# ADVERSE DRUG REACTION PATTERN OF ANTI DEPRESSANT DRUGS PRESCRIBED IN PSYCHIATRY OUT-PATIENT DEPARTMENT IN A TERTIARY CARE HOSPITAL

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**Abstract :** OBJECTIVE To study the pattern of adverse drug reactions (ADRs) of anti depressant drugs in patients attending the Psychiatry out-patient department in a tertiary care hospital METHODOLOGY 400 Patients receiving antidepressant drugs as monotherapy at psychiatry outpatient department, in a tertiary care hospital were enrolled in the study. Duration of study was 2 months from September 2014 to October 2014. Adverse drug reactions were documented and analysed. Causality assessment of ADR was done using WHO causality assessment scale. Severity assessment was done using modified Hartwig Siegel causality assessment scale. RESULTS Most of the patients were in the age group of 31-40 years. Male constituted 26 percentage and female 74 percentage of population. Imipramine was the most commonly prescribed antidepressant drug as monotherapy. Among 400 patients 298 patients developed ADR. Postural dizziness were more common with Imipramine (31percentage) and Amitriptyline(23 percentage). Insomnia (41percentage) and Anxiety (27 percentage) were more common with Fluoxetine. 67 percentage of ADRs came under possible category of WHO causality assessment scale. 95percentage of ADRs fell under mild category of severity assessment scale. CONCLUSION Imipramine was the most commonly prescribed antidepressant drug as monotherapy. 75 percentage of patients developed at least one adverse drug reaction Most of ADRs were mild and comes under Possible category of WHO causality assessment scale.

**Keyword :** Antidepressant drugs, ADRs, Side effects.

An adverse drug reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in humans for the prophylaxis, diagnosis, and treatment of disease, or for modification of physiological function.1 Drugs can be remarkably beneficial and improve the quality of life by reducing the signs and symptoms associated with disease. However, most of the drugs produce some adverse effects even if used properly. As innovation in medicine continues and as the new medicines are being developed, there is potential for the occurrence of increasing number of ADRs. Generally the drugs act by interfering with one or more aspects of molecular and cellular function, all of them have the risk of producing some reaction which may not be desirable all the times. 10-15% of all patients receiving medications are affected by ADR2. The incidence of serious ADRs is 6.7 %. ADR accounts for 5 to 9 %3

of hospital expenditure and almost 1 lakh death globally per year4. ADRs has been recognised as a major public health issue since they contribute to a sizeable percentage of hospital admissions and also an economic burden to the society. Hence one of the goals of pharmacotherapy is to ensure that, the risks associated with the drugs are kept as low as possible. The depressive illnesses are important because of their chronicity and the inherent risk of suicides associated with the disease. 5 Anti depressant medications are the main mode of treatment. These drugs have their primary effects on the serotonergic or noradrenergic neurotransmitter systems.6 As the incidence of depressive illness is on increase, the use of anti depressant drugs is also increasing day by day. These drugs are capable of causing a number of adverse drug reactions (ADR), some of which are serious. ADRs associated with anti depressant drugs, as such any drug can lead to noncompliance and at times discontinuation of therapy. Hence, a proper data about the adverse effects helps the physicians to prescribe drugs, balancing the benefits and hazards. Pharmacovigilance in Psychiatry units can play a vital role in detecting ADRs and alerting physicians to the possibility of such events, thereby protecting the patients from avoidable harm.7 This prompted us to evaluate the ADR profile of anti depressant drugs prescribed to the patients in a tertiary care hospital.

**STUDY OBJECTIVE:**
To study the pattern of adverse drug reactions of anti depressant drugs in patients attending the Psychiatry out- patient department in a tertiary care hospital

**STUDY DESIGN:**
Prospective, observational study.

**STUDY POPULATION:**
Patients receiving antidepressant drugs as monotherapy at psychiatry out-patient department in a tertiary care hospital.

**SAMPLE SIZE**: 400 patients

**STUDY DURATION**: 2 months.

**STUDY PERIOD:** September 2014 - October 2014

**INCLUSION CRITERIA:**
1. Age : 19-70 years
2. Gender: both male and female
3. Patients on anti depressant drug as monotherapy.
4. Patients willing to give informed consent.

