Alexandria Journal of Medicine 54 (2018) 597–603

HOSTED BY

Contents lists available at ScienceDirect

Alexandria Journal of Medicine

journal homepage: http://www.elsevier.com/locate/ajme

Original Article

Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital

Meda Venkatasubbaiah [a,*], P. Dwarakanadha Reddy [b], Suggala V. Satyanarayana [c]

[a] Research Scholar, JNTUA, Ananthapuramu, Andrapradesh, India
[b] Department of Pharmaceutics, Annamacharya College of Pharmacy, Rajampet, Andrapradesh, India
[c] Department of Chemical Engineering, JNTU College of Engineering, Anantapuramu, Andrapradesh, India

ARTICLE INFO

Article history:
Received 2 July 2018
Revised 14 October 2018
Accepted 14 October 2018
Available online 29 November 2018

Keywords:
Adverse drug reaction
Pharmacovigilance
Reporting
Causality

ABSTRACT

Objectives: To analyze and report adverse drug reactions (ADRs) in a tertiary care teaching hospital.
Methods: This was an observational study, conducted to analyze and communicate the ADRs reported from July 2016 to June 2017 in a south Indian tertiary care teaching hospital. On daily basis, ADRs reported by healthcare professionals (HCPs) were analyzed and the reports that meet pharmacovigilance programme of India (PvPI) reporting criteria were communicated to PvPI through a specified updated Indian Pharmacopoeia Commission (IPC) suspected ADR reporting form. In this study, ADRs were summarised based on demographics, drug, incidence, type of reaction and its outcome. Causality, severity, seriousness, and predictability were assessed through WHO causality assessment scale, Hartwig and Siegel Severity Assessment Scale and PvPI criteria.
Results: A total of 254 ADRs communicated to PvPI through specified, updated IPC suspected ADR reporting form. The incidence of ADRs in both males and females was identical. The occurrence of ADRs in adult patients (71.26%) was significantly higher than other age groups. Of total ADRs, most of them were with Antibiotics (24.01%) followed by antipsychotics (11.42%). In causality assessment, a majority of ADRs (48.82%) were considered possibly related to the drug or treatment and 55.12% were mild in severity. Overall, 36.22% patients were recovered from ADRs. Most of the reported ADRs (54.33%) were probably preventable.
Conclusions: The results provided an insight to the HCPs on the importance of monitoring and reporting of ADRs. High-quality data gathered through a reporting system, most of the reported ADRs were probably preventable; the proper review of patient history and monitoring by HCPs can reduce the incidence of ADR. Our study results emphasize a need for establishing a pharmacovigilance centre to ensure the safe use of drugs.

1. Introduction

The development of drugs in the last decades has brought remarkable benefits for the patients, at the same time the incidence of Adverse Drug Reaction (ADR) has raised remarkably. ADR is defined by World Health Organization (WHO) as "a response to a medicinal product which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function".[1,2] It is universally accepted that "No drug absolutely free from side effects". From the literature it is observed that 5% of all hospital admissions were related to drug-induced problems and 10–20% of hospitalized patients are developing ADRs, it is estimated that ADRs are the fourth to the sixth leading cause of death.[3]

According to the WHO, "Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problem, particularly long-term and short-term adverse effects of medicines".[4–7] Pharmacovigilance aims at

Abbreviations: ADR, Adverse Drug Reaction; AMC, ADR Monitoring centre; PvPI, Pharmacovigilance Programme Of India; WHO, World Health Organization; UMC, Uppsala Monitoring Centre; ICU, Intensive Care Unit; ENT, Ear Nose Throat; HCP, Health Care Professional; OBG, obstetrics and gynecology; DVL, Dermatology Venereology and Leprosy.

Peer review under responsibility of Alexandria University Faculty of Medicine.

