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RESEARCH ARTICLE

ADVERSE DRUG REACTION MONITORING AT A TERTIARY CARE HOSPITAL IN SOUTH INDIA

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ABSTRACT

An adverse drug reaction (ADR) is an injury caused by taking a medication. ADR's may occur following a single dose or prolonged administration of a drug or result from the combination of two or more drugs. The aim of the present study was to monitor, assess and report the suspected adverse drug reaction at a tertiary care hospital. Prospective observational study was conducted for a period of six months and hospitalized patients were recruited in various wards based on inclusion and exclusion criteria. Each adverse drug reactions were assessed for its causality and severity based on "Naranjo's causality assessment scale" and "Modified Hartwig and Siegel scale". "Schumock and Thornton scale" was applied to assess preventability of adverse drug reactions. A total of 137 ADR's were identified from 112 patients during the study period. Patient demographic data revealed that 36% of ADRs were reported from the age group of 31- 45 years, 52% of ADR's were documented from General Medicine ward, 25% from surgical ward, and 16 % from paediatric. ADR monitoring need to be done in hospital setting continuously so that untoward effect caused by different medicines can be identified and documented. Strategies such as arranging educational programme for health care professionals related to importance of ADR's reporting would substantially reduce ADR's occurrence in hospital ward and remaining from other wards.

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INTRODUCTION

India is the fourth largest producer of pharmaceuticals in world. It is emerging as an important clinical trial hub in the world. Many new drugs are being introduced in our country to protect the population from the potential harm that may be caused by some of these new drugs. The Central Drug Standard Control Organization (CDSCO) has initiated a well-structured and highly participative National Pharmacovigilance Programme. (National Pharmacovigilance Program) Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems. Pharmacovigilance programs can play an important role in elderly detection and prevention of Adverse Drug Reactions (ADRs). (Palaian Subish *et al*., 2009) Information about rare but serious adverse drug reactions, chronic toxicity, use in special groups (e.g., pregnant women, children, elderly) and drug interactions are often incomplete or not available.

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Certain adverse drug reactions may not be detected until a large number of people have received the medicine. Pharmacovigilance is therefore one of the important post-marketing tools in ensuring the safety of pharmaceuticals and related health products. The programme aims to foster the culture of ADE notification in its first year of operation and subsequently aims to generate broad based ADR data on the Indian population and share the information with global health care community through World Health Organization - Uppsala Monitoring Centre (WHO-UMC). The World Health Organization (WHO) defines an Adverse Drug Reaction (ADR) 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'. (Parthasarathi *et al*., 2004) The terms adverse drug reaction and adverse drug event are not synonymous. The WHO definition of an adverse event is 'any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment'. As soon as someone suspects a causal relationship between the untoward occurrence and an administered medicine, the event is turned into a 'suspected adverse drug reaction'.

Classification

Traditionally ADRs are classified into two categories – Type A and Type B reactions.

Type A - (Augmented) reactions are usually the exacerbation of pharmacological effects of a drug and thus are dose dependent. Ex: Insulin induced hypoglycemia. The mortality rate is relatively low however, since most type A reactions will disappear by reduction of dose or by discontinuation of the drug.

Type B – (Bizarre) reactions are hypersensitivity reactions and are not dose dependent. An example is penicillin induced hypersensitivity reaction. These reactions are often not predictable and preventable (unless the patient has a known history of this type of reaction). This type of reaction is often serious with a high mortality rate.

Wills and Brown Classification: (Arulmani *et al*., 2008)

Type A: Augmented reactions

Type A reactions are dose related actions of a medicine upon the human body, which could have been predicted based upon a knowledge of the mode of action and pharmacology of a drug or excipient. These reactions can only occur while the subject is still receiving the preparation and improve partially or completely when the causative agent is withdrawn or the dose reduced.

Type B: Bugs reactions

These are adverse reactions that rely upon promoting the growth of certain microorganisms. These type B reactions are pharmacologically predictable events, but they are not type A according to the definition used in the preceding section, since the direct and principal pharmacological action is on the bodies of microorganism rather than on the human body. An infection arising as a result of drug-induced immunosuppression would not be a type B reaction. The primary adverse event in such a case would be suppression of the human immune system, which is usually a type a reaction. Infections arising as a result of this would be a secondary event.

Type C: Chemical reactions

A number of adverse reactions depend upon the chemical nature of a drug or excipient rather than pharmacological properties. They are all basically forms of chemical irritation, which makes it likely that, when exposed to the preparation, most people could experience a similar reaction. The severity of a type C reaction is more a function of concentration of the offending substance than dose. Typical side-effects in this category include extravasation reactions, phlebitis, pain at the site of an injection owing to the irritant action of a drug or excipient, acid or alkali burns, contact (irritant) dermatitis and gastrointestinal mucosa damage caused by local irritant action. These reactions are not pharmacologically predictable, but knowledge of the physicochemical characteristics of the causative agents may enable them to be foreseen.

