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Original Research Article

Pattern of adverse drug reactions occurring at department of neurology of a tertiary care hospital in India

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ABSTRACT

Background: The objective of the study was to study the pattern and trends of adverse effects of drugs used in department of neurology in a tertiary care hospital.
Methods: A prospective, observational study was carried out for a duration of 12 months from November 2018 to October 2019 at Department of Neurology and Department of Pharmacology and Therapeutics, G.S.V.M. Medical College, Kanpur after getting an approval from institutional ethical committee. Data was collected by analyzing OPD prescription slip, treatment charts and investigation reports. All relevant information regarding adverse drug reactions (ADRs) were collected as per norms of Indian Pharmacopoeia commission (IPC).
Results: During the study period, a total of 130 ADRs reported. Most of the ADRs were reported due to antiepileptic drugs followed by antiparkinsonian drugs. Dizziness was the most frequent ADR reported. Most of the ADRs were reported due to phenytoin. Other ADRs observed were drowsiness, nausea/vomiting, weakness, joint pain, dyskinesia.
Conclusions: Most of the ADRs were due to anti-epileptic drugs. Most of the reactions were of mild severity.

Keywords: Anti-epileptic drugs, Anti-parkinsonian drugs, Adverse drug reactions, Indian Pharmacopoeia commission

INTRODUCTION

Adverse drug reactions (ADRs) are most important cause of morbidity and has an economic burden to the developing countries like India.[1] Studies from India and overseas countries have demonstrated that polypharmacy is associated with increased risk of ADRs.[2]

In India ADR monitoring and reporting activities is in growing phase. In our country this rate is <1% in pharmacovigilance as against world rate of 5%.[3] India is the fourth largest producer of various drugs in the world.

An ADR is defined as "any response to a drug that is noxious and unintended, and that occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function".[4]

Monitoring of ADRs helps to evaluate the effectiveness and risk of medications, empower safe and rational use of drugs and enhance general patient care and well-being. The cost of ADRs in the community is high, and under-reporting by health professionals is a major problem. ADR identification and its reporting help in prevention of ADRs and reduce [6]drug related issues in future.[5] Globally there is main concern about the safe use of drugs in

hospital. It is well known that ADR constitute a major problem in drug therapy and in Indian scenario is a major health care problem and an economic burden.

Drugs that are used commonly in Neurology such as antiepileptic, anti-parkinsonian, antipsychotic and anxiolytic contribute to ADRs such as extrapyramidal symptoms, insomnia, sedation, and even serious effects such as increasing suicidal tendency and depression. Studies have showed that the rate of ADRs in neurology department is 23.5%.[7] As drug side effects have a basic role in the selection of an appropriate drug, patient compliance and quality of life in patients.

The objective of the present study was to study both documented and newer drugs side effects due to drugs used in neurology department.

METHODS

A prospective, observational study approved by the Institutional Ethics Committee (IEC) was conducted for a duration of 12 months from November 2018 to October 2019 at Department of Neurology and Department of Pharmacology and therapeutics, GSVM Medical College Kanpur. Patients belonging to either gender and of all age-groups, who were receiving treatment for various neurological disease under any standard regimen, were included for the study. All suspected ADR cases were collected from patient for all the relevant information accordingly as per norms of Indian Pharmacopoeia Commission (IPC). After obtaining informed consent from the patients attending Neurology department, the data regarding age, gender, detailed medical history, age of onset of disease and its duration, clinical signs and symptoms, drugs prescribed for treatment of various neurological disorders and other concomitant medications, comorbid conditions and adverse treatment reactions were collected by interacting with the patient and from patient's case record. Information was collected again from the study participants during their routine follow up visits to monitor the symptoms and adverse drug reaction (if any) occurring due to treatment. The patient's subjective response of relief or no relief of symptoms during the follow up visits was recorded. Adverse reactions (ADRs) to the drugs, if any were noted. The data was analysed using the Microsoft excel software, descriptive analysis was performed.

RESULTS

Percentage of occurrence of ADRs

In present study, a total of 290 patients were enrolled and of which, 130 patients (44.82%) were presented with at least one ADR.

