A PROSPECTIVE STUDY ON COMBINATION OF OLANZAPINE OR RISPERIDONE WITH FLUOXETINE AND THEIR IMPACT ON QUALITY OF LIFE IN PSYCHOSIS PATIENTS.

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ABSTRACT:

Objectives: To assess the quality of life, medication adherence and the ADRs in psychosis patients taking a combination of olanzapine with fluoxetine and risperidone with fluoxetine.

Methods: A six-month prospective observational cohort study with 100 participants on antipsychotics was conducted at Krishna Rajendra Hospital, Mysuru, in 2023. Data, including quality of life, ADRs, and medication adherence, was collected and assessed using SF-12, Naranjo scale, and MARS-10.

Results: The study encompassed 100 participants, with those aged 36-45 (29%) more prone to psychosis. Males (52%) exhibited higher susceptibility than females (48%), and higher literacy levels (65%) increased the risk. Weight range 51-70kg (74%) was common, and most with psychosis were non-alcoholic (93%) and non-smokers (85%). Regimens improved quality of life and medication adherence. Adverse drug reactions included sleeplessness (13.02%) and weight gain (13.02%), with a total of 307 reported, 201 deemed probable and 106 possible.

Conclusion: The study population shows strong adherence, indicating the efficacy and tolerance of the current medication regimen. Findings underscore the need to address both physical and mental health for overall wellbeing. Emphasizing ADR assessment aids physicians in safe treatment selection, necessitating an active surveillance system for identifying and reporting ADRs linked to antipsychotic medicines

INTRODUCTION:

Due to the country's rapid demographic and epidemiological transformation, the burden of neurological illnesses is also anticipated to rise in India. 14.3% of the population in India, or 197.3 million people, suffer from a mental disorder. [1]Psychiatric disorders are a broad category of mental health conditions that affect a person's thoughts, feelings, actions, and daily functioning. Schizophrenia and bipolar disorder have been labels for the functional psychoses, the most severe psychiatric diseases with adult onset, for more than a century. [2] Psychosis is a prominent symptom associated with numerous psychiatric, neurodevelopmental, neurologic, and medical conditions, which makes it a crucial area for diagnosis and treatment in neurologic and psychiatric practises. PSYCHOSIS Symptoms include: Hallucinations and Delusions Disorganised thoughts, Disorganised behaviour, Catatonia and Negative symptoms

Schizophrenia is a severe behavioural disorder that affects 24 million people around the world, or 1 in 300 folks. Schizophrenia can have a significant impact on all aspects of life, including personal, family, social, academic, and economic life. It also causes psychosis and can lead to severe impairment. [5]

A major mood condition called bipolar disorder is characterised by recurrent episodes of depression that alternate with periods of hypomania and/or mania, usually separated by intervals of mood and functioning that are more or less normal. Bipolar disorder type 1 (BP-I) and type 2 (BP-II) are distinguished in the Diagnostic and Statistical Manual, Fourth Edition (DSM-IV: American Psychiatric Association, 1994) by the severity of the manic episode.[10]Depression is characterised by a wide variety of symptoms, including sadness or low mood, absence of interest in activities, lack of strength and energy, feeling weak or weaker, lack of

self-assurance, guilt, helplessness, or hopelessness, difficulty paying attention, restlessness, difficulties sleeping, constant feelings of worthlessness, suicidal thoughts, changes in appetite, irritability, discomfort, tiredness, or weakness despite physical cause and changes in appetite. [13]

Atypical antipsychotic medications have been used more and more frequently in older patients in recent years. These medications have unique receptor binding patterns, good efficacy against negative symptoms, and few side effects, especially in terms of decreased extrapyramidal symptoms. [20]Atypical antipsychotic medications have been used more and more frequently in older patients in recent years. These medications have unique receptor binding patterns, good efficacy against negative symptoms, and few side effects, especially in terms of decreased extrapyramidal symptoms. [20]The primary evidence-based therapy for schizophrenia and other major psychotic illnesses is antipsychotic medication. Antipsychotic drugs usually provide dramatic symptomatic relief for delusions and visions, as well as improvement for disruptive thinking and behaviour.

Psychosis characterized by psychotic symptoms that may arise in conditions like major depressive disorder, bipolar disorder, and schizophrenia. As psychosis is such a complex medical conditions, patients frequently need to have their quality of life evaluated and adhere to treatment plans. Evaluating the patient's quality of life helps to determine the patient's general state of health, comprising their psychological, social, and physical functioning. Knowing this aspect makes it easier to adjust treatment plans to address specific problems and improve patients' overall health and output. Antipsychotics and antidepressants together can help improve psychotic treatment approaches and provide further relief from the depressive symptoms commonly associated with psychosis Treatment adherence is important.

