A consummate study of olanzapine and patient related outcome measure by quality of life scale assessment in tertiary care teaching hospital

Swetha A[1], Tamil Bharathi S[1*],Gandhibabu R[2], Venkatesan P[2]

1Pharm.D VI Year (INTG), Department of Pharmacy, Annamalai University, Annamalai Nagar, Chidambaram, Tamil Nadu – 608002.
1*Pharm.D VI Year (INTG), Department of Pharmacy, Annamalai University, Annamalai Nagar, Chidambaram, Tamil Nadu – 608002.
2Head and Professor, Department of Psychiatry, Government Cuddalore Medical College and Hospital, Chidambaram, Tamil Nadu – 608002.
2Associate Professor, Department of Pharmacy, Annamalai University, Annamalai Nagar, Chidambaram, Tamil Nadu – 608002.

Corresponding Author:
Tamil Bharathi S, Pharm. D VI Year (INTG), Department of Pharmacy, Annamalai University, Annamalai Nagar, Chidambaram, Tamil Nadu – 608002.

Abstract

Background: Antipsychotic agents are used to treat schizophrenia and bipolar disorder symptoms. Schizophrenia is a complex mental illness, with symptoms ranging from abrupt to chronic. Olanzapine is a drug commonly used in treating schizophrenia, bipolar disorder, anxiety disorders, agitation, and aggression. **Objectives:** This study explores the drug utilization pattern

of olanzapine, focusing on prescribing trends, dosing regimens, adherence rates, treatment duration and summarize the consummate data on measure of patient related outcome through various quality of life assessment scale and to provide complete information to help policy maker and medical practitioner make informed choices in the better usage of olanzapine. **Method:** This was a prospective observational study conducted from November 2023 to April 2024 in the Psychiatry Department of Government Cuddalore Medical College and Hospital. A total of 60 patients, of all ages, with and without co-morbidities, from the outpatient department of the mental health centre, were included in this study after obtaining ethical approval and informed consent. It examines the real-world application of olanzapine in healthcare settings, identifying areas for optimization and ensuring safe use and impact on patient care through scales like PANSS, HAM-D, QULOS, and UKU. **Results:** Out of 60 patients, 42 were male and 18 were female. The study found that 27% of psychiatric patients had schizophrenia, 18% had depressive disorders, 5% had substance-induced disorders, 5% had psychoaffective disorders, 15% had mania, 28% had hypomania, and 2% had severe ID/ADHD. The quality of life of the patients was assessed using the QULAS scale, with 2% experiencing a terrible phase of life, 31% being mostly dissatisfied, 25% having mixed feelings, 10% being mostly satisfied, and only 4% being pleased. The UKU side effects scale revealed that 35 patients experienced adverse effects, including weight increase, abnormal hunger, inner rest, sedation, failing memory, emotional indifference, and concentration problems. Out of 60 patients who took olanzapine, 55% continued the drug, and 45% withdrew from the drug. **Conclusion:** From this study, though the drug has better medical adherence and is best in curing negative symptoms, it also causes other complications, so the drug is being replaced. Through various life assessment scales, patients who receive proper follow-up and exhibit perfect medical adherence show better improvement. If BMI, Lipid profile, and Age factor are regularly monitored in every review of patient OLANZAPINE, with tapering dose, it will be more effective than other drugs, and the quality of life of the patient will be improved.

Keywords: Olanzapine, Schizophrenia, Consummate, Adherence, Improvement, Withdrawal.

INTRODUCTION

Antipsychotic agents are used to treat schizophrenia and bipolar disorder symptoms, with atypical categories including clozapine, risperidone, olanzapine, and paliperidone. Schizophrenia is a complex mental illness with defiant behavior and intracellular processes. Most cases are diagnosed between 20 and 25, with symptoms ranging from abrupt to gradual. Post-onset patients can experience full recovery or chronic debilitation, with comorbid conditions like substance abuse common. Course determiners include male sex, early age, poor premorbid functioning, and family history.(1) The pathophysiology and aetiology of schizophrenia remain unclear, with research suggesting a combination of genetic factors and environmental stressors. Schizophrenia is classified into five subtypes: paranoid, disorganized, catatonic, undifferentiated, and residual. The DSM-5, revised in 2013, provides a more reliable classification for schizophrenia, with its symptoms.(3)

