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Original Article

Assessment of Adverse Drug Reactions in Treating Common Mental Health Disorders-Findings from a Tertiary Care Teaching Hospital in Puducherry

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ABSTRACT

Background: As per National Institute for Health and Care Excellence (NICE) guidelines, depression and anxiety are common mental health disorders. Antidepressants are used in the treatment of these disorders. It is well acknowledged that antidepressants can lead to Adverse Drug Reactions (ADRs). Comprehending the common ADRs linked to antidepressants is beneficial for improving patient safety, promoting rational prescribing practices and encouraging enhanced adherence to treatment. **Purpose:** To analyze the incidence of adverse drug reactions and evaluate their causality, severity and predictability for medications utilized in the treatment of common mental health disorders. **Materials and Methods:** This prospective longitudinal observational study was conducted in a tertiary care teaching hospital in Puducherry from July 2020 to November 2023. The participants were patients diagnosed with a common mental health disorder as per DSM-5. Participants were monitored for ADRs during every follow-up visit for 6 months from the baseline visit. **Results:** This research enrolled 216 patients and data from 144 patients who attended at least one follow-up appointment during the six-month follow-up period were included in the analysis. The overall incidence rate of ADRs was found to be 38.2%. Selective Serotonin Inhibitors (SSRIs) contributed to over 60% of the reported ADRs. The majority of reactions were classified as possible (85.8%) in causality assessment and a noteworthy proportion of these reactions were mild (63.2%) and predictable (91.5%). **Conclusion:** The research reveals a 38.2% incidence rate of ADRs. Majority of the ADRs were 'possible', 'mild' and 'predictable'. Ongoing surveillance can aid in the detection, mitigation and prevention of ADRs.

Keywords: Adverse Drug Reactions, Antidepressants, Common Mental Health Disorders, Pharmacovigilance.

INTRODUCTION

As per National Institute for Health and Care Excellence (NICE) guidelines, common mental health disorders include depression, generalized anxiety disorder, panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder and phobias. A lifetime pattern of relapse and remission is common in depression and anxiety disorders. The seriousness of these common mental health disorders differs considerably and all of them have the potential to result in significant long-term disability.[1]The primary treatment approach for these mental health disorders involves the use of antidepressants.[2,3] It is indisputable that antidepressants can lead to Adverse Drug Reactions (ADRs). While these medications typically produce comparable effects, variations exist in their safety and the adverse reactions they may induce.[4] ADRs are commonly associated with the use of medications in treating psychiatric illnesses, primarily because of the chronic nature of the diseases and the prolonged duration of the treatment process.[5] ADRs can significantly impact adherence to antidepressants and contribute to the decision to discontinue treatment.[6]

In India, ADR reporting stands at less than 1%, in contrast to the global rate of 5%. This discrepancy underscores the imperative for heightened awareness regarding Pharmacovigilance (PV) and ADR monitoring among healthcare providers and patients in the country.[7] Pharmacovigilance has been defined by the World Health Organization (WHO) as the science and activities related to the detection, assessment, understanding and prevention of adverse drug effects.[8] In psychiatry, where long duration of treatment is common, medical practitioners are in

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an advantageous position to recognize and communicate ADRs to regulatory bodies.[9] Ensuring treatment adherence is a primary objective for psychiatric patients. Maintaining a continuous watch on ADRs and making necessary dose adjustments can enhance the safety and efficacy of therapy with psychotropic drugs.[10] Detecting ADRs in the hospital setting is vital as it provides valuable insights into the risk-benefit ratio, contributing to the rational use of the drug.[11] Vigilantly observing ADRs is essential as it facilitates the identification of patients prone to such reactions and sheds light on the characteristics and types of these ADRs.[12] Consistently monitoring ADRs in mental health conditions is essential for promptly identifying and addressing ADR-related risks. This proactive strategy has the potential to elevate the standard of care, minimize overall healthcare expenses and promote better adherence to medications.[13] Initiatives aimed at enhancing the identification and reporting of ADRs by all healthcare professionals need to be implemented to safeguard patient safety.[14] Overall, monitoring the side effects of antidepressants is crucial for recognizing, managing and minimizing the risks posed by these adverse effects. With this in consideration, the study is undertaken to observe and track the adverse effects of medications prescribed for common mental health disorders.