Type D: Delivery reactions

A variety of adverse reactions occur as a specific consequence of the method of drug delivery. These reactions do not depend upon the chemical or pharmacological properties of the constituents of the preparation, but occur because of the physical nature of the formulation and/or the method of administration. These reactions will be heterogeneous. Methods of delivery vary and so the specific nature of the adverse reactions must also vary. The unifying characteristic is that, if the method of delivery is changed, the adverse reaction will cease to occur. Examples include inflammation or fibrosis around implants, particles in injections causing thrombosis or blood vessel occlusion, a tablet lodging in the throat, inhaling the 'dust cap' of an inhaler, cough after using a dry powder inhaler, infections at the site of an injection (owing to the opening of a port of entry for bacteria) and infections due to contamination of injection solution with microorganisms.

Type E: Exit reactions

These are known as withdrawal reactions, and are a manifestation of physical dependence. It is only possible for them to occur after administration of the medicine has ceased or the dose suddenly reduced. Unlike all other adverse reactions, which typically worsen if the causative agent is continued, reintroduction of the drug will actually ameliorate symptoms. The likelihood of a reaction is linked more to duration of administration than dose.

Type F: Familial reaction

Certain adverse drug reactions occur only in susceptible individuals with genetically determined, inherited metabolic disorders. Some of the more common familial disorders include phenyl ketonuria, glucose 6-phosphate dehydrogenase deficiency; esterase inhibitor deficiency, porphyria and sickle cell anemia. These reactions must not be confused with those that occur because of the normal variation in ability to metabolize a drug among the population. For example, up to 10% of the population of the western world are deficient in CYP 2D6. However, this does not make them liable to suffer unique adverse effects compared with the rest of the population.

Type G: Genotoxicity reactions

A number of drugs can produce genetic damage in humans. Notably, some are potentially carcinogenic or genotoxic. Some, but not all, teratogenic agents damage genetic material within the fetus.

Type H: Hypersensitivity reactions

These are side-effects caused by allergy or hypersensitivity. They are probably the most common adverse reactions after Type A reactions. There are many different types, but all involve activation of an immune response. They are not pharmacologically predictable, and neither are they dose related according to the definition of 'dose dependent' given above (although very small doses can sometimes be used for desensitization).. Some examples are anaphylaxis, allergic skin rashes, Stevens–Johnson syndrome, photoallergy, acute angioedema, hypersensitivity.

Type U: Unclassified reactions

Some ADRs have a mechanism that is not understood and these must remain unclassified until more is known about them. This

may necessitate the introduction of new adverse reaction categories in the future. Examples include drug induced taste disturbance, muscular adverse effects of simvastatin, and nausea and vomiting after a gaseous general anaesthetic.

Assessing causality

Causality assessment is the method by which the extent of relationship between a drug and a suspected reaction is established. The assessment of causality relationship is often highly subjective, based upon an individual clinician's assessment. In Assessing causality any of the following approaches may be appropriate. These include:

- Opinion of individual expert
- Opinion of a panel of expert
- Formal algorithms

If an ADR is suspected, the assessment starts with collection of all the relevant data pertaining to patient demographics; medications including non-prescription drugs (OTC); 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 outcomes of the treatment; and relevant investigational reports. Using formal algorithms, collected data are subjected and critically assessed by using one or more standard algorithms. Some of the important algorithms (causality assessment scales) used for assessing the causality relationship include

- Naranjo's
- WHO
- European ABO system
- Kramer
- Bayesian
- Karch and Lasagna's
- French imputation method

Different scales categorize the causality relationship in different ways
For ex: The WHO scale categorizes the casuality relationship into

- Certain
- Probable
- Possible
- Unassessable/ unclassifiable
- Unlikely
- Conditional/ unclassified

The Naranjo's scale categorizes the reaction as either

- Definite
- Probable
- Possible
- unlikely

While assessing the causality one should consider many factors. These factors differ only slightly between algorithms.

- The temporal(time) relationship between the administration of the suspected drug and the reaction
- Exclusion criteria
- Outcomes of the reaction upon cessation of drug (dechallenge)
- Outcome of the reaction upon reintroduction of drug (rechallenge)
- Serum plasma concentration of drug.

Communicating ADRs

It is essential that the health professional giving advice to the patient has access to information on the benefits and risks of available medicines. The present situation is, however far from ideal. Knowledge about benefits and risks of medicines, accumulated in reference books in medical libraries, at adverse drug reaction monitoring centers, with pharmaceutical manufacturers or with regulatory authorities, often does not reach the users. Knowledge about the rational and safe use of medicines needs to be provided:

- During the basic training of health professionals.
- Through continuous education programs to health professionals
- By specially designated drug information centers
- Through package inserts and patient counseling
- Through continuous mass media campaigns using, newspapers, radio, television and the internet. This is of particular importance in countries with a high proportion of self-medication.

MATERIALS AND METHODS

Study site: Malla Reddy Hospital located at Suraram, Hyderabad, Telangana, India.

