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A Prospective study on adverse drug reactions of antibiotics in a tertiary care hospital.

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Abstract

The aim of this study was to evaluate and analyse adverse drug reactions to antibiotics in patients of a tertiary care hospital at Hyderabad. Prospective observational study was carried out for a period of one year from January 2015-December 2015 in both outpatient clinics and hospital wards. A total number of 138 ADRs were reported during this one year period .98 were males and 40 were females . .Maximum number of patients were from General Medicine department followed by General Surgery followed by Dermatology. Most of the reactions were mild (77.4%). Gastrointestinal system was the most commonly affected organ. In majority of the ADRs the suspected drug was withdrawn (60.8%). Maximum reporting of the ADRs was done by the attending doctors and Pharm-D students making regular rounds in the wards. In the outpatient clinics, reporting was through senior residents and faculty. The association between a drug and ADR was evaluated using the Naranjo scale. In order to prevent or reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring public health, evaluating and monitoring the safety of medicines in medical use are vital.

Keywords: antibiotics, tertiary care hospital, ADR, Naranjo scale.

Introduction

Adverse drug reactions are a significant cause of morbidity and mortality worldwide. (1)According to the definition provided by the WHO “An ADR is any noxious, unintended and undesired effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis or therapy.”Adverse drug reactions are inevitable consequences of pharmacotherapy. It is well known that all drugs carry the potential to produce both desirable and undesirable effects. No drug is absolutely safe under all circumstances of use or in all patients and ADRs may occur even if a drug is correctly selected or dosed.ADR monitoring and reporting programs encourage ADR surveillance, facilitate ADR documentation, promote the reporting of ADRs. (2).

ADR monitoring provides educational feedback to prescribers, other health care professionals and patients. The Causality assessment system proposed by the World Health Organisation is collaborating Centre for international drug monitoring, the UPPSALA Monitoring Centre(WHO-UMC).The Naranjo Probability Scale are the generally accepted and most extensively used method for causality assessment in clinical practice.(3)

ADRs have a considerable negative impact on both health and health care costs.ADR monitoring and reporting activity is in its infancy in India. India is a developing country with a large drug consuming population. It is the fourth largest producer of pharmaceuticals in the world with more than 6000 licensed drug manufactures and over 60,000 branded formulations. Thus it is essential that the drug treatment should be safe, efficacious and cost effective. (4)..

