MONITORING AND REPORTED THE ADVERSE DRUG REACTIONS OF DIFFERENT DRUGS IN RURAL GOVERNAMENT HOSPITAL IN NALGONDA SPONTANEOUS REPORTING METHOD

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ABSTRACT

Adverse drug reactions (ADRs) are one of the major problems associated with medicines. The effectiveness and success of any pharmacovigilance system depends highly on the participation of all health care professionals. An observational, prospective study was conducted based on ADRs reported between Feb 2nd to 18 th march to the ADR reporting unit of the hospital. The ADRs reported by spontaneous reporting system were from patients attending in-patient department (IPD) and casualty of IGGMC&H Nalgonda Evaluation of the data was done for various parameters which included patient demographics, drug and reaction characteristics, and outcome of the reactions. Assessment was also done for causality and severity. Total 75 ADRs were reported with in the period from 2_{nd} Feb. to 18th March. Cefrioxome were the drug class most commonly involved and next Cefixime a well established agent was the individual drug most frequently reported in this study. Upon causality assessment, majority of the reports were rated as probable (13.043%). The pattern of ADRs reported in our hospital is comparable with the results of studies conducted in hospital set up elsewhere. Cefrioxome were causing maximum ADRs. This study provides a database of ADRs due to common drugs used in our hospital, which will help clinicians for optimum and safe use of these drugs. Hence strict vigilance is required for the use of these likely drugs and their safety assessment.

KEYWORDS: adverse drug reactions, hospital based monitoring, pharmacovigilance, survey of patients.

INTRODUCTION

Adverse drug reactions are defined as any noxious unintended and undesired effects of a drug that occur at doses used for prevention, diagnosis or treatment. Although many drug reactions are preventable. Such as those associated with prescription errors while others are not preventable. The adverse drug reactions are often not discovered until after the drug has been marketed. Pharmaceutical companies strive to work out the adverse effect profile of a drug before it is marketed, but because the complete range of adverse effects is not known, therefore, most severe drug induced reactions cannot be elucidated before licensing, therefore efficient post marketing surveillance is needed. Since patients often cannot recall important details clearly, so all relevant medical records should be visualized. This information is not only vital to the physicians but it also makes patients less anxious.[1,2,3] since they can become frustrated and embarrassed if they cannot recall specific details. the most ADRs have recently emerged as leading killers. The management of drug-induced illnesses requires more than 100 billion US dollars annually. These astronomical figures are currently unmatched by money involved in common system failure has been to disseminate the knowledge of pharmacovigilance to the individuals actually involved in prescribing, i.e., the physicians. Principles and practice of pharmacovigilance seem to be more often discussed in an academic manner, rather than in a pragmatic or applied sense. Several times, such discussion is held amongst pharmacologists and pharmacists who are not directly involved in patient care; and physicians who treat cases and use drugs generally keep themselves uninvolved.

SCHEMATIC SYSTEM OF WORK

Reporting: ⟶ Reporting form
↓
Where to report
↓
What to report
↓
Advice to report
↓
Report follow-up
↓
When to report
↓
Who should report?
↓
Reports feed back
↓
Alternating reporting methods
↓
Data entry and Data management

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM
For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

IPC

INDIAN PHARMACOPOEIA COMMISSION	FOR AMC/NCC USE ONLY
(National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002	AMC Report No. :

Report Type □ Initial □ Follow up | Worldwide Unique No. :

A. PATIENT INFORMATION | 12. Relevant tests/ laboratory data with dates

1. Patient Initials	2. Age at time of Event or Date of Birth _____	3. M □ F □ Other □
		4. Weight_____Kgs

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery   (dd/mm/yyyy)

7. Describe reaction or problem

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No □if Yes □ (please tick anyone)

□ Death (dd/mm/yyyy)   □ Congenital-anomaly

□ Life threatening   □ Required intervention to
                                                   Prevent permanent

□ Hospitalization/Prolonged   impairment/damage

□ Disability   □ Other (specify)

