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ORIGINAL ARTICLE

A STUDY OF EFFICACY OF LURASIDONE IN PATIENTS SUFFERING FROM SCHIZOPHRENIA AND RELATED DISORDERS

V. P. Mahla[1], Abhishek Kapoor [2], Avisha Mahla [3], Rahul Rai[4]

[1]Professor and HOD, [2]Assistant Professor, [4]Senior Resident, Department of Psychiatry, SGT Medical College and Hospital, Gurugram -122505, NCR, Delhi, [3]Junior Resident, Psychiatry, Medical College, Baroda (Gujarat)

ABSTRACT:

Background: Persistent symptoms, or experience side effects are associated with many outpatients with schizophrenia or schizoaffective disorder, associated with their current maintenance antipsychotic. Treatment strategies include dose adjustments, addition of adjunctive medications, or allowing the passage of time in the hopes of achieving further symptom reduction and the diminution of adverse effects. Hence; we planned the present study to assess the efficacy of Lurasidone in Patients Suffering from Schizophrenia and Related Disorders. **Materials & methods:** 30 adult patients diagnosed as suffering from schizophrenia and related disorders (Psychosis NOS) according to DSM 5 were administered Tablet Lurasidone - a new atypical anti-psychotic medicine. The patients were evaluated at day 0, 20, 50 and 80 days of the Study in an open clinical trial. The efficacy and side effects of drugs were assessed with the help of Brief Psychiatric Rating Scale, The Schizophrenia Cognition Rating Scale, Clinical Global Impression Scale, Dosage and Treatment Emergent Scale and Abnormal Involuntary Movement Scale. Laboratory investigations were also done in each patient before and after the study. The dosage ranged from 40 mg – 80 mg daily, the majority being on 80mg/day. All the results were compiled and analyzed by SPSS software. **Results:** There was statistically significant clinical improvement measured on Severity of Illness sub-scale, at day 20, 50 and 80 in comparison with that at day 0. The same was true for Brief Psychiatric Rating Scale and its three sub-scales- The Depression Sub-Scale, Thinking Disorder Sub-scale and Anergia Sub-Scale. 2 patients didn't complete the study. There was significant improvement on Schizophrenia Cognition Rating Scale on day 20, 50 and 80 in comparison to day 0. Akathesia was the main side effect requiring reduction of dosage or switch to another anti- psychotic. None of the patients showed any abnormal involuntary movements. **Conclusion:** Lurasidone is an effective and useful drug for the treatment of schizophrenia and related disorders.

Key words: Lurasidone, Psychotic, Schizophrenia

Corresponding author: Dr Ved Mahla, 163, Sector 14, Rohtak 124001 (Haryana)

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INTRODUCTION

A significant population of outpatients with schizophrenia or schizoaffective disorder continue to suffer from persistent symptoms, or experience side effects associated with their current maintenance antipsychotic. Treatment protocols for the same includes dose adjustments, addition of adjunctive medications, or allowing the passage of time in the hopes of achieving further symptom reduction and the diminution of adverse effects.[1] Whether or not to change antipsychotic medications is one of the important treatment consideration. The substitution of one antipsychotic agent by another is informally known as "switching."[2] Based on the above, it is not surprising that switching between antipsychotic medications commonly occurs in the routine treatment of schizophrenia, in an effort to find the optimal regimen for an individual patient. Switching can be motivated by the desire to improve efficacy, tolerability, or both.[3, 4] A number of switch techniques have been employed in evaluating optimal approaches to the initiation of the new antipsychotic and/or the discontinuation of the pre-switch agent.[5] Despite the appeal of switching antipsychotics, there are also potential concerns of complications from attempting a switch, such as symptom exacerbation, insufficient efficacy, and new tolerability problems emerging from the "post-switch" medication.[6]

Lurasidone is a second-generation antipsychotic medication that has received regulatory approval for the treatment of adults with schizophrenia.[7] Hence; we planned the present study to assess the efficacy of Lurasidone in Patients Suffering From Schizophrenia and Related Disorders.

