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STUDY THE ADVERSE DRUG REACTIONS IN PATIENTS PRESCRIBED WITH ANTIPARKINSONIAN DRUGS.

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Abstract

Introduction: Adverse drug reactions (ADRs) are a major cause of morbidity and mortality, and the leading cause of hospital admission. An active pharmacovilgilance program is the need of the hour in all hospitals especially in Indian setup, as ADRs cause a significant burden to the patients and also to the economy.

Aims: The present study aims are to monitor and assess adverse drug reactions in patients diagnosed with Parkinsonism disease.

Material and Methods: A prospective, observational study was conducted in department of pharmacology in association with department of neuromedicine. Total number patients included in the study were 150 Parkinsonism patients. Duration of study was 01 years. Parkinsonism patients were analyzed types of ADR, side effects and anti-parkinsonism drugs

Results: A prospective, observational study was conducted in department of pharmacology in association with department of neuromedicine.Majority of the patients were male age group between 50 to 59 years there were 58 in males and 18 in females. Parkinsonism patients symptoms observed at the time of enrolment in the study majority of the patients having Bradykinesia 24.70% followed by Rigidity 22.35%, postural instability 16.47%, hypomania 14.11%, pain 10.58%, GI disturbances 4.70% and mood disturbances 7.05%. There are different types of ADRs but in our study we observed only three types of ADRs majority of ADR observed was type A 62.00% followed by type B 29.33% and type C 8.66%. Parkinsonism patients were prescribed with Antiparkinsonian drugs shows ADRs, in our study we observed total of 167 ADRs majority of ADRs observed was Dizziness 28.44%, followed by Dry mouth 21.55%, Dyskinesia 13.17% Akathisia & sedation 7.18%, Anorexia, Nausea & Fatigue 5.98 % and constipation 3.59%. drugs as per our study majority of Antiparkinsonian prescribed to the patients was combination of levodopa/carbidopa 76 patients followed by pramipexole 38

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patients, Trihexyphenidyl 26 patients and amantadine 10 patients. Total of 150 parkinsonism patients.

Conclusion: Antiparkinsonian drugs used for the treatment of Parkinsonism. As per the study majority of the patients were male in the age group of 50 – 59 having symptoms of Bradykinesia, rigidity and postural instability. Majority of patients prescribed with levodopa/carbidopa, after ADRs monitored Dizziness followed by Dry mouth, Dyskinesia, Akathisia, sedation, Anorexia, Nausea, Fatigue and constipation was observed.

Keywords: Parkinsonism, Levodopa/carbidopa, anti-parkinsonian drug.

Introduction: Adverse drug reactions (ADR) are common occurrences in a hospital setting, attributed to the severity and complexity of the disease process, the use of multiple drugs, drug interactions, and possible negligence.[1]It is noteworthy that individuals who are diagnosed with neurological diseases are more susceptible to the occurrence of drug-related problems, once medications indicated to manage most common conditions have complex dosage regimens, the potential for interaction with other drugs and/or are associated with the occurrence of important adverse reactions.[2]Adverse drug reactions (ADRs) are a major cause of morbidity and mortality, and the leading cause of hospital admission. An active pharmacovilgilance program is the need of the hour in all hospitals especially in Indian setup, as ADRs cause a significant burden to the patients and also to the economy[3]. This project is aimed to work in this regard to monitor, detect, assess, and disseminate the ADRs which ensures patient safety and minimizes the cost of health care[4]. Detection and monitoring of ADR in the inpatient department of neurology is lacking in Indian literature.

Aims:

The present study aims are to monitor and assess adverse drug reactions in patients diagnosed with parkinsonism disease.

Objectives:

- To assess the type(s) of ADRs.
- Symptoms at the time of enrolment in the study
- ADR monitoring after prescribing anti-parkinsonism drugs
- To find the drugs mostly used in treatment of Parkinsonism ADRs.

Material & Method:

Study area and duration: A prospective, observational study was conducted in department of pharmacology in association with department of neuromedicine.

