Adverse Drug Reaction Monitoring in a Tertiary Level Referral Hospital, Kerala

Dilip C*[1], Lisa M M[2], Saraswathi. R[2] , Divya R[2]

[1]Research Scholar, Karpagam University, Coimbatore

[2]Al Shifa College of Pharmacy, Kizhattur, Perinthalmanna, Kerala - 679325

Submitted: 25/04/2012 *Accepted: 17/05/12012*

ABSTRACT

This was a prospective spontaneous reporting study conducted for a period of one year, to assess the Causality, level of severity, predictability, and preventability of reported ADRs in tertiary level referral hospital. Clinical pharmacist prompted the clinicians with personal reminders and leaflets to report more ADRs.During the study period a total of 44 ADR reports were received from various departments of the hospital. We observed male 30(71.428%) predominance over female 12(28.571%)) from our study. Among the age groups, Geriatric patients 17(40.476%) reported more number of ADRs, compared to adults 22(52.3809%) and children 3(7.14285%). Maximum number of ADRs came from General Medicine department 27(27.2727%). Multiple drug therapy 18(42.857%) and intercurrent diseases 13(30.952%) were the most prominent predisposing factors of ADRs seen in our hospital. Causality assessment of suspected drugs was assessed using Naranjo scale. According to Naranjo scale most of the reported ADRs were found to be probable 22(50%) followed by possible 18(40.909%) and definite 4(9.0909%). The severities of the reactions were done using Hart Wig Scale. Majority of the reactions were moderate 25(56.818%).Withdrawal of the drug 30(68.188 %) was the main line of the management of the adverse drug reactions in the present study. Adverse drug reactions are an inevitable risk factors associated with the use of modern medicines. However careful attention to dosage, age and renal function can minimise the risk of developing ADRs in many patients. Our study shows that most of the developed ADRs during hospital stays were managed by withdrawing the offending drug and specific treatment. In this pharmacist, physician, nurses, patients and patient's volunteers must help in reporting ADRs If this culture is adopted and practiced well, ADRs can be minimised and good quality of life can be provided to the patients.

Keywords: Adverse drug reaction; severity; causality assessment; clinical pharmacist

INTRODUCTION

Adverse drug reaction is a recognised hazard of drug therapy. The pharmacist, along with the prescriber has a duty to ensure that patients are aware of the risk of side effects. With their detailed knowledge of medicine, pharmacists have the ability to relate unexpected symptoms experienced by patients to possible adverse effects of their drug therapy. The practice in clinical pharmacy also ensures that ADRs can be minimised by avoiding drugs with potential side effects in susceptible patients. Thus pharmacist has a major role to play in relation to prevention, detection and reporting of ADRs.[1] WHO defines any response to a drug which is noxious, unintended and which occur at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or the modification of physiological function. Thus this definition excludes overdose (either accidental or intentional), drug abuse, and treatment failure and drug administration errors[2] . A more recent definition, also taking causality assessment into account, defines an ADR as an adverse drug event that is judged to be caused by the drug[3]. ADRs are a major clinical problem accounting for 2-6% of all hospital admissions. It causes significant financial burden on national health budget. ADRs are important causes of mortality and morbidity in both hospitalised and ambulatory patients.[4] Many ADRs are 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. Over to million serious ADRs reported yearly, one lakh deaths yearly caused due to ADRs which adversely affects the patients' quality of life. This causes patients to lose confidence in their doctors. It increases costs of patients care and may mimic disease resulting in unnecessary investigations and delay in treatment. So there is a need to study ADRs seriously, to create awareness about it among patients, to motivate healthcare professionals in reporting ADRs to minimize the risk. [5,6] This ADR study was planned to carry out in Tertiary Level Referral Hospital located in Perinthalmanna at Malappuram district which is a 350 bedded tertiary level referral hospital.

***Address for Correspondence:**

Dilip.C, Associate professor, Al Shifa College of Pharmacy, Kizhattur, Poonthavanam P.O, Perinthalmanna.

