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Prevalence of Atypical Antipsychotic's ADR among all Psychotic Patients Attending Outpatient Department Service in St. Mary Neuropsychiatry Hospital, Eritrea, Africa

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Abstract: ***Objectives: Adverse drug reactions (ADRs) to psychotropic agents are common and can lead to noncompliance or even discontinuation of therapy. There is paucity of such data in the Eritrean context. We deemed it worthwhile to assess the suspected ADR profile of psychotropic drugs in an ambulatory setting in St. Mary's Neuro Psychiatric Hospital. Materials and Methods: An observational study was conducted in the outpatient department (OPD) of the concerned psychiatry unit. Irrespective of their psychiatric diagnosis, were screened for suspected ADRs, 5 days in a week.Drugs and system organ class involved in ADRs were coded according to Anatomical Therapeutic Chemical Classification System and World Health Organization Adverse Reaction Terminology respectively. Results: A total of 404 patients were monitored, among the 41 patients who were experienced ADR to Antipsychotic medications, 20 (48.7%) were males and 21 (51.2%) were females. The average age of the patients who experienced ADR was found to be 29 to 58 years. The maximum numbers of ADRs were documented in the age group of 29 to 38 (34.1%). The prescribed number of drugs 80.4 % were single drug and 19.55 were two drugs (combination therapy) of Antipsychotics.The most common organ system affected by ADRs was the CNS and peripheral nervous system (48.7%). Conclusions: This study offers a representative profile of ADRs to be expected in psychiatry out-patients in an Eritrean National Referral Hospital. Establishment of a psychotropic drug ADR database can be a worthy long-term goal in the Eritrean context. Keywords: Adverse drug reactions, pharmacovigilance, psychiatry, psychotropic drugs***

1. Introduction

[1]Psychiatry, perhaps uniquely in health care, operates from an established multidisciplinary approach. The opportunity, as well as the responsibility, exists for all clinicians to be involved in medication decisions as appropriate to their discipline. As treatment approaches in mental health continue to evolve, it is likely that current practices will expand and demand participation from knowledgeable therapists.

[2]Psychopharmacologic advances continue dramatically to expand the parameters of psychiatric treatments. Greater understanding of how the brain functions has led to more effective, less toxic, better-tolerated, and more specifically targeted therapeutic agents. With the ever-increasing sophistication and array of treatment options, clinicians, however, must remain aware of potential adverse effects, drug interactions, and how to manage the emergence of unwanted or unintended consequences.

[2]Newer drugs may lead ultimately to side effects that are not recognized initially. Keeping up with the latest research findings is increasingly important as these findings proliferate. A thorough understanding of the management of medication-induced side effects (either through treating the effect with another agent or substituting another primary agent) is necessary.

Both genetic and environmental factors influence individual response to, and tolerability of, psychotropic agents. Thus, a drug that may not prove effective in many patients with a disorder can dramatically improve symptoms in others. In these cases, identification of characteristics that might predict potential candidates for that drug becomes important, but often remains elusive.

[2]Drugs, even within the same class, are distinguished from one another by often subtle differences in molecular structure, types of interactions with neurotransmitter systems, differences in pharmacokinetics, the presence or absence of active metabolites, and protein binding. These differences, combined with the biochemistry of the patient, account for the profile of efficacy, tolerability, and safety and the risk-to-benefit ratio for the individual. These multiple variables, some poorly understood, make it difficult to predict a drug's effect with certainty. Nevertheless, knowledge of the nature of each property increases the likelihood of successful treatment. The clinical effects of drugs are best understood in terms of pharmacokinetics, which describes what the body does to a drug, and pharmacodynamics, which describes what the drug does to the body.