Source of data: Parkinsonism patients attending OPD/IPD of Neuromedicine during the study period one yearfrom Sep 2020 – 2021.

Data collection: Data was collected by analyzing OPD prescription slips, treatment charts, and investigation reports. A request was made to health care professionals for data collection, by interviewing patients or patient's attendants, by discussing with health care professionals. Adverse drug reaction reporting form provided by the Indian Pharmacopoeia commission was used for data collection. Patients were asked in detail about adverse drug reactions. ADR monitoring was done in a systematic manner adopting both spontaneous and intensive monitoring approaches.

Inclusion criteria-

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1. Patients of both genders.
2. Patients attending Neuromedicine IPD/OPD and taking treatment with Parkinsonism.
3. Patients who will give written informed consent.

Exclusion Criteria-

1. Patients taking medication other than prescribed medicine.
2. Pregnant and lactating females.
3. Patients were unable to respond to verbal questions.

Data analysis

- **Type of ADR:** To understand the better impact of ADRs, it is pertinent to review various classifications of ADRs.
- According to Rawlins and Thompson's classification, ADRs are broadly classified as type A and type B. Type A reaction is associated with the pharmacological actions of the drug and is predictable while type B reaction is not associated with the pharmacological actions of the drug and is not predictable. It is also known as an idiosyncratic reaction. Type A reaction is more prevalent than type B. The original Rawlins and Thompson's classification of ADRs into type A (augmented) and type B (bizarre) has been expanded to six types A to F.
- **Causality assessment-** causality assessment is the method by which the extent of the relationship between a drug and a suspected adverse reaction is established. The causality assessment system proposed by Naranjo's Probability scale is the generally accepted and most widely used method for causality assessment in clinical practice as they offer a simple methodology. This scale is structured, transparent, consistent, and easy to apply assessment methods.
- **Naranjo's probability scale:** Naranjo's algorithm is a questionnaire designed by Naranjo et al for determining the likelihood of whether an ADR is actually due to the drug rather than the result of other factors. In Naranjo's algorithm probability is assigned in terms of definite, probable, possible, or doubtful according to the total score.

Predictability of ADRs: Based on modified guidelines developed by the Council for International Organizations of medical sciences (CIOMS) ADRs can be divided into two types: predictable and not predictable. For those patients who have had the drug on the previous occasion and if the drug was previously well-tolerated at the same dose and route of administration, the ADR is not predictable. If there was a history of allergy or previous reactions to the drug, the ADR is predictable. Patients who have never had the drug previously: incidence of the ADR [5]

- Reported in product information or other literature determines its predictability.
- **The severity of ADRs:** According to the Modified Hartwig severity scale, ADRs are classified into various levels of severity as mild, moderate, and severe.
- **The seriousness of ADRs:** Seriousness of ADRs was assessed according to criteria given by W.H.O.

Statistical analysis: The data were collected, entered and a master table was prepared using MS Excel software. The data were analyzed using appropriate statistical tools like percentage, chi-square test, etc, and a conclusion was drawn accordingly.

Ethical clearance-The ethical clearance of the study was obtained from the ethical committee of the institute.

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Observations & Results:

The present study was planned and carried out in the department of pharmacology. All spontaneously reported ADRs included in the study. All cases are properly assessed and discussed with associated clinicians and persons. A total of 150 suspected ADR cases were reported during the study period. All cases were analyzed for types of ADR, adverse drug effects and prescribed anti-parkinsonism drugs.

