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Original Article

DRUG UTILIZATION STUDY OF ANTIPSYCHOTICS AND ITS COMMON ADR'S IN THE PSYCHIATRY OPD OF OHRC

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ABSTRACT

Objective

- To determine the safety and efficacy of the drug used.
- To analyze drug utilization pattern.
- To identify the ADR's caused by psychotropic drugs

Methods: IRB approval was obtained and a hospital based cross sectional study was carried out at psychiatric OPD of OHRC. 500 prescriptions were collected and information was recorded in data collection form and analyzed.

Results: From 500 prescriptions, 46.8% of prescriptions were of males and 53.2% of prescriptions were of females. Schizophrenia accounted for 29.6% of prescriptions whereas, 38.4% were of mood disorder, 21.6% were of anxiety and 10.4% were of other disorders.Drug Utilization Pattern in different psychiatric disorders**:** Mood disorder was the most common diagnosis followed by schizophrenia and anxiety. In mood disorder, the most commonly prescribed drug was escitalopram and the least commonly prescribed drug was fluoxetine. In schizophrenia the most commonly prescribed drug was diazepam and the least commonly prescribed drug was aripiprazole. In anxiety, the most commonly prescribed drug was clonazepam and the least commonly prescribed drug was haloperidol. PDD/DDD ratio of escitalopram and sodium valproate was nearer to one.

Conclusion: In this study we get to know about the current prescribing trend of the psychotropic drugs and we also came to know the corresponding ADR'S of the drugs prescribed.

Keywords: Psychiatry, Schizophrenia, aripiprazole.

INTRODUCTION

According to WHO, Drug Utilization Study is defined as study of marketing, distribution, prescription and uses of drugs in a society highlighting on the resulting medical, social and economic consequences[1-3]. However, their utilization in actual clinical practice, effectiveness and safety in real life situation need continuous study [1]. Use of antipsychotic medications entails a difficult trade-off between the benefit of alleviating psychotic symptoms and the risk of life-shortening adverse effects. All antipsychotic medications are associated with an increased likelihood of sedation, sexual dysfunction, postural hypotension, cardiac arrhythmia, and sudden cardiac death. Primary care physicians should understand the individual adverse effect profiles of these medication. The increased interest in DUR has resulted from recognition of the virtual explosion in the marketing of new drugs, the wide variation in the patterns of the drug in prescribing and consumption[4]. They should be vigilant for the occurrence of adverse effects, be willing to adjust or change medications as needed and be prepared to treat any resulting medical sequel**.** According to medical aspects, there is need to balance between the risk and the benefits. The benefits are measured on the basis of drug efficacy in preventing, relieving and curing disease or else by symptoms and complications. Risk includes short term and long term side effects including special risk factor which are associated with genetics, disease, environment, age, sex, pregnancy and lactation. A social aspect primarily deals with the impact of the drug in the society. It includes the usage of drug by the people and ongoing treatment trends [2]. Antipsychotics are the drugs which are able to reduce psychotic's symptoms in a wide range of conditions like major depressive disorder, schizophrenia, Bipolar disorder, psychotic depression. Psychosis is a serious mental disorder characterized by thinking and emotions that are so impaired, that they indicate that the person experiencing them has lost contact with reality. Common psychotic disorders are mood disorder with psychotic features, delusion disorder and schizophrenia. There are two groups of mood disorder broadly recognized; the division is mania and depression. Antipsychotic prescription pattern varies in different countries and regions due to variation in health care policies. There are depressive disorders, of which the best-known and most researched is major depressive disorder. The current study was conducted to evaluate the prescribing pattern of Antipsychotics and its common adverse effects.

MATERIAL AND METHODS

Study Design

A retrospective cross sectional study was conducted after taking Institutional review board approval in psychiatry outpatient department (OPD) of Owaisi Hospital and research center Hyderabad, India.