* Corresponding author.
E-mail address: pharmachinna@gmail.com (M. Venkatasubbaiah).

https://doi.org/10.1016/j.ajme.2018.10.005
2090-5068/

making the best use of medicines with the help of high-quality data gathered through a reporting system. Good pharmacovigilance helps in the minimization or prevention of ADRs through early detection and effective communication, which ultimately help each patient to receive optimum therapy. It can generate evidence that will inspire public confidence and trust in drugs.[8]

ADRs are more common with the multiple drug therapy and with each additional medication taken by the patient the hazard of an ADR episode gets multiplied by 1.14 thereby directly increasing the length of stay.[9,10] ADRs may also result in the slackened quality of life, increased physician visits, hospitalizations, and even death. In addition, they result in increased health care costs. Thus they place a substantial encumbrance on health care resources.[7] A study conducted in south Indian tertiary referral hospital revealed that 0.7% of total admissions were drug-related and 1.8% fatal ADRs.[11]

Therefore, medicines safety monitoring is an essential element of the healthcare system and for high-quality medical care. Currently, WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre) has a strong network of 194 Member States worldwide,[12] these states collects, reviews and reports suspected ADRs, to the Uppsala Monitoring Centre for entry into the WHO database (largest database of over 3.5 million case reports).[8]

In India, in the year 2010 the Ministry of Health and Family Welfare (MoHFW), launched the nationwide Pharmacovigilance Programme of India (PvPI). Indian Pharmacopoeia Commission (IPC) under the MoHFW has been functioning as the National Coordination Centre (NCC) for PvPI since April 2011, since then rapid progress in reporting of ADRs by the healthcare professionals is seen.[11] PvPI stated that during the period of April 2011 to March 2016, a total of 181,656 reports have been received through various reporting modalities.[13] Through this data PvPI regularly recommends the drug regulatory authorities and suggests the Healthcare professionals (HCPs) in improving the safe use of drugs.

Still, there is a greater need to create and enhance awareness in community and healthcare professionals about the importance of close monitoring of drug outcomes especially newer ones. Awareness regarding the detection, management, prevention, and reporting of ADR is utmost important in improving patient care and to reduce cost. This present study is aimed to strengthen the ADR database through analysis and reporting of ADRs and to improve the reporting culture among HCPs.

2. Methodology

An observational study was carried over a period of 12 months from July 2016 to June 2017 in Rajiv Gandhi Institute of Medical Sciences (RIMS) General hospital at Kadapa district, Andhra Pradesh, India.

Study site description:

A 750 bedded tertiary care government teaching hospital providing both in-patient and out-patient services with Medicine, Surgery, OBG, Pediatrics, Orthopaedics, Psychiatry, Skin and VDL, ENT, Ophthalmology. The average daily out-patient consultancy is 900–1000 and in-patient is 100–120. On average 90–100 Pharm. D students, 200–250 medical and 300–350 Nursing students will be available in different departments for better patient care.

Ethical considerations:

This study was conducted after obtaining the ethical approval from the institutional ethics committee of RIMS and with patient's permission.

Functioning of the ADR reporting system:

On daily basis, HCPs were informed regarding the importance of monitoring and reporting of ADRs. At the time of admission, all the patients were assessed for the previous allergies, ADRs, and past medical history and were noted in the case sheets. The symptoms/signs observed through the clinical review process were assessed for their relation with the drug(s), if any new symptom(s) experienced by the patient during the hospital stay (In-Patient)/ course of therapy (Out Patient) were suspected as drug-induced and analyzed for their relationship with the drugs than with the disease and its possible complications. If the reaction is not related to the underlying disease and/or its complication or if the possible causal relation is more with the drug than other possible causes, then it will be suspected as an ADR and was confirmed with the support of literature (if any). Such ADRs reported by the HCPs in institutional suspected ADR reporting form and ADR notification form were analyzed for their completeness, credibility, and correctness. Suspected ADRs that meet PvPI reporting criteria were separated, reported and documented in PvPI suspected ADR reporting form.[14]

We have also encouraged the patients and their caretakers to report all ADRs using reporting modalities like directly reporting, either to the treating physician or clerkship and internship practicing students of Pharm D or Nurses.

Data were carefully evaluated for quality, based on the following essential elements by analysing patient and reaction characteristics: patient initials, gender, date of reaction (onset), description of the reaction or problem, suspected medication(s), indications for use, concomitant medical products including self-medication and herbal remedies, de-challenge, re-challenge and outcomes.

After initial notification of a suspected ADR, additional details were collected concerning previous allergies, concomitant medications, co-morbidities, ADR management and outcome, and other details necessary for evaluation through direct interview with the reporter and patients, and/or evaluation of patient medical records.