E-mail: dillu7@rediffmail.com

METHODOLOGY

It was a prospective spontaneous reporting study including both active and passive methods

- Active methods - Pharmacist actively looking for suspected ADRs
- Passive methods - Stimulating prescribers on report a suspected ADRs.

All the suspected ADRs due to medication both prescribed and over the counter, taken by patients were noted and reported by various departments in the hospital were included in this study and drug reactions that results due to- Medication errors**,** use of alternative systems of medicines**,** and departments like dentistry, surgery etc were excluded.[13] The data for the study was taken from case sheets, treatment charts, investigation reports of patients who had experienced an ADR**,** personal interviews with patient/patient's attendant**,** personal interviews with reporting persons / clinicians**.** For the purpose of the study various forms like**,** Adverse drug reaction reporting card, adverse drug reaction reporting & documentation form, Thank you form, and Alert card were used. Ethical committee clearance and formal permission from Medical Superintendent (MS) of the Hospital was obtained prior to initiation of the study. All patients and doctors in various departments were included in this study .An awareness lecture was given prior to starting the study, to increase the awareness about the adverse drug reactions among the clinicians and to announce the starting of the study. Further clinical pharmacist prompted the clinicians with personal reminders and leaflets to report more ADRs as and when they came up. Only those cases, which fulfilled the criteria, were included in the study. Complete histories of the patients were taken from case reports, medication charts, and personal interviews with them and their attendants. Disease status of the patients and other co morbid conditions were properly enquired and noted down. Medication history of the patient was obtained from the patient medication slips, prescriptions and also from in-depth patient interview regarding medication use. Discussions were conducted regularly with reporters / clinicians to give feed back on the reaction and management of the patient condition by providing reports and drug information services. The causality assessment of the reported ADRs was carried out using “Naranjo causality assessment scale”. The assessment of outcome of each ADR was done by monitoring the length of stay and by categorizing them as Continuing, Recovered, and Fatal. Severity, Preventability, and Predictability were also assessed using standardized Scales. Thank you forms were issued to all doctors who were reporting ADRs, so as to encourage their continuous reporting. ALERT CARDS were provided to all the patients who were admitted to the hospital due to ADRs. This is to prevent the future occurrence of similar ADRs in same patients. Thus various campaigning methods were undertaken by the clinical pharmacists to promote an increased and continued reporting of ADRs.

Analysis of the results: The data collected in the one year period was analysed for the following parameters.

- The total number of ADRs reported.
- Reports received from different departments of the AlShifa Hospital.
- Age groups and gender of the patients
- Assessment of causality based on ' Naranjo Scale’
- Assessment of level of severity of ADRs using 'Hart wig Scale’
- Assessment of Preventability using ' modified Shumock and Thornton method’

RESULTS

A total of 44 ADRs were reported during the one year period of study. 42 patients reported 44 ADRs, among them 2 patients reported more than 1 ADRs. Males 30(71.428%) reported more number of ADRs compared to females 12(28.576%). Maximum number of ADRs were reported from adults (20-59) – 22(52.3809%) followed by geriatrics (>60) – 17(40.476%) and children (0-19) –3(7.1428%). Results are summarised in Fig1 and 2. Maximum number of ADRs were reported from the general medicine 12(27.27%) followed by Cardiology 11(25%), Psychiatry 10(22.72%), gastro enterology 5(11.3636%), dermatology 4(6.818%), Nephrology 1(2.272%), Pulmnology1 (2.27%), ,gynaecology 0% (Fig-3).Majority of patients with an ADR were receiving more than 2-4 drugs at the time of experiencing an ADR. Of the reported ADRs 18(42.857%) occurred due to the multiple drug therapy followed by intercurrent diseases 13(30.952%) age 5(11.90476%) and gender 5(11.111%).(Fig-4).In 30(68.1818%) cases the suspected drug was withdrawn while no change was made with the suspected drug in 11(25%) and the dose was altered in 3(6.818%) cases. Specific treatment was given in 22(50%) while 6(13.639%) cases required symptomatic treatment and 16(36.363%) cases required no treatment. (Fig 5 and Fig 6.) Predictability of the reactions was based on the incidence of the reactions and literature reports. Analysis showed that most of them were predictable 33(75%) while of them 11(25%) were not predictable. Results are shown in Fig7.Severities of the reactions were done using Hart wig scale. Of the reported ADRs 25(56.818%) moderate reactions accounted of followed by mild reactions 18(40.909%) Only 1(2.272%) of the reactions were severe. (Fig 8.) Preventability of reported ADRs was assessed using modified Shumock and Thornton