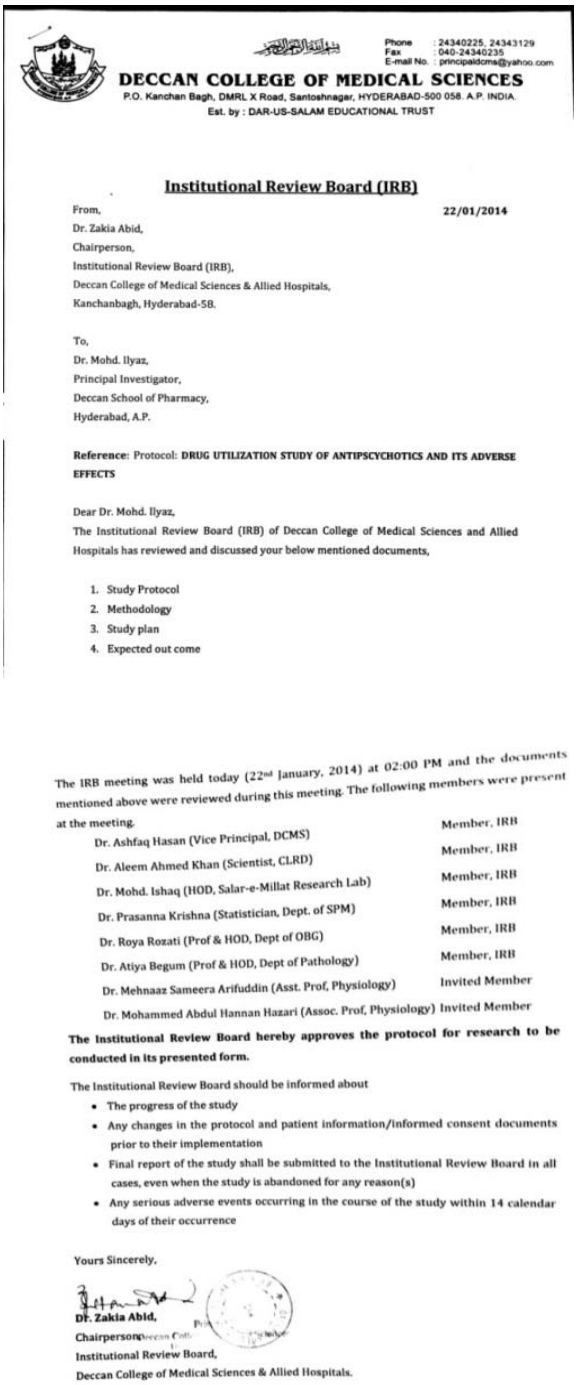
Selection criteriass

- Prescription of patients irrespective of age and sex were collected.
- The study population included all patients whose diagnosis/ clinical history suggest a neuropsychiatric disorder and those patients for whom an antipsychotic agent was prescribed either as main drug or concomitantly with other drug.

Exclusion Criteria

- Pregnant women, lactating women, those unable to comply due to mental retardation or unconsciousness.

• Epilepsy patients and those patients who are unable to speak were excluded.



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Institutional Review Board (IRB)

From, 22/01/2014
Dr. Zakia Abid,
Chairperson,
Institutional Review Board (IRB),
Deccan College of Medical Sciences & Allied Hospitals,
Kanchanbagh, Hyderabad-58.

To,
Dr. Mohd. Ilyaz,
Principal Investigator,
Deccan School of Pharmacy,
Hyderabad, A.P.

Reference: Protocol: **DRUG UTILIZATION STUDY OF ANTIPSCYCHOTICS AND ITS ADVERSE EFFECTS**

Dear Dr. Mohd. Ilyaz,
The Institutional Review Board (IRB) of Deccan College of Medical Sciences and Allied Hospitals has reviewed and discussed your below mentioned documents,

1. Study Protocol
2. Methodology
3. Study plan
4. Expected out come

The IRB meeting was held today (22nd January, 2014) at 02:00 PM and the documents mentioned above were reviewed during this meeting. The following members were present at the meeting.

Dr. Ashfaq Hasan (Vice Principal, DCMS)	Member, IRB
Dr. Aleem Ahmed Khan (Scientist, CLRD)	Member, IRB
Dr. Mohd. Ishaq (HOD, Salar-e-Millat Research Lab)	Member, IRB
Dr. Prasanna Krishna (Statistician, Dept. of SPM)	Member, IRB
Dr. Roya Rozati (Prof & HOD, Dept of OBG)	Member, IRB
Dr. Atiya Begum (Prof & HOD, Dept of Pathology)	Member, IRB
Dr. Mehnaaz Sameera Arifuddin (Asst. Prof, Physiology)	Invited Member
Dr. Mohammed Abdul Hannan Hazari (Assoc. Prof, Physiology)	Invited Member

The Institutional Review Board hereby approves the protocol for research to be conducted in its presented form.