MATERIALS AND METHOD:

Study site: Krishna Rajendra Hospital, a tertiary care hospital attached to Mysore Medical College & Research Institute, Mysuru.

Study design: The study was designed to be a prospective observational study. The sample size of the study was 100 patients.

Study period: The study was carried out for a period of six months.

Ethical approval: Institutional Human Ethical Committee of Mysore Medical College and Research Institute, Mysuru approved the study.

Study criteria:

Inclusion criteria:

1. Patients aged 18 to 65 years old.
2. Patients of either gender.
3. Patients receiving Olanzapine with fluoxetine and Risperidone with fluoxetine.
4. Patients diagnosed with psychosis according to ICD 11 criteria

Exclusion criteria:

1. Patients who are not willing to participate.
2. Patients with severe medical conditions that may interfere with the study.
3. Pregnant and lactating women

Source of data: All the relevant and necessary data will be collected from Interviewing patients and caretakers, Prescription of the patient, Communicating with concerned clinicians and health care professionals, Medical and Medication records of the patient

Study procedure: The study involved the following steps: -

1. Preparation of informed consent form (ICF): An inform consent form was designed in English and the same was translated to native speaking language: Kannada for obtaining consent from patients who are willing to participate in the study. The aims and objectives of the study was properly explained to the patient and the consent was obtained. In the case of illiterate patients, the study aspects were explained to care takers and consent acquired from study population.

2. Preparation of data collection form (DCF): A data collection form was properly designed that included all the relevant data including demographic details like name, age, gender, weight, address, phone number ,clinical data such as diagnosis, past medical and medication history, past history of medication adherence and interventions made, co-morbidities, therapeutic data such as name of the drug, dose, frequency, route and duration of administration, concurrent medication(s) from various available data sources and documented in a suitably designed data collection form.

3. Patient enrollment: Patients who met the study criteria were enrolled in the study after obtaining informed consent. Enrolment took place during outpatient visits. Patients who are receiving olanzapine, risperidone, and fluoxetine as part of their treatment were recruited into the study.

4. Data collection: The patient was initially provided the informed consent form, and all the details of the study were described. Each relevant details about the enrolled patients, including demographics (age, gender, family history, etc) and treatment information was gathered from interviews (hospital visit and telephone calls), their medical records and questionnaires and documented in the data collection form.

5**. Statistical analysis:** Microsoft Office Excel 2016 was used for the statistical analysis and evaluation of the data. The descriptive statistics like percentage, mean , tables, graphs are applied

to simulate the outcome of the study and standard deviation is used in the study.

RESULTS:

A total of 100 study participants from the Psychiatry OPD who met our inclusion criteria were examined.

Demographic Data:

The study population comprised between the ages of 36-45y (n=29, 29%) were more likely to experience psychosis. Moreover, it reveals that males (n=52, 52%) exhibit a higher susceptibility to psychosis than females (n=48, 48%) and individuals with higher levels of literacy (n=65, 65%) are at an increased risk of developing the condition. Additionally, the study finds that those with psychosis tend to fall within the weight range of 51-70kg (n=74, 74%) and significant proportion of individuals with psychosis are non-alcoholic (n=93, 93%) and non-smokers (n=85, 85%).

QUALITY OF LIFE:

The quality of life in psychosis patients by using SF-12 scale for 77 subjects who were prescribed with fluoxetine and olanzapine regimen

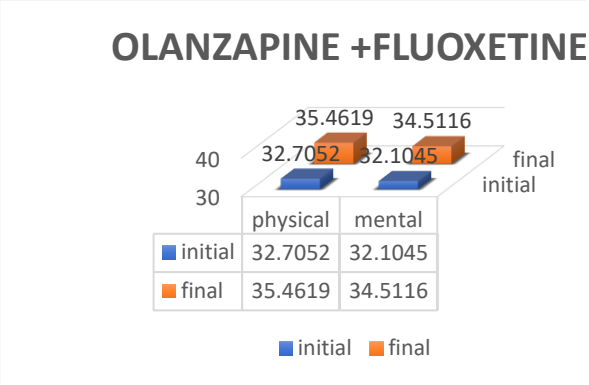

Figure 1: Graphical representation of quality of life within psychosis patients with olanzapine and fluoxetine.

