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Adverse drug reaction monitoring in tertiary level referral hospital, Perintalmanna

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ABSTRACT

An attempt was made to observe the pattern and extent of occurrence, various reasons and severity of ADRs and their causality in a tertiary level referral hospital at Perintalmanna and also to understand the overall trend of adverse effect of drug in our locality. In this study, Pharmacist prompted spontaneous reporting method was followed. The study was conducted for a period of four months from August 1st to November 31st 2009. Clinical pharmacists prompted the clinicians with personal reminders and leaflets to report more ADRs. The reported ADRs were analyzed and assessed for causality using Naranjo causality assessment scale. During the study a total number of 16 reports were received. For the month of August (12.5%), September (50%), October (25%) and November (12.5%) ADRs were reported. The drugs that caused ADRs were Antibiotics, Antiemetics, NSAIDs, Anticoagulants, & Antidiabetics. Causality assessment of ADRs was done by Naranjo causality assessment scale. Results revealed that (68.75%) reports were probable, (25%) were possible and (6.25%) were certain. Pharmacist prompted ADR monitoring and reporting program increased the ADR reports in the hospital. Appropriate information about the causality of ADRs and measures to overcome the reactions have improved the clinical outcome and contributed for decreasing the morbidity.

Key words: ADRs, Prompted spontaneous reporting, Causality. Naranjo assessment scale

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INTRODUCTION

Modern medicines have changed the way in which diseases are managed and controlled. However, despite all their benefits, evidence continues to mount that adverse reactions to medicines are a common, yet often preventable, cause of illness, disability and even death. In some countries. ADRs rank among the top ten leading causes of mortality [1] .ADRs increase morbidity, mortality and add to the over all healthcare cost. Early detection, evaluation and monitoring of adverse drug reactions are essential to reduce harm to patients and thus improve public health. The world health organization (WHO) defines an ADR as a response to a drug which is noxious and unintended, and which occurs at the doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological functions [2]. Many ADRs which is due to irrational prescribing under diagnosis, more than four drugs in one prescription may lead to ADRs; 8-10% of hospital admissions may develop ADRs. Reporting of ADRs reactions to either a government or some other agency is a recent phenomenon in most countries. WHOs programme for international drug monitoring was started in 1968. Initially a pilot project in 10 countries which established national reporting systems for ADRs. The network has since expanded significantly as more countries worldwide developed pharmacovigilance centers for the recording of ADRs. Currently, 86 countries participate in the programme, which is coordinated by WHO together with its collaborating center in Uppsala, Sweden [1,3]. Monitoring of ADRs started in India about two decade ago (1982) . Under the chairman ship of the drug controller of India, five centers were established with the idea of starting a monitoring programme nation wide. Its nodal center (National Pharmacovigilance centre) is located in the department of Pharmacology, All India institute of medical sciences, New Delhi. It is affiliated to WHO collaborating centre for ADR monitoring, Uppsala Sweden. It consists of three phases, the first one being monitoring of reactions in the institutes, second one in governmental bodies like central governmental health scheme, and the third phase proposed to include general practitioners [4]. Throughout the world, most of the ADR monitoring programmes rely on physician initiated reporting (voluntary reporting) and have been partially successful [5]. Under reporting has been the biggest challenge in the voluntary reporting method and several reasons like increase in work load, perception that reporting will not result in any improvement, and lack of knowledge that an adverse event has occurred and fear of exposing oneself to litigation [6]. To overcome the problems in the voluntary reporting of ADRs, Prompted spontaneous reporting is followed wherein physicians are prompted by Medical residents, Pharmacists or Nurses to report any adverse drug reactions[7]. This method of prompting the physicians every day is reported to increase the reporting and reducing the morbidity and mortality [8]. The present study of ADR monitoring is carried out in a tertiary level referral hospital by following pharmacist prompted spontaneous reporting method [9]. The aim of the present study was to observe the pattern and extent of occurrence of ADR, their causality, and to create awareness about ADRs among patients and to motivate the health care professionals in the hospital to report ADRs, so as to minimize the risk of adverse drug reactions [10].

MATERIALS AND METHOD

An attempt was made to study about the adverse drug reactions, its reasons and preventive measures in a tertiary level referral hospital, Perintalmanna, Malappuram district by monitoring the patient. The method was based on survey. Detailed survey was carried out for a period of four months. All the patients, Nursing Superintendent and selected doctors of this hospital were included in the survey. An awareness lecture was given prior to starting the study to increase the awareness about the Adverse drug reactions among the clinicians .Further clinical pharmacist prompted the clinicians with personal reminders and leaflets to report more ADRs. Only those cases, which fulfilled the criteria, were included in the study. Sets of ADRs monitoring forms were distributed to the doctors. Complete medication history of the patients was obtained from WHO monitoring form, case reports, and personal interviews with patient and patients attendants. The present disease status of the patients before and after drug intake and other co- morbid conditions were properly enquired and noted down. During the study, the prescription pattern of different physicians and their treatment were studied. Every month discussion was conducted with doctor and nursing Superintendent and thus obtained the feed back. More than 150 forms were filled in, & analyzed the percentage of the people affected by ADRs based on different factors. The causality assessment of the reported ADRs was carried out using Naranjo causality assessment scale. Adverse drug reactions were submitted to medical superintendent of the hospital.