These suspected ADRs were then reported to 3 PvPI ADR monitoring centres (AMCs); Kurnool Medical College, Madras Medical College or Sri Venkateswara Medical College. Care was taken to avoid the duplication of reporting i.e., one ADR was reported to one centre only. On monthly basis, we have received the acknowledgments with unique numbers i.e. AMC number and Worldwide Number of reported ADRs from these centres. The worldwide number and AMC number were entered into the documented reporting forms and ADR database and the same was communicated to the reporters.

2.1. Evaluation of data

The reactions were categorized based on patient demographics (age and gender) and ADR characteristics (the type of ADRs, drug characteristics, system organ class, outcome and management, de-challenge/re-challenge and reporter status).

2.1.1. Patient demographics characteristics

The ADRs were summarized based on the patients' age and gender. Patients were divided into four age groups such as paediatrics (0–12 years), adolescents (13–17 years), adults (18–65), and geriatrics > 65.

2.1.2. Adverse drug reaction characteristics

The ADRs were analyzed for their seriousness, severity, causality and the organ system affected.

The seriousness of the ADRs was assessed by using the PvPI criteria[14] i.e. life-threatening, required intervention to prevent permanent impairment/damage, hospitalization/prolonged hospital stay, disability, congenital anomaly, and death.

The severity of the reaction was determined and categorized as mild, moderate or severe according to the classification system of Hartwig and Siegel Severity Assessment Scale.[15]

No single method was universally accepted for assessing the causal relationship of the drug to adverse reactions as various algorithms and methods are in use according to the individual preference.[16–18] Here, we have assessed the causality to establish the relationship between the drug and the reaction by using WHO Causality assessment scale, as it is recommended by Uppsala Monitoring Centre (UMC) and PvPI.[14,19,20] Preventability was assessed using the classification system of modified Schumock and Thornton scale.[21]

Further, ADRs were categorized based on de-challenge/re-challenge, class of the causative drug, outcomes, management of ADR and the reporter status.

3. Results

A total of 254 reported/notified suspected ADRs from different departments were analyzed and reported to PvPI. Reports were scrutinized based on patient demographics, drug characteristics, type of ADRs, outcomes, Causality, Severity, Preventability, and seriousness.

3.1. Data evaluation based on demographics of the patient

Of the 254 ADRs 125 were experienced by males and 129 by females patients. The incidence of ADRs among males and female was similar. The majority (71.26%) of ADRs were reported in adults then the geriatric (17.32%), pediatric (7.87%), and adolescent (3.54%) patients. which was shown in Table 1.

3.2. Department wise distribution

Out of 254 ADRs, 56.6% ADRs were reported from the General Medicine department followed by Psychiatry (13.38%), Dermatology, Venerology and Leprosy (11.0%), ICU (4.72%), Pulmonology (4.72%), Pediatrics (3.9%), Orthopedics (2.7%), Surgery (1.57%), ENT (0.78%) and OBG (0.39%).

3.3. Analysis of ADRs

3.3.1. Causality

Upon causality we found the majority (48.82%) of the reported ADRs were possible, followed by probable (27.17%), certain (12.20%) and unassessable (11.42%), which was shown in Table 2.

3.3.2. Severity

Assessment of severity is essential to take necessary action against the drug continuation, in our study most of the ADRs were mild and only a few were severe. The severity distribution of ADRs was represented in Table 2.

Table 1
Distribution based on demographics.

Parameter	Number of ADRs *n = 254*	Percentage
Gender		
Male	125	49.21%
Female	129	50.79%
Age group		
Pediatrics	20	7.87%
Adolescents	9	3.54%
Adults	181	71.26%
Geriatrics	44	17.32%

Table 2
Analysis of ADR.

Parameter	Number of ADRs n = 254	Percentage
Causality[*]		
Certain	31	12.20%
Possible	124	48.82%
Probable	69	27.17%
Un-assessable	29	11.42%
Unclassifiable	1	0.39%
Severity[+]		
Mild	140	55.12%
Moderate	101	39.76%
+Severe	13	5.12%
Preventability[#]		
Not preventable	2	0.79%
Definitely preventable	114	44.88%
Probably preventable	138	54.33%
Seriousness[$]		
No	90	35.43%
Hospitalization initial/prolonged	71	27.95%
Life-threatening	4	1.57%
Required intervention to prevent impairment/damage	81	31.89%
Death	1	0.39%
Disability	1	0.39%
Others	6	2.36%

[*] UMC-WHO Scale is used.
[+] Hartwig and Siegel ADR Severity Assessment Scale.
[#] Modified Schumock and Thornton Preventability Scale.
[$] As per PvPI Criteria.

