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ASSESSMENT OF MANAGEMENT OF ADVERSE DRUG REACTIONS REPORTED IN A TERTIARY CARE HOSPITAL IN CALICUT

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Abstract:

Aim: Adverse drug reactions are a serious problem with increasing incidence as more medicines become available and more people become exposed to them. Detection and management of adverse drug reaction is one of the major areas in the medication process, where the management is not emphasized much. This study was done to determine the difference in the management of adverse drug reactions reported in the study site with the evidence based management.

Method: Retrospective cross- sectional observational study design was followed for a period of five years. Inpatient related suspected ADRs reported by physician-in-charge or other healthcare professionals directly involved with the patient care was included as the observed. Parameters such as causality, type of reaction, severity, management given were assessed. Further the management given in the hospital was compared with standard treatment guideline or available evidence-based treatment for ADRs.

Results: Out of 59 patients 57.6% were male and 42.3% were female. As per Naranjo's causality assessment 66.1% of reactions were probable, 28.8% were possible, 5.08% were definite. As per Modified Hartwig and Siegel severity assessment majority of the ADRs were moderate (50%) and mild (46.6%). Wills and Brown classification showed Type A (augmented) 64.4%, Type H (hypersensitivity) 30.5%, Type C (chemical) 3.38% and Type D (delivery) 1.7% reactions. Most of the patients with ADR (56.3%) completely recovered after treatment and 33.4% were recovering process. The management followed for stopping the suspected medication was 27.1% of cases and in 10.2% cases the suspected medication was stopped as well as an antidote/antagonist was also prescribed.

Conclusion: The major portions of management were not reported and many cases the outcome of management was not specified. The clinical pharmacy department should give more emphasis on the reporting standards so the that in future the references and interventions will have more clarity.

Keywords: Adverse drug reaction, Causality, Classification, Severity, Management, Evidence based medicine.

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INTRODUCTION:

As per WHO, Adverse drug reaction (ADR) is defined as any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function [1]. ADRs are the fourth leading cause of death ahead of pulmonary disease, diabetes, AIDS, pneumonia, accidents and automobile deaths. Serious ADRs account for 6.7% of all hospital admissions [2]. Due to lack of reporting the real picture of ADRs is difficult to estimate. ADRs are a serious problem with increasing incidence as more medicines become available and more people become exposed to them. The United Kingdom's National Health Service reports that ADRs resulted in approximately 2,50,000 admissions each year and cost the health system $466 million yearly [3]. ADRs are thus main problem of drug therapy associated with morbidity, mortality, decreased compliance and high direct and indirect medical cost. Indian ADR Monitoring Center (AMC) functional rate was 56.45%. The average number of individual case safety reports reported by the AMC through Vigiflow software per month was 48.038. In a period of 3 years the total number of ADR reported was 3024. The average number of reports per month was 80.08. The active surveillance versus spontaneous reporting contributed 66.13% versus 33.86% of total ADR. Outpatient department contribution was 76.05% and indoor contribution was 23.94% of total reports [4].

Detection and management of adverse drug reaction is one of the major areas in the medication process and pharmacovigilance. This study was done to determine the variance in the management of adverse drug reactions reported in the study site with the evidence-based management.

METHODOLOGY:

Study was conducted in PVS Hospital (P) Ltd, a 310 bedded tertiary care hospital in Calicut. Retrospective cross- sectional observational study design was followed for a period of five years study from January 2017 to December 2021. Inpatient related suspected ADRs reported by physician-in-charge or other healthcare professionals directly involved with the patient care was included as the observations in the study. Study instruments used included- Naranjo's causality assessment form, Wills and Brown classification of adverse drug reaction, and Modified Hartwig and Siegel adverse drug reaction severity assessment scale.

Spontaneous reporting method was followed in the study site for ADR monitoring. The ADR documents in the drug information center and the reports maintained in the nursing unit was used for the data mining. The various parameters in observation were causality, type of reaction, severity, and management given. Further the management given in the hospital was compared with standard treatment guideline or available evidence-based treatment for ADRs. Approval from the registered Institutional Ethics Committee of PVS Hospital (P) Ltd, Calicut was obtained for the conduct of this study.

RESULTS:

A total of 59 patient cases were reported with ADR during the study period. Out of 59 patients, 34 (57.6%) were male while 25 (42.3%) were female. Among the 59 patients, 50 had single ADR. The median age of the patients was 30 - 65. The youngest patient who experienced ADR was of 14 years and oldest was 91 years. Majority of patients experienced ADRs belonged to age group of 18 - 60 years (49.1%). Table No. 1 represents the demographics characteristics of the study cases.

Table No. 1: Demographic details

Demographic Characteristics		Number	Percentage
Gender	Male	34	57.6%
	Female	25	42.3%
Age Group	Less than 18	3	5.08%
	18-60	29	49.1%
	More than 60	27	45.7%

According to Naranjo's algorithm scale, 39 (66.1%) suspected ADRs were probable, 17 (28.8%) ADRs were possible, 3 (5.08%) ADRs were definite. As per Modified Hartwig and Siegel severity assessment scale majority of the ADRs were moderate 30 (50%), 28 (46.6%) ADRs were mild. As per Wills and Brown classification, majority of the ADRs were Type A (augmented) 64.4%, Type H (hypersensitivity) 30.5%, Type C (chemical) 3.38% and Type D (delivery) 1.7%. Table No. 2 represents the assessments done for the various adverse drug reactions reported.

