Original Article

Focused Pharmacovigilance of Neuropsychiatry Drugs in A Tertiary Care Hospital, India

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Abstract

Background: Adverse drug reactions (ADRs) to neuro-psychiatry drugs are frequent and add to patient suffering in terms of health and cost. These ADRs often overlap with the clinical picture, necessitating differentiation of disease symptoms and ADRs. Moreover, with the recent development of newer drugs, the pattern of ADRs has continuously evolved, making their monitoring and reporting vital. **Materials and Methods:** This was a prospective, observational study including both outpatients and inpatients reporting ADRs to neuropsychiatric drugs in a tertiary care hospital in northern India over a 3-month period. ADR characteristics such as seriousness, outcomes, severity and causality were noted. Descriptive statistics were used to analyze the results. **Results:** Out of the 124 ADRs reported by 102 patients, 98 (96%) were outpatients, 60 (59%) were males, and 44 (43%) were aged 29–39 years. Slightly more than half (56%) of the patients were taking 1-2 drugs. The majority (89, 87%) reported a single ADR. Most ADRs (118 (95%)) were type A. Epilepsy was the most common neurological diagnosis (13 (45%)), whereas depression (31 (42%) predominated in psychiatry. The most common ADR for neurology drugs was sleepiness (9, 26%), whereas dizziness (16, 18%) was common in psychiatry. In neurology, phenytoin and sodium valproate (4 (14% each) were the main culprits, whereas paroxetine (13 (18%) was the offending agent in psychiatry. Most of the ADRs observed during the study were nonserious [114 (92%)], and almost half of the patients recovered 63 (51%). Most ADRs (86 (69%) were of moderate severity and their causality was probable (89 (72%). **Conclusion:** Our findings suggest that ADRs are quite common in patients receiving neuro-psychiatry medications. Young people of the male gender have a higher ADR reporting rate. Most of the reported ADRs were Type A. Anti-epileptics and anti-psychotics were the main neuro-psychiatric medications implicated in causing ADRS, even though most of the ADRSs had recovered and were not serious. The current study adds to the knowledge database, highlighting a varying pattern of presentation of ADRs. However, further research involving targeted pharmacovigilance activity or active surveillance could strengthen the database.

Keywords: Adverse Drug Reactions, Neuropsychiatry, Patients.

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Introduction

Adverse drug reactions (ADRs) present a major challenge concerning human agony and increased health care expenditures.[1] The WHO defines ADRs as "a response to a drug which is noxious and unintended and which occurs at a dose that is normally used in humans for the prevention, diagnosis and treatment of a disease or for modification of physiological process".[2] Globally, ADRs are reported to be the most common cause of hospital admission and the fourth or sixth leading cause of patient mortality.[3]

The incidence of neuropsychiatric disorders, including substance abuse, has increased worldwide. According to the recent global burden of disease studies, neuropsychiatric disorders are among the top 30 causes of all years lived with disability, with the highest contributors being anxiety, depression, and substance abuse disorders.[4] According to research, one out of seven Indians suffer from a psychiatric disorder. From 1990--2017, the relative contribution of psychiatric disorders to the total disease burden in India increased twofold.

Moreover, worldwide data suggest that the burden, including morbidity and mortality, of all neurological diseases has been increasing.[5] Interestingly, the drug group often implicated in ADRs is the drugs used for therapy for neurological disorders.[6] Neurology and psychiatry have long been linked throughout history, and these branches of science often overlap, sharing common ground, i.e., the brain. It is not infrequent that this demarcation of neurologic and psychiatric disorders seems capricious, as some well-documented illnesses with a neurological basis, such as schizophrenia, are classified under psychiatry, whereas other disorders, such as Huntington's disease with evident behavioral and affective features, are listed

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as neurological disorders.[7]

Although antipsychotics and antidepressants are effective treatments for some patients, approximately 75% of patients experience adverse effects.[8,9] These adverse effects are diverse and can adversely affect patients' quality of life.[10, 11] In addition, these factors contribute to morbidity and mortality rates, create stigma, and result in poor medication concordance and thus an increased risk of relapse of psychiatric illness. Indeed, adverse effects are key factors that people with depression and schizophrenia primarily consider when making prescription decisions, and concerns about side effects represent a barrier to the treatment of mental illness.[12,13] Psychiatric disorder-related adverse drug reactions often overlap with the clinical presentation, necessitating differentiation to affirm whether it is worsening of the disease or an ADR.[14]