method. Using this scale results revealed that 27(61.3636%) of the ADRs were definitely preventable, while 12(27.272%) were probably preventable and 5(11.3636%) were not preventable. Results are in (Fig 9). The causality assessment of ADRs had been done using Naranjo scale. As per Naranjo scale 22(50%) were probable, 18(40.909%) were possible, 4(9.0909%) were definite and 0% were unlikely. (Fig 10).

Fig.1: Based on the gender of the patient

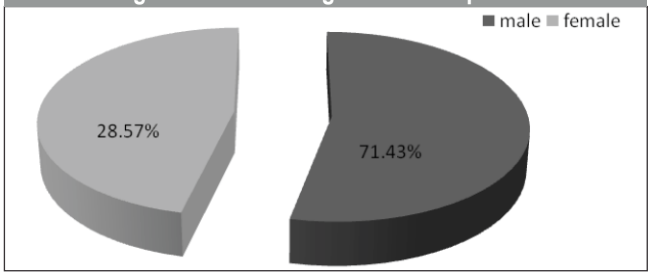


Fig. 2: Based on the age group of the patients

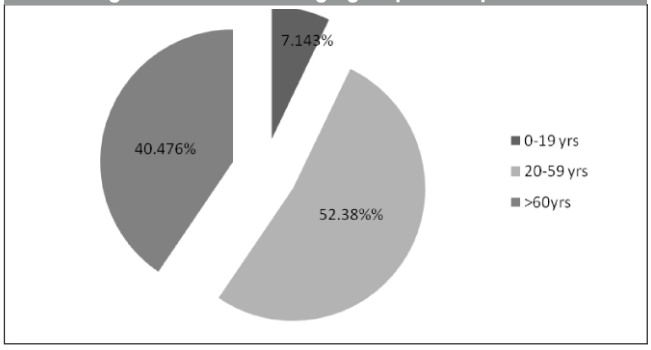


Fig. 3: Number of ADRs reported from different departments

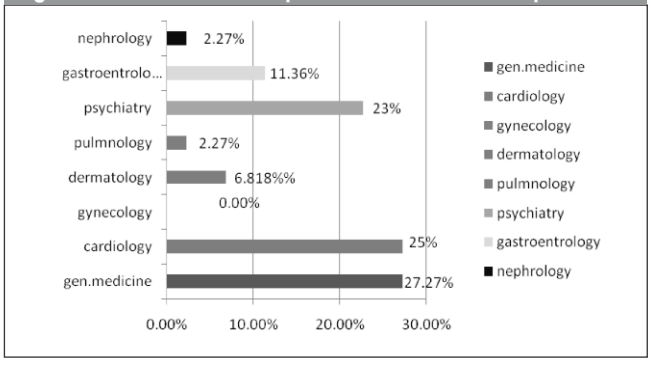


Fig. 4: Predisposing factors of ADR

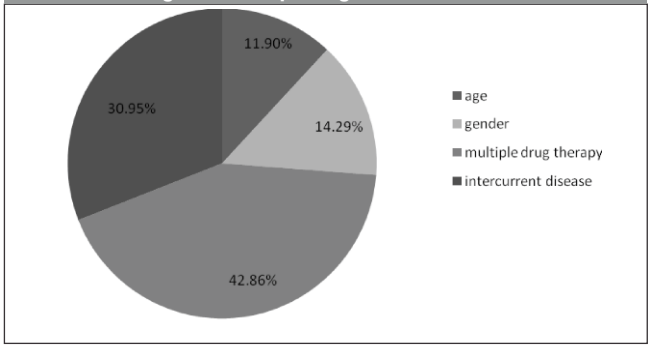


Fig. 5: Fate of suspected drug

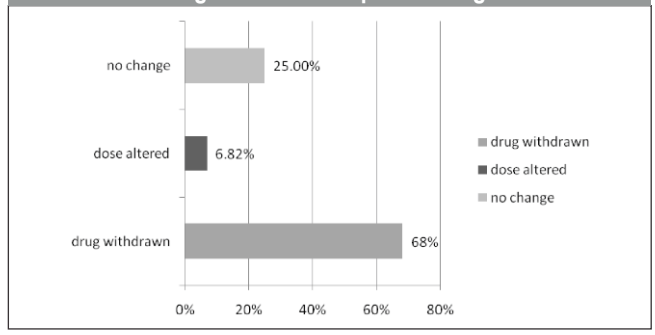


Fig. 6: Treatment given

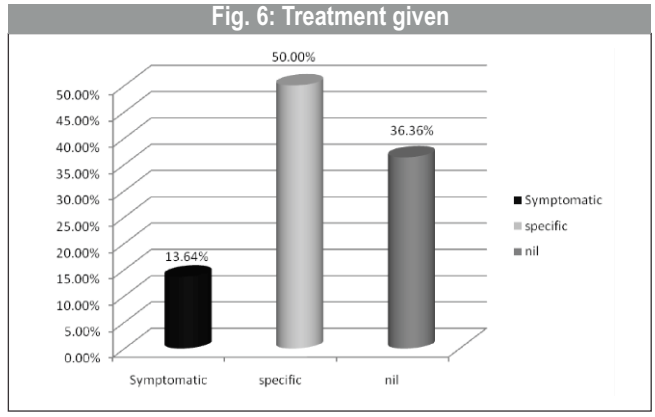


Fig. 7: Predictability of ADRs

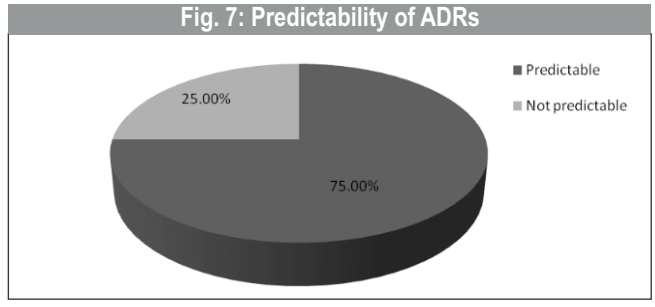


Fig. 8: Level of severity of ADRs

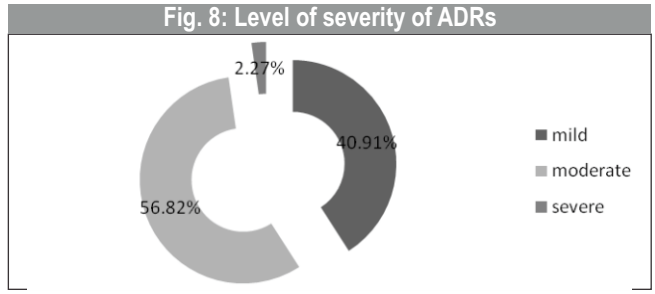


Fig. 9: Preventability of ADRs

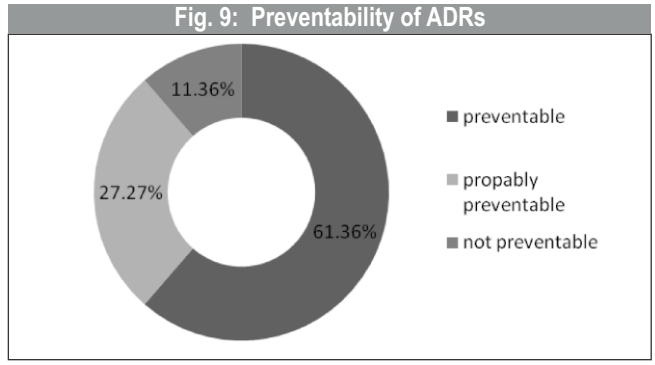
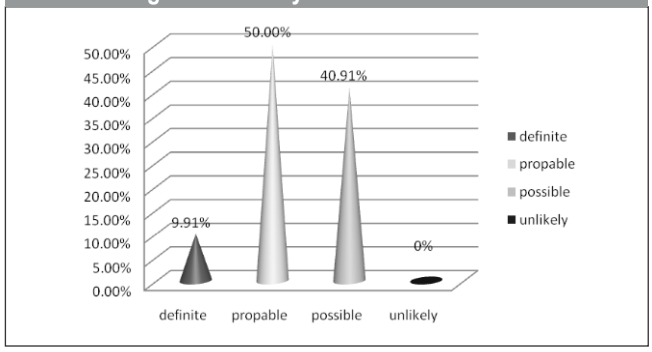


Fig. 10: causality assessment of ADRs



DISCUSSION

The study was conducted in Tertiary Level Referral Hospital with more than 60 consultants of national reputations and about 85% patients in the hospital were prescribed with more than two drugs every day. In this study, we followed the spontaneous reporting method. We received a total of 44 ADRs from our hospital during one year study. From this study we found out that, males 30(71.428%) reported more number of ADRs compared to females 12(28.576%). This may be due to fact that compared to females; males have a tendency to use more number of drugs than the females. This result is consistent with the results of the study carried out by Palanisamy.S S et.al [6] and which was something