p>0.05$, unpaired t-test), both the groups were comparable. Over the course of treatment, at 8 weeks the Mean ± SD were compared statistically there was no significant difference between the groups at 8 weeks ($p>0.05$, unpaired t-test,). In both the groups, serum IL-6 levels decreased significantly after 8 weeks of therapy as compared to baseline ($p<0.05$, paired t-test).

When a decline in mean score was compared statistically, there was no significant difference between the groups (p>0.05, unpaired t test). Both the drugs have a comparable effect on neuro-immune marker. Many studies, which report elevated interleukin-6 (IL-6) levels in patients of schizophrenia. One study in schizophrenic and manic panic patients concluded that plasma IL-6 and IL-1 was significantly higher in elderly schizophrenic patients.[24] Similarly other study concluded that IL6s levels significantly increased in patients with acute exacerbation of schizophrenia.[25] Other study in schizophrenic and depressive patients also concluded an increase of IL-6 levels during the acute state of illness may be due to stress response.[26] Similarly, in other study in schizophrenic patient, it was showed that IL-6 was elevated and also reduced after taking treatment.[27] The present study also shows the significant decline in serum IL-6 levels after 8 weeks of therapy with Lurasidone. On contrary one study showed there was no significant decline in elevated IL-6 level in patient with schizophrenia after antipsychotic treatment.[28]

Safety assessment

The side effects of the psychotropic medication used, was measured using the UKU side effects scale. UKU side effect rating scale includes psychic side effects (e.g., concentration difficulties, fatigability, depression, increased duration of sleep), neurological side effects (e.g., dystonia, rigidity, hypokinesia, akathisia), autonomic side effects (e.g., increased salivation, nausea, diarrhoea, orthostatic dizziness) and other side effects (e.g., headache, rash, sexual side effects). Various side effect scores present in both the groups after 4 weeks and 8 weeks of therapy, were significantly higher with Risperidone as compared to Lurasidone (p<0.001, Mann-Whitney U test). Lurasidone appears to be better molecule than Risperidone as far as side effect profile is concerned.

Weight gain is the troublesome adverse effect of some of the atypical antipsychotics. In Lurasidone group, when statistically compared there was a significant loss in weight as compared to baseline after 8 weeks of therapy (p=0.043, paired t-test). In Risperidone group when statistically compared there was a significant increase in weight from baseline after 8 weeks of therapy (p<0.001, paired t-test). When the difference in mean scores was compared, there was statistical difference between the groups (p<0.001, unpaired t-test). Similar finding found in one study, in which mean change in weight by Lurasidone from baseline was - 0.97±5.06 kg as compared to risperidone was +1.47±5.03 kg.[18]

Some of the limitations present in the study were sample size and duration of the study was not large enough to make it a generalized for the overall population. Serum IL-6 is a sensitive marker of schizophrenia but it lacks specificity as it is increased in other psychiatric conditions like depression and autoimmune diseases like rheumatoid arthritis. The study was unicentric and was done in tertiary care centre located at urban area. So representation of subjects was not uniform.

CONCLUSION

The decrease in PANSS scores in both the groups was comparable and homogenous across times, implying that both the treatment modalities are efficacious in improving schizophrenia symptomatology. Evaluation on SCoRS, Lurasidone proved significantly more effective in improving cognition as compared to group Risperidone. The serum IL-6 showed normalization with both the groups. Evaluation on UKU side effect rating scale scores revealed that Lurasidone was comparatively better than Risperidone as far as adverse effect profile is concerned. Also, weight gain was seen less with Lurasidone.

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