All ADR cases were divided in four age groups (40-50 years, 51-60 years, 61-70 years, 71-80 years) and analysed. Over all 31 (23.84%) ADRs were found in 40-50 years age group, 30(23.07%) ADRs in 51-60 years age group, 33(25.38%). ADRs in 61-70 years age group and 36 (27.69%) ADRs in 71-80 years age group (Table 1).

Table 1: Age wise distribution of ADRs.

Age group (in years)	No. of patients	Percentage
40-50	31	23.84
51-60	30	23.07
61-70	33	25.38
71-80	36	27.69

Table 2: Age and gender wise distribution of ADRs.

Age group (in years)	Male		Female	
	No	**%**	**No**	**%**
40-50	29	20.30	2	1.53
51-60	28	21.53	2	1.53
61-70	32	24.61	1	0.76
71-80	35	26.92	1	0.76
Total	124	95.38	6	4.61

Among 40-50 year age group 20.30% ADR cases were reported in male patients and 1.53% were in female patients. In 51-60 year age group 21.53% cases were reported in male patients and 1.53% in female patients.In 61-70 year age group 24.61% cases were reported in male patients and 0.76% were reported in female patients while in the age group 71-80 year 26.92% cases were reported in male patients and 0.76% cases were reported in female patients (Table 2).

In present study most common ADR monitored was dizziness followed by drowsiness. Most common drug causing ADRs was phenytoin followed by valproic acid (Table 3).

Among 130 ADR cases, the most common organ system involved was Central Nervous system (59.23% cases were reported), followed by gastrointestinal system (16.92% cases were reported). Other organ system involved was ocular (0.76% cases were reported), musculoskeletal (3.07% cases were reported), dermatological (14.61% cases were reported) and hematological (5.38% cases were reported) (Table 4).

Among 130 ADRs 82 cases (66.15%) were of type A, while type B and type C cases were 41 (31.5%) and 03 (2.30%) respectively (Table 5).

In severity assessment there were 96 (74.61%) mild cases, 30 (22.05%) moderate cases, 4 (3.07%) severe cases reported. Among type A ADRs, 82 (63.07%) were mild cases, 4 (4.65%) were moderate cases. There was no severe case reported among type A ADRs. Among type B ADRs there were 15 (36.58%) mild cases, 25 (60.97%) moderate cases and 1 (2.43%) were severe cases. Among

type C ADRs there were no mild cases, no moderate cases and 03 severe cases. (Figure 1).

Table 3: ADR event and suspected drug.

ADR event	Suspected drug	Percentage
Dizziness	Pramipexole, Phenytoin, oxcarbazepine, pregabalin, Topiramate, levodopa/carrbidopa, amantadine, trihexyphenidyl	26.92
Allergic reaction	Phenytoin, oxcarbamazepine	7.69
Blood dyscrasia	Phenytoin	0.76
Depression	Phenytoin	1.53
Leucopenia	Phenytoin	0.76
Weakness	Phenytoin	0.76
Joint pain	Phenytoin	1.53
Drowsiness	Clonazepam , valproic acid, zonisamide, oxcarbazepine, flunarizine	11.53
Ataxia	Carbamazepine	1.53
vertigo	Carbamazepine	3.84
Nausea/ vomiting	Oxcarbazepine, valproic acid,carbamazepine,levodopa/carbidopa, pregabalin	7.69
Increased appetite	Valproic acid	3.07
thrombocytopenia	Valproic acid	3.84
Weight gain	Valproic acid, clonazepam	3.84
Headache	Valpric acid	0.76
Skin rashes	Zonisamide, valproic acid, flunarizine	5.38
Hypersensitivity reaction	Topiramate, pregabalin	5.38
Fatigue	Topiramate	1.53
Sedation	Clonazepam, trihexyphenidyl, topiramate, levodopa/carbidopa, topiramate, pramipexole	6.15
Blurred vision	Amantadine	0.76
Ankle edema	Amantadine	0.76
Dryness of mouth	Trihexyphenidyl, flunarizine	5.38
Dyskinesia	Pramipexole	1.53
Sertraline	hallucinations	0.76

Table 4: System organ classification of ADRs.