Table No 1: Tabular representation of study population diagnosed with Parkinson's disease

Age in years	Male (106)		Female (44)	
	No of patients	% no of patients	No of patients	% no of patients
40-49	10	9.4%	8	18.18%
50-59	58	54.71%	18	40.90%
60-69	26	24.52%	10	22.72%
70-80	12	11.32%	8	18.18%
	106	100%	44	100%

Table No 02: Tabular column represents symptoms at the time of enrolment in the study

S.No	Symptoms at the time of enrolment	No of patients	Percentage
1	Bradykinesia	42	24.70%
2	Rigidity	38	22.35%
3	Postural instability	28	16.47%
4	Hypominia	24	14.11%
5	Pain	18	10.58%
6	GI disturbances	8	4.70%
7	Mood disorders	12	7.05%
Total No of ADR Reported		170	100%

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Figure No 01: Graphical represents symptoms at the time of enrolment in the study

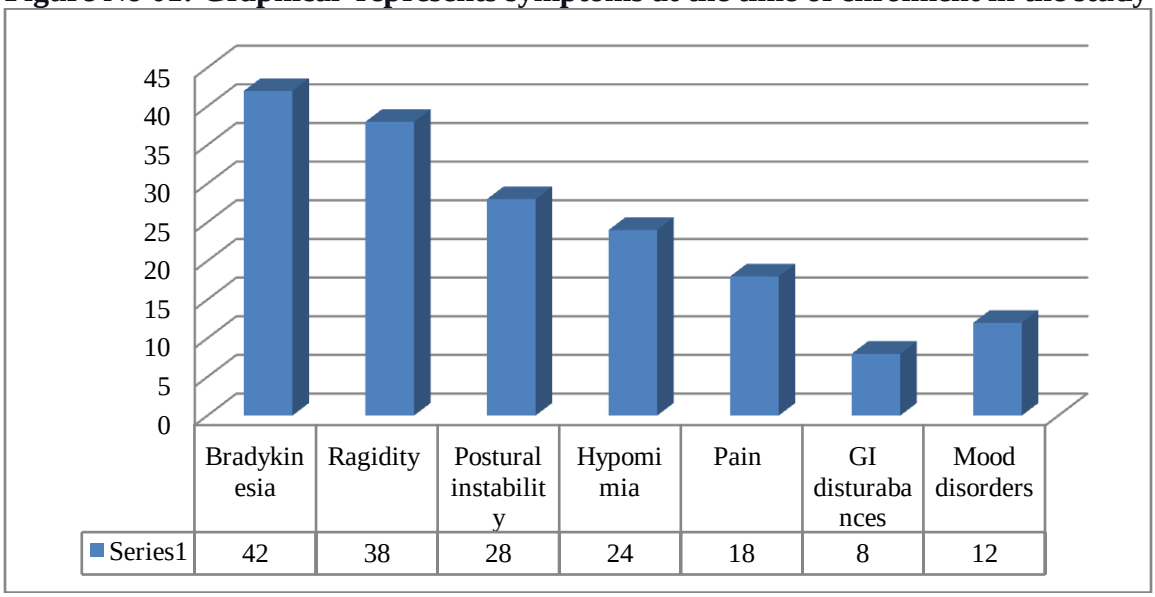

Table No 03: Types of Adverse drug effects after prescribing Antiparkinsonian drugs

Types of ADR's	No of patients	% no of patients
A	93	62.00%
B	44	29.33%
C	13	8.66%
Total No patients	150	100%

Figure No: 04 Graphical representation of Types of ADR after prescribing Antiparkinsonian drugs

S.No	ADR reported	No of patients reported with ADR	% No of ADR
1	Akathisia	13	7.78%
2	Dizziness	48	28.74%
3	Anorexia	10	5.98%
4	Dry mouth	36	21.55%
5	Dyskinesia	22	13.17%
6	Sedation	12	7.18%
7	Fatigue	10	5.98%
8	Constipation	6	3.59%
9	Nausea	10	5.98%
Total No of ADR Reported		167	100%

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Figure No 02: Graphical representation of ADR observed after prescribing Antiparkinsonian drugs