Study design: Prospective observational study.

Study duration: 6 months of study from March 2012 to September 2012.

Inclusion criteria: In patients, who were exposed to any adverse drug reactions during hospital stay and inpatients who were admitted for the treatment of ADRs.

Exclusion criteria: Pregnant women, patients with intentional and accidental poisoning, patients with drug abuse, All mentally compromised (or) unconscious patients and patients unable to respond were excluded from the study.

Study method

- Various forms were designed for the purpose of the study. These include ADR Notification form, ADR documentation form. Designing and distribution of alert card.
- Patients were interviewed, monitored daily throughout their hospital stay and their
  Medical records were reviewed.
- Suspected ADRs detected were identified from objective finding (i.e.) from biochemical investigation results and subjective markers of ADRs were identified through review of clinicians and nurses notes.
- In case of patient categorized as having an adverse drug reaction, data related to all drug details, nature of the reaction, the outcome, the total time spent in hospital were recorded.

- An informed consent form was taken from patient participating in the study.
- The suspected ADRs were carefully analyzed and documented after confirming with the duty doctor in charge of concern ward.
- The ADRs confirmed were classified according to Wills and Brown classification (Arulmani *et al*., 2008) of ADRs.
- The causality relationship between the ADRs and the suspected drug therapy was assessed using the Naranjo's probability scale. (Annexure 1)
- The severity of each of the suspected adverse drug reactions were assessed by modified Hartwig and Siegel ADR severity assessment scale. (Annexure 2)
- The preventability of each suspected adverse drug reactions were assessed by Schumock and Thornton preventability scale. (Annexure 3)

Statistical Analysis

- Descriptive statistics were utilized for data analysis and results were expressed as percentage. Frequencies with percentage were used to summarize gender, organ system involved and severity of adverse drug reactions.
- Chi - square test was used to find an association between genders. Chi-square equals 3.934 with one degree of freedom. The two tailed p value equals 0.0473. All the statistical analysis was performed using SPSS 15

RESULTS

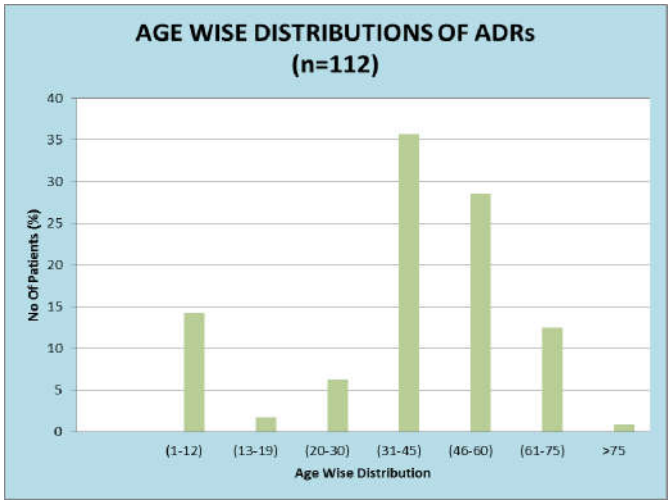

Figure 1.1. Age wise distribution of patients reported with adverse drug reactions

A total of 40 adverse drug reactions were observed in the patient age group of 31-45 years, 32 ADRs from age group of 46-60yrs, 16 ADRs from 1-12 years, 14 ADRs from 61-75 years, 8ADRs from 20-30yrs, 2ADRs from age group of 13-19 years, followed by 1 ADRs in patients greater than 75yrs. Relatively more number of ADRs were reported from age group of 31-45 years because of polypharmacy and concomitant diseases. Higher number of ADRs (i.e.) 51% were documented from General medicine ward, 25% from surgical ward, 16% from Paediatric ward and remaining 8% ADRs documented from orthopaedics, ENT, and ophthalmology. The most commonly reported ADRs in patient's were13 cases of inflammation at the injection site, 12 cases of head ache, 10 cases of urticaria, 10 cases of constipation and 9 cases of Dizziness. The class of drugs most commonly associated with the documented adverse drug reactions were antimicrobials 38(28%) which includes beta lactam antibiotics, macrolides, flouroquinolones, aminoglycoside antibiotics followed by 21(15%) of anti hypertensives and 15(10%) of Non-steroidal anti inflammatory drugs All documented ADRs after confirmation from duty doctor in charge, were classified according to Wills and Brown classification. In our study Type A Augmented reactions were found to be 40%, followed by Type H Hypersensitivity reactions 28% and remaining were classified as Type C Chemical reactions and Type U unclassified reactions.