System	Percentage
Central nervous system	59.23
Gastrointestinal	16.92
Ocular	0.76
Musculoskeletal	3.07
Dermatological	14.61
Hematological	5.38

Table 5: Type of ADRs.

Type of ADR	No.	Percentage
Type A	82	66.15
Type B	41	31.5
Type C	03	2.30
Total	130	

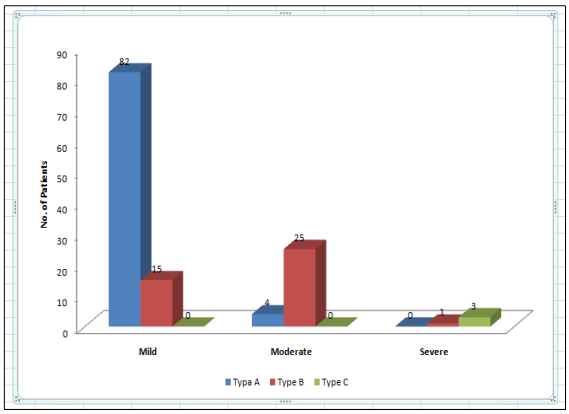

Figure 1: Severity of ADRs.

In seriousness assessment out of total 130 ADRs 10 cases were serious and 120 cases were non-serious. In a case of antiparkinsonian drugs the most common ADR monitored was dizziness (13) patients suffered, followed by dryness of mouth (06) and sedation (04).

In a case of anti-epileptic drugs the most common ADRs monitored is dizziness (22 cases reported) followed by drowsiness (13 cases reported), nausea/vomiting (09 cases reported). Among other drugs (Flunarizine, Sertraline) Adverse reactions reported were drowsiness (01 case), rashes (01 case), dry mouth (01 case), hallucination (01 case) and confusion (01 case). Among anti-epileptic drugs most prescribed drug was phenytoin followed by valproic acid and carbamazepine. Among anti-parkinsonian drugs most prescribed drug was Levodopa/ Carbidopa followed by trihexyphenidyl and pramipexole.

DISCUSSION

In present study 130 ADRs were reported. During this study it was found that maximum ADRs are of type A (66.15%) followed by type B (31.53%), type C (2.30%). This finding is supported by study conducted by Prudhivi et al, in which out of 130 ADR cases reported, type A

cases were 66.15%.[8] On age distribution maximum ADRs were found in age group 71-80 years age group, as there is lower renal and hepatic microsomal drug metabolizing activity, elderly are more prone to develop cumulative toxicity while receiving prolonged medication. This distribution is in contrast to a study conducted by Thaha et al in which majority of patients were in age group 50-59 years.[9]

In present study male preponderance of cases were more. 124 ADR (95.38%) cases were reported in male patients, while 06 ADR (4.61%) cases were reported in female patients. This finding is supported by the study conducted by Kalyani et al.[10] Based on the severity of adverse drug effects there were mild, moderate and severe cases. In this study total mild cases were 96, moderate cases were 30 and severe cases were 04. This is supported by study conducted by Akalu et al (54% mild cases, 46% moderate cases, none of the reactions were severe).[11]

Overall only 1.53% reactions were serious in nature. Rest 98.47% were not serious. Various other published studies have quoted an incidence of serious ADRs from 0% to 20%. Maximum no of serious ADRs were found with type B (76.92%) followed by type C (23.07%). The most common ADR monitored in this study was dizziness (26.92%), which is followed by drowsiness (11.53%), nausea/vomiting (7.69%), sedation (6.15%), dryness of mouth (5.38%). This finding is supported by the study conducted by Bhattacharjee et al.[12]

In present study highest rate of ADRs was observed in anti-epileptics (73.52%) followed by anti-parkinsonian drugs (22.79%). Some ADRs are also reported from Flunarizine and Sertraline. This is similar to study conducted by Grace et al which most of the ADRs were reported with antiepileptic drugs (29.5%).[13]

CONCLUSION

The present study found that maximum ADR cases were found between 71-80 years age group. On severity scale majority of ADRs were of mild severity. Most of reactions were reported from anti-epileptic drugs. Maximum reactions were of type A. In our country ADR reporting is less and more work on continuous reporting is needed.

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