[3]Not only effective but also safe and well tolerated medication is one of the major goals of today's drug development. In spite of all these efforts the number of serious and life threatening adverse drug reactions seems not to decrease. A meta-analysis from 2008 showed an incidence of 6.7% serious adverse drug reactions (SADR), whereas fatal reactions involved 0.32% of hospitalized patients; calculated for the population of the United States of America (USA) meaning that about 2.2 Mio inpatients suffer annually from SADR and 100 000 die from it. A study from the Food and Drug Administration (FDA) in the USA show a 2.6 fold increase in SADR and related deaths over the period from 1998 to 2005.

Several factors account for the dearth of information about adverse drug events among outpatients. Such patients obtain and administer their own medications. Since contact with physicians is intermittent, communication about problems may be infrequent. Inadequate documentation of outpatient care and high costs limit the usefulness of chart review, which is most commonly used to ascertain adverse drug events among inpatients.

These factors make it difficult to identify adverse drug events among outpatients. We performed a study to determine theconsequences of adverse drug events among outpatients. In addition, we assessed the preventability of such events and identified strategies to keep them from occurring or to ameliorate them.

2. Objectives

General Objectives
To identify the prevalence of Antipsychotic's ADR among all psychotic patients attending outpatient department service in St. Mary Neuropsychiatry Hospital.

Specific Objectives
1) To identify the Antipsychotic's ADR among all psychotic patients attending outpatient department service in St. Mary Neuropsychiatry Hospital.
2) To find out the association between the most common factor for Antipsychotic's ADR among all psychotic patients attending outpatient department service in St. Mary Neuropsychiatry Hospital.

Research Question
What are the common Antipsychotic's ADR among psychotic patients attending outpatient department service in St. Mary Neuropsychiatry Hospital.

3. Methodology

Research Approach
A descriptive research approach was used.

Research Design:
Descriptive cross-sectional Design

Variables
Dependent Variable: Antipsychotic ADR
Extraneous variable: In this study, extraneous variables are age,gender, use of alcohol and tobacco and type of drug.

Setting of the Study
The study was conducted in the outpatient service of St. Mary Neuropsychiatry hospital which having average out patients' around 3000 per month

Population
The study was targeted to outpatients have to diagnosed as psychosis according to DSM IV diagnostic criteriaat least one year before and compliance to their drug in St. Marry NeuropsychiatryHospital

Sampling Technique: Census method

Selection Criteria

Inclusion criteria
- Psychosis patients who are willing to participate in this study.
- People who are above the age of 19 years to below the age 68 years.
- Psychosis patients who had been diagnosed at least before one year and compliance to their drug.

Exclusion Criteria
- Psychotic patient who were in acute psychotic state (agitated).
- Psychotic patientassociated with Serious medical condition and mental retardation.

Tools
Type of underlying disorders in patients who experienced ADRs was classified according to International Classification of Diseases Ninth Revision, Clinical Modification. Drugs and system organ class involved in ADRs were coded according to Anatomical Therapeutic Chemical Classification System and World Health Organization Adverse Reaction Terminology respectively.

Data Collection Process
The researchers received ethical approval from Ministry of Health. After obtaining informed consent from the patient, the nurse clinician assessed the patient about their Adverse Drug Reaction through objective and subjective data. Short term (4 Days in a week May 2018) data has collected by 10 nurse clinicians among 404 patients and adverse reaction noticed among 41 patients.

Plans for Data Analysis
Tables, graphs, frequencies and meanwere used to describe the variables for categorical and continuous ones as per their need. Chi-Square were used to find out the association between prevalence of ADR and selected demographic variables and factors. P-values less than 0.05 were considered as significant.

Protection Of Human Subjects
1) Permission
2) An informed consent

4. Results

A total of 404 patients were monitored, among the 41 patients who were experienced ADR to Antipsychotic medications, 20 (48.7%) were males and 21 (51.2%) were females. The average age of the patients who experienced ADR was found to be 29 to 58 years. The maximum numbers of ADRs were documented in the age group of 29 to 38 (34.1%). The prescribed number of drugs 80.4 % were single drug and 19.55 were two drugs (combination therapy) of Antipsychotics.