3.3.3. Preventability

Preventability assessment helps in improving drug use, out of 254 ADRs, most were probably preventable (54.33%) followed by definitely preventable (44.88%) and only a few (0.7%) were not preventable and this was clearly showed in Table 2.

3.3.4. Seriousness

Seriousness was assessed by using standard criteria given by the PvPI and found the majority of them were serious (65%). Distribution of ADRs based on seriousness in accordance with criteria was demonstrated in Table 2.

3.3.5. De-challenge and re-challenge

The causative drugs were withdrawn from the prescription (dechallenge) in the majority of the cases i.e. 149 (58.7%), in 9 (3.5%) cases rechallenge was performed, and in remaining cases, this information was lacking or de or re-challenge was not performed.

3.4. Drug class

A higher number of ADRs were reported for antibiotics 61 (24.01%) followed by antipsychotics 29 (11.42%) and analgesics and antipyretics 19 (7.48%). Detailed list of offending drugs is shown in detail in Table 3.

3.5. System affected

We observed that 67 (26.4%) ADRs were related to Gastro-Intestinal (GI) system organ class followed by Skin 61 (24.0%) and Central Nervous System 37 (14.6), the involvement of other systems is illustrated in Table 4.

Table 3
Characterization of drugs involved in ADRs.

Class of the drug	Offending drug	Total number of ADRs (%) *n = 254*
Anticonvulsants	Phenytoin	13(5.118%)
	Carbamazepine	3(1.18%)
	Sodium Valproate	5(1.968%)
Antidiabetics	Pioglitazone	1(0.394%)
	Metformin	1(0.394%)
	Glimepride	2(0.787%)
Antiulcer and Antacids	Pantoprazole	6(2.362%)
	Sucralfate	1(0.394%)
Benzodiazepines	Clonazepam	1(0.394%)
	Lorazepam	2(0.787%)
	Midazolam	1(0.394%)
Antiplatelets	Aspirin	5(1.968%)
	Clopidogrel	1(0.394%)
Antibiotics	Amikacin	2(0.787%)
	Augmentin	7(2.755%)
	Azithromycin	1(0.394%)
	Cefixime	4(1.574%)
	Ceftriaxone	14(5.511%)
	Ciprofloxacin	4(1.574%)
	Cefoperazone	1(0.394%)
	Vasone (Cefoperazone and Sulbactam)	1(0.394%)
	Dapsone	2(0.787%)
	Doxycycline	1(0.394%)
	Norfloxacin	1(0.394%)
	Ofloxacin	1(0.394%)
	Piperacillin and tazobactam	6(2.362%)
	Metronidazole	2(0.787%)
	Ornidazole	1(0.394%)
	Streptomycin	13(5.11%)
Antipsychotics	Clozapine	1(0.394%)
	Escitalopram	2(0.787%)
	Fluoxetine	1(0.394%)
	Haloperidol	2(0.787%)
	Fluphenazine	1(0.394%)
	Risperidone	8(3.149%)
	Olanzapine	8(3.149%)
	Quetiapine	4(1.574%)
	Sertraline	1(0.394%)
	Tri hexyphenidyl	1(0.394%)
Analgesics & Antipyretics	Aceclofenac	3(1.181%)
	Ibuprofen	1(0.394%)
	Diclofenac	8(3.149%)
	Tramadol	1(0.394%)
	Paracetamol	5(1.968%)
	Mefenamic Acid	1 (0.394%)
Anti-malarials	Artesunate	5(1.968%)
	Hydroxychloroquine	1(0.394%)
Corticosteroids	Dexamethasone	6(2.362%)
	Hydrocortisone	3(1.181%)
	Prednisone	12(4.724%)
	Prednisolone	2(0.787%)
Anti-hypertensives	Amlodipine	11(4.33%)
	Clonidine	1(0.394%)
	Telmisartan	2(0.787%)
	Furosemide	3(1.181%)
ART	ZLN (zidovudine, lamivudine, nevirapine)	4(1.574%)
	TEL (Tenofovir, efavirenz, lamivudine)	4(1.574%)
Haematinics	Iron Folic Acid (IFA)	5(1.968%)
	Blood transfusion	3(1.181%)
	Platelet transfusion	1(0.394%)
	Multi vitamin	1(0.394%)
Immune suppressants	Sulfasalazine	1(0.394%)
	Azathioprine	1(0.394%)
	Methotrexate	1(0.394%)
Miscellaneous	Ondansetron	1(0.394%)
	Salbutamol	1(0.394%)
	Sorbitrate	1(0.394%)
	Xylometazoline	1(0.394%)
	Acitretin	1(0.394%)
	Alcoliv (Metadoxine)	1(0.394%)
	Amiodarone	1(0.394%)
	Atropine	1(0.394%)
	Bioenax (Enoxaparin)	2(0.787%)