different from that observed from other study done by Subish.P et.al [7]. The study revealed that Maximum number of ADRs were reported from adults (20-59) – 22(52.3809%) followed by geriatrics (>60)-17(40.476%) and children (0-19) –3(7.1428%). This may be due to the fact that the number of hospital admissions of adults were more in our hospital when compared to Paediatrics. Paediatricians tend to use only a limited number of drugs for their patients, as paediatric patients rarely presented with multiple co morbidities. This finding was consistent with the results of the study carried out by Ramesh.et.al [9] but different from the study carried out by Chuenjid Kongkaew et.al.[8] It was reported that drug related hospitalizations were significantly higher in the geriatric population. Before the starting of study, an awareness lecture was given to the doctors of all the departments about the importance of reporting ADRs. With effect to this, maximum number of ADRs were reported from General medicine department12(27.27%) compared to other departments. This is because in our hospital the patients were primarily consulted by general medicine department and then referred to the other specialists. So this department uses more drugs than other departments. This result was consistent with the study carried out by S.A Samuel et.al [10], but different from the study carried out by Palanisamy.S et.al [6] wherein highest percentages of ADRs were reported from neurology department. Majority of patients who developed ADR were receiving more than 2-4 drugs at the time of experiencing an ADR. Multiple drug therapy18 (42.857%) and intercurrent diseases 13(30.952% were the most prominent predisposing factors of ADRs. Majority of the patients who developed ADRs were having co-morbidities like Diabetes, Tuberculosis, Bronchial Asthma, renal failure, Coronary artery disease, Hypertension, Depression, Rheumatoid