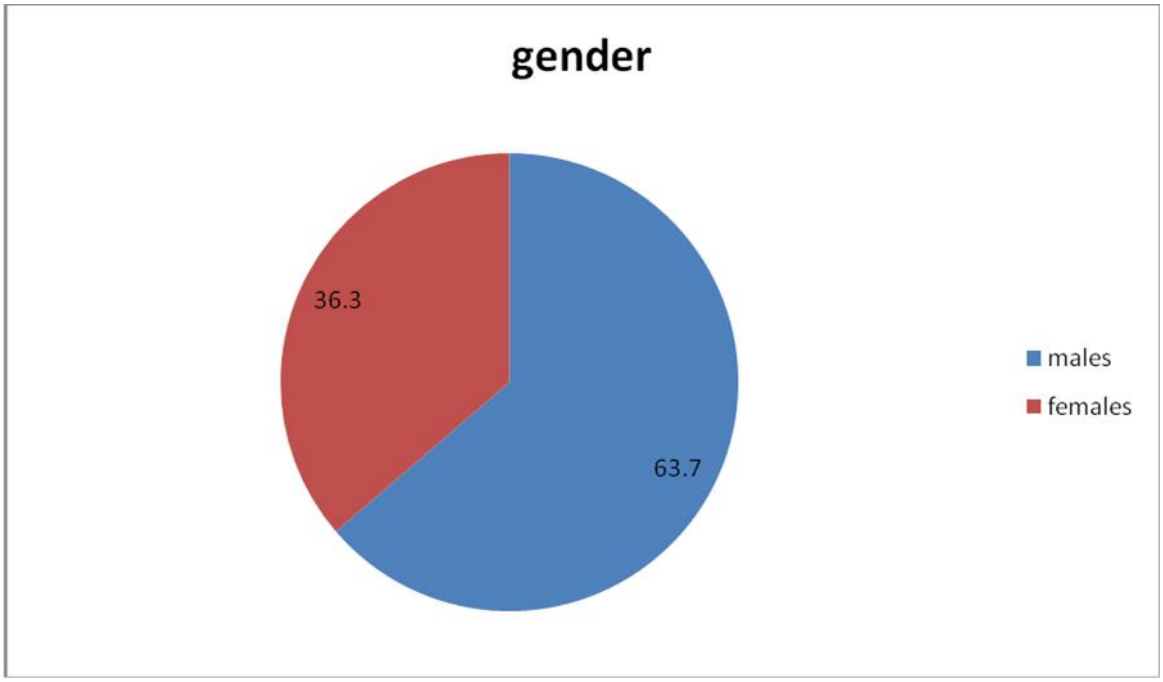
Methodology

This prospective –observational study was conducted in a tertiary care teaching hospital, Hyderabad. The study was carried for a period of one year. ADRs were collected from different departments like General medicine, Dermatology, Paediatrics, Orthopaedics, Pulmonology and general surgery. All patients of either sex and of any age who developed an ADR during the study period were included in the study. Pregnant women and nursing mothers were excluded. The protocol of the study was approved by Institutional Ethics Committee. We obtained ADR reporting by means of health care professionals and regular ward rounds. Demographic data like patient initials, Hospital number, age, sex, marital status, medical history, surgery history, allergies, herbal and cosmetic use had been recorded on the case record form. The prescription given to the patient including the drug prescribed, dose, frequency and duration of the treatment was noted on the case record form. The type of reactions, causality and severity were assessed using Rawlins and Thomson, Naranjo and modified Hartwig scale respectively.

Results

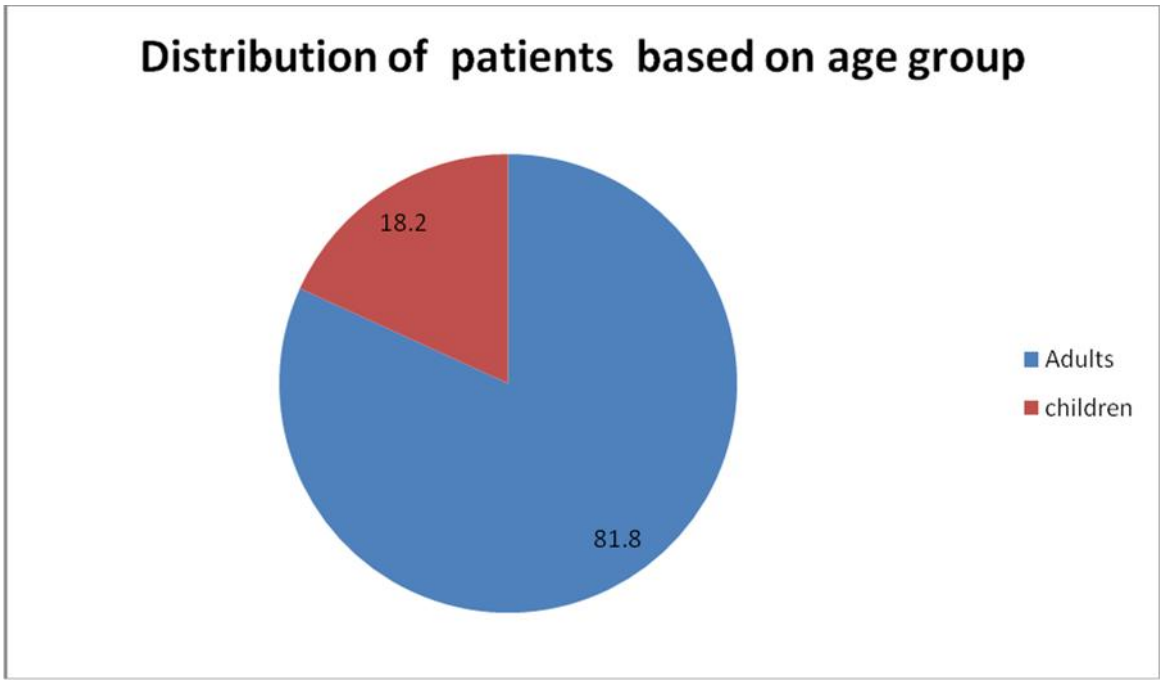
During the study period, 18 ADRs were reported. Of these 98 (63.7%) were males and 40 (36.3%) were females (Fig.1). The no. of adults who experienced ADRs were 113 (81.8%) and children below 12 years were 25 (18.2%) (Fig.2).