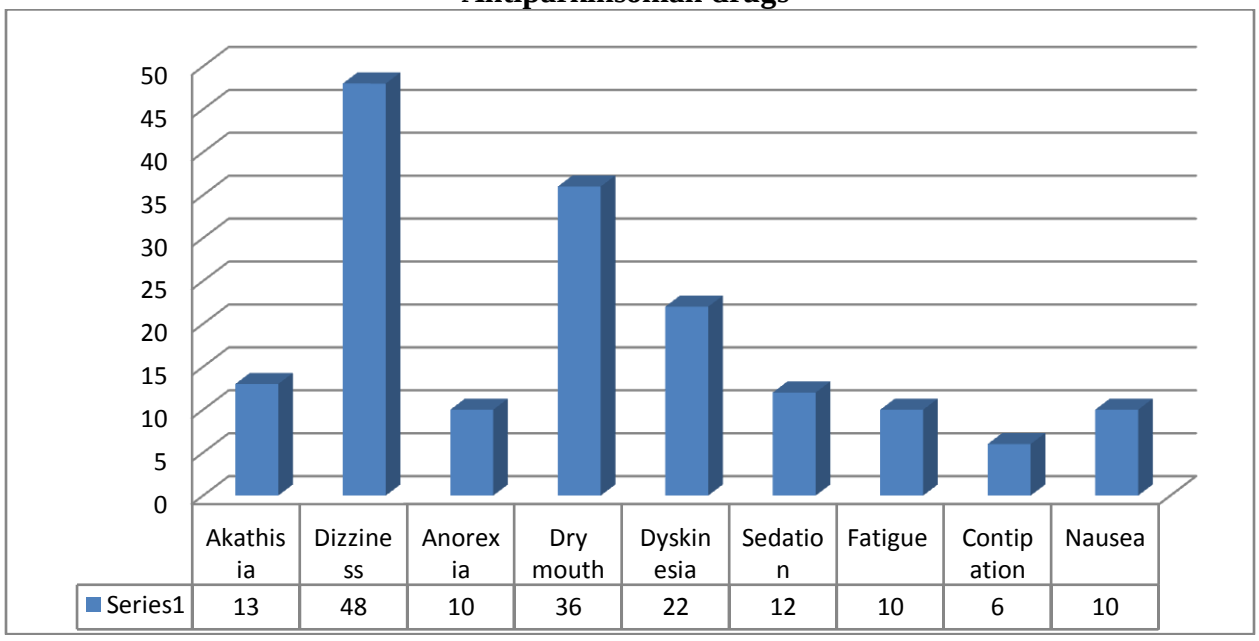
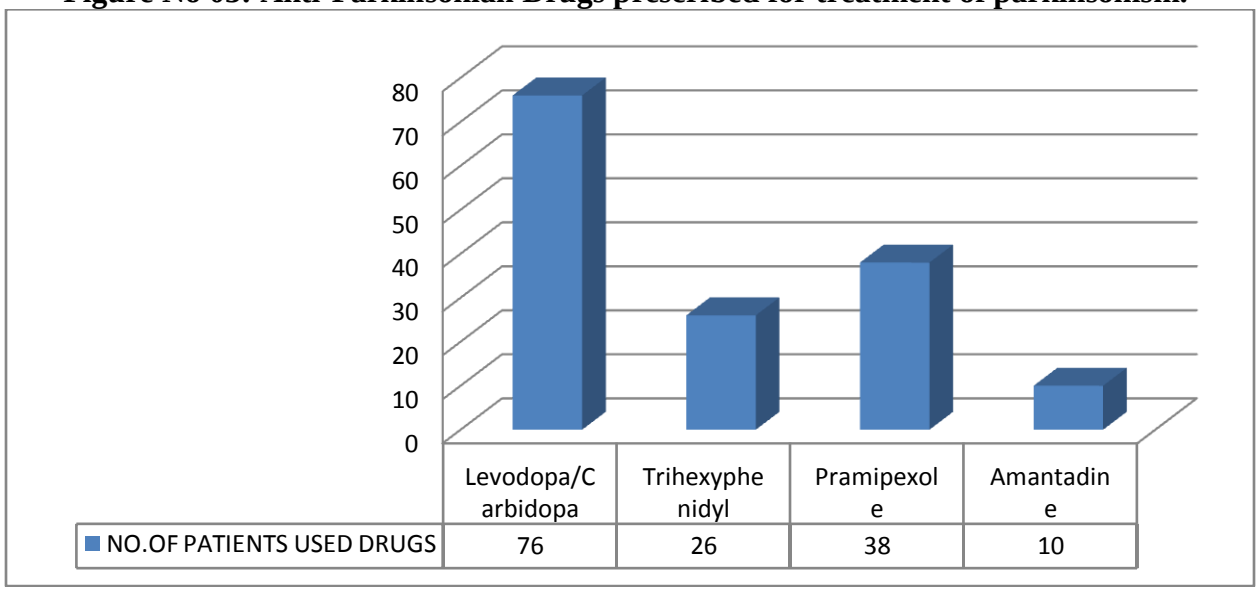