Table 1.1. Classification of type of reaction observed from reported adverse drug reactions

S.No	Type of reaction	No. of ADRS (n=137)	Percentage (%)
1.	Fatigue	5	3.64
2.	Heart burn	1	0.72
3.	Arthralgia	2	1.45
4.	Cough	3	2.18
5.	Drowsiness	3	2.18
6.	Dizziness	9	6.56
7.	Nausea & vomiting	11	8.02
8.	Inflammation at the injection site	10	7.29
9.	Dehydration	2	1.45
10.	Diuresis	1	0.72
11.	Headache	12	8.75
12.	Dryness of mouth	6	4.37
13.	Loss of appetite	4	2.91
14.	Anaemia	1	0.72
15.	Diarrhoea	8	5.83
16.	Stomach pain	2	1.45
17.	Urticaria	13	9.48
18.	Delusion	1	0.72
19.	Haemorrhage	1	0.72
20.	Disoriented speech	1	0.72
21.	Confusion	1	0.72
22.	Dyspnoea	1	0.72
23.	Eosinophilia	2	1.45
24.	Peripheral neuropathy	1	0.72
25.	Constipation	10	7.29
26.	Hypoglycaemia	1	0.72
27.	Tinnitus	3	2.18
28.	Rapid heart beat	2	1.45
29.	Bronchospasm	2	1.45
30.	Syncope	2	1.45
31.	Abdominal pain	2	1.45
32.	Paresthesia	1	0.72
33.	Insomnia	3	2.18
34.	Restlessness	3	2.18
35.	Anaphylaxis	1	0.72
36.	Hypotension	5	0.36
37.	Transient deafness	1	0.72

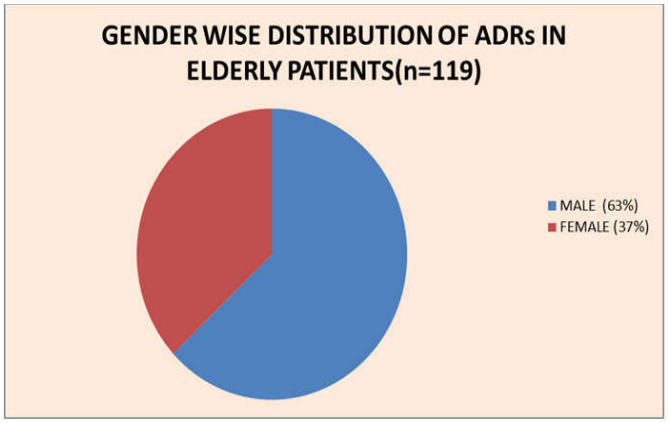

Figure 1.2. Males were about 63% and females were about 37% amongst the total ADRs shown in the population

Table 1.2. Classification of drugs associated with adverse drug reactions

S.No	Type or class of drugs	Name of the drug	No. of ADRS (n=137)
1.	Non-steroidal anti inflammatory drugs	Ibuprofen Aspirin Diclofenac Ibuprofen+paracetamol Tramadol	15
2.	Loop diuretics and potassium sparing diuretics	Furosemide Torsemide Hydrochlorthiazide	10
3.	Sulphonyl ureas and biguanides	Glimepiride Metformin Insulin Glipizide	7
4.	Beta blockers	Atenolol,metoprolol	6
5.	Cephalosporins	Ceftriaxone, Cefuroxine, Cefotaxime	19
6.	Macrolide antibiotics	Azithromycin	3
7.	Beta lactam antibiotics	Piperacillin + tazobactum	1
8.	Flouroquinolones	Ciprofloxacin, ofloxacin, levofoxacin	7
9.	Penicillin antibiotics	Amoxicillin clavulanate	1
10.	Anticholinergic bronchodilator	Ipatropium bromide	3
11.	Aminoglycoside antibiotics	Amikacin	6
12.	Beta 2 adrenergic agonist	Salbutamol	2
13.	Proton pump inhibitors	Pantoprazole Esomeprazole	8
14.	Non Opioid analgesics	Dextromethorphan	1
15.	HMG CoA inhibitor	Atorvastatin	10
16.	5 HT3 receptor antagonist	Ondansetron	4
17.	Fibrates	Fenofibrate	1
18.	Antimalarial drug	Chloroquine	3
19.	H2 receptor antagonist	Ranitindine	1
20.	ACE inhibitors	Ramipril	2
21.	Calcium channel blocker	Amlodipine	1
22.	Benzodiazepine	Chlordiazepoxide	2
23.	Anticoagulant	Enoxaparin, heparin	2
24.	Antiprotozoal	Metronidazole	2
25.	Anti histamine	Cetrizine	3
26.	Antiepileptic	Carbamazepine	1
27.	Tricyclic antidepressants	Amitriptyline	3
28.	Opioid Analgesics	Fentanyl	1
29.	Angiotensin receptor blocker	Losartan	1
30.	Beta adrenergic blocker	Carvedilol	1
31.	Nitrofurantoin antibiotic	Nitrofurantoin	1
32.	Antivertigo	Betahistine	1
33.	Anticholinergic	Hyoscine butyl bromide	1
34.	Nucleotide reverse transcriptase inhibitors	Stavudine	3
35.	Sedatives and hypnotics	Zolpidem	2
36.	Glucocorticosteroids	Budesonide	1
37.	Tetracycline	Doxycycline	1