Bipolar affective disorder is a chronic mood disorder characterized by manic, hypomanic, and depressive episodes. It has a lifetime prevalence of around 1% for bipolar type I and 2.4% for

bipolar spectrum disorders. Symptoms include mood changes and behavioral changes. Types of bipolar disorder include bipolar I Disorder, bipolar II Disorder, Bipolar Disorder not otherwise specified (BP-NOS), and Cyclothymic disorder. The most significant risk factor for BPAD is a family history of mental illness, with genes accounting for 80% of cases.(2) Bipolar disorder is often diagnosed as major depressive disorder, requiring a careful medical history to avoid a mistaken diagnosis. Treatment includes antipsychotic medications, psychotherapy, lifestyle changes, antidepressants, interpersonal and social rhythm therapy (IPSRT), and regular monitoring. Long-acting injectable antipsychotics are available for those struggling with oral regimens.(2)

MATERIALS AND METHODS

This prospective observational study was conducted from November 2023 to April 2024 in the Psychiatry department of the Government Cuddalore Medical College and Hospital in Chidambaram, India. Around 60 patients of all ages with and without any co-morbidities from the outpatient department of the mental health centre were included after receiving approval from the institutional ethical committee. The patients received appropriate counselling before the procedure, and their written informed consent was obtained. The sociodemographic information, clinical history, and other required tests were gathered together with their review reports. A vital factor to examine in the regular review is BMI and Lipid profile for weight gain. If the patient had diabetes mellitus and was more than 80 years of age, they were excluded from the study. All patients received the initial dosage of 2.5-5mg/kg with adjustments based on their age and severity. Subjects with increased negative symptoms and side effects during the drug therapy of olanzapine were switched to the drug risperidone, and sometimes, along with fluoxetine, were also allowed to participate in the study. It examines the real-world application of olanzapine in healthcare settings, identifying areas for optimization and ensuring safe use and impact on patient care through scales like PANSS, HAM-D, QULOS, and UKU.

RESULTS

This prospective observational study was carried out in the Psychiatry department. The study included 60 patients who met the inclusion and exclusion criteria. The purpose of the current study was to examine and enhance the olanzapine by measuring patient-related outcomes through various quality of life assessment scales. A significant demographic characteristic. Out of the total 60 patients, 42 were men and 18 were women, which depicts that males make up 70 % whereas women make up 30%. The study has 47 patients who cover 78% of the age group below 50 and 13 patients who cover 22% of the age group 50 and beyond. According to this study, the patients on olanzapine treatment were 27% of schizophrenia, 18% of depressive disorders, 5% of substance-induced disorders, 5% of psychoaffective disorders, 15% of mania, 28% of hypomania, and 2% of severe ID/ADHD.

TABLE.1 DIAGNOSTIC WISE DISTRIBUTION OF PATIENTS

Diagnosis	Number of people diagnosed [n=60]	Percentage
Schizophrenia	16	27%
Depressive Disorder	11	18%
Substance induced disorder	3	5%
Psychoaffective disorder	3	5%
BPAD in Mania	9	15%
BPAD in Hypomania	17	28%
Severe ID /ADHD	1	2%

DRUG PRESCRIBED WISE DISTRIBUTION:

In this chart, the patients were given only Olanzapine, Olanzapine Clonazepam, Olanzapine + risperidone, Olanzapine Haloperidol, and Olanzapine + Fluoxetine. By the way, in 60 Patients,18 patients (30%) consumed olanzapine alone, and 8 patients (14%) consumed. Olanzapine with Clonazepam, 14 patients (23%) consumed Olanzapine with Risperidone,6 patients (10%) consumed Olanzapine with Haloperidol, and 14patients (23%) consumed olanzapine with Fluoxetine.