Figure 1:Division of ADR’s based on gender of the patient



98 males – 63.7%; 40 females – 36.3%

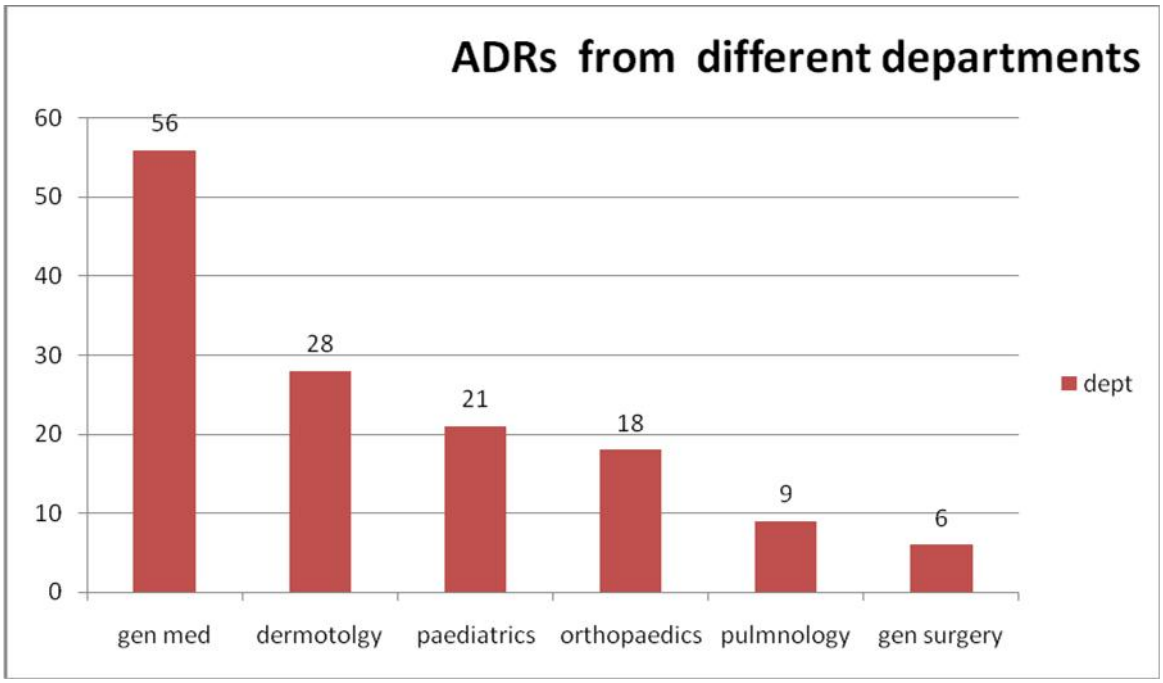
Figure 2: Division of ADR'S based on the age group of patients