Quality of life in psychosis patients by using SF-12 scale for 23 subjects who were prescribed with fluoxetine and risperidone regimen

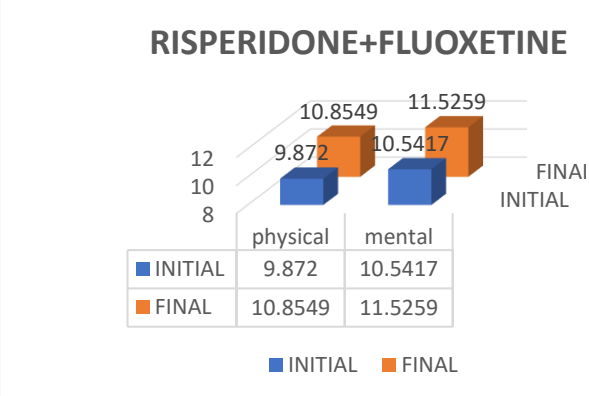

Fig 2: Graphical representation of quality of life within psychosis patients with risperidone and fluoxetine regimen

Quality of life of study population based on age group below 45(18-45) years.

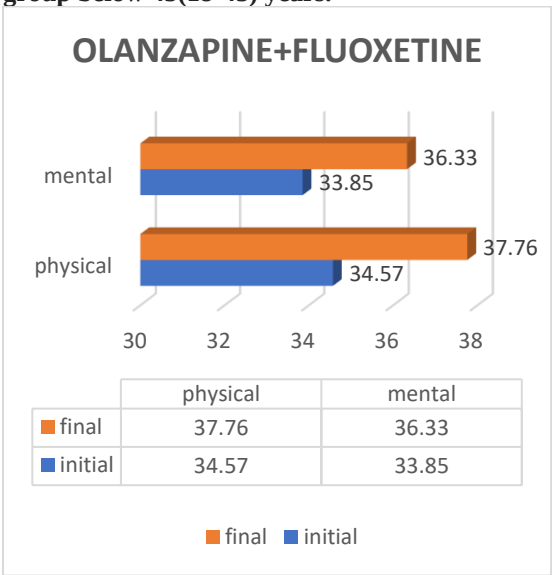

Fig 3: Graphical representation of quality of life of patients within age group 18-45years who were on olanzapine with fluoxetine regimen

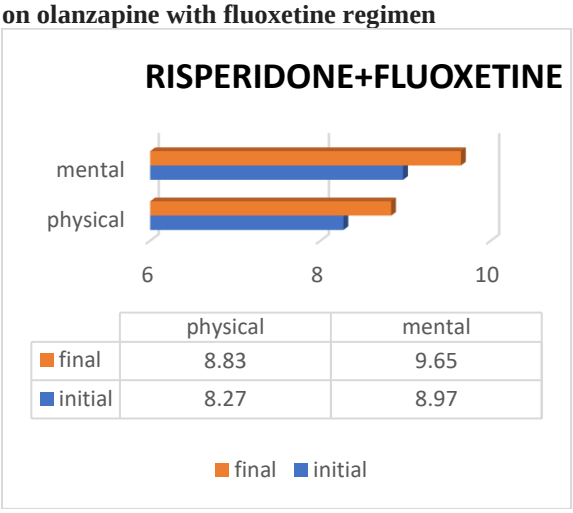

Fig 4: Graphical representation of quality of life of patients within age group 18-45years who were on risperidone with fluoxetine regimen

Quality of life of study population based on age group above 45(46-65) years.

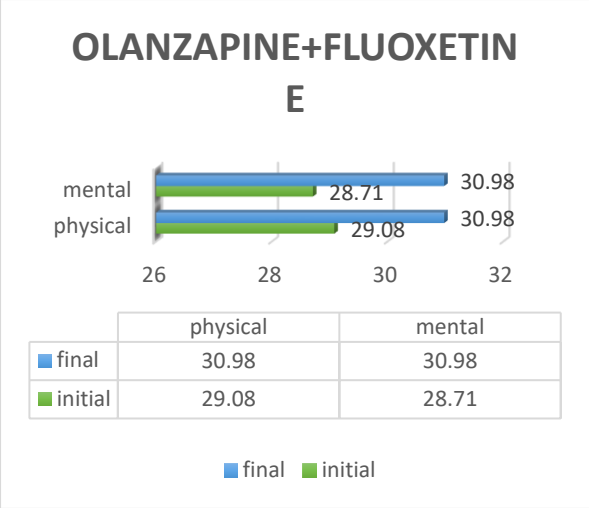

Fig 5: Graphical representation of quality of life of patients within age group 46-65years who were on olanzapine with fluoxetine regimen.

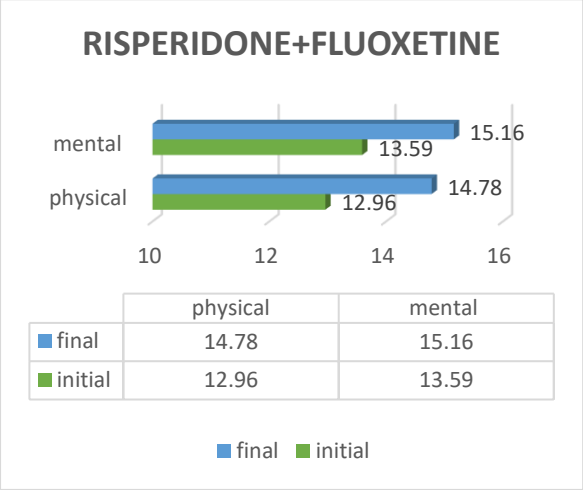

Fig 6: Graphical representation of quality of life of patients within age group 46-65years who were on risperidone with fluoxetine regimen.