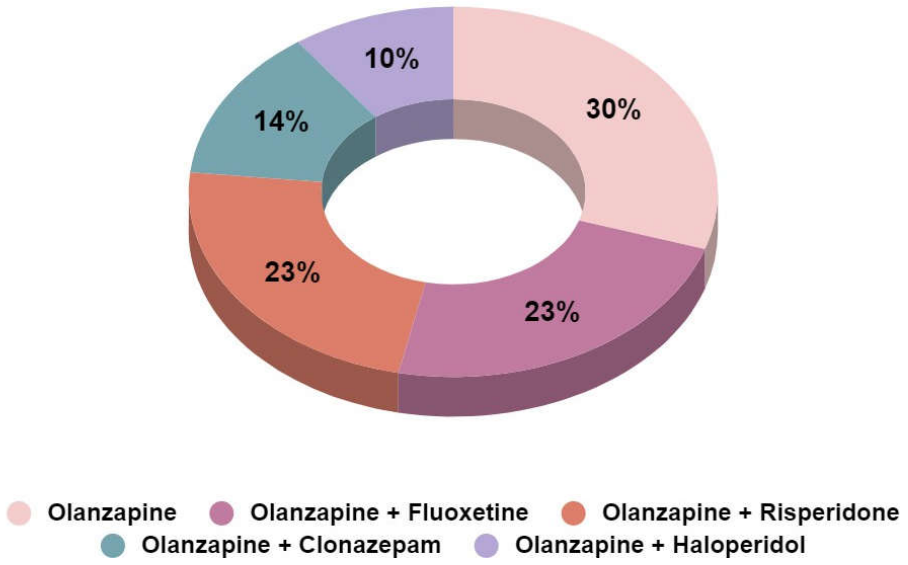


FIGURE.1 DRUG PRESCRIBED WISE DISTRIBUTION

PATIENT RELATED OUTCOMES THROUGH QULOS SCALE:

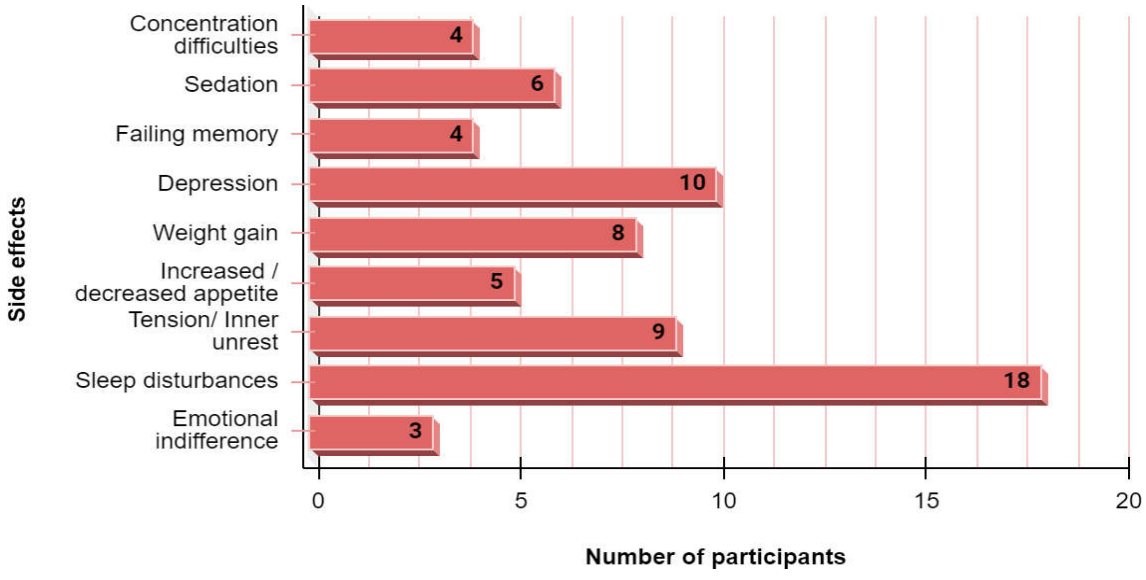
After the review period, the QULOS scale scores show the quality of life of the patients: 2% of them were experiencing a terrible phase of life, 27% were unhappy, 10% were mostly dissatisfied, 25% had mixed feelings, 31% were mostly satisfied, and only 4% were pleased.