Adults – 113 – 81.8%; Children – 25 – 18.2%

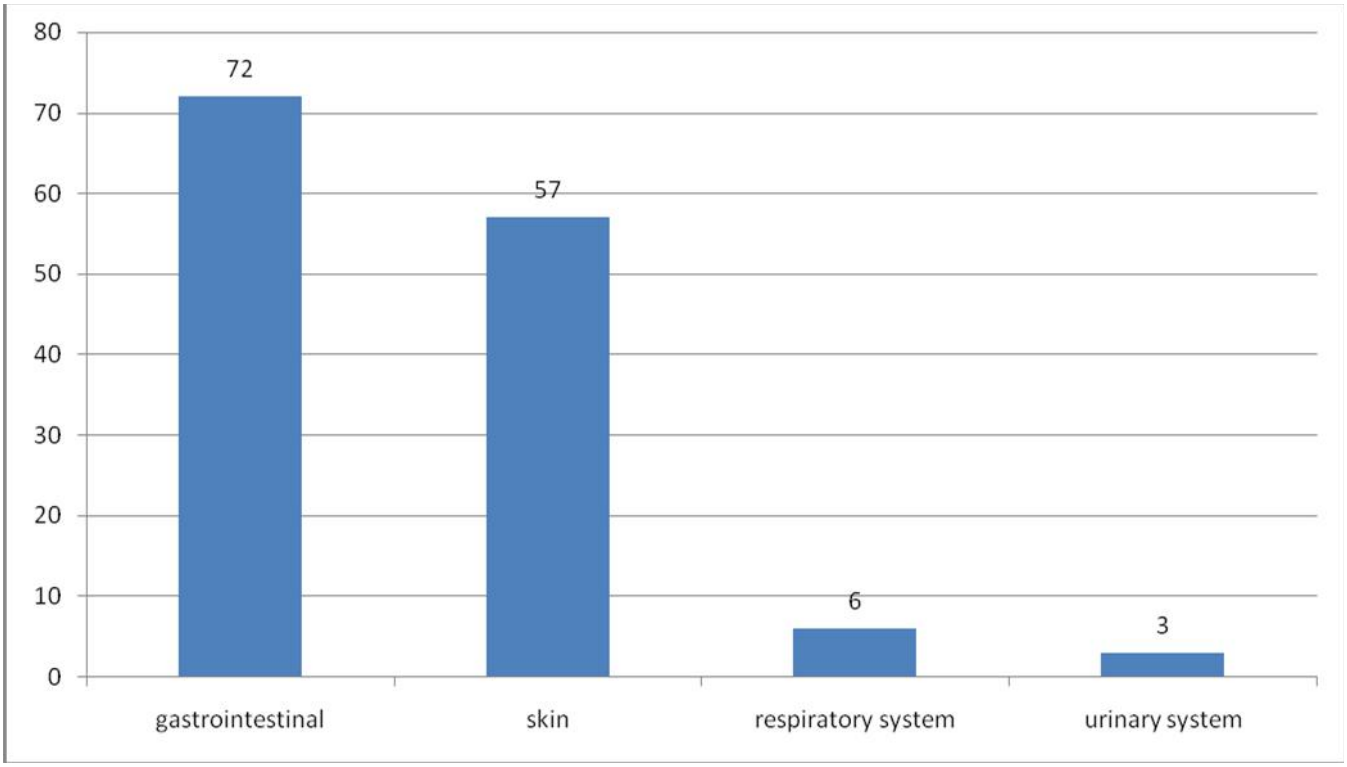
As shown in fig. 3, the maximum number of ADRs were received from General Medicine department-56, followed by Dermatology -28, Paediatrics -21, Orthopaedics -18, Pulmonology -9 and General Surgery-6. The most commonly affected organ system was Gastrointestinal system -72(52.2%) followed by skin-57 (41.4%), Respiratory system-6 (4.3%) and urinary system-3 (2.1%). This is depicted in Figure-4.

Figure 3: Number of ADR's received from different – departments



General Medicine – 56; Dermatology – 28; Pediatrics – 21 ; Orthopedics – 18 ; Pulmonology – 9; Gen. Surgery – 6

Figure 4: Distribution of organ system affected due to ADR'S



Organ systems affected due to ADRs

Gastrointestinal system – 72 – 52.2%; Skin - 57 – 41.4%; Respiratory System - 6 – 4.3%; Urinary system- 3 – 2.1%

Table 1 shows that Piperacillin-31(22.4%) is causing the highest no. of ADRs i.e. followed by Ceftriaxone -26(18.8%) and Cefotaxime-17(12.3%). Combination of Amoxicillin with Clavulanic acid showed 16(11.6%) of ADRs. Ofloxacin -15(10.8%)and Amikacin showed 9(6.5%) of ADRs.