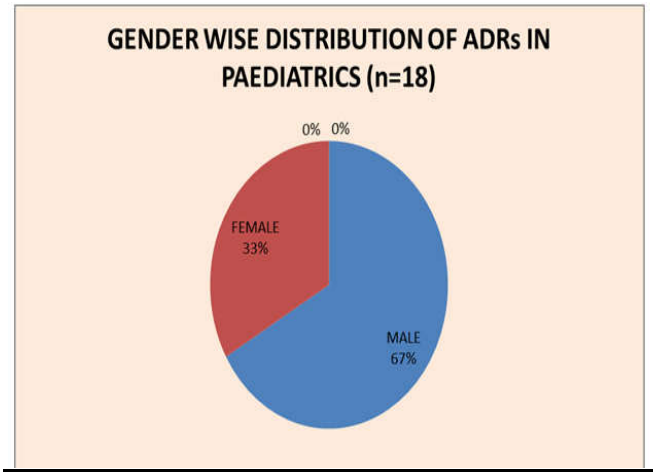

Figure 1.3. Gender wise distribution of adverse drug reactions in pediatrics

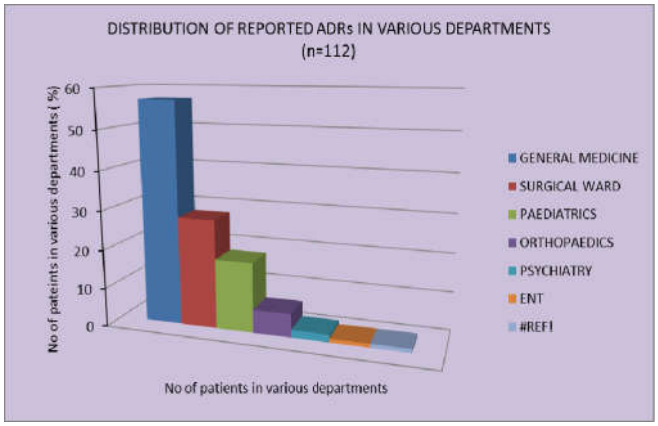

Figure 1.4.

According to Naranjo's scale of causality assessment 58% of ADRs were probable, 30% were possible and 12% of them categorized as definite.

Severity of the suspected ADRs assessed using Hartwig &Siegel scale revealed that 33% of ADRs were moderate (level 3), 21% of ADRS were mild (level1), 21% of ADRs were moderate (Level 4), 18% were mild (level 2) and 8% were severe (level 5).

Table 1.3. Classification of reported adverse drug reactions according to Wills and Brown

Parameter	Number (n=137)	Percentage (%)
Type of reaction		
Type A Augmented reactions	55	40
Type B Bugs reactions	0	0
Type C Chemical reactions	20	15
Type D Delivery reactions	0	0
Type E Exit reactions	0	0
Type F Familial reactions	0	0
Type G Genotoxicity reactions	0	0
Type H Hypersensitivity reactions	39	28
Type U Unclassified reactions	23	17

Table 1.4. Causality assessment of individual adverse drug reaction by Naranjo's algorithm

S.No	Casuality Assessment	Number (n=137)	Percentage (%)
1.	Definite	17	12
2.	Probable	79	58
3.	Possible	41	30
4.	Doubtful	0	0

Table 1.5. Outcome of reported adverse drug reactions

Outcomes	Number (n=137)	Percentage (%)
Fatal	0	0
Fully recovered	67	49
Recovering	70	51
Unknown	0	0

Preventability of suspected ADRs were assessed by using modified Schumock and Thornton scale, revealed that 55% of ADRs were probably preventable and 45% were not preventable. In case of outcome of patients with ADRs 67(49%) of patients were recovered and 70(51%) were recovering during treatment. No fatal cases were reported. In 18 (13%) patients, the offending drug were withdrawn, another drug was added to relieve the symptoms in 81(59%) and the dose was reduced to ameliorate the symptoms in 38(28%) patients.

DISCUSSION

Adverse drug reactions (ADRs) reported from male patients were 64% which was found to be higher than female patients of 36%.