Table No. 2: Assessments related to ADRs reported

Assessments			Number	Percentage
Naranjo's Causality	Definite		3	5.0%
	Probable		39	66.1%
	Possible		17	28.8%
	Unlikely		0	0
Wills and Brown Classification	Type A (Augmented)		38	64.4%
	Type B (Bugs)		0	0
	Type C (Chemical)		2	3.38%
	Type D (Delivery)		1	1.7%
	Type E (Exit)		0	0
	Type F (Familial)		0	0
	Type G (Genotoxicity)		0	0
	Type H (Hypersensitivity)		18	30.5%
	Type U (Unknown)		0	0
Modified Hartwig and Siegel Severity	Mild	Level 1	4	6.7%
		Level 2	20	33.8%
	Moderate	Level 3	29	49.1%%
		Level 4 (a)	5	8.47%
		Level 4 (b)	1	1.7%
	Severe	Level 5	0	0
		Level 6	0	0
		Level 7	0	0

Most of the patients with ADR 56.3% were completely recovered after treatment and 33.4% were recovering. Among 59 patients, 16 (27.1%) suspected medication was stopped. In addition, the suspected medication was stopped and the antidote prescribed for the condition 6 (10.2%) for the condition. Table No. 3 represents the management of the various adverse drug reactions reported.

Table No. 3: Management of ADRs reported

Management	Number	Percentage
Suspected drug discontinued	16	27.1%
Dose altered	1	1.7%
Antidote prescribed	5	8.5%
No change	7	11.8%
Suspected drug discontinued and antidote prescribed	6	10.2%

The management given in the study site for the various adverse drug reactions reported were compared with the evidence-based management (EBM) for the same. Only for 50 adverse drug reactions the evidence-based management was found and compared with treatment provided in the hospital. Treatment of 62% of cases had similarity with the evidence-based management.

Table No. 4: Evidence based management compared to the provided treatment

Management plan	Number	Percentage
Similar	31	62%
Partial	16	32%
Variant	3	6%
Total	50	100

DISCUSSION:

In our study 59 suspected offending drugs were reported to induce various ADRs of which majority (27.1%) of the drugs were withdrawn for the management of ADR. Results from our study illustrate that antiepileptics (27.1%) were the most commonly involved medication classes associated with ADRs, followed by antibiotic medicines (22%). This could be due to the wide usage of antiepileptics at our study site and based on the number of medications, the chances are high for developing an ADR. A recent study reported that antibiotics (20.8%) were the second most common medication classes associated with ADRs [5]. Wills and Brown classification of ADR reveals that type A (augmented) reactions (64.4%) were most commonly reported, followed by type H (hypersensitivity) reactions (30.5%), type C (3.38%), and type D (1.7%) reactions which is consistent with literatures studied [5]. Naranjo's causality algorithm found that most of the reactions had probable relation to the suspected medications (66.1%) followed by possible relation (28.8%), though various measures mentioned in Naranjo's algorithm were not practically possible at the study site, such as placebo response and drug concentration estimation in body, and these findings would have made a difference in the assessment of causality. Similar findings were reported by Emma and colleagues from the United Kingdom among 3695 hospitalized inpatients [5]. The study observed that the documentation of ADRs were unintentionally missed which could be because of work related stress and forgetfulness, lack of knowledge and awareness about the importance of drug safety monitoring, poor knowledge of ADR reporting programme objectives, and busy outpatient setting, and many clinicians do not consider reporting a priority. This study suffers the main drawback of spontaneous reporting system i.e., underreporting. Thus, ADR monitoring should be strengthened in this diversified region by sensitizing and encouraging healthcare providers to report ADRs.

Observation of management of adverse drug reaction reported and its comparison to the evidence-based treatment was a study which was not much conducted and there are no literatures available exclusively for the intervention for adverse drug reaction management. As per our study majority of the management was complying with the evidence base. The reason could be that the basic strategy of treatment remains the same. But our study faced a major drawback that the management plan completely followed and mainly the outcome of management was not recorded in the documents. The study suggests for prospective study design with rectifying all the drawbacks for coming to a clearer inference.

CONCLUSION:

The pattern of ADRs reported by the clinical pharmacy department was comparable with the results from studies conducted elsewhere in a hospital setting. Although the study was able to showcase the role of clinical pharmacist in monitoring the ongoing safety of medicines through continuous ADR reporting the documents maintained still had lot of lacunas. The major portions of management were not reported and many cases the outcome of management was not specified. The outcome assessments could have added a lot of meaning while comparing the conventional method of treatment with the evidence-based management.

The clinical pharmacy department should give more emphasis on the reporting standards so the that in future the references and interventions will have more clarity. This study also suggests for the need of spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of ADRS. This study also warrants further research in same work in a prospective manner that will provide a wider scope for possible interventions if any.

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