TABLE.2 PATIENT RELATED OUTCOMES THROUGH QULOS SCALES

Normal scores	Number of participants between these scores [n=60]	Patient related outcomes	Percentage (%)
0-16	1	Terrible	2%
17-32	16	Unhappy	27%
33-48	6	Mostly dissatisfied	10%
49-64	15	Mixed	25%
65-80	18	Mostly satisfied	31%
81-96	4	Pleased	5%
97-112	0	Delighted	0

UKU SCALE OUTCOMES WISE DISTRIBUTION:

Of the 60 patients receiving olanzapine, 35 experienced adverse effects. Those adverse effects fall into the following categories according to the UKU side effects scale, so after the review period, the scale's result indicates that out of the 35 people who experienced side issues and 8 of them experienced weight increase, 5 experienced abnormal hunger, 9 experienced inner rest, 8 experienced sedation, 6 experienced failing memory, 3 experienced emotional indifference, and 10 experienced concentration problems.



PANSS SCALE OUTCOMES WISE DISTRIBUTION:

This outcome shows that 19 patients are moderately ill (32%),18 patients are markedly ill (30%), 15 patients are severely ill (25%), and lastly, 8 patients are mildly ill (13%).

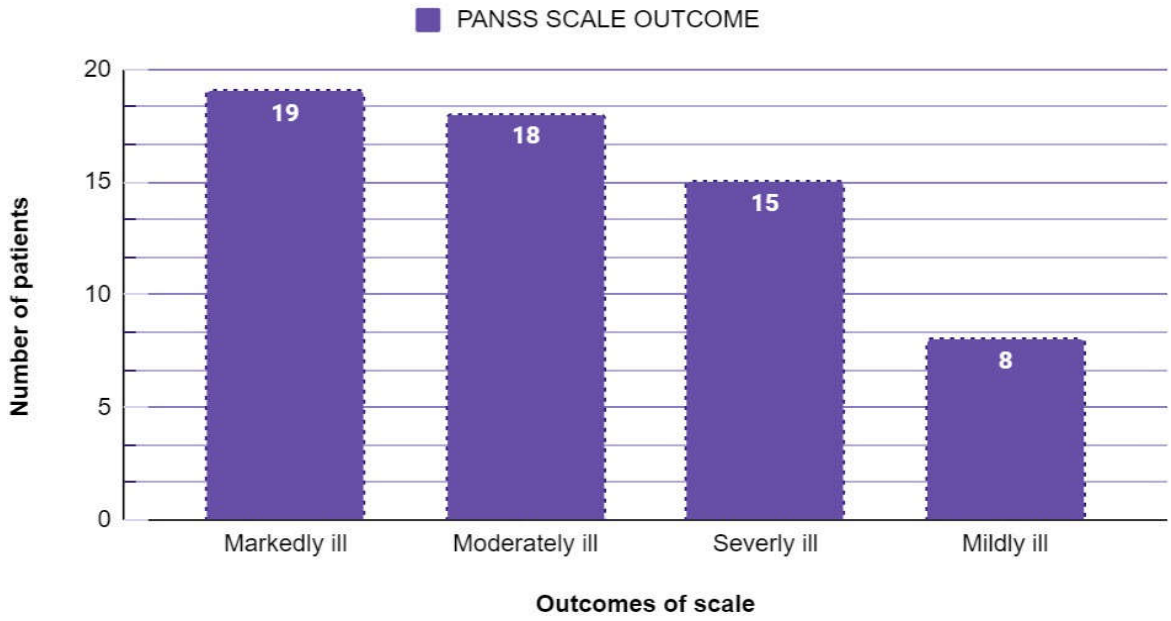


FIGURE.3 PANSS SCALE OUTCOME WISE DISTRIBUTION

DRUG CONTINUED OR WITHDRAWAL WISE DISTRIBUTION:

Among 60 patients who took Olanzapine drug therapy, 33 patients (55%) continued the drug and 27 patients (45%) withdrew the drug. Also, the withdrawal of Olanzapine was switched to Risperidone. This is depicted by the waterfall chart to show the continued and withdrawal as positive and negative sides.