15. Outcomes

□ Recovered   □ Recovering   □ Not recovered

□ Fatal   □ Recovered with sequelae □ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates Date started	Therapy dates Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick) Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unkn own	10. Reaction reappeared after reintroduction (please tick) Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates Date started	Therapy dates Date stopped	Indication
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____

Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

METHODS

The assessment of causality relationship is often subjective, based upon an individual clinician's assessment. One clinician's judgement may appear unlikely to another clinician. If an ADR is suspected, the assessment starts with collection of all the relevant data pertaining to patient demographics, medications, including non-prescription[4,5,6] (OTC) drugs, comprehensive ADR details including a description of the reaction, time of onset and duration of the reaction, complications and/or sequelae treatment of the reaction and outcome of the treatment and further relevant investigation reports. The collected data were used to correlate and categorize the relationship between the suspected drug and the adverse drug reaction. The data were also analyzed as per severity (Mild, Moderate and Severe) of the suspected adverse drug reaction and categories as death, life threatening, hospitalization (initial or prolonged), disability, congenital anomaly, required intervention to prevent permanent impairment or damage not serious, and others. This study was a concurrent, spontaneous reporting, involving both active and passive methods. Active methods include physicians, pharmacists and nurses actively looking for suspected ADRs and passive methods include stimulating prescribers to report suspected ADRs. The study was conducted in a 35-bed internal medicine ward of the Rural Government Hospital, Nalgonda. over a period of 3 consecutive months, starting from Feb 2016 to March 2016. An Adverse Drug Reaction Reporting Form was designed and made available at all nursing stations of the ward of the hospital for easy access to all healthcare professionals. The Adverse Drug Reaction Reporting Form was prepared with reference to the ADR reporting form of the Indian Pharmacopeia Commission (IPC).

which includes information about the patient, like name, age, sex, medication history, diagnosis history, name of the suspected drug along with batch number, lot number manufacturing date and expiry date. The route of drug administration, frequency and dose is also mentioned in the form. Basic information of adverse reaction caused by the suspected drug was also included. We defined adverse drug reactions according to the World Health Organization definition, as being all "noxious and unintended drug response, which occur at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function (WHO, 1972). By this definition, ADRs primarily include allergic reactions and adverse effects.[7,8,9] Therefore, we excluded all the intentional overdoses, poisonings and therapeutic failures.

The relationship between ADR and the suspected drug was assessed. The severity of the ADRs was also assessed in different categories as mild, moderate and severe for each ADR. All the reported ADRs were assessed for their preventability criteria. Personalized letters and circulars signed by the director of the hospital were circulated to all residents and practitioners, visiting practitioners and nursing stations. These letters contained information on the number of suspected ADRs that had been reported till date, need for continuing reporting of ADRs and a request to maintain a high degree of suspicion for the ADRs. The data observed were analyzed in order to study the characteristics of the ADRs and to determine the nature and pattern of ADRs related to hospital admission and difference in the severity of ADRs and management and outcome of management of the reported ADRs.

RESULTS

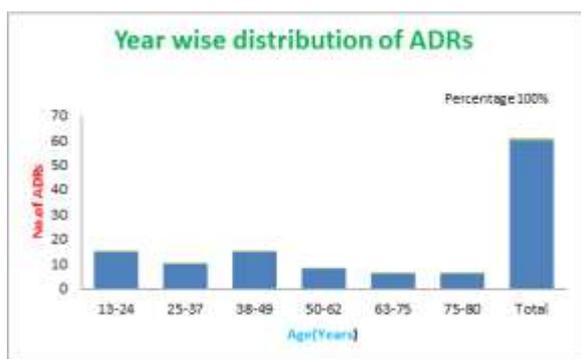| YEARS	NO OF ADRS	PARCANTAGE (%)
13-24	15	24%
25-37	10	16%
38-49	15	25%
50-62	8	13%
63-75	6	10%
75-80	6	10%
TOTAL	60	100%