This study aimed to analyze the incidence of adverse drug reactions and evaluate their causality, severity and predictability for medications utilized in the treatment of common mental health disorders.

MATERIALS AND METHODS

This study was conducted in the pharmacology department in collaboration with the psychiatry department at a tertiary care teaching hospital in Puducherry from July 2020 to November 2023. This was a prospective longitudinal observational study. The participants in the study were individuals diagnosed with a common mental health disorder as per DSM-5 and they consisted of both males and females aged between 18 and 65 years. The institutional ethics committee approved the study (Ref No: IEC:RC/2020/46). Written informed consent was obtained from the study participants.

The first participant was enrolled in July 2020, while the last was enrolled in May 2023. Patients were monitored for adverse effects during every follow-up visit six months from baseline. We enlisted the common adverse effects of antidepressants from existing literature and gathered baseline data for these effects from the patient at the first visit. This was done to ensure that any adverse drug reactions reported during follow-up visits could be reliably linked to the medication. Data regarding adverse drug reactions were collected from the participants if they had come at least for one follow-up visit after the recruitment. The necessary data were obtained from patients' electronic medical records and/or through interviews with patients and their family members. This information was meticulously documented using the Adverse Drug Reaction (ADR) reporting and documentation form. The overall incidence of ADR was assessed by calculating the proportion of patients who experienced at least one ADR to the total number of patients who came for at least one follow-up during the study period.

Causality was assessed using the WHO causality assessment scale. Causality is categorized into certain, probable/likely, possible, unlikely, conditional/unclassified, Unassessable / unclassifiable. The WHO causality assessment scale determines the causal relationship of a suspected drug to the ADR in question.[15] Severity was assessed using the Modified Hartwig and Siegel scale. The Modified Hartwig's and Siegel scale classifies the severity of ADR as mild, moderate and severe. Mild is again subclassified into Level 1 and Level 2. Moderate is subclassified into Level 3 and Level 4 (4 (a), 4(b)). Severe is subclassified into Levels 5, 6 and 7.[16] The Rawlins and Thompson scale was used to analyze the predictability of the reported ADRs. The ADRs were categorized as type A (dose-dependent and predictable form) and type B (idiosyncratic, no clear dose-response relationship and not predictable form) according to the system introduced by Rawlins and Thompson.[17]

Statistical analysis

Descriptive statistics was used to analyze data. Categorical variables were represented as frequencies and percentages. Continuous variables were summarised as means and standard deviations.

RESULTS

A total of 216 patients were recruited, comprising 81 males and 135 females. Out of the total 216 participants, only 144 (comprising 82 females and 62 males) attended at least one follow-up appointment within the six-month follow-up period and were included in the analysis of ADRs. Notably, 55 patients, including 32 (58%) females and 23 (42%) males, exhibited at least one ADR. The mean age of the patients who experienced ADR was 37.26±11.43 years. Out of the 55 patients assessed, 41 were diagnosed with depressive disorders and the remaining 14 were found to have anxiety disorders. Details are given in Figure 1.

The most frequently prescribed category of drug was SSRIs, with 107 (74.3%) out of 144 patients receiving it as the primary medication. The commonly prescribed SSRIs included sertraline (56 patients), escitalopram (36 patients) and fluoxetine (15 patients). Out of the 107 patients, 41 experienced at least one ADR. Tricyclic antidepressants (TCAs) were prescribed infrequently compared to other drug classes. Out of the nine patients who received TCA, namely dothiepin (seven) and imipramine (two), four of them experienced at least one ADR. Several patients had experienced more than one ADR, with 55 patients collectively reporting a total of 106 ADRs. The average