TABLE.3 DRUG CONTINUED OR WITHDRAWAL WISE DISTRIBUTION

Drug intake/Withdrawal	No. of Participants [n=60]	Percentage (%)
Drug continued	33	55%
Drug withdrawal	27	45%

DISCUSSION

This study aimed to understand the prescribing pattern of antipsychotic drugs in a tertiary care teaching hospital's psychiatric outpatient department. Out of 60 patients, 42 were male and 18 were female, with males being affected more than females which is similar to the study by **Ochoa et al**(4). The study found that among the patients intaking olanzapine, 27% of psychiatric patients had schizophrenia, 18% had depressive disorders, 5% had substance-induced disorders, 5% had psychoaffective disorders, 15% had mania, 28% had hypomania, and 2% had severe ID/ADHD, the findings consistent to the study by **Martin et al** (5).

Three reviews were conducted for 60 patients for six months, with the majority (28%) taking olanzapine alone, 14% with Clonazepam, 23% with Risperidone, 10% with Haloperidol, and 23% with Fluoxetine, similar to the study by **Li et al (6)**. The quality of life of the patients was assessed using the QULAS scale, with 2% experiencing a terrible phase of life, 31% being mostly dissatisfied, 25% having mixed feelings, 10% being mostly satisfied, and only 4% being pleased, similar to the study by **Wehmeier et al** (7).

The UKU side effects scale revealed that 35 patients experienced adverse effects, including weight increase, abnormal hunger, inner rest, sedation, failing memory, emotional indifference, and

concentration problems, similar to the study by **Iversen et al** (8). Based on the symptoms experienced by the patient PANSS categorize the severity of the patients, here outcome shows that 19 patients are moderately ill (32%),18 patients are markedly ill (30%), 15 patients are severely ill (25%), and lastly, 8 patients are mildly ill (13%), symptoms included hallucinations, delusions, disturbing thoughts, lack of emotions, anxiety, anger outbursts, and extrapyramidal symptoms. Substance abuse was common among patients, with only 3 involved in substance abuse. Many patients developed suicidal intent and aggressive behavior **Case et al** (9). Out of 60 patients who took olanzapine, 55% continued the drug, and 45% withdrew from the drug, similar to the study by **Ganguli et al** (10). To enhance the efficacy of the drug and for precise treatment, patients' weight, BMI, lipid profile test, age, and blood cell count should be considered with dosage tapering.

CONCLUSION

From this study, OLANZAPINE is prescribed not only for schizophrenia and other related bipolar disorders but also for BPAD with hypomania, and is also given in combination with Fluoxetine to treat Mixed Depression. Though the drug has better medical adherence and is best in curing Negative symptoms, it also causes other complications such as sedation and weight gain. Hence, the drug is sometimes withdrawn or replaced by the other drugs like risperidone to reduce the complications. Through PANSS, the patient with proper follow-up has improved measurements, and QOLAS has better improvement with perfect medical adherence. But if BMI, Lipid profile, and Age factor are regularly monitored in every review of patient OLANZAPINE, with tapering dose, it will be more effective than other drugs, withdrawal of the drug will be reduced and the quality of life will be improved.

REFERENCE

1. https://www.nimh.nih.gov/health/topics/schizophrenia
2. Rowland TA, Marwaha S. Epidemiology and risk factors for bipolar disorder. Ther Adv Psychopharmacol. 2018 Apr 26;8(9):251-269. doi: 10.1177/2045125318769235. PMID: 30181867; PMCID: PMC6116765.
3. Pathirathna ML, Nandasena HMRKG, Atapattu AMMP, Weerasekara I. Impact of the COVID-19 pandemic on suicidal attempts and death rates: a systematic review. BMC Psychiatry. 2022 Jul 28;22(1):506. doi: 10.1186/s12888-022-04158-w. PMID: 35902951; PMCID: PMC9331016.
4. Ochoa S, Usall J, Cobo J, Labad X, Kulkarni J. Gender differences in schizophrenia and first-episode psychosis: a comprehensive literature review. Schizophr Res Treatment. 2012;2012:916198. doi: 10.1155/2012/916198. Epub 2012 Apr 8. PMID: 22966451; PMCID: PMC3420456.
5. Martin A, Bessonova L, Hughes R, Doane MJ, O'Sullivan AK, Snook K, Cichewicz A, Weiden PJ, Harvey PD. Systematic Review of Real-World Treatment Patterns of Oral Antipsychotics and Associated Economic Burden in Patients with Schizophrenia in the United States. Adv Ther. 2022 Sep;39(9):3933-3956. doi: 10.1007/s12325-022-02232-z. Epub 2022 Jul 18. PMID: 35844007; PMCID: PMC9402774.
6. Li Y, Du C, Jiaxiang N, Liqiang Y, Qi F. Olanzapine versus placebo for people with schizophrenia. Cochrane Database Syst Rev. 2019 Apr 15;2019(4):CD013310. doi: 10.1002/14651858.CD013310. PMCID: PMC6462848.