MATERIALS & METHODS

The present study was conducted in the Rohtak Psychiatry Centre during the period between September 2016 and November 2016 and included assessment of 30 adult patients diagnosed as suffering from schizophrenia

and related disorders (Psychosis NOS). Ethical approval was taken from the institutional ethical committee and written consent was obtained after explaining in detail the entire research protocol. A total of 30 subjects were included in the present study according to DSM 5 and were administered Tablet Lurasidone - a new atypical anti-psychotic medicine. All the patients remained OPD patients at Rohtak Psychiatry Centre for the duration of study. The patients were evaluated at day 0, 20, 50 and 80 days of the Study in an open clinical trial. The efficacy and side effects of drugs were assessed with the help of Brief Psychiatric Rating Scale (BPRS), The Schizophrenia Cognition Rating Scale (SCoRS) ,Clinical Global Impression Scale (CGI) , Dosage and Treatment Emergent Scale (DOTES) and Abnormal Involuntary Movement Scale (AIMS). Laboratory investigations were also done in each patient before and after the study. The dosage ranged from 40mg-80mg daily, the majority being on 80mg/day. All the results were analyzed by SPSS software. Chi-square test and student t test were used for the assessment of level of significance. P-value of less than 0.05 was taken as normal.

RESULTS

There was statistically significant clinical improvement measured on Severity of Illness sub-scale, at day 20, 50 and 80 in comparison with that at day 0 (P<.01) . The same was true for BPRS and it's three sub-scale- The Depression Sub-Scale, Thinking Disorder Sub-scale and Anergia Sub-Scale. 2 patients didn't complete the study. There was significant improvement on SCoRS on day 20, 50 and 80 in comparison to day 0. Akathesia (8 out of 30) was the main side effect requiring reduction of dosage or switch to another anti- psychotic. None of the patients showed any abnormal involuntary movements.

Table 1: Associated adverse events

Adverse effect		Number of patients
Nervous system disorder	Akathisia	8
	Dizziness	3
	Headache	2
	Sedation	2
	Tremor	1
Psychiatric disorders	Insomnia	2
	Anxiety	3
	Schizoaffective disorder	2
	Agitation	1
	Depression	4
	Hallucination	2

Graph 1: Adverse events observed in the present study

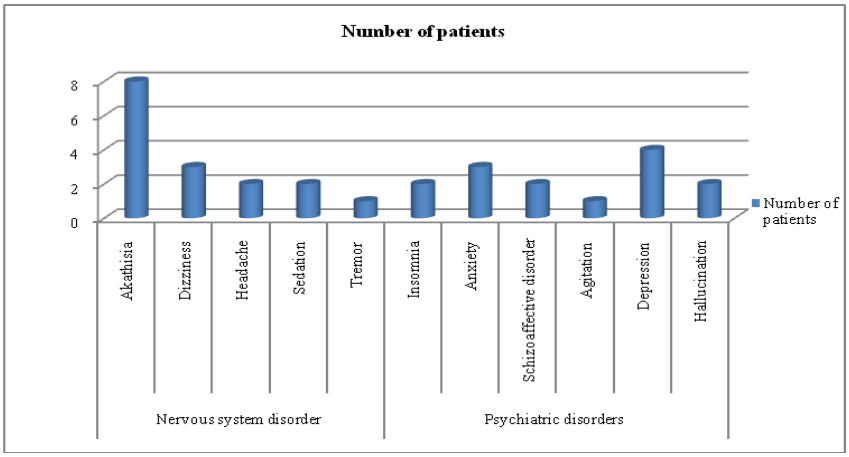

Table 2: Efficacies of drugs assessed with Brief Psychiatric Rating Scale (BPRS)

Parameter	Baseline time	20 days	50 days	80 days	P-value
Mean BPRS score	55.2	49.1	37.1	25.1	0.02*

*: Significant

Table 3: Efficacies of drugs assessed with Clinical Global Impression Scale (CGI) and Schizophrenia Cognition Rating Scale (SCoRS)

Parameter	Baseline time	20 days	50 days	80 days	P-value
Mean CGI score	7	6	4	2	0.01*
Mean SCoRS score	9	7	5	2	0.03*