number of ADRs per patient was found to be 1.9. The majority of ADRs were attributed to SSRIs, amounting to a total of 81 cases. Among the 106 documented ADRs, 37 (34.9%) were linked to sertraline, with escitalopram responsible for 29 cases (27.4%) and fluoxetine for 15 cases (14.2%). The frequency of ADRs associated with different medications is provided in Table 1. The overall incidence rate of ADR was determined to be 38.2% in this study (55/144 ×100). The most commonly reported ADR was weight gain (13 cases) followed by fatigue (12 cases), heartburn (10 cases) and indigestion (8 cases). The drug that most commonly led to weight gain was mirtazapine. Mirtazapine was responsible for weight gain in six out of the 13 reported cases. Other drugs which caused weight gain in our study were escitalopram sertraline and fluoxetine. Fatigue was widely reported with escitalopram. Most of the ADRs were linked to the gastrointestinal system. Heartburn and indigestion were more prevalent with escitalopram, followed by sertraline. Details about the adverse drug reactions associated with the treatment of common mental health disorders are provided in Table 2.

According to the WHO causality assessment criteria, 91 ADRs (85.8%) were classified as possible, while 15 ADRs (14.2%) fell into the probable category. Causality assessment of various ADR is given in Table 3. The suspected medication was changed in seven cases and the dose was reduced in eight cases. Following the medication change, two cases recovered and five cases were recovering. Out of seven cases requiring medication changes due to ADR, five were associated with SSRIs, namely sertraline, escitalopram and fluoxetine, while the remaining two were due to mirtazapine. Among these, in four out of five cases where SSRIs were involved, they were substituted with mirtazapine, while in the remaining one case, a different SSRI was chosen. Conversely, mirtazapine was substituted with SSRIs in the remaining two cases. After lowering the dosage, all cases experienced recovery. In 14 instances, an additional medication was introduced to address and manage ADRs. In Hartwig's severity assessment scale, 67 (63.2%) ADRs were classified as mild, while 39 (36.8%) were categorized as moderate. None of the ADRs was severe. Out of the total 106 ADRs, 97 (91.5%) adverse drug reactions were considered predictable, whereas 9 (8.5%) were unpredictable. Details of severity and predictability assessment are given in Table 4.

DISCUSSION

There are two primary methods for reporting adverse drug reactions: passive (spontaneous) surveillance and active (intensive) surveillance. Passive surveillance involves a health jurisdiction receiving reports voluntarily submitted by health professionals and pharmaceutical companies, making it a cost-effective strategy. On the other hand, active surveillance entails dedicated staff consistently reaching out to healthcare providers or the population for the systematic and continuous pre-organized collection of case study information. While active surveillance provides the most accurate and timely data, it is a more expensive approach.[18] In our research, the investigator interviewed patients during their visits to the Outpatient Department (OPD) and reviewed their medical records. Additionally, we considered the spontaneous reporting provided by both doctors and patients.

In our research, we observed a higher occurrence of adverse effects among females compared to males, consistent with findings from a prospective observational study conducted in India by Sankhi *et al.*[19] Conversely, a different prospective observational study done by Kushwaha *et al.*, indicated a higher frequency of ADRs among males with antidepressants.[5] The mean age of the patients who experienced ADR was 37.26±11.43 years. The findings were similar to those of a retro-prospective observational study conducted in Nepal, where the average age of patients was reported as 40.9±/-12.8, which suggested that depression could impact individuals across a broad age spectrum.[20] Our study observed an ADR incidence rate of 38.2%. This figure is notably higher when compared to the overall incidence of 19.2% reported in a longitudinal observational study done in India by Munoli *et al.*[21] A comparable incidence rate of 42% was observed in a prospective observational study in India, which adopted active surveillance along with spontaneous reporting done by Lucca *et al.*[22]

SSRIs contributed more than 70% of the ADRs. Sertraline (37), escitalopram (29), fluoxetine (15) presented a greater number of

Table 1: Frequency of Adverse drug reactions during treatment period.

Name of the drug	Number of patients receiving each drug	Number of patients with at least one ADR	Number of ADRs (*n*=106, %)
Sertraline	56	21	37(34.9%)
Escitalopram	36	14	29(27.4 %)
Mirtazapine	25	9	18(16.9%)
Fluoxetine	15	6	15(14.2%)
Dothiepin	7	3	4(3.8%)
Venlafaxine	3	1	2(1.8%)
Imipramine	2	1	1(1%)
Total	144	55	106

Table 2: Adverse drug reaction profile in common mental health disorder treatment.