7. Wehmeier PM, Kluge M, Schneider E, Schacht A, Wagner T, Schreiber W. Quality of life and subjective well-being during treatment with antipsychotics in out-patients with schizophrenia. Prog Neuropsychopharmacol Biol Psychiatry. 2007 Apr 13;31(3):703-12. doi: 10.1016/j.pnpbp.2007.01.004. Epub 2007 Jan 16. PMID: 17289237.
8. Iversen TSJ, Steen NE, Dieset I, Hope S, Mørch R, Gardsjord ES, Jørgensen KN, Melle I, Andreassen OA, Molden E, Jönsson EG. Side effect burden of antipsychotic drugs in real life - Impact of gender and polypharmacy. Prog Neuropsychopharmacol Biol Psychiatry. 2018 Mar 2;82:263-271. doi: 10.1016/j.pnpbp.2017.11.004. Epub 2017 Nov 7. PMID: 29122637.
9. Case M, Stauffer VL, Ascher-Svanum H, Conley R, Kapur S, Kane JM, Kollack-Walker S, Jacob J, Kinon BJ. The heterogeneity of antipsychotic response in the treatment of schizophrenia. Psychol Med. 2011 Jun;41(6):1291-300. doi: 10.1017/S0033291710001893. Epub 2010 Oct 7. PMID: 20925971; PMCID: PMC3080711.
10. Ganguli R, Brar JS, Mahmoud R, Berry SA, Pandina GJ. Assessment of strategies for switching patients from olanzapine to risperidone: a randomized, open-label, rater-blinded study. BMC Med. 2008 Jun 30;6:17. doi: 10.1186/1741-7015-6-17. PMID: 18590519; PMCID: PMC2474645.
11. Crossley NA, Alliende LM, Czepielewski LS, Aceituno D, Castañeda CP, Diaz C, Iruretagoyena B, Mena C, Mena C, Ramirez-Mahaluf JP, Tepper A, Vasquez J, Fonseca L, Machado V, Hernández CE, Vargas-Upegui C, Gomez-Cruz G, Kobayashi-Romero LF, Moncada-Habib T, Arango C, Barch DM, Carter C, Correll CU, Freimer NB, McGuire P, Evans-Lacko S, Undurraga E, Bressan R, Gama CS, Lopez-Jaramillo C, de la Fuente-Sandoval C, Gonzalez-Valderrama A, Undurraga J, Gadelha A. The enduring gap in educational attainment in schizophrenia according to the past 50 years of published research: a systematic review and meta-analysis. Lancet Psychiatry. 2022 Jul;9(7):565-573. doi: 10.1016/S2215-0366(22)00121-3. PMID: 35717966.
12. Kiraz S, Demir E. Global Scientific Outputs of Schizophrenia Publications From 1975 to 2020: a Bibliometric Analysis. Psychiatr Q. 2021 Dec;92(4):1725-1744. doi: 10.1007/s11126-021-09937-4. Epub 2021 Aug 3. PMID: 34341886.
13. Gaebel W, Zielasek J. Schizophrenia in 2020: Trends in diagnosis and therapy. Psychiatry Clin Neurosci. 2015 Nov;69(11):661-73. doi: 10.1111/pcn.12322. Epub 2015 Jul 1. PMID: 26011091.
14. Citrome L, McEvoy JP, Todtenkopf MS, McDonnell D, Weiden PJ. A commentary on the efficacy of olanzapine for the treatment of schizophrenia: the past, present, and future. Neuropsychiatr Dis Treat. 2019 Sep 5;15:2559-2569. doi: 10.2147/NDT.S209284. PMID: 31564881; PMCID: PMC6733343.