Table 1:- Antibiotics causing ADR'S

Drugs	No. of ADR'S	Percentage
1. Piperacillin	31	22.4%
2. Ceftriaxone	26	18.8%
3. Cefotaxime	17	12.3%
4. Amoxicillin + Clavulanic acid	16	11.6%
5. Ofloxacin	15	10.8%
6. Amikacin	9	6.5%
7. Norfloxacin	7	5.0%
8. Gentamicin	6	4.3%
9. Azithromycin	4	2.8%
10. Erythromycin	4	2.8%
11. Doxycycline	3	2.1%

Majority of the reactions were Type A-Augmented reactions as shown in Table 2. Severity of reported ADRs were assessed using the Modified and Siegel scale (Table3). Most of the ADRs were mild (101) (73.1%), 28(20.28%), were moderate and only a few9 (6.3%) were severe. In this study, ADRs were assessed based on Naranjo's Casuality assessment scale. Most of the reported ADRs were possible-119(86.23%) and some were probable-19(13.76%) (Table 4). From this study it was found that there was a recovery from ADRs in total of 132 (95.6%) patients, although 0% had fatal ADRs . Unknown outcome was 0%. 6(4.3%) cases were recovering (Table 5).

Table 2- Type of reaction
(Classification according to Rawlin & Thomson)

Category	No. of ADR'S	Percentage
Type A	108	78.2
Type B	30	21.8

Table 3: Level of Severity of reported ADR'S
(Using the modified Hartwig & Siegel scale)

Level of Severity	No. of ADR'S	Percentage
Mild	101	73.1%
Moderate	28	20.28%
Severe	9	6.5%

Table 4:- Causality assessment
(According to Naranjo's Scale)

Causality parameters	No. of ADR'S	Percentage
Definite	0	0%
Probable	19	13.76%
Possible	119	86.23%
Unlikely	0	0%

Table 5:- Outcome

Parameters	No. of ADR'S	Percentage
Fatal	0	0%
Recovering	6	4.3%
Recovered	132	95.6%
Unknown	0	0%

Discussion

Treatment of infections always includes antibiotics. As the drug resistance incidence is on the raise, there is a huge need for taking steps to promote rational use of antibiotics. Antibiotics are the most commonly used and misused drugs by patients and prescribers. (5).This study tried to find out the pattern of Adverse drug reactions of antibiotic drug class in the post marketing surveillance studies. Antibiotics are used for treatment and prophylaxis of various infectious conditions and are considered as safer drugs when used rationally. Antibiotics are considered as

the second most prescribed drugs in the world, only next to the drugs indicated for cardiovascular diseases.(6). The males in our study extranumbered the females. In our study, it shows that Piperacillin has maximum number of ADRs. Usually Piperacillin is used in combination with Tazobactum. All reported adverse effects are those which could occur with Piperacillin alone. Adverse effects with Piperacillin being diarrhea, nausea, vomiting, abdominal pain and dermatological reactions. These reactions are mild but occur commonly. Piperacilin is effective against many infections. As It is the most frequently used antibiotics adverse effects observed also would have been maximum in this study. The second group of drugs causing ADRs in this study was the 3rd generation Cephalosporins, Ceftriaxone and Cefotaxime.The most common system associated with ADRs to Cephalosprins were the Skin and Gastrointestinal system. The finding is consistent with many studies that have reported high percentage of dermatological manifestations.(7). Maculopapular rash was most commonly reported due to amoxicillin which was in conformity with the findings of Ghosh .et.al. In our study there was one patient of Stevens Johnson syndrome due to Amoxicillin- Clavulanic acid combination similar to the findings by salvo et.al.(8)From the above findings, ADRs to beta lactum antibiotics were maximum and the skin and its appendages followed by gastrointestinal system were involved. (9).Patterns of organ system involvement and of signs and symptoms were quite similar, with gastrointestinal effects predominating(nausea, Vomiting, diarrhea or abdominal pain), followed by effects on the Central nervous system(dizziness, headache or insomnia). In regard to the reported adverse effects of Flouroquinolones, bodyaches along with muscle and joint pains were also observed in a few number of patients on Ciprofloxacin. Difficulty in hearing, vertigo and tinnitus were reported from patients prescribed with Gentamycin and Amikacin. A woman was given Gentamycin and developed myoclonus, involuntary muscle jerks and spasm. One child showed abnormal kidney function tests treated with Amikacin. (10)(11).