Table 1.6. Adverse drug reactions detected and implicated drugs

S.No.	Type of ADR	Number (n=137,%)	M/ f ratio	Suspected drug (n)
1.	Fatigue	5(3.6)	2/3	Metoprolol(1) torsemide(1), chlordiazepoxide(1), glimiperide+metformin(2
2.	Heartburn	1 (0.7)	0/1	Diclofenac (1)
3.	Arthralgia	2(1.4)	0/2	Ofloxacin(1) ,atorvastatin (1)
4.	Cough	3(2.1)	3/ 0	Aspirin(1),ramipril(2)
5.	Drowsiness	3 (2.18)	2/1	Chlordiazepoxide(1), metronidazole(2)
6.	Dizziness	9(6.5)	5/4	Ibuprofen+paracetamol(1),fentanyl(1),cetirizine(1),ipratropium bromide(1) dextromehtorphan, (1)glimepiride(2), metoprolol (1) Amlodipine (1)
7.	Nausea &vomiting	11(8.02)	6/5	Tramadol(3),metronidazole(1),carbamazepine(1), nitrofurantoin (1), azithromycin(1), cefotaxime(2), ceftriaxone(1),stavudine(1)
8.	Inflammation at injection Site	10(7.29)	5/5	Cefotaxime(2), cefuroxime(1),ceftriaxone(3),amikacin(3),enoxaparin(1)
9.	Dehydration, drymouth	8(5.83)	5/3	Furosemide (1),cetirizine(2),tramadol(1),amitryptyline(1), furosemide + spironolactone(2), atorvastatin(1)
10.	Diuresis	1 (0.7)	0/1	Furosemide(1)
11.	Headache	12(8.75)	7/5	Esomeprazole(3),budesonide(1), ondansetron, (1)salbutamol (1), atorvastatin(3), ondansetron(1), ceftriaxone(2)
12.	Anorexia	4(2.7)	2/2	Losartan(1),ofloxacin(1), amitriptyline(1), cefotaxime(1)
13.	Anemia	1 (0.7)	1/0	Carvedilol(1)
14.	Diarrhoea	8(5.83)	5/3	Pantoprazole (5),doxycycline(1), levofloxacin(2)
15.	GI disturbances	2(1.4)	1/1	Betahistine(1),diclofenac (1)
16.	Urticaria	13(9.48)	9/4	Ceftriaxone (5),metformin(1),glipizide(1), stavudine,ibuprofen ,Ciprofloxacin (2) Ondansetron (1), Piperacillin +tazobactun (1),
17.	Paraesthesia	1(0.7)	0/1	Atorvastatin +fenofibrate(1)
18.	Syncope	2(1.4)	0/2	Metoprolol (1) Metformin +glimiperide (1)
19.	Hemorrhage	1 (0.7)	1/0	Heparin(1)
20.	Hypoglycemia	1(0.7)	1/0	Human actrapid (1)
21.	Disorientation of speech	1 (0.7)	1/0	Zolpidem(1)
22.	Hypotension	5(3.6)	5/0	Hydrochlorthiazide(1), telmisartan(1), salbutamol(1), atenolol (2)
23.	Tinnitus	3(2.1)	3/0	Amikacin (3)
24.	Rapid heart beat	2(1.4)	2/0	Salbutamol (2)
25.	Dyspnoea	1(0.72)	3/0	Levosalbutamol +ipratropium (1)
26.	Constipation	10(7.29)	6/4	Hyoscine butyl bromide(1), ceftazidime (1), Atorvastatin (3), Ceftriaxone (2) Ondansetron (1), Furosemide(1)
27.	Anaphylaxis	1(0.7)	1/0	Aspirin (1)
28.	Abdominal pain	2(1.4)	1/1	Aspirin (2)
29.	Bronchospasm	2(1.4)	1/1	Ibuprofen (2)
30.	Restlessness	3(2.1)	3/0	Furosemide(1), chloroquine (1), Azithromycin(1)
31.	Insomnia	3(2.1)	3/0	Azithromycin(1) Chloroquine (1) Furosemide (1)
32.	Delusion	1(0.7)	0/1	Amityrptyline (1)
33.	Eosinophilia	2(1.4)	1/1	Ceftriaxone(2)
34.	Peripheral neuropathy	1(0.7)	1/0	Stavudine(1)
35.	Transient deafness	1(0.7)	1/0	Furosemide(1)

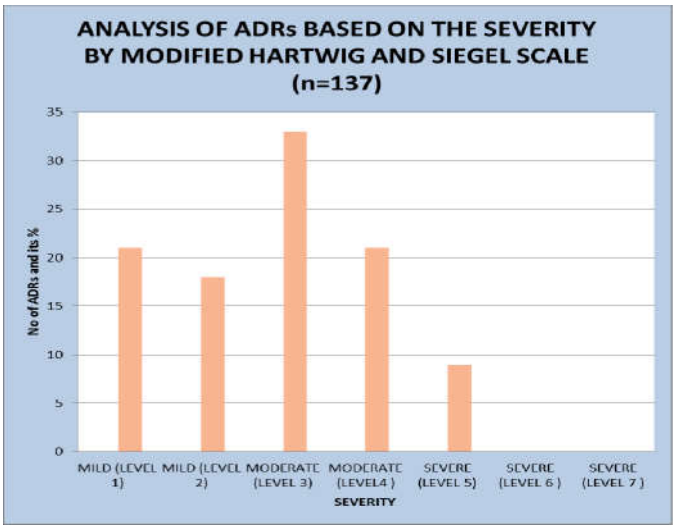

Figure 1.5. Analysis of adverse drug reactions based on the severity by modified Hartwig and Siegel scale