arthritis, hepatitis, cirrhosis, anaemia, seizures etc necessitating them to receive multiple drugs. This result was consistent with the study carried out by Rajesh et.al [11]. When ADRs were identified, all the necessary and relevant data were collected from the various sources like patient case sheets. Treatment charts, laboratory reports, patient interview and filled in the **ADR card and ADR Reporting and Documentation Form**. Through patient interview and interaction with doctors and healthcare professionals, causality was assessed as per **Naranjo Scale**. According to Naranjo scale 22(50%) were probable, 18(40.909%) were possible, 4(9.0909%) were definite and 0% were unlikely. The severities of the reactions were done using *Hart Wig Scale.* Study reveals majority of ADRs were moderate reactions 25(56.818%) followed by mild reactions 18(40.909%), only 1(2.272%) of the reactions were severe . No fatal cases reported. This indicates the good health status of our hospital. Withdrawal of the Drug 30(68.1818%) was the main line of management of ADRs, while no change was made with the suspected drug in 11(25%) and the dose was altered in 3(6.818%)) cases. During the study Specific treatment was given in 22(50%) while 6(13.639%) cases required symptomatic treatment and 16(36.363%) cases required no treatment. There was a complete recovery from ADRs in 44 cases (100%). No fatal cases reported. This indicates the good health status of the hospital. Reported ADRs were assessed for their preventability by using modified *Shumock and Thornton method.* We concluded that 27(61.3636%) of the ADRs were definitely preventable, while 12(27.272%) were probably preventable and 5(11.3636%) were not preventable. Predictability of ADRs was assessed based on the incidence of the reactions and literature reports. Results revealed that most of ADRs were predictable 33(75%) while, 11(25%) were not predictable.