**EXCLUSION CRITERIA:**
1. Patient with other medical co-morbidities.
2. Patients not willing to give informed consent.
**STUDY PROCEDURE:**
Patients with chronic depressive illness receiving treatment with antidepressant drugs at the out patient department of Psychiatry were explained about the study purpose in their local language. Informed consent was obtained from those who were willing to participate in the study. When the patient could not understand the purpose of the study, the same was explained to their caretakers /relatives and informed consent was obtained from them. Study conducted as per ICH-GCP guidelines after Istitutional Ethics Committee approval. Anti depressant drugs are issued every fortnightly to the patients in psychiatry OPD. The routine anti depressant drugs prescribed in our Psychiatry out-patient department are, Tab.Imipramine 25 mg, Tab.Amitriptyline 25 mg , Cap.Fluoxetine 20 mg.The patients receiving above drugs were enrolled in the study.
The following parameters were recorded:
Ø Age
Ø Gender
Ø Prescribing pattern of Anti depressant drugs
Ø Adverse drug reaction pattern
-incidence
-severity
Causality assessment of the ADR was done by establishing the temporal association of drug with ADR using WHO causality assessment scale and Severity assessment was done by using modified Hartwig Siegel scale. Data were entered into Excel spreadsheets and descriptive statistics was used to analyse the data.
**RESULTS**
**I. DEMOGRAPHIC PROFILE OF THE STUDY POPULATION**
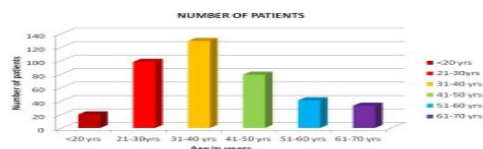**A.      AGE DISTRIBUTION**



Figure 1: Age distribution
- Most of the patients were in the age group of 31- 40 years.

**B. SEX DISTRIBUTION**

TABLE 1

| SEX | NUMBER OF    PATIENTS | PERCENTAGE |
|---|---|---|
| MALE | 105 | 26% |
| FEMALE | 295 | 74% |
| TOTAL | 400 | 100% |

Table: 1 represents the sex distribution of the patients.
- Male to Female ratio was 1: 2.8

**II.PRESCRIBING PATTERN OF ANTIDEPRESSANTS**

TABLE 2

| ANTI-DEPRESSANT DRUGS | NUMBER OF PRESCRIPTIONS | PERCENTAGE |
|---|---|---|
| IMIPRAMINE | 181 | 45% |
| AMITRIPTYLINE | 98 | 25% |
| FLUOXETINE | 121 | 30% |
| TOTAL | 400 | 100% |

Table: 2 show the prescribing pattern of anti-depressants. Imipramine was the most commonly prescribed anti-depressant drug as monotherapy.

**III. ADVERSE DRUG REACTIONS ENCOUNTERED**

TABLE 3

| ADR | NO OF PATIENTS | PERCENTAGE |
|---|---|---|
| PATIENTS WITH ADRs | 298 | 75% |
| PATIENTS WITHOUT ADRs | 102 | 25% |
| TOTAL | 400 | 100% |

Table: 3 gives percentage of patients with ADRs

**IV.PATTERN OF ADVERSE DRUG REACTIONS:**

**A.   ADVERSE DRUG REACTION PATTERN OF IMIPRAMINE**

TABLE 4

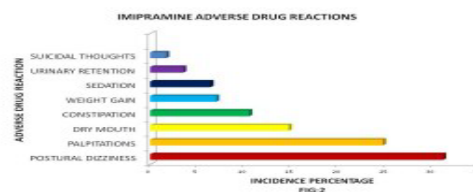| ADVERSE DRUG REACTIONS | NO.OF ADRs | PERCENTAGE (%) |
|---|---|---|
| POSTURAL DIZZINESS | 53 | 31.1 |
| PALPITATIONS | 42 | 24.7 |
| DRY MOUTH | 25 | 14.7 |
| CONSTIPATION | 18 | 10.5 |
| WEIGHT GAIN | 12 | 7.0 |
| SEDATION | 11 | 6.4 |
| URINARY RETENTION | 6 | 3.5 |
| SUICIDAL THOUGHTS | 3 | 1.7 |
| TOTAL | 170 | |

**FIGURE 2**



Table 4 and Figure 2 represents the adverse drug reaction pattern of Imipramine in our study. Postural dizziness was the most common ADR (31.1%)