The Institutional Review Board should be informed about

- The progress of the study
- Any changes in the protocol and patient information/informed consent documents prior to their implementation
- Final report of the study shall be submitted to the Institutional Review Board in all cases, even when the study is abandoned for any reason(s)
- Any serious adverse events occurring in the course of the study within 14 calendar days of their occurrence

Yours Sincerely,

Dr. Zakia Abid,
Chairperson
Institutional Review Board,
Deccan College of Medical Sciences & Allied Hospitals.

Study Duration

The duration of the study was six months (December 2013-May 2014).

Study Population

The present study was conducted on 500 patients who visited the psychiatric outpatient department during December 2013-May2014.

Data Analysis

The following data was collected

a. Patient details like age, gender etc.

b. Patient diagnosis.

c. Prescription details like date, the number of drugs, names of individual drugs.

d. The adverse effects were reported according to the WHO causality assessment scale.

The data analysis was done as follows

1. Assessment of prescription pattern as per WHO drug use indicator.

2. The prescribed drugs were classified according to the Anatomical Therapeutic classification (ATC)-Defined Daily Dose (DDD) Classification.[4]

3. The prescribed Daily Dose (PDD) was calculated by taking the average of the daily doses of psychotropic drugs as the PDD. The PDD to DDD ratio was then calculated[4].

Statistical Analysis

The data collected was analysed with the following criteria- level of significance was fixed at 5%($p<0.005$) with 95% confidence interval. The chi-square test was used and all statistical calculation was carried out with open Epi: A web based epidemiological and statistical calculator[4].

RESULTS AND DISCUSSION

Characteristics of study participants

• Out of 500 patients, males and females were 46.8% and 53.2% respectively.
• Relative distribution of different psychiatric disorders in different age groups and gender is shown in the graph.

Pattern of psychiatric disorders

29.6% of prescription was of schizophrenia, 38.4% of prescription was of mood disorder, 21.6% of prescription was of anxiety. The disorders like childhood behavioural disorder, substance abuse disorder etc were grouped as other psychiatric illness (10.4%).

Table 1: Distribution of psychiatric disorder based on age

Age	Schizophrenia	Mood disorder	Anxiety	Other
<20	13	14	8	6
20-40	95	106	59	31
41-60	16	50	34	13
>60	24	22	7	2

Table 2: Distribution of psychiatric disorder based on gender

Gender	Schizophrenia	Mood disorder	Anxiety	Other
Male	74	91	43	26
Female	74	101	65	26

Table 3: Distribution of psychiatric disorder based on disease

S. No.	Diseased condition	No. of males	No. of females
1	Schizophrenia	74	74
2	Mood disorder	91	101
3	Anxiety disorder	43	65
4	Others	26	26

Table 4: Pattern of psychotropic drug use as per ATC/DDD classification

S. No.	Drug use indicator	Result
1	Total no of drugs prescribed	1407
2	Average no of drugs per prescription	4.74
3	Total no of psychotropic drugs prescribed	1211
4	Average no of psychotropic drugs per prescription	3.64

Table 5: Distribution of psychiatric disorder

S. No.	Psychiatry disorder	No. of patients
1	Schizophrenia	148
2	Mood disorder	192
3	Anxiety disorder	108
4	Others	52

Assessment of prescription pattern, as per various drug use indicators in a sample of 500 patients attending psychiatric outpatient department. Total no. of drugs prescribed for 500 patients is 1407, Mean of drugs prescribed per prescription is 4.74, Total no. of psychotropic drugs prescribed is 1211, The other drugs commonly co-prescribed were vitamin B complex, multivitamins, PPI's etc.

