A Study on Adverse Effects of Antidepressants in a tertiary care teaching hospital

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Abstract
Objective: To identify the adverse effects of antidepressants at the initiation of therapy. To make causality assessment of the adverse effect identified using WHO ADR probability scale.

Materials and Methods: Patients prescribed with at least one antidepressant were randomly selected and monitored for adverse drug reactions (ADRs), irrespective of their age and gender.

Results: Of the 100 patients who received antidepressants, 33 patients experienced 10 ADRs. Selective serotonin receptor inhibitors (SSRIs) were the most common therapeutic class of drugs associated with ADRs. Gastrointestinal system was most commonly affected system organ class. Gastritis and dry mouth were the most frequently reported ADRs. Majority of the ADRs were ‘mild’ in their severity.

Conclusion: In this study, incidence of adverse reaction to antidepressants was 32% and the most common group of Antidepressants implicated are SSRIs.

Introduction
Depression is a heterogeneous disorder that affects person’s mood, physical health and behavior. Patients with major depression have symptoms that reflect changes in brain monoamine transmitters, specifically norepinephrine, serotonin and dopamine. [1]

Major depression represents a significant public health problem worldwide. The high prevalence of suicide in depressed patients (up to 15%), coupled with complications arising from stress and its effects on the cardiovascular system, have suggested that it will be the second leading cause of death by the year 2020 and studies show depression as a contributory factor to fatal coronary disease. [2]

Despite the advent of new molecules in the pharmacotherapy of depression, many cases of depression are undiagnosed and untreated. Although the currently prescribed molecules provide some improvement in the clinical condition of the patient, it is at the cost of bearing the burden of their adverse effects. ADRs associated with psychotropic drugs can lead to noncompliance, and at times discontinuation of therapy. [3-4]

The rate of ADRs due to psychiatric hospitalization has been reported to be 4.2 events per hundred admissions. Moreover 10/1000 patient days in psychiatric hospital are due to ADRs.[5]

This study is focused to identify the adverse effects of antidepressants in a tertiary care teaching hospital.

Objectives
- To identify the adverse effects of antidepressants at the initiation of therapy
- To make a causality assessment of the adverse effect identified using WHO ADR probability scale

Materials and Methods
The study was carried out in the Psychiatry department in a tertiary care teaching hospital in Kancheepuram district in Tamilnadu after obtaining the Institutional Ethical Committee approval (No: 2018/389). Patients of any age and either gender who presented with clinical features suggestive of Depression who reported ADR after initiation of antidepressants were taken into study. Review was done to identify any new symptoms that were not present prior to the start of the drug therapy. Drugs received and ADRs experienced by the study patients were recorded. If an adverse event was identified/ reported, causality of suspected ADR was established using the WHO probability scale. 32 patients of the newly diagnosed 100 patients over a period of 6 months reported ADRs. The reported ADRs were collected and analyzed.

Results
Of the reported 32 ADRs, the common system to be involved was gastrointestinal system, with Nausea, Vomiting and Gastritis accounting for 1/3rd of the cases. The other ADRs reported were as below in the Figure 1.
Among the above drugs, Fluoxetine was the most commonly prescribed drug. But cases of gastritis, nausea and vomiting were reported with Fluoxetine. Sertraline was better tolerated drug. Mirtazapine led to sleep disturbances and weight gain in some patients. Two cases of sexual dysfunction in the form of impotence were also reported with Fluoxetine. Venlafaxine was a better tolerated drug, but due to its cost factor it was used only for a fewer patients.

Though Fluoxetine caused GIT disturbances, it was the most commonly prescribed drug, considering its cost and therapeutic efficacy.

Discussion

The prevalence of ADRs to antidepressants prescribed in our study was 32%, which was higher when compared to a study (26.87%) conducted by Swati et al (Indian study) and a western study (1.87%) conducted by Grohmann et al. The difference could be because of the variations in the methodology utilised. Our study included both inpatients as well as outpatients and while Swati et al study included only outpatients [6-7].

The most common organ system affected by ADR was gastrointestinal system (57.5%). This finding is in contrast to the study conducted by Swathi et al wherein cardiovascular system was the major system affected by the ADR. Nausea, vomiting, dry mouth and Gastritis were the most commonly reported ADRs. This may be attributed to the possible pharmacological actions of the drugs implicated in causing ADRs. This finding is in contrast to the study conducted by Swathi et al, wherein insomnia was the most commonly reported ADR. This difference could be due to the reasons that in our study, SSRI were the most commonly prescribed class of drugs. SSRIs have minimal effects on histamine H1 receptors and therefore can cause less sleep disturbances than other antidepressants. We also observed 2 cases of weight gain over a period of 12 weeks. It is well known that antidepressants like mirtazapine can increase appetite and carbohydrate craving and that may lead to significant weight gain[8].

Majority of the ADRs were due to SSRIs. This could be attributed to increased frequency of used prescription of these drugs due to lesser ADRs. When assessed by using the WHO probability scale, none of the ADRs belonged to ‘certain’ in their causality assessment, rechallenge was not attempted in all those cases where dechallenge was done. This finding can immensely be correlated with the most of the Indian studies6 but in contrast to Brazilian study wherein 24 cases were categorized as ‘definite’ in their causality category after the positive rechallenge[9]. Most of the reported ADRs were ‘mild’ to ‘moderate’ in their severity and hence did not require withdrawal of the suspected drug when the benefits outweighed the risk. None of the reported ADRs in our study was fatal.

Conclusion

In our study SSRI were the most commonly used antidepressants and at the same time they were the one to cause ADRs as well. Fluoxetine was commonly prescribed...
drug along with other drugs like Venlafaxine and mirtazapine. Gastrointestinal system was most commonly involved where ADRs like Nausea, Vomiting, Gastritis and Dry mouth were reported. Most of the reported ADRs were mild to moderate in their severity and hence did not require withdrawal of the suspected drug when the benefits outweighed the risk. None of the reported ADRs in our study was fatal.

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