TABLE-2: Sex wise Distribution of ADRs:

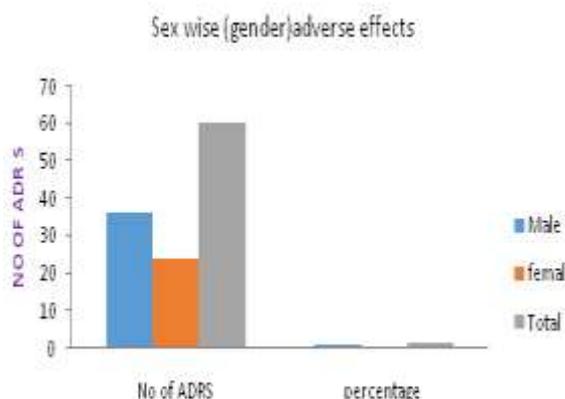| SEX	NO OF ADRS	PARCANTAGE (%)
MALE	36	60%
FEMALE	24	40%
TOTAL	60	100%

Figure:2

Figure:2
NOTE: sex wise distubustion of ADRS

TABLE -3: DEPATMENT WISE DISTRIBUTION OF ADRS

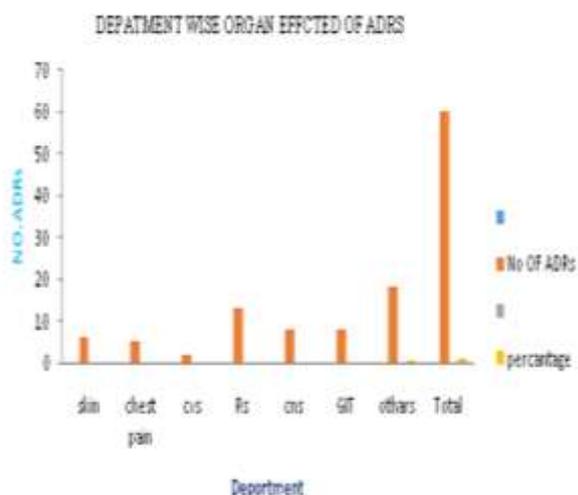| DEPATMENT	NO OF ADRS	PERCANTAGE (%)
SKIN	06	10%
CHEST PAIN	05	08%
CVS	02	03%
RS	13	21%
CNS	08	13%
GIT	08	26%
OTHERS	18	30%
TOTAL	60	100%

Fuigar 3

DEPATMENT WISE ORGAN EFFCTED OF ADRS
Table: 4 Oragan Systam Afftad By Adrs

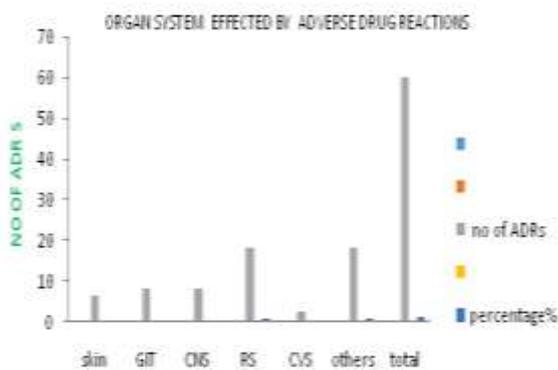| ORAGAN	NO OF ADRS	PARCANTAGE (%)
SKIN	06	10%
GIT	08	13%
CNS	08	13%
RS	18	30%
CVS	02	03%
OTHER	18	30%
TOTAL	60	100%