Table 3 (*continued*)

Class of the drug	Offending drug	Total number of ADRs (%) *n = 254*
	Chlorpheniramine	1(0.394%)
	Deriphylline (Theophylline and Etophylline)	4(1.574%)
	Desvenlafaxine	1(0.394%)
	Cyclopam (Dicyclomine)	1(0.394%)
	Digoxin	4(1.574%)
	Herbal Remedy (*Ricinus communis* leaves' paste)	2(0.787%)
	IV Fluids	3(1.181%)
	Isolyte P	1(0.394%)
	Isotretinoin	1(0.394%)
	Lidocaine	1(0.394%)
	Menadione	1(0.394%)
	Mycophenolate Mofetil	1(0.394%)

Table 4
Characterization of systems affected with ADRs.

Organ system involved	Number of ADRs *n = 254*	Percentage
GI	67	26.38%
SKIN	61	24.02%
CNS	37	14.57%
Renal system	22	8.66%
Blood and Lymphatic	18	7.09%
Endocrine	13	5.12%
Hepato-Biliary	13	13.00%
CVS	10	3.94%
Others	13	5.12%

3.6. Outcomes of ADRs

Among 254 patients, 92 (36.2%) patients have recovered from the reactions and 78 (30.7%) were at recovering stage during the study period while the outcomes of 52 (20.47%) patients were unknown, 30 (11.81%) were not recovered and 1 ADR each was fatal and continuing which were demonstrated in Table 5.

3.7. Management of ADRs

Out of 254, 144 (56.7%) patients have received treatment with at least one additional drug for the reported ADR with or without dechallenge, and in 54 (21.3%) patients offended/suspected drug was withdrawn from the prescription and no treatment was given for the ADR. Table 5 illustrate clearly the management of ADRs.

Table 5
Characterization of ADRs based on outcome and management.

Parameter	Number of ADRs *n = 254*	Percentage
Outcome of ADR		
Fatal	1	0.39%
Recovering	78	30.71%
Unknown	52	20.47%
Continuing	1	0.39%
Recovered	92	36.22%
Not-recovered	30	11.81%
ADR management		
Addition of another drug with/without dechallenge	144	56.69
Drug withdrew only	54	21.26
Substituted with another drug	6	2.36
No change	28	11.023
Dose reduced	13	5.12
No information	9	3.54

3.8. Reporter professional status

ADRs were reported by Pharm D students and other HCPs like the physician, nurses. During the study period, we observed that the majority of ADRs were reported by students (96.06%) followed by physicians and nurses (3.93%).

4. Discussion

PvPI gathers the ADRs from all healthcare setups and the public in India, and communicates the significant data to drug regulatory authorities for necessary action on the drugs; it also communicates the healthcare professionals and the public regarding the risk of ADRs, by this it improves the patient safety and welfare, and it is the responsibility of all healthcare professionals to support the PvPI in promoting safe use of medicine, in this view we have reported a total of 254 ADRs to the PVPI through AMCs according to the standard criteria given by National Coordinating Centre (NCC) for monitoring ADR.

We have found no significant difference in the occurrence of ADR among males (49.21%) and females (50.79%). Studies conducted in northeast India by Lihite et al.,[3] and in south Indian study conducted by Vijayakumaret al.,[22] have reported only 8% more ADRs in females than in males.

The incidence of ADRs was more in adult population than pediatrics, adolescents and geriatrics as this population was found to be visiting frequently hospitals and drug usage is often more in them.

The generated results exhibited similarity with a certain population[6,9,23,25] and same were conflicted in another study[22] which justified that the geriatrics were more vulnerable population.