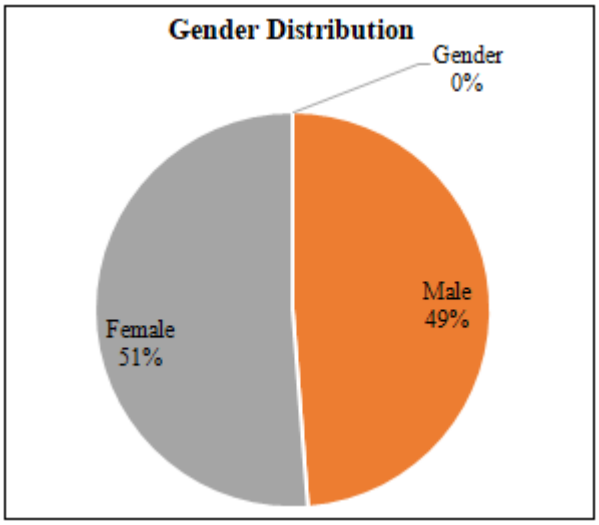

Figure 1

The above figure reveals that the study participant 51% were females and 49% were males.

Table I, N= 41

Age Distribution in this study	Number	Percentage
19- 28	6	14.6%
29-38	14	34.1%
39-48	10	23.4%
49-58	8	19.5%
59-68	3	7.3%

The above table reveals that the maximum ADR documented from the age group of 28 to 38 (34.1%)

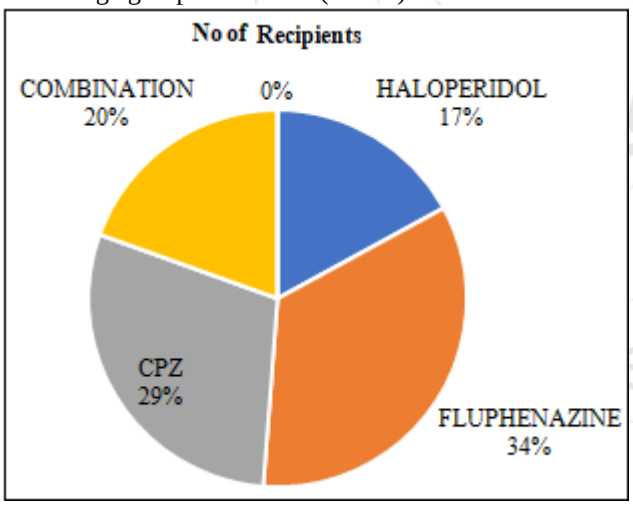

Figure II

The above figure states that maximum number of participants who were developed ADR from Fluphenazine.

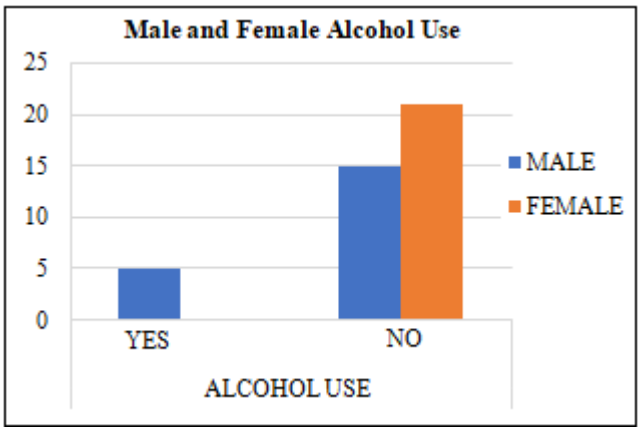

Figure III

The above figure reveals that the 12.1% from males were alcoholic and 87.8% were non-alcoholic from both the gender.