Table 6: Percentage of drug utilized in schizophrenia

S. No.	Name of drug	% of drug utilized
1	Resperidone	40.8
2	Olanzepine	4.02
3	Quetipine	8.62
4	Amisulpiride	4.02
5	Aripiprazole	0.57
6	Diazepam	41.95

Table 7: Percentage of drug utilized in anxiety

S. No.	Name of the drug	% of drug utilized
1	Clonazepam	42.55
2	Imipramine	14.18
3	Haloperidol	1.41
4	Resperidon	29.07
5	Olanzepine	3.54
6	Etizolam	2.83
7	TCA	6.38

Profile of study patients

More female patients visited the psychiatry OPD than men., Reproductive age group (20-40years) accounted for majority of psychiatric disorders.[4]

Prescription pattern analysis

Total no. of drugs prescribed for 500 patients is 1407, Mean of drugs prescribed per prescription is 4.74, Total no. of psychotropic drugs prescribed is 1211, Mean of psychotropic drugs per prescription is 3.64[4].

Observed drug use pattern in mood disorder

SSRI's were more commonly prescribed. Imipramine was 1.68% prescribed. Fluvoxamine was 0.33% prescribed. Escitalopram was 40.70% prescribed. Mirtazepam was 5.57% prescribed. Clonazepam was 8.44% prescribed. Lithium was 0.33% prescribed. Quitiapine was 2.02% prescribed. Olanzapine was 0.84% prescribed. Divalproex was 20.27% prescribed. Valproate was 19.76% prescribed.[4]

Table 8: Percentage of drug utilized in mood disorder

S. No.	Name of the drug	% of drug utilized
1	Imipramine	1.68
2	Fluoxetine	0.33
3	Escitalopram	40.70
4	Mirtazipam	5.57
5	Clonazepam	8.44
6	Lithium	0.33
7	Quetipine	2.02
8	Divaloproex	20.27
9	Olanzepine	0.84
10	Valproate	19.76

Table 9: Adverse drug reaction reported in our study

Adverse drug reaction	No of cases(%) n=67
Tremor	14(20.89%)
Extrapyrimdal symptoms	10(14.92%)
Insomnia	7(10.44%)
Weight gain	7(10.44%)
Anxiety	7(10.44%)
Constipation	4(5.97%)
Irritability	3(4.47%)
Drying of mouth	4(5.97%)
Alopecia	4(5.97%)
Anemia	4(5.97%)
Hyperglycemia	2(2.98%)
Nausea	3(4.47%)

Observed drug use pattern in anxiety

Clonazepam was more commonly prescribed drug (42.55%). Imipramine was 14.18% prescribed. Haloperidol was 1.41% prescribed. Resperidone was 29.07% prescribed. Olanzapine was 3.54% prescribed. Etizolaam was 2.83% prescribed. TCA was 6.38% prescribed.[4]

Observed drug use pattern in schizophrenia

Atypical antipsychotics were more commonly prescribed. Among all resperidone was 40.8% prescribed. Olanzapine was 4.02% prescribed. Quetiapine was 8.62% prescribed. Amisulpiride was 4.02% prescribed. Aripiprazole was 0.57% prescribed. Diazepam was 41.95% prescribed[4].

Table 10: PDD Values and PDD/DDD Ratio of psychotropic drugs prescribed in a sample of 500 patients

S. No.	Drug	ATC code	DDD(mg)	PDD(mg)	PDD/DDD
1	Escitalopram	N06AB10	10	6.42	0.642
2	Imipramine	N06AA02	100	3.8	380
3	Quetipine	N05AH04	0.4	34.4	0.086
4	Sodium valproate	NO3AG01	1500	855	0.54
5	Clonazepam	NO3AE01	8	2.22	0.227
6	Aripiprazole	N05AX12	15	0.03	0.002
7	Olanzepine	N05AH03	10	0.36	0.036
8	Lithium	N05AN01	24	0.027	0.187
9	Resperidone	N05AX08	5	1.01	0.202
10	Amisulperide	N05AL05	0.4	5.6	0.014
11	Chlordiazepoxide	N05BA02	30	0.42	0.014

CONCLUSION

Mood disorder was the most common diagnosis followed by schizophrenia and anxiety. In mood disorder the most commonly prescribed drug was escitalopram and the least prescribed drug was fluoxetine.

• In schizophrenia the most commonly prescribed drug was diazepam. The least commonly prescribed drug was Aripiprazole.

• In Anxiety the most commonly prescribed drug was clonazepam. The least commonly prescribed drug was haloperidol.

Thus the current prescribing trends were studied

CONFLICTS OF INTEREST

There is no conflict of interest.

ACKNOWLEDGEMENTS

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