ADRs are implicated in poor medication adherence, morbidity, mortality and increased health care expenditures, eventually presenting itself as a public health problem globally as well as in India.[15,16]

However, adverse drug reactions have also been studied worldwide in the Indian population. An extensive literature search yielded no studies on the clinical pattern of adverse drug reactions to neuropsychiatric drugs together in a tertiary care hospital in the Indian population. Hence, the present study aims to identify and characterize the pattern of ADRs caused by drugs commonly used in neuropsychiatry in tertiary care teaching hospitals, assess causality and identify drugs that are offending. This information may be useful in identifying and minimizing preventable ADRs; at the same time, it may help clinicians address ADRs more efficiently.

This study aimed to assess the pattern of adverse drug reactions to neuropsychiatric drugs and to evaluate the causal relationship and severity of these adverse drug reactions.

Materials and Methods

Study Design: This study was a prospective, observational study. The study included inpatients (IPDs) admitted and outpatients (OPDs) who visited or were referred and reported adverse drug reactions to neuropsychiatric drugs for a period of three months. Patients were enrolled after they provided written informed consent.

Inclusion Criteria

1. All diagnosed or suspected cases of ADRs due to neuropsychiatric drugs from both OPD and IPD.[17]
2. All age groups of patients of either sex.

Exclusion Criteria

1. Reactions where the drugs taken are not known.
2. Patients not willing to give consent.
3. Pregnant women and nursing mothers.[18]
4. Patients with mental retardation or drug abuse.[19]

Methodology: Suspected cases of adverse drug events were assessed. Written informed consent was obtained from the participants. Detailed data, including demographic data, drug history, reaction time, previous allergic history, duration of reactions, type of reactions, severity of reaction, causality assessment, relevant investigations and improvement after dechallenge, were recorded in a spontaneous adverse drug reaction reporting form of the Central Drugs Standard Control Organization (CDSCO) and a specially designed proforma. The types of events A, B, C, D, E and F were noted per the extended Rawlin-Thompson classification.[20] The severity of events was subsequently assessed via Hartwig's severity assessment scale.[21] The relationship of adverse drug events was noted as unlikely, probable, possible and definite according to the Naranjo algorithm.[22] The collected ADR data on the Central Drugs Standard Control Organization form were sent to the national database through the pharmacovigilance center of the Institute.

Statistical Analysis

The data were analyzed statistically via descriptive statistics, namely, percentages and proportions.

Results

The characteristics of patients reporting ADRs to neuro-psychiatry medications are listed in [Table 1]. Over the study period, a total of 102 patients reported ADRs to neuro-psychiatry drugs. Among the patients reporting ADRs, the majority 98 (96%) were outpatients, with 71 (97.2%) in psychiatry departments and 27 (93%) in neurology departments. The total number of ADRs reported from these patients was 124, constituting 89 (72%) from psychiatry departments and 35 (28%) from neurology departments. A greater number, i.e., (60)59%, of the patients reporting ADRs were males, whereas 42 (41%) and 18 (18%) were from psychiatry and neurology, respectively. The age group representing the majority of the 44 (43%) participants was 29--39 years, with 32 (31%) from psychiatry departments and 12 (12%) from neurology departments. The number of prescribed drugs in most (56%) of the patients was 1--2, with 42 (41%) from psychiatry departments and 15 (15%) from neurology departments. In particular, 89 (87%) of the patients reported a single ADR. Overall, 99 (97%) patients reported ADRs to the drug when it was administered orally in solid dosage form as a tablet or a capsule.

Table 1: Patient characteristics

Characteristic	Neurology	Psychiatry	Total n (%)
Total number of patients	29	73	102
Inpatients	2	2	4(4)
Out- patients	27	71	98(96)
Total number of ADRs	35	89	124
Gender			
Male	18	42	60(59)
Female	11	31	42(41)

Age (in years)			
< 18	1	2	3(3)
18-28	8	21	29(28)
29-39	12	32	44(43)
40-49	4	7	11(11)
50-59	2	8	10(10)
>60	2	3	5(5)
Number of prescribed drugs			
1-2	15	42	57(56)
3-4	11	19	30(29)
>5	3	12	15 (15)
Number of ADRs documented per patient			
1	22	67	89(87)
>1	7	6	13(13)
Dosage Form			
Tablet/Capsules	27	72	99(97)
Others	2	1	3(3)

According to the extended Rawlins-Thompson classification of adverse drug reactions, out of 124 ADRs reported, 118 (95%) ADRs were type A. Among these, 86 (69%) were reported to be drugs used in psychiatry, whereas 32 (26%) were reported to be drugs used in neurology, as shown in [Figure 1] which depicts the type of ADRs.