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The data collected in the four months period was analyzed for the following parameters.

1. The total number of ADRs that are reported.
2. Reports received from different departments
3. Average number of reports per month.
4. Age groups and gender of the patients
5. Different organ systems affected by the reactions
6. Classification of drugs that causing reaction
7. Assessment of causality based on Narenjo assessment scale.

RESULTS

During the four month study of ADR monitoring from August 2009 to November 2009, total 150 forms were filled in, out of 150 reports, 16 ADRs were reported and were included in the study. (Table 1). In the month of august 2 ADRs were reported which accounted 12.5% of the total number of ADRs reported during the study. For the month of September, October and November 8 (50%), 4 (25%), 2 (12.5%) ADRs were reported respectively. (Table 2 & figure 1) .Maximum numbers of 11 ADRs (68.75%) were reported from the department of Medicine followed by Orthopedics department, which reported 5ADRs (31.28%). (Table 3 & figure 2) Maximum number of ADRs were reported from geriatric patients 10 (62.5%) followed by Adult 5 (31.25%) and Children 1(6.25%). No ADRs were reported from neonates. (Table 4 & figure3). From the ADR reports, we observed male predominance over female in ADR occurrences during our study period. The table 5 & figure 4 illustrate the categorization of ADR according to the gender of the patients. Results revealed that gastrointestinal system was most affected by the adverse reactions of drug 10 (62.5%) followed by CNS 5(31.25%) and skin 1(6.25%) respectively. (Table 6 & figure 5). Antibiotics 6(37.5%) & Antiemetics 4 (25%) were responsible for the maximum number of ADRs, followed by NSAIDS, 3(18.75%), Anticoagulants (6.25%), Anti diabetics (6.25%), Corticosteroids 1(6.25%). (Table 7 & figure 6). Causality assessment of ADRs reports using Naranjo scale assessment revealed that 6.25 % (N=1) were definitely due to drugs, 68.75% (N=11) reports were found to be probable due to drugs and, 25% (N=4) were possible due to drugs respectively. (Table 8 & figure 7)

CONCLUSION

The four month study conducted in Medicine and Orthopedics departments of the hospital reports a systemic analysis of ADRs. Pharmacist prompted ADR reporting and monitoring program increased the ADR reports in the hospital. During the study period a total of 16 reports were received, which was indeed a high number compared to the previous years. During the frequent visit to the hospital, awareness was created among the patients and regular reminders of dosage regimen were also given. Proper information about the causality of ADRs, various methods to overcome the reactions etc, have improved the clinical outcome and contributed for decreasing the morbidity. Physicians have found the ADR monitoring program highly useful. An ongoing ADR monitoring program can provide benefits to the organization, pharmacist, other health care professionals and patients. A combined effort with the participation of all other departments, taking more time and including more patients will be beneficial.

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SURVEY AND FINDINGS

Table - 1: List of ADRs reported during the study period

Sl. No.	DRUGS	ADRS	No.
1.	Inj. Amikacin	Vertigo	5
2.	Inj. Prochlorperazine	Constipation	3
3.	Inj. Ketorolac Trometamol	Diarrhea	2
4.	Inj. Diclofenac	Constipation	1
5.	Tab. Pioglitazone	GI Disturbances, Headache	1
6.	Inj. Ondansetron	Constipation	1
7.	Inj. Cefoperazone + Sulbactum	Nausea, Vomiting	1
8.	Dalteparin Sodium	Hypersensitivity, irritation	1
9.	Inj. Dexamethasone	Increase appetite	1

Table - 2: Number of ADRs received per month during the study period

MONTH	NUMBER	%
August	2	12.5
September	8	50
October	4	25
November	2	12.5

Table – 3: Number of ADRs reports received from the two departments

DEPARTMENT	NUMBER	%
Medicine	11	68.75
Orthopedics	5	31.28

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Table – 4: Division of ADRs based on age group of patients

PATIENT AGE GROUP	NUMBER	%
Geriatrics	10	62.5
Adults	5	31.25
Children	1	6. 25
Neonates	0	0

Table –5: Division of ADRs based on gender of the patients

SEX	NUMBER	%
Male	10	62.5
Female	6	37.5

Table - 6: Organ system affected due to ADRs

ORGAN SYSTEMS	NUMBER	%
CNS	5	31.25
GIT	10	62.5
SKIN	1	6.25

Table – 7: Therapeutic classes of drugs implicated to cause ADRs

CLASS OF DRUG	NUMBER	%
Antibiotics	6	37.5
Antiemetics	4	25
Anticoagulants	1	6.25
NSAIDs	3	18.75
Antidiabetics	1	6.25
Corticosteroids	1	6.25

Table - 8: Causality assessment of ADRs using Naranjo scale

CAUSALITY	NO	%
Definite.	1	6.25
Possible drugs	4	25
Probable drugs	11	68.75