Drug	Adverse drug reactions
Sertraline	Nausea (3), Heart burn (2), Indigestion (3), Constipation (2), Reduced appetite (3), Bloating (2), Dry mouth (1), Disturbed sleep (2), Headache (2), Fatigue (3), Dizziness (2), Drowsiness (1), Weight gain (3), Weight loss (1), Swelling of lips (1), Numbness over extremities (1), Loss of libido (1), Tremor (2), Breast pain (1), Pruritus (1).
Escitalopram	Nausea (2), Heartburn (4), Indigestion (4), Dry mouth (2), Disturbed sleep (1), Increased sleep onset (2), Headache (2), Fatigue (4), Dizziness (1), Drowsiness (3), Excessive sweating (1), Weight gain (3).
Mirtazapine	Heartburn (1), Indigestion (1), Dry mouth (1), Disturbed sleep (1), Fatigue (3), Drowsiness (2), Bitter taste (1), Weight gain (6), Increased urine frequency (1), Numbness over hand (1).
Fluoxetine	Nausea (1), Heart burn (2), Reduced appetite (1), Dry mouth (2), Fatigue (2), Drowsiness (1), Bitter taste (1), Disturbed sleep (1), Headache (1), Weight gain (1), Neck pain (1), Hair fall (1).
Dothiepin	Heartburn (1), Dry mouth (1) Increased heart rate (1), Premature ejaculation (1).
Venlafaxine	Reduced appetite (1), Constipation (1).
Imipramine	Tremor (1).

ADRs. This can be potentially attributed to the higher prescription rates of SSRIs. Similar findings were observed in a prospective observational study, proving a higher number of ADRs associated with SSRIs.[19] The most frequently reported ADR in our study was weight gain (13 cases). A study conducted in the United Arab Emirates (UAE) yielded similar results, identifying weight gain as the most prevalent side effect.[12] Mirtazapine emerged as the most commonly associated drug leading to weight gain in our study. Studies have demonstrated that antidepressant therapy involving mirtazapine is linked to a substantial increase in weight.[23] Most of the ADRs in our study were linked to the gastrointestinal system, aligning with findings from a prospective observational study from India done by Lucca *et al.*[22]

Assessing the Adverse Drug Reactions (ADRs) with the WHO causality assessment scale revealed that the majority of the ADRs were categorized as possible (85.8%) followed by probable (14.2%). None of them were classified as 'certain' in terms of causality. This aligns with the prevailing pattern observed in two cross-sectional studies done in India by Das *et al.* and Sidhu *et al.*[11-24] According

Table 3: Causality assessment of Adverse drug reactions -WHO UMC scale.

Adverse drug reaction (*n*=106)	Causality	
	Possible (*n*=91, 85.8%)	Probable (15, 14.2%)
Nausea (6)	4	2
Heartburn (10)	8	2
Indigestion (8)	7	1
Reduced appetite (5)	4	1
Constipation (3)	2	1
Bloating (2)	2	0
Dry mouth (7)	6	1
Disturbed sleep (5)	4	1
Increased sleep onset (2)	2	0
Headache (5)	5	0
Fatigue (12)	11	1
Dizziness (3)	2	1
Drowsiness (7)	6	1
Bitter taste (2)	2	0
Excessive sweating (1)	0	1
Weight gain (13)	12	1
Weight loss (1)	1	0
Sexual side effects (2)	2	0
Tremor (3)	2	1
Swelling of lips (1)	1	0
Neck pain (1)	1	0
Numbness over extremities (1)	1	0
Numbness over hand (1)	1	0
Breast pain (1)	1	0
Pruritus (1)	1	0
Increased urine frequency (1)	1	0
Increased heart rate (1)	1	0
Hair fall (1)	1	0

to Hartwig's severity assessment scale, 63.2% of the ADRs were classified as mild and 36.8% were categorized as moderate. None of the reactions were severe. This outcome is comparable with findings from another longitudinal observational study conducted in patients on antidepressants in India by Munoli *et al.*[21] The majority of adverse reactions observed in this study were predictable. This observation is significantly higher than the findings reported in a retrospective observational Indian study done by Shajahan *et al.*[25]