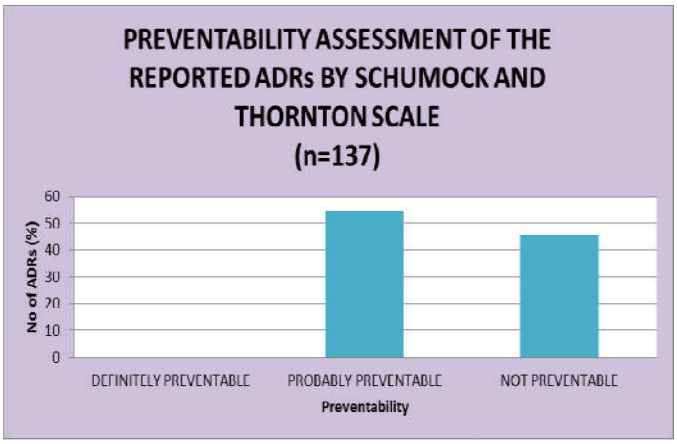

Figure 1.6. Preventability assessment of reported adverse drug reactions by Schumock and Thornton scale

Table 1.7. Management of adverse drug reactions

Parameters	Number (n=137)	No. of ADRs (%)
Withdrawn	18	13
Dose altered	38	28
Added another drug	81	59

Table 1.8. Onset of reported adverse drug reactions

Onset of Adrs	Number (n=137)	Percentage (%)
Acute(<1 hr)	25	18.24
Subacute (1-24 h)	73	53.2
Latent(>2 days)	39	28.4
Unknown	0	0

Table 1.8. Demographic biostatic characteristics of the hospitalized patients during study

S.No	Parameters	Mean	Standard Deviation	Minimum-Maximum
1.	Age	42.15	21.14	1-80
2.	No. of days of hospital stay	5.42	3.01	2-28
3.	No. of medications taken	7.06	2.89	2-17

This finding was consistent with the study reported by Shanmugam sriram *et al*. (Shanmugamsriram *et al*., 2011). Maximum numbers of ADRs were reported between age group of 31- 45 years. About 51% of ADRs were documented from general medicine ward. The most commonly observed ADRs were inflammation at the injection site, headache, urticaria, constipation, dizziness. The Central nervous system & Gastro intestinal system were considered to be more frequently affected organ system with ADRs. These results were similar to the study observed in Iman Karimzadeh *et al*. (Imankarimzadeh *et al*., 2011) Causality assessment of suspected ADRs using Naranjo's scale showed that 58% of them were probable, 30% were possible and 12% categorized as definite, which was similar to the results of other study by Mahendra *et al*. (2011) and Arulmani *et al*. (2008) In our study majority of the ADRs were found to be moderate (54%) according to modified Hartwig and Siegel Adverse drug reaction severity assessment scale. These results were consistent with the study observed in G.Parthasarathi *et al*. (2003) Preventability assessment shows that 55% of the ADRs were probably preventable which was similar to Mahendra *et al*. (2011) study. The Study results reveals antimicrobials were the class of drugs causing the highest number of ADRs followed by antihypertensive drugs. This was similar to the previous study reported by Iman Karimzadeh *et al*. (2011) and Jha *et al*. (2012)

The present study reported Type A Augmented reactions were found to be 40%, these reactions were predicted by known pharmacology of the drug and Type H Hypersensitivity reactions were found to be 28%, which were not preventable. This finding was similar to the reports generated by Asawari Raut *et al*. (2011) In the present study pharmacists were involved in adverse drug reaction monitoring by way of creating awareness, documentation and assessment of the reports. There were no reports found from nursing department. This may be due to lack of awareness among nurses on adverse drug reaction monitoring. The provision of alert card was aimed at preventing the occurrence of the similar ADRs to the same drug or other drug belonging to the similar class. Hence alert card was given to the patients for easy identification of their adverse drug reaction towards the drug.

CONCLUSION

This was the first study related to adverse drug reaction monitoring carried out in our Malla Reddy Hospital. Steps were undertaken to improve adverse drug reaction reporting rate by providing feedback to clinicians by circulating newsletters (or) ADR bulletin and also conducting educational seminar related to importance of reporting adverse drug reactions to other health care professionals. Detection and prevention of ADRs at the earliest is very important, as they can cause not only morbidity and mortality but also increase the health care cost in their management. Well trained pharmacist in the area of ADRs detection, reporting and monitoring could prove as an asset providing better patient care.

REFERENCES

Arulkumaran, K.S.G., Palanisamy S. and Rajasekaran, A. 2009. A Study On Assessment, Monitoring, Documentation And Reporting Of Adverse Drug Reactions At A Multi-Specialty Tertiary Care Teaching Hospital In South India. *International Journal of Pharmtech Research*, Oct-Dec 2009 Vol.1, No.4: Pp1519-1522.

Arulmani, R. Sd Rajendran, and B Suresh, 2008. Adverse Drug Reaction Monitoring In a Secondary Care Hospital in South India. *British Journal Of clinical Pharmacology,* February 65(2): 210–216.