*: Significant

DISCUSSION

Lurasidone is a second-generation antipsychotic agent that initially received regulatory approval for the treatment of adults with schizophrenia in the United States in 2010.[8] Lurasidone received marketing authorization for this indication by the European Medicines Agency in March 2014, and it has also been approved in Switzerland, Canada, the United Kingdom, and Australia. Additionally, lurasidone recently received US and Canadian regulatory approval for the treatment of adults with major depressive episodes associated with bipolar I disorder (bipolar depression), as either a monotherapy or as adjunctive therapy with lithium or valproate.[9] Detailed systematic reviews of the overall efficacy, tolerability, safety, and place in therapy of lurasidone can be found elsewhere, including analyses of the number needed to treat (NNT) and number needed to harm (NNH).[10, 11] Hence; we planned the present study to assess the efficacy of Lurasidone in Patients Suffering From Schizophrenia and Related Disorders.

In the present study, we observed statistically significant clinical improvement measured on Severity of Illness sub-scale, at day 20, 50 and 80 in comparison with that at day 0 (P<.01) . The same was true for BPRS and its three sub-scales- The Depression Sub-Scale, Thinking Disorder Sub-scale and Anergia Sub-Scale. Citrome L et al evaluated the long-term safety and tolerability of lurasidone in schizophrenia and schizoaffective disorder patients switched to lurasidone. Patients in this multicenter, 6-month open-label, flexible-dose, extension study had completed a core 6-week randomized trial in which clinically stable, but symptomatic, outpatients with schizophrenia or schizoaffective disorder were switched to lurasidone. The primary safety endpoints were the proportion of patients with treatment emergent adverse events (AEs), serious AEs, or who discontinued due to AEs. Secondary endpoints included metabolic variables and measures of extrapyramidal symptoms and akathisia, as well as the Positive and Negative Syndrome Scale (PANSS), Clinical Global Impressions-Severity (CGI-S), and the Calgary Depression Scale for Schizophrenia (CDSS). Lurasidone 40, 80, and 120 mg were the modal daily doses for 19, and 64 of patients, respectively. Overall mean (SD) daily lurasidone dose was 102.0 mg. The mean PANSS total score, mean CGI-S score, and mean CDSS score decreased consistently from core study baseline across extension visits, indicating an improvement in overall condition. In this 6-month, open-label extension study, treatment with lurasidone was generally well-tolerated with sustained improvement in efficacy measures observed in outpatients with schizophrenia or schizoaffective disorder who had switched to lurasidone from a broad range of antipsychotic agents.[12]

McEvoy JP et al examined the effectiveness of switching patients to lurasidone using 3 different dosing strategies. Adults with DSM-IV-defined schizophrenia or schizoaffective disorder in a nonacute phase of illness were randomized to 1 of 3 lurasidone dosing regimens for the initial 2 weeks of the study: (1) 40 mg/d for 2 weeks; (2) 40 mg/d for 1 week, increased to 80 mg/d on day 8 for week 2 (up-titration group); and (3) 80 mg/d for 2 weeks. Lurasidone was then flexibly dosed (40-120 mg/d) for the subsequent 4 weeks of the study. The preswitch antipsychotic agent was tapered by day 7 to 50% of the original dose and discontinued by the end of week 2. Subjects were stratified on the basis of whether the primary preswitch antipsychotic medication was classified as "sedating" (olanzapine or quetiapine) or "nonsedating" (all other antipsychotics). The primary outcome measure was time to treatment failure, defined as any occurrence of insufficient clinical response, exacerbation of underlying disease, or discontinuation due to an adverse event. The study was conducted from June 2010 to May 2011. No clinically relevant differences were observed when the 3 randomized switch groups were compared. Switching patients to lurasidone can be successfully accomplished by starting at 40 mg/d for 2 weeks, or 80 mg/d for 2 weeks, or 40 mg/d for 1 week followed by 80 mg/d the second week.[13] Addington DE et al compared ziprasidone and risperidone in patients with acute exacerbation of schizophrenia or schizoaffective disorder. Patients with DSM-III-R acute exacerbation of schizophrenia or schizoaffective disorder were randomly assigned to double-blind ziprasidone 40 to 80 mg b.i.d. (N = 149) or risperidone 3 to 5 mg b.i.d (N = 147) for 8 weeks. Primary efficacy measures included Positive and Negative Syndrome Scale (PANSS) total score and Clinical Global Impressions-Severity of Illness scale (CGI-S) score; secondary measures included scores on the PANSS negative sub-scale, CGI-Improvement scale (CGI-I), and PANSS-derived Brief Psychiatric Rating Scale (BPRSd) total and core items. Risperidone exhibited a significantly higher Movement Disorder Burden (MDB) score ($p < .05$) and higher incidences of prolactin elevation and clinically relevant weight gain. However, compared with current recommendations, study dosing may have been high for some risperidone-treated patients and low for some ziprasidone-treated patients. Both agents equally improved psychotic symptoms, and both were generally well tolerated, with ziprasidone demonstrating a lower MDB score and less effect on prolactin and weight than risperidone.[14]