Majority of the ADRs were reported from the Department of General Medicine than other departments, where the rate of consultation is more than in the other departments, observational studies conducted in India have also reported that most of the ADRs identified were from the same the General medicine Department.[4,24,26,27]

Causality assessment is essential to confirm whether the reaction is because of drug alone or other factors also involved in ADR occurrence, we did causality assessment using WHO-UMC causality assessment scale and found that the majority of ADRs were possible, other observational studies conducted in South Indian tertiary care teaching hospitals[4,23,29] have also reported that the majority of the reported ADRs were possible with the same scale.

Assessment of severity is also essential to take necessary action against the drug continuation, in our study most of the ADRs were mild, and fortunately, the incidence of severe ADRs is low, as in the case of similar studies conducted by other researchers.[9,22,23]

Preventability assessment helps in improving rational drug use; in our study, the majority of ADRs were of probably preventable, which indicates that proper history taking and individualized drug therapy can minimize these ADRs and most of the patients were illiterates and they have not maintained their medical records properly and also they were unaware of their previous ADR occurrence. Other Studies conducted in India have also reported that the incidence of probably preventable ADRs is more.[4,6]

The seriousness of the reaction gives information on the risk involved, which is an important parameter to be considered in the marketing of drugs. The seriousness was assessed by using PvPI criteria and found the majority of ADRs were serious reactions, which required intervention to prevent permanent damage and increased hospitalization. In an Indian study conducted by Sneha et al.[4] also reported that majority of the ADRs were led to the Hospitalization/Prolonged (52.33%) and required intervention (38.31%), a considerable number of serious ADRs were identified. And in another Indian study conducted by Singh et al.[9] reported that 6.5% ADRs were of life-threatening.

In our study, the majority of ADRs were observed in admitted patients, and antibiotics were involved in the majority of ADRs, this is due to the reason, that almost all inpatients have received antibiotic therapy either for prophylactic or curative therapy. The results were consistent with previous studies.[4,6,9,22,23,25,28,29]

In outcomes of the reactions, most of the patients have shown recovery after the withdrawal of offending drug and/or with the treatment of ADRs, and the outcome was unknown for a predominant number of ADRs. Fortunately, only one fatal reaction was noted in this study.

This study suggests that there is a need for spontaneous ADR reporting from all the departments of this tertiary care hospital for monitoring and assessment of ADRs. This study also warrants further research for the development of possible intervention strategies to reduce the burden of ADRs. The present study showed a major reporting among student clinical pharmacists (Pharm D clerkship and internship practicing students) with the continuous education and motivation. Throughout the study period, clinical pharmacists have actively monitored the patients and interacted with the treating physicians regarding the outcomes of the treatment to get complete information on the suspected ADRs. The student clinical pharmacists were actively involved in the ADR analysis and reporting to PvPI. Out of all 254 ADRs, only 10 were reported by the physicians and the reporting rate was nil among nurses. Most of the studies conducted in India[9,23] and Saudi Arabia[30] have concluded under-reporting by physicians and Nurses. But, studies in Brazil[5,25] reported that physicians and nurses are actively involved in ADR reporting.

There are various probable reasons identified for underreporting such as lack of aptitude (physicians limited their role to identifying and treating of ADRs, and only a few physicians have extended their role to the reporting to the Pharmacovigilance centres), time constraint, non-accessibility of ADR (IPC) reporting forms, lack of incentives (no encouragement to the physicians in reporting ADRs with the form of appreciation letters/credits) etc. A Study conducted in northeast India[3] has also stated the same reasons for underreporting.

But all the health care professionals provided their support in confirming the ADR. In our study centre, ADR database maintenance is almost nil; this could be mainly due to lack of strong arrangements like drug safety monitoring system which could guide and encourage the healthcare professionals in monitoring and communicate ADRs. Though, PvPI and Medical Council of India insisting an active drug safety monitoring system in every Government and Private hospitals, most of the hospitals are not showing complete interest in the establishment of an ADR monitoring centre.

5. Conclusion

This study concluded that the spontaneous reporting of ADRs is fairly good in this hospital. Although the ADRs in the present study were serious and preventable, monitoring and management of such ADRs through therapeutic interventions would be beneficial in better patient care. Hence clinical pharmacists have an important responsibility in monitoring and reporting of ADRs. During this study period, we have encouraged all the HCPs in the monitoring and reporting of ADRs. With continuous awareness and motivation, reporting culture can be improved; this can be achieved through a well -structured and dedicated pharmacovigilance system running by a clinical pharmacist. Pharm. D graduates can visit all the departments and encourages HCPs by conducting awareness and/ training programs on ADR reporting.