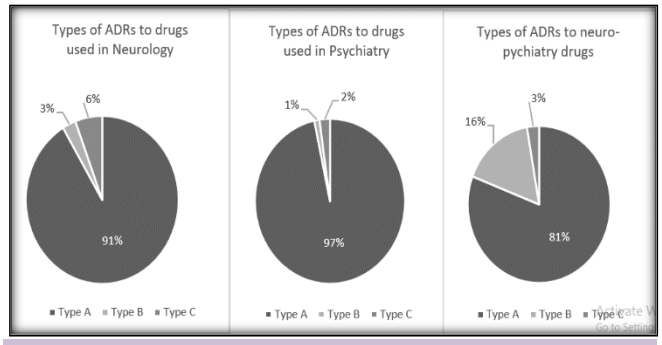

Figure 1: Types of ADRs*.

The spectrum of the illnesses listing the diagnosis of the patients disclosing ADRs is depicted in [Figure 2]. The majority of the patients reporting ADRs to drugs used in neurology were suffering from epilepsy (13 patients; 45%), followed by headache (8 patients; 28%), and the lowest number were diagnosed with memory-related disorders (2 patients; 7%). A greater percentage of the patients who divulged ADRs to psychiatric medications had depression 31 (42%), anxiety 19 (26%), whereas only 3 (4%) had obsessive–compulsive disorders.

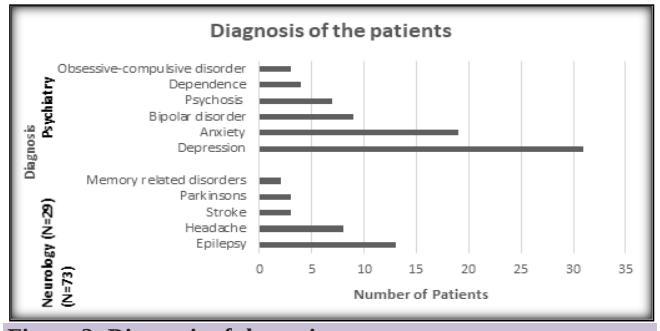

Figure 2: Diagnosis of the patients

The various reported clinical presentations of adverse drug reactions from patients receiving drugs used in neurology and psychiatry department respectively are depicted in [Figure 3 and Figure 4]. The most prevalent adverse drug reaction to drugs used in neurology was sleepiness (9 (26%)), followed by agitation, dizziness, and headache (4 (11%)). With respect to adverse drug reactions to psychiatric medications, the most common adverse drug reaction encountered was dizziness (16, 18%), followed by sedation (14, 16%), headache (12, 13%), weight gain (9, 10%), decreased libido (7, 8%) and so on.

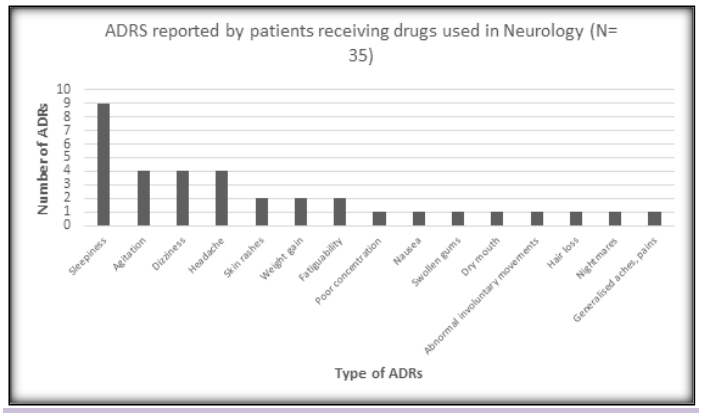

Figure 3: ADRS reported by patients receiving drugs used in Neurology

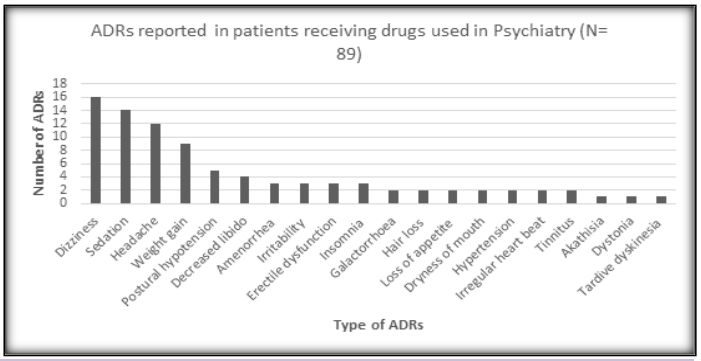

Figure 4: ADRs reported in patients receiving drugs used in Psychiatry

The various drugs implicated in the reported adverse drug reactions have been listed in [Table 2].