CONCLUSION

It is concluded that Lurasidone is an effective and useful drug for the treatment of schizophrenia and related disorders. However, future studies are recommended.

REFERENCES

1. Kane JM, Correll CU Past and present progress in the pharmacologic treatment of schizophrenia. J Clin Psychiatry. 2010; 79(9): 1115–1124.
2. Faries DE, Ascher-Svanum H, Nyhuis AW, Kinon BJ Clinical and economic ramifications of switching antipsychotics in the treatment of schizophrenia. BMC Psychiatry. 2009; 9: 54.
3. Covell NH, Jackson CT, Evans AC, Essock SM Antipsychotic prescribing practices in Connecticut's public mental health system: rates of changing

medications and prescribing styles. Schizophr Bull. 2002;28(1): 17–29
4. Weiden PJ Switching antipsychotics as a treatment strategy for antipsychotic-induced weight gain and dyslipidemia. J Clin Psychiatry. 2007; 68(Suppl 4): 34–39
5. Weiden PJ, Buckley PF Reducing the burden of side effects during long-term antipsychotic therapy: the role of "switching" medications. J Clin Psychiatry. 2007; 68(Suppl 6): 14–23.
Weiden PJ, Aquila R, Dalheim L, Standard JM Switching antipsychotic medications. J Clin Psychiatry. 1997; 58(Suppl 10): 63–72
6. Weiden PJ Switching in the era of atypical antipsychotics: an updated review. Postgrad Med. 2006; Spec No: 27–44
7. Latuda® (lurasidone HCl) tablets [package insert] Marlborough, MA: Sunovion Pharmaceuticals Inc; 2013. [Accessed March 25, 2015]. Available from: http://www.latuda.com/LatudaPrescribingInformation.pdf.
8. Citrome L. Lurasidone for schizophrenia: a review of the efficacy and safety profile for this newly approved second-generation antipsychotic. Int J Clin Pract. 2011;65(2):189–210.
9. Citrome L. Lurasidone in schizophrenia: new information about dosage and place in therapy. Adv Ther. 2012;29(10):815–825.
10. Citrome L. Lurasidone for the acute treatment of adults with schizophrenia: what is the number needed to treat, number needed to harm, and likelihood to be helped or harmed? Clin Schizophr Relat Psychoses. 2012;6(2):76–85.
11. Citrome L, Weiden PJ, McEvoy JP, et al. Effectiveness of lurasidone in schizophrenia or schizoaffective patients switched from other antipsychotics: a 6-month, open-label, extension study. CNS Spectrums. 2014;19(4):330-339. doi:10.1017/S109285291300093X.
12. McEvoy JP1, Citrome L, Hernandez D, Cucchiaro J, Hsu J, Pikalov A, Loebel A. Effectiveness of lurasidone in patients with schizophrenia or schizoaffective disorder switched from other antipsychotics: a randomized, 6-week, open-label study. J Clin Psychiatry. 2013 Feb;74(2):170-9. doi: 10.4088/JCP.12m07992.
13. Addington DE1, Pantelis C, Dineen M, Benattia I, Romano SJ. Efficacy and tolerability of ziprasidone versus risperidone in patients with acute exacerbation of schizophrenia or schizoaffective disorder: an 8-week, double-blind, multicenter trial. J Clin Psychiatry. 2004 Dec;65(12):1624-33.

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