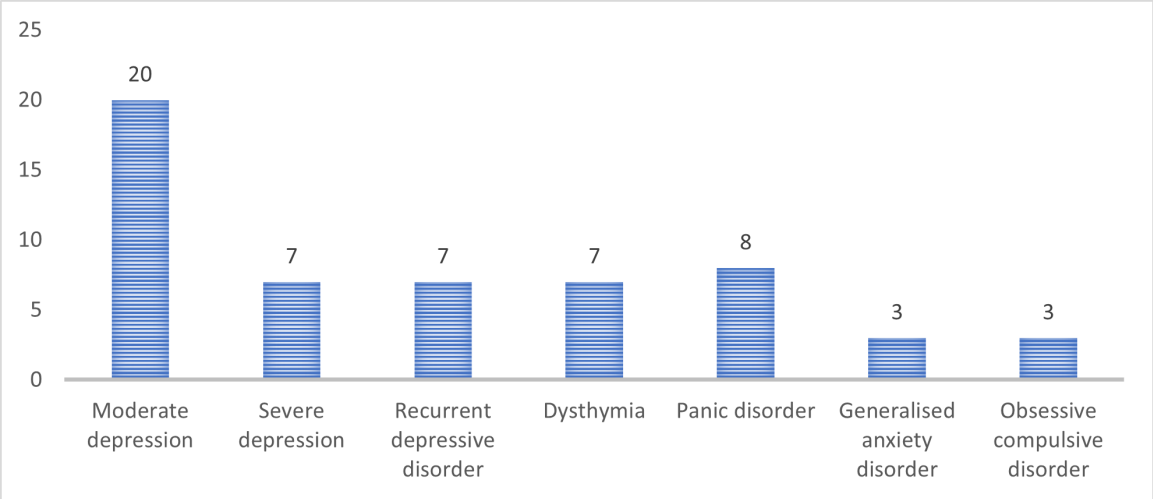

Figure 1: Distribution of common mental health disorders.

Table 4: Assessment of severity, predictability and preventability of Adverse drug reactions.

Assessment	Number of ADRs (*n*-106, %)
Severity assessment	
Mild	
Level 1	62(58.5%)
Level 2	5(4.7%)
Moderate	
Level 3	39(36.8%)
Level 4	0(0%)
Severe	
Level 5, 6, 7	0(0%)
Predictability Assessment	
Predictable	97 (91.5%)
Not predictable	9(8.5%)

Strengths

The prospective and longitudinal design of the study enables a careful method for collecting data and allows for exploring temporal patterns. The utilization of both spontaneous and intensive surveillance in the data collection strategy ensures the accuracy and thoroughness of the information gathered concerning adverse drug reactions.

Limitations

The study's restriction to a single center could potentially restrict the applicability of our findings to a broader population. Diverse healthcare settings or geographical regions may exhibit differences in prescribing patterns, patient demographics and healthcare practices. The relatively brief observation period of 6 months in the study might hinder the comprehensive understanding of the long-term effects of ADRs that become apparent after extended medication use.

CONCLUSION

This study investigated potential adverse drug reactions linked to antidepressants in treating common mental health disorders. The research revealed a 38.2% incidence rate of ADRs. The majority of reactions were deemed possible in the WHO causality assessment. Many of these reactions were classified as mild in Hartwig's severity assessment scale and predictable by Rawlings and Thompson's classification. Reporting ADRs is crucial for the judicious use of medication. Regular monitoring of ADRs and open communication between patients and healthcare professionals are imperative to minimize risks. Promoting awareness and reporting of adverse drug reactions within healthcare systems can lead to more effective identification and management of ADRs, improving patient outcomes and enhancing overall healthcare quality.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

NICE: National Institute for Health and Care Excellence; **ADRs:** Adverse Drug Reactions; **WHO:** World Health Organization; **SSRIs:** Selective Serotonin Reuptake Inhibitors; **TCAs:** Tricyclic

antidepressants; **DSM-5:** The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

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