Table 2: Drugs responsible for 124 adverse drug reactions noted among 102 patients

Causative drug	Number of patients	Percentage
Neurology (N=29)		
Phenytoin	4	14
Sodium valproate	4	14
Levodopa + Carbidopa	3	10
Carbamazepine	2	7
Propranolol	2	7
Rivastigmine	2	7
Levetiracetam	2	7
Selegiline	1	3
Galantamine	1	3
Rosuvastatin	1	3
Telmisartan	1	3
Mannitol	1	3
Amlodipine	1	3
Topiramate	1	3
Rizatriptan	1	3
Atorvastatin	1	3
Aspirin + Clopidogrel	1	3
Psychiatry (N=73)		
Paroxetine	13	18
Amitriptyline	9	12
Risperidone	9	12
Haloperidol	8	11
Clozapine	6	8
Olanzapine	5	7
Lithium	5	7
Duloxetine	3	4
Aripiprazole	3	4
Fluoxetine	3	4
Chlordiazepoxide	3	4
Desvenlafaxine	2	3
Clonidine	1	1
Topiramate	1	1
Tapentadol	1	1
Escitalopram	1	1

The characteristics of the various ADRs observed during the study period are presented in [Table 3]. In total, 114 (92%) of the ADRs encountered during the study were nonserious. Among the 10 (8%) serious ADRs reported, 8 (80%) were medically important and required corrective measures. With respect to the outcomes, a greater percentage, i.e., 63 (51%) of the ADRs, had recovered, whereas 37 (30%) were in the recovery stage. According to Hartwig's severity assessment scale, 86 (69%) of the ADRs were moderate in severity, followed by 36 (29%), whereas only 2 (2%) were severe. The establishment of causality according to the Naranjo causality scale revealed that most of the ADRs were likely 89 (72%), followed by 35 (28%).

Table 3: Characteristics of adverse drug reactions

Characteristic		Number	Percentage
Seriousness	Non serious	114	92
	Serious	10	8
	Other medically important (Required corrective measures)	8	
	Hospitalization-initial/Prolonged	2	
	Disability	0	
	Death	0	
	Life- threatening	0	
	Congenital anomaly	0	
Outcomes	Recovered	63	51
	Recovering	37	30
	Not recovered	17	14
	Recovered with sequalae	5	4
	Unknown	2	2
	Fatal	0	0
Severity as per Hartwig's severity assessment scale	Moderate	86	69
	Mild	36	29
	Severe	2	2
Causality as per Naranjo causality scale	Definite	0	0
	Probable	89	72

	Possible	35	28
	Doubtful	0	0

Discussion

The current research was conducted to determine the pattern of ADRs to neuropsychiatric drugs used in a tertiary care hospital in northern India. The results of our study revealed that 98 (96%) of the patients who reported ADRs were outpatients. These observations align well with those of another study in which the majority of patients (91.7%) reporting ADRs were from outpatient departments, whereas only 8.2% were from inpatient departments.[20] This could be due to the higher load of patients coming to the OPD than to the lower number of patients admitted to the ward per day. The underreporting of ADRs from inpatients could be circumvented by computerized medical records surveillance or by developing an active surveillance method.

Sixty (59%) male patients reported adverse drug reactions. These observations align well with those of other studies in which 64% of the ADRs were reported by male patients.[23] Another study reported contrasting findings in which most of the reported ADRs were females.[16] The age group reporting most of the ADRs was 29--39 years, i.e., 44 (43%) adolescents, followed by 18--28 (29 (28%)). Another study reported findings in which the mean age of the patients with ADRs was 20–39 years.[24]

Fifty-seven (56%) patients were taking 1-2 drugs as part of the treatment of their neuropsychiatric disorders. These conclusions derived from our study do not match those obtained from other studies where the average number of medications per person was 4–5 in the majority, i.e., 43% of the patients.[25] The reported ADR was 89 (87%) in a large number of patients. These findings are similar to those of another study in which at least 50% of the reports had one ADR.[26]