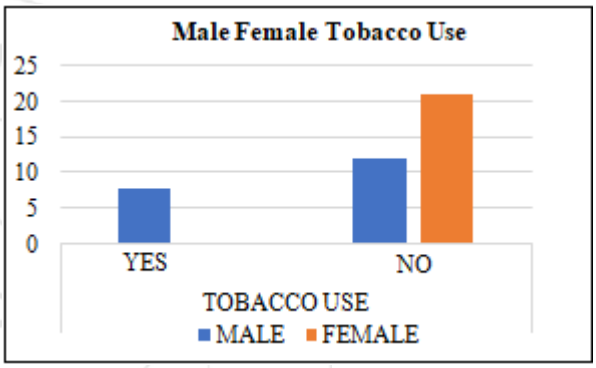

Figure IV

The above figure reveals that the 19.5% from males were Tobacco users and 80.4% were non-Tobacco users from both the gender.

Adverse Event by System Organ Class

System affected	*Percentage in each system*
Central Nervous System Tremors (6) Somnolence (3) Dizziness (7) Headache (2) Cognitive disturbance **EPSE** Akathisia(7) Rabbit neck syndrome (0) Tardive dyskinesia (2) Pseudo parkinsonism (4)	75.6%
Gastro Intestinal System Constipation (2) Nausea (0) Epigastric discomfort (1) Dry mouth (3) Hypersalivation (2)	19.5%
Metabolic and nutritional disorder Weight gain (1) Anorexia (0)	2.4%
Cardio vascular system Palpitation (0) Orthostatic/Postural hypotension (0)	0 %
Psychiatric disorder	0%

Anxiety (0)	
Urinary system Urinary hesitancy (0) Polyuria (0)	0%
Reproductive system Oligomenorrhea (1) Reduced libido (1)	4.8%
General disorder Fatigue (2)	4.8%

The above table reveals that the major ADR (75.6%) were found in Central Nervous System and 19.5% were from Gastro Intestinal System.

5. Discussion

A total of 404 patients were monitored, among the 41 patients who were experienced ADR to Antipsychotic medications, 20 (48.7%) were males and 21 (51.2%) were females. It is well-reported that ADRs are slightly more common in females, and the present study showed the same.

The mean age (36.5 years) of patients presented with ADRs falls within the range observed in Sengupta et al. study. Approximately, one-third of the patients were at the age of 29-38 years. One of the reasons could be that onset of the most of the psychiatric disorders such as schizophrenia and psychosis were typically begun at adult hood. [5]One of the reasons could be that psychiatrists possibly consider the special requirements of elderly and paediatric patients and monitor them more intensively, prescribe lower dosages or avoid high-risk drugs and dangerous combinations thus reduces the risks of ADRs in these patients.

[5]CNS and application site disorders were the most commonly affected system organ class in patients; gastrointestinal system disorders and metabolic and nutritional disorders too. The most common organ system affected by ADRs was the CNS and peripheral nervous system (48.7%). This finding is immensely correlated with the most of the Indian studies. This result perhaps may due to the pharmacological actions of the drugs implicated in ADRs. EPS accounted for almost 50% of the CNS and peripheral nervous system ADRs. In all these cases the suspected drug was withheld. [6]The second most commonly reported ADR in CNS was dizziness and tremors. For most of our patients, tremors and dizziness were self-limiting, but patients with distressing and troublesome tremors were managed by dose reduction. The most metabolic and reproductive adverse effects observed in our study include weight gain, Decreased Libido and oligomenorrhea. Weight gain can be controlled by weight reduction programme but Decreased libido reason should first rule out properly it could be aging or medical condition.

Tardive dyskinesia, which is a remote side effect and shown only after years associated with Antipsychotics. It was observed that limited numbers of patients were on Fluphenazine.

6. Conclusion

Extrapyramidal symptoms were most common ADRs in our study followed by anticholinergic side effects from Gastro intestinal system. Fluphenazine was most commonly prescribed drug followed by chlorpromazine. This study thus adds to the existing information on prevalence of adverse effects to typical antipsychotic drugs. Although antipsychotics clearly reduce the morbidity and mortality of psychiatric illness, they may also be associated with adverse side-effects, which often cause distress to the patient and may lead to noncompliance. Thus, the recognition of these side-effects and their management can lead to strategies, which ensure optimal care for the patient.

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