CONCLUSION

Adverse drug reactions are an inevitable risk factors associated with the use of modern medicines. However careful attention to dosage, age and renal function can minimise the risk of developing ADRs in many patients. Our study shows that most of the developed ADRs during hospital stays were managed by withdrawing the offending drug and specific treatment. In this pharmacist, physician, nurses, patients and patient's volunteers must help in reporting ADRs. If this culture is adopted and practiced well, we can minimise

ADRs and also provide a good quality of life to the patients. This can provide benefits to the organization, pharmacists, other healthcare professionals and patients.

REFERENCE

1. Camargo AL, Ferreira MBC, Isabela Heineck. Adverse drug reactions: a cohort study in internal medicine units at a university hospital. Eur J Clin Pharmacol 2006;62:143-9.
2. Pirmohamed M, BreckenridgeAM, Kitteringham NR, Park BK, Adverse drug reaction .BMJ 1998;316:1295-8.
3. Strom BL. Pharmacoepidemiology. 3rd ed. New York; John Wiley and Sons. 2000:851.
4. Abimanyu Phatak, B.G Nagari: Safety of medicines. Pharma times Vol.35, December 2003:19-21.
5. Palaian S, Mishra P, Shankar PR: Safety Monitoring of Drugs-Where do we stand? Kathmandu University Medical Journal 2006;4(13):119-27.
6. Palanisamy S: 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 Pharm Tech Research 2009;1(4):1519-22.
7. Subish.P et.al: Systemic adverse drug reactions: a preliminary report from the regional pharmacovigilance center, western Nepal. Pak. J. Pharm. Sci 2008;28(4):465-7.
8. Chuenjid Kongkaew et.al: Hospital Admissions Associated with Adverse Drug Reactions: A Systematic Review of Prospective Observational Studies. The annals of pharmacotherapy 2008 published online.
9. Mehta DJ. Methods of reporting adverse drug reactions. Ind J Pharmac1972; 4(2): 69-74.
10. Samuel S.A, Rajendran S.D,.Ebenezzar S, Jayaharan S, Azir P. Surveillance of adverse drug reactions at two multidisciplinary hospitals and an outpatient speciality clinic in India. The international journal of pharmacy practice 10(2):115-20
11. Rajesh. R, Ramesh M: A study on adverse drug reactions related hospital admission and their management. Indian journal of hospital pharmacy 2008; 45:143-8.
12. Peyriere H et.al Adverse drug events associated with hospital admission .The annals of pharmacotherapy 2003;37.
13. Dilip.C, Adverse drug reactions monitoring in tertiary level referral hospital, Perinthalmanna,kerala.Indian journal of hospital pharmacy 2011;48:107-11