MEDICATION ADHERENCE:

The results of the study, which looked at 100 participants using the treatment regimens olanzapine + fluoxetine and risperidone + fluoxetine among individuals with psychosis, showed improved adherence.

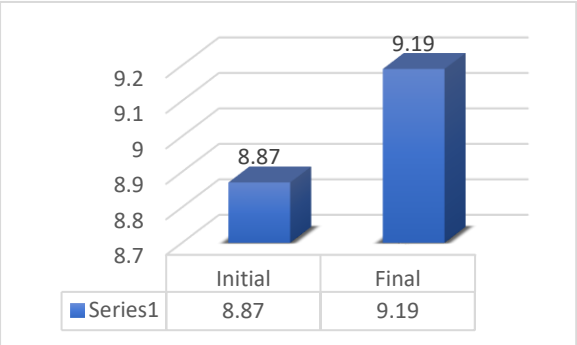

Fig7: Graphical representation of medication adherence within psychosis patients

ADVERSE DRUG REACTION:

Fig 8 illustrates the ADRs quantified by using Naranjo causality assessment scale in the study population. Most patients reported sleeplessness (n=40, 13%) and weight gain (n=40, 13%) followed by fatigue (n=28, 9.12%), headache (n=23, 7.49%) and dry mouth (n=22, 7.16%). The least reported ADRs were diarrhoea, vomiting, tachycardia, asthenia, urinary incontinence and sore throat which was only seen in a patient each.

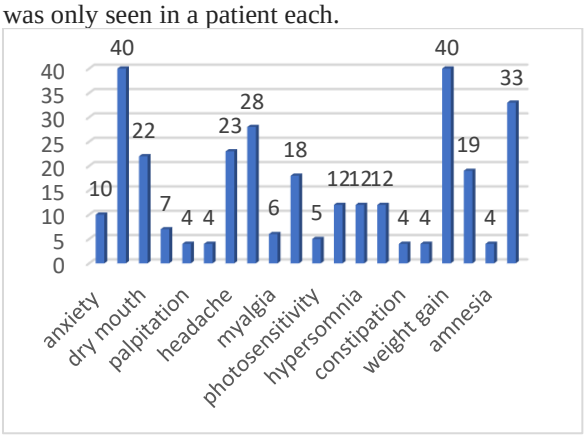

Fig 8: Graphical representation of total number of ADRs in psychosis patients

NUMBER OF PROBABLE AND POSSIBLE ADRS IN THE STUDY POPULATION:

NAME	RESULT
DEFINITE	0
PROBABLE	201
POSSIBLE	106
UNLIKELY	0

Table 1: Details of Naranjo Causality Assessment Scale of Study Population

ORGAN SYSTEM CLASSIFICATION IN STUDY POPULATION OF PSYCHOSIS

According to the MedDRA Organ System Classification, the ADRs were categorized into several classes. Of this, the highest number of ADRs belong to Nervous system (n=70, 22.80%) followed by GI system (n=59, 19.21%) and Metabolic system (n=59, 19.21%) and the least number of ADRs belong to Respiratory system (n=1, 0.32%).

Table 2: Distribution of ADR's based on organ system classification in study population of psychosis

ADRS	NO OF ADRS	PERCENTAGE
CVS	9	2.93%
NERVOUS SYSTEM	70	22.80%
MUSCULOSKELETAL SYSTEM	10	3.25%
GI SYSTEM	59	19.21%
RENAL SYSTEM	3	0.97%
DERMATOLOGICAL SYSTEM	14	4.56%
RESPIRATORY SYSTEM	1	0.32%
REPRODUCTIVE SYSTEM	2	0.65%
METABOLIC SYSTEM	59	19.21%
CIRCULATORY SYSTEM	2	0.65%
OPHTHALMIC SYSTEM	12	3.90%
CNS	66	21.49%

CONCLUSION:

The study population demonstrates a higher level of adherence, which suggests that the current medication regimen is effective and well tolerated by patients. Our findings highlight the importance of addressing both the physical and mental health to enhance the overall wellbeing. It is vital to be familiar with the assessment of ADRs caused by various antipsychotics. It assists physicians in selecting safe treatment and lowering the risk of occurrence of ADRs. As we get more information about ADRs, we require an active surveillance system for identifying and reporting ADRs associated with antipsychotic medicines

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