Table No.05:Anti-Parkinsonian Drugs prescribed for treatment of parkinsonism.

S.NO.	DRUGS	NO.OF PATIENTS USED DRUGS
1.	Levodopa/Carbidopa	76
2.	Trihexyphenidyl	26
3.	Pramipexole	38
4.	Amantadine	10
Total No of drug prescribed for treatment of parkinsonism.		150

Figure No 03: Anti-Parkinsonian Drugs prescribed for treatment of parkinsonism.



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Discussion:

The objective of this study was to assess the type(s) of ADRs, symptoms at the time of enrolment in the study, ADR monitoring after prescribing Antiparkinsonian and to find the drugs mostly used in treatment of Parkinsonism ADRs. We conducted this study at the Department of Pharmacology & Therapeutics, ADR Cases were collected from the Department of Neuromedicinewhich is a tertiary care center and covers a large population of both urban and rural backgrounds. Majority of the patients were male 106 and females 44 patients. As per the age majority of the patients were in the age group between 50 to 59 years there were 58 in males and 18 in females. Our study coincides with the study of **Monalisa Jena et al (2016)[6]** in his study he observed that majority of the patients are males and in the age group range of 50 to 59 years. Parkinsonism patients symptoms observed at the time of enrolment in the study majority of the patients having Bradykinesia 24.70% followed by Rigidity 22.35%, postural instability 16.47%, hypomania 14.11%, pain 10.58%, GI disturbances 4.70% and mood disturbances 7.05%.**Monalisa Jena et al (2016)[6]**in his study he observed that majority of the patients having Bradykinesia 416 (90.04), Rigidity 403 (87.2) and Postural instability 226(48.9). There are different types of ADRs but in our study we observed only three types of ADRs majority of ADR observed was type A62.00% followed by type B29.33% and type C 8.66%. Parkinsonism patients were prescribed with Antiparkinsonian drugs shows ADRs, in our study we observed total of 167 ADRs majority of ADRs observed was Dizziness 28.44%, followed by Dry mouth 21.55%, Dyskinesia 13.17% Akathisia & sedation 7.18%, Anorexia, Nausea & Fatigue 5.98 % and constipation 3.59%. Our study conducted by the study of **Thaha F et al (2017)[7]** reported that the most common reactions were sedation, dizziness, dry mouth, and fatigue. there are different classes of Antiparkinsonian drugs for the treatment of parkinsonism but in our study we selected four Antiparkinsonian drugs as per our study majority of Antiparkinsonian prescribed to the patients was combination of levodopa/carbidopa 76 patients followed by pramipexole 38 patients, Trihexyphenidyl 26 patients and amantadine 10 patients. Total of 150 parkinsonism patients. **Thaha F et al (2017)[7]** most commonly prescribed Antiparkinsonian drug was Pramipexole. **Monalisa Jena et al (2016)[6]**he prescribed class the classes of Antiparkinsonian drugs but majority of the prescribed with levodopa/carbidopa.

Conclusion:

Antiparkinsonian drugs used for the treatment of Parkinsonism. As per the study majority of the patients were male in the age group of 50 – 59 having symptoms of bradykinesia, rigidity and postural instability. Majority of patients prescribed with levodopa/carbidopa, after ADRs monitored Dizziness followed by Dry mouth, Dyskinesia, Akathisia, sedation, Anorexia, Nausea, Fatigue and constipation was observed.

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