Tablets/capsules constituted the majority (99 (97%)) of the dosage form of the culprit drug suspected of having adverse drug reactions. Among the 124 ADRs reported, 118 (95%) were type A. Another study suggested that most of the ADRs were due to drugs administered via the oral route and that the majority of the ADRs were type A.[27] In another study, more than half of the reported ADRs were type B.[28] Epilepsy was the diagnosis of most 13 (45%) of the patients reporting ADRs to drugs used in neurology, whereas the majority of the patients disclosing ADRs to psychiatric medications were afflicted with depression (31 (42%)). These findings align well with those of previous research, which revealed that 50% of patients with epilepsy on treatment reported ADRs.[29] Moreover, patients with depression report 50% of all ADRs reported in a previous study.[30]

The most common adverse drug reaction to drugs used in neurology was sleepiness (9 (26%)), followed by agitation, dizziness, and headache (4 (11%)). These interpretations slightly differ from those of our study, where dizziness was the most common ADR reported, followed by sedation, nausea and fatiguability.[31] Dizziness (16, 18%), followed by sedation (14, 16%), was most frequently encountered in patients on psychiatric medications. The findings of our study are parallel to those of another study by Sidhu and coworkers, who reported that dizziness is the most common ADR reported in patients on psychiatric medications.11 However, another study suggested that weight gain was the most common ADR reported by psychiatric patients on medication.[32]

Anti-epileptics such as phenytoin and sodium valproate (4 (14% each) followed closely by levodopa-carbidopa 3 (10%) were identified as suspected drugs that cause adverse drug reactions. These findings differ slightly from observations of other studies in which sodium valproate caused the most ADRs, followed by carbamazepine and phenytoin.[33] However, the drugs implicated in the adverse effects observed in psychiatric patients were paroxetine (13 (18%)), followed by amitriptyline, risperidone (9 (12%) each) and haloperidol (8 (11%)). Paroxetine was identified as the major culprit involved in adverse drug reactions in another study.[11]

Regarding the severity of the adverse drug reactions, 114 (92%) of the ADRs observed during the study were nonserious. Parallel observations were made in another study in which most of the reported ADRs were of a nonserious nature.[34] Another study reported varied results in comparison to our study, where most of the reported ADRs were serious.[35] The majority 63 (51%) of the adverse drug reactions that were disclosed had recovered as an outcome. These findings go hand in hand with findings from another study by Giardina and coworkers, where most of the reported ADRs had an outcome of recovery.[36]

Most 86 (69%) of the ADRs were moderate in severity according to the Hartwig severity assessment scale. Another study by Srisuriyachanchai and colleagues reported that most patients reported ADRs that were of moderate severity.[24] In contrast to the findings of our research, Ferreira and coworkers reported that most ADRs were mild in nature in terms of severity.[37]

Causality determination according to the Naranjo causality scale suggested that most of the ADRs were probable (89 (72%)), followed by 35 (28%). Most of the reported ADRs were probable, according to another study.[38] A retrospective study of adverse drug reactions reported in a tertiary care hospital reported ADRs, which were most likely due to causality assessment.[39] However, causality determination according to another study revealed that most ADRs are possibly linked with the adverse drug reactions reported.[40]

Limitations

Owing to ethical concerns, suspected drug re-administration could not be performed; therefore, we could not determine if any ADR was “definite”. In addition, the study was relatively short in duration, and further research can augment the data gathered by our study, as over time, many newer drugs for neuro-psychiatric illnesses continue to be

developed and approved.

Conclusion

Our findings suggest that ADRs are quite common in patients receiving neuro-psychiatric medications. Young people of the male gender have a higher ADR reporting rate. Most of the reported ADRs were Type A. Anti-epileptics and anti-psychotics were the main neuro-psychiatric medications implicated in causing ADRS, even though most of the ADRSs had recovered and were not serious. The present study supplements the existing information on the pattern of ADRs following the administration of drugs useful in the treatment of psychiatric and neurological conditions. However, active surveillance can increase data collection in this field of research, as passive surveillance has the limitation of underreporting. Additionally, with the continuous development of newer drugs, post-marketing surveillance can provide evidence of ADRs to neuropsychiatric drugs. A diligent built-up database will enable physicians to effectively and judiciously utilize medications for neuropsychiatric disorders.

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Conflicts of interest

There are no conflicts of interest.

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