Asawariraut, Arundhatidiwan, Chintanpatel, Palakpatel, Atmarampawan, 2011. Incidence, Severity and Financial Burden Association with Adverse Drug Reaction in Medicine Inpatients. *Asian Journal of Pharmaceutical and Clinical Research*, Volume 4 Suppl 2; Page 108-111.

Griffin, J. P. 1986. Survey of the Spontaneous Adverse Drug Reaction Reporting Schemes in Fifteen Countries. *British Journal of Clinical Pharmacology,* February, Volume 22, Issue S1: Pages 83s–100s.

Imankarimzadeh, Sohanamazi, Gloria Shalviri and Kheirollahgholami, 2011. Cardiovascular Drug Adverse Reactions in Hospitalized Patients in Cardiac Care Unit. *African Journal of Pharmacy and Pharmacology*, April Vol. 5(4), Pp. 493- 499.

Jason Lazarou, Msc, Bruce H. Pomeranz and Paul N. Corey. 1998. Incidence Of adverse Drug Reactions in Hospitalized Patients: A Meta-Analysis of Prospective Studies. *Journal of American Medical Association*, Feb, 279(15):1200-1205.

Jha, N., Pr.Shankar, O Bajracharya, Sb Gurung, and Singh, KK. 2012. Adverse drug Reaction Reporting in a Pharmacovigilancecentre of Nepal. *Australasian Medical Journal,* 5(5): Pages: 268–271.

Kheirollahgholami and Gloria Shalviri, Shadiziaie, 1999. Factors Associated With Preventability, Predictability, And Severity Of Adverse Drug Reactions. The Annals of Pharmacotherapy -1999 February, Volume 33; Pg 236 To 239.

Mahendra, K.B.J. 2011. Ramanath KV, Santoshand Naveen. Assessment Of Adverse Drug Reaction Reports In Tertiary Care Hospital. *Indian Journal of Pharmacy Practice*, Page No 16-19.

Malhotra, S., Jhaj, R. and Uppal, R. 2000. Adverse Drug Reactions among Inpatients in A North Indian Referral Hospital. *National Medical Journal of India,* 13: 16-18.

National Pharmacovigilance Program. National Pharmacovigilance Protocol, Ministry of Health & Family Welfare, Govt of India (internet). Jipmer. http://www. jipmer.edu/charu/npvp.html

Palaian Subish, Saval Khanal, Kadir Alam, and Arjun Paudel, 2009. Introducing pharmacovigilance to post graduate pharmacy students in Nepal. *American Journal of Pharmaceutical Education,* Oct 1; 73(6):114.

Parthasarathi, G. Karin Nyfort-Hansen, Milap C. Nahata, 2004. A textbook of Clinical Pharmacy Practice. Hyderabad: Orient Longman; 2004.

Parthasarathi, G., Jayeshpandit, Ramesh, M. 2003. Adverse Drug Reactions in a South Indian Hospital—Their Severity and Cost Involved. *Official Journal of the International Society for Pharmacoepidemiology*, December, Volume 12, Issue 8: Pages 687–692.

Ruchikanandha, Anithaguptha and Arifhashmi 2011. Cutaneous Adverse Drug Reactions In A Tertiary Care Teaching Hospital: A North Indian Perspective. International *Journal of Applied Basic Medical Research*, Volume 1, Issue 1; Page: 50-53.

Shanmugamsriram, Ali Ghasemi, Rajeshwariramasamy, Manjula Devi, Rajalingam, Balasubramaniam, Thengungalkochupayravi, and Ali Mohammad Sabzghabaee 2011. Prevalence of Adverse Drug Reactions at a Private Tertiary Care Hospital in South India. *Journal of Research in Medical Sciences,* 2011 January; 16(1): 16-25.

Sheena Derry and Yoon K Loke, 2001. Reporting Of Adverse Drug Reactions in Randomised Controlled Trials – A Systematic Survey**.** *BMC Clinical Pharmacology,* 1:3.

Smitapattanaik, Punitdhamija, Samir Malhotra, Navneet Sharma and Promilapandhi, 2009. Evaluation of Cost of Treatment of Drug-Related Events in A Tertiary Care Public Sector Hospital In Northern India: A Prospective Study. *British Journal of Clinical Pharmacology*, March Volume 67, Issue 3: Pages 363–369.

Steven. Chartwig, Jerrysiegel and Philip J Schneider, 1992. Preventability and Severity Assessment in Reporting Adverse Drug Reaction. *AMJ Hospital Pharm.,* Volume 49; Sep 2229-32.

Thirzatitchen, Noel Cranswick and Sean Beggs, 2005. Adverse Drug Reactions To nonsteroidal Anti-Inflammatory Drugs, Cox-2 Inhibitors and Paracetamol in a Paediatric Hospital**.** *British Journal of Clinical Pharmacology,* June, Volume 59, Issue 6: Pages 718–723.

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