Adverse reactions to Macrolide antibiotics were few in comparison with the other antibiotics. The adverse effects were also mild being Gastrointestinal reactions occurring with both Erythromycin and Azithromycin. Macrolides are considered to be one of the safest anti-infective groups in clinical use, with severe adverse reactions being rare. Erythematous rash and allergic reactions were seen in a few patients. In one study, an erythematous rash in sun exposed parts of the body had been reported taking Doxycycline for Malaria prophylaxis. It was also found that doxycycline did not cause a significantly higher percentage of all skin events, when compared with other antimicrobials.

Analysis of the type of reported ADRs according to Rawlin and Thompson showed Type A predominance. This result coincides with the study conducted by Oshikoyo et. al and Starveva et.al.(12).Type A reactions are dose related and preventable. Type B reactions comprise approximately21% and include hypersensitivity reactions.(13).

Conclusion

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. Monitoring of the adverse effects of newer drugs and potentially risky drugs is mandatory. This study concluded that the spontaneous reporting of adverse drug reactions of antibiotics is good in our hospital setting.

The health system should promote the spontaneous reporting of adverse drug reactions to antibiotics and other drugs, proper documentation and periodic reporting to pharmacovigilance centre to ensure drug safety. The active involvement of a well trained clinical pharmacist for detecting the adverse drug reactions and delivering the awareness classes for the health care professionals regarding the need of reporting the incident could improve in all hospitals.

References

1. Lazarou, J.Pomerang BH,Corey PN.Incidence o adverse drug reactions in hospitalized patients: A metaanalysis of prospective studies,JAMA1999;279: 1200-5 [Pub med].
2. ASHP Guidelines on Adverse drug reaction monitoring and reporting.
3. Naranjo C.A. Busto.U Severs E.M.Sander P, Ruiz. Roberts E.A.A method for estimating the probability of adverse drug reactions. Clin pharmacol Ther, 30:239-45[pubme].(1981).
4. Amrita.P.Singh.S.P.Status of spontaneous reporting of adverse drug reaction by physicians in Delhi.Indian J.Pharm.pract. 2011:4(2):29-36.
5. Fonacier L, Hirschberg R ,Gerson 5.Adverse drug reactions to Cephalosporins in hospitalized patients with a history of penicillin allergy.Allergy Asthma Proc.2005:26:135-41].
6. Tunger O, Dinc.G.Ozbakkaloglu B, AtmanUC,Algun U.Evaluation of rational antibiotic use. Int.J. Antimicrbial agents 2000;15:131-5.
7. Cross ref. Jose J. and P.G..Rao.Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital.Pharmacol.Res, 54: 226-233.
8. Salvo F , Polimneni G. Maretti,U,Conforti A, Leone R, Leone O,et.al.Adversed drug reactions related to amoxicillin alone and in association with clavulanic acid. Data fro spontaneous reporting in Italy. J. Antimicrobial Chemotherap 2007: 60.121-6.
9. Marie RL,Sanders CV,Faro S, Janney A. Williams ww, Derks F, Aldridge KE, Piperacillin vs Carbenicillin in the thwerapy of serious infections.Arch.Intern.Med 1982 ,oct 25; 142(1).2000-2005[pubmed].
10. Sarva, H and panichpisal, K.(2012).gentamicin induced myoclonus. A case report and literature reviewof antibiotics-induced myoclonus.Neurologist 18(6); 385-388.
11. Mudd, P.A, Edmunds,Al, Glatz,F. Campbell,k,C.M.& Rybak L.P.(2014).Ototoxicity. Medscape. (May7, 2012).
12. Oshikoyo,K.A. Najokamma O.F chukwara Ha, ojo 10, 2007.Adverse drug reactions in Nigerian children. Paediatric Perinat drug Ther 8,81-88.
13. Games, Rabeto E. Pascal D,2005, Epidemiology of hypersensitivity drug reactions curr.opin. allergy clin.Immunol 5,309-316.

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