FIugar: 4

TABLE 5: Top 10 Drug causing ADRs

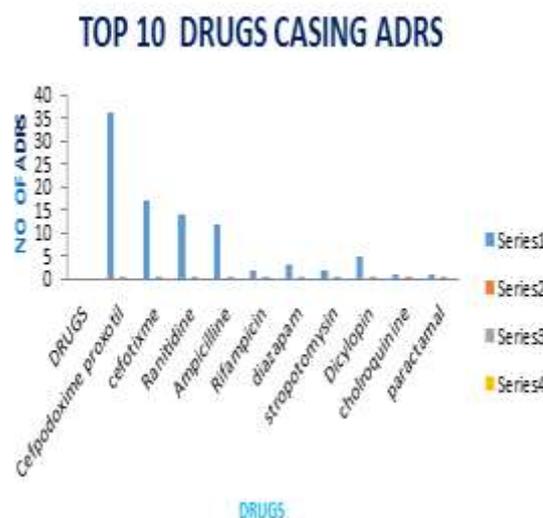| DRUGS	NO OF ADRS	PARCANTAGE
Cefpodoxineproxetil	36	60%
Rantdine	14	23%
Cefotixme	17	28%
Ampicilline	12	20%
Rifampicin	2	3%
Diazapam	3	5%
stropotomysin	2	3%
Dicylopin	5	8%
Cholroquinine	1	1%
paracetamal	1	1%

Fiugar: 5
NOTE: Top 10 drugs casing adrs such git toxicity

Total 60 ADRs were reported in the span of period from Feb 8. 2016 to March 18. 2016. The year wise distribution of ADR sindicates that almost similar number of ADRs were reported in each year but in year June 06 to May 07 there was slight rise in the number of ADRs might be due to the epidemic of chickenguinea

Out of total ADRs 60 male suffered from ADRs while only 36 Males. Females 24 affected more due to ADRs as compared to males. All were mostly in age group of 13- 80 years

It was seen that most of the ADRs were reported from the other departments like Skin (10%), Chest and TB (08%) etc.

In this study, RS is the most commonly affected organ system (21%). CVS (03%) Gastrointestinal tract system (GIT) is involvedin 26% of ADRs. Other organ systems involved are centralnervous system (CNS)13%, autonomic nervous system (ANS).

Wide varieties of side effectsare observed. The most important were gastrointestinal such asdyspepsia, nausea, vomiting gastritis and cutaneous reactionssuch as fixed

drug eruption, itching, urticaria, maculopapular rashes, vasculitis phototoxic reactions, erythema multiforme, toxic epidermal necrosis and diclopian, paractamal Steven Johnson syndrome.

The top tine drugs causing ADRs in our study are shown in. cefpodoximeproxetil (60%), ranitidine (23%), ampicilline(20%), cefotixme(28%), rifampicin(03%), diazapam(05%), stropotomysin(03%), dicylopin(08%), choulroqinine(1%), Paractamal(01%) has found to be most commonly offending drug. Thirty four ADRs were reported serious, as per WHO definition, out of These were CVS (03%), anaphylaxis nephrotoxicity and angioedema paractamal,

Upon causality assessment, majority of the reports were rated as probable (53.7%). 60 possible and only 34 ADRs were classified as certain. Mild and moderate reactions accounted for 50.5 And 43.9%, respectively.

The routes of administration of drugs are depicted .Majority of ADRs were noted with oral route of administration (49%). Drugs administered by parenteral route (26%), accounted. While of the drugs given topically (16) caused ADRs.

DISCUSSION
Every day we visit the Government head hospital in Gollaguda at Nalgonda. During the visiting hours we spent with patients along with doctors. We observed the prescribed Antibiotics and Anti-Malaria's. From these two categeories of drugs most adverse effects observed in antibiotics when compared to Anti-malaria's.

CONCLUSION
The stimulated spontaneous reporting used in the present study turned out to be a pragmatic method which allowed the detection and characterization of ADRs. However, monitoring of adverse drug reactions is an ongoing ceaseless and continuing process. Since newer and newer drugs hit the market, the need for pharmacovigilance grows more than ever before. Whenever during the ill ness condition antibiotic usage is better for good health and for every small illness or injuries antibiotic usage is not for good health .Why because during the infection time antibiotic not properly worked due to resistance of antibiotics,

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