**B. ADVERSE DRUG REACTION PATTERN OF AMITRIPTYLINE**

TABLE 5

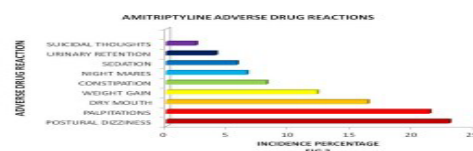| ADVERSE DRUG REACTIONS | NO.OF ADRs | PERCENTAGE (%) |
|---|---|---|
| POSTURAL DIZZINESS | 28 | 22.9 |
| PALPITATIONS | 26 | 21.3 |
| DRY MOUTH | 20 | 16.3 |
| WEIGHT GAIN | 15 | 12.2 |
| CONSTIPATION | 10 | 8.1 |
| NIGHTMARES | 8 | 6.5 |
| SEDATION | 7 | 5.7 |
| URINARY RETENTION | 5 | 4 |
| SUICIDAL THOUGHTS | 3 | 2.4 |
| TOTAL | 122 | |

**FIGURE 3**
Table



Table 5 and Figure 3 represents adverse drug reaction pattern of Amitriptyline in our study. Postural dizziness was the most common ADR (22.9%)

**C.ADVERSE DRUG REACTIONS PATTERN OF FLUOXETINE:**

TABLE 6

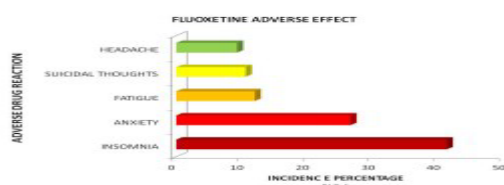| ADVERSE DRUG REACTIONS | NO.OF PATIENTS | PERCENTAGE (%) |
|---|---|---|
| INSOMNIA | 31 | 41.3 |
| ANXIETY | 20 | 26.6 |
| FATIGUE | 9 | 12.0 |
| SUICIDAL THOUGHTS | 8 | 10.6 |
| HEAD ACHE | 7 | 9.3 |
| TOTAL | 75 | |

**FIGURE 4**



Table 6 and Figure 4 represent the adverse drug reaction pattern of Fluoxetine in our study. Insomnia (41.3%) was the most common ADR.

**V. SEVERITY ASSESSMENT**

Table 7

| ASSESSMENT CATEGORY | NO.OF ADRs | PERCENTAGE |
|---|---|---|
| MILD | 350 | 95% |
| MODERATE | 17 | 5% |
| SEVERE | 0 | 0% |
| TOTAL | 367 | 100% |

Table 7: shows the severity assessment of adverse drug reactions using modified Hartwig Siegel scale.

**VI. CAUSALITY ASSESSMENT:**

Table 8

| ASSESSMENT CATEGORY | NO.OF ADRs | PERCENTAGE |
|---|---|---|
| CERTAIN | 0 | 0% |
| PROBABLE | 120 | 33% |
| POSSIBLE | 247 | 67% |
| TOTAL | 367 | 100% |

Table 8: represents the Causality assessment of adverse drug reactions using WHO causality assessment scale

**DISCUSSION:**

Depression is a growing worldwide health problem associated with increased morbidity and also mortality. As a result of their high prevalence, onset at an earlier age and chronic persistence, they contribute substantially to the burden of illness worldwide. In our study, 400 patients were evaluated for adverse drug reactions. Most of the patients were in the age group of 31- 40 years. Females constituted 74% and Males 26% of test population. Among 400 patients who were on anti depressant drugs, 75% of patients (298 patients) developed at least one adverse drug reaction Postural dizziness and palpitations were more common in patients taking Imipamine & Amitriptyline . Insomia was the most common ADR encountered in patients taking Fluoxetine, hence

Fluoxetine was less favoured by our hospital psychiatrist as monotherapy . About 67% of ADR comes under Possible category of WHO causality assessment scale. Most of the ADRs were mild which did not require discontinuation of therapy . The adverse drug reaction pattern reported in our study differs with the results of western studies conducted by Rudolf Uher et al. 8 Their study shows anticholinergic side effects (dry mouth, constipation) were more common with tricyclic anti depressants , which necessitates need for more studies to uncover the ADR profile in Indian scenario. Our study offers a representative idea of the ADR profile of anti depressant drugs in India. Constant vigil in detecting ADRs and subsequent dose adjustments can make therapy with anti depressant drugs safer and more effective. This in turn, will improve compliance in patients with depressive illness.

**CONCLUSION:**

From our study we conclude that, Imipramine was the most commonly prescribed Anti depressant drug as monotherapy. 75% of patients developed at least one adverse drug reaction Most of ADRs were mild and comes under Possible category of WHO causality assessment scale.

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