Conflict of interest

No conflict of interest.

Acknowledgments

We thank all health care Professionals for their timely response, as well as the volunteers who generously provided assistance at the hospital. Authors are grateful to 3 ADR monitoring centres viz., MMC, Chennai, SVMC, Tirupathi and KMC, Kurnool for their continuous guidance and support for this study.

References

1. Jayesh KMR, Kajal S, Srivastav AK. Pharmacovigilance: a review article. *Innov J Med Sci*. 2016;4:6–7.
2. Maysa S, Doaa F, Rana AF. Pharmacist's knowledge, practice, and attitudes toward Pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharma J*. 2015;23:147–153.
3. Ratan JL, Mangala L, Sukirti D, et al.. A study on adverse drug reactions in a tertiary care hospital of northeast India. *Alex J Med*. 2017;53:151–156.
4. Sneha G, Sowmya N, Prem KG, et al.. An observational prospective study on prevalence and monitoring of adverse drug reactions in tertiary care teaching hospital. *BJPR*. 2016;11:1–9.
5. Marilia BV, Cinthia M, Catarina MSS, et al.. Adverse drugs reactions and quality deviations monitored by spontaneous reports. *Saudi Pharma J*. 2015;23:130–137.
6. Neha T, Mohd I, Syedazizullah G, Ashok R, Mohd M. Dermatological adverse drug reactions in tertiary care hospital. *IJPSR*. 2015;6:816–824.
7. Peter OA, Abiodun KE, Eyo OA, Chuku I. Incidence of adverse drug reactions in patients on antiretroviral therapy: a study of pharmaceutical care in HIV interventions in a tertiary health facility in southern Nigeria. *Res Hum Soc Sci*. 2016;6:103–107.
8. Safety of Medicines In Public Health Programmes: Pharmacovigilance an essential tool, World Health Organization 2006. Available from: <http://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf?ua=1> [Accessed 18 May 2016].
9. Singh H, Dulhani N, Kumar BN, Singh P, Tewari P, Nayak K. A Pharmacovigilance study in medicine department of tertiary care hospital in Chhattisgarh (Jagdalpur), India. *J Young Pharm*. 2010;2:95–100.
10. Emma CD, Christopher FG, Stephen T, Paula RW, David RM, Munir P. Adverse drug reactions in hospital in-patients: a prospective analysis of 3695 patient-episodes. *PLoS ONE*. 2009;4:e4439.
11. Kalaiselvan V, Thota P, Singh GN. Pharmacovigilance programme of India: recent developments and future perspectives. *Ind J Pharmacol*. 2016;48:624–628.
12. World Health Organization: Countries. Available from: http://www.who.int/countries/en/ [accessed 18 May 2016].
13. Pharmacovigilance Programme of India (PvPI) Performance Report 2015-16. Available from: http://www.ipc.gov.in/PvPI/pub/Pharmacovigilance%20Programme%20of%20India%20Annual%20performance%20Report%202015-2016.pdf [accessed 19 May 2017].
14. Indian Pharmacopoeia Commission (IPC) Guidance Document for Spontaneous Adverse Drug Reaction Reporting. Available from: http://ipc.nic.in/writereaddata/mainlinkFile/File268.pdf; 2014 [accessed 13 December 2017].
15. Srinivasan R, Ramya G. Adverse drug reaction-causality assessment. *IJRPC*. 2011;1:606–612.
16. Agbabiaka TB, Savovic J, Ernst E. Methods for causality assessment of adverse drug reactions: a systematic review. *Drug Saf*. 2008;31:21–37.

17. Macedo AF, Marques FB, Ribeiro CF, Texeira F. Causality assessment of adverse drug reactions: comparison of the results obtained from published decisional algorithms and from the evaluations of an expert panel. *Pharmacoepidemiol Drug Saf*. 2005;14:885–890.
18. Lagier G, Vincens M, Castot A. Imputability in drug monitoring. Principles of the balanced drug reaction assessment method and principal errors to avoid. *Therapie*. 1983;38:303–318.
19. The use of the WHO-UMC system for standardized case causality assessment. Available from: https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf [accessed 13 December 2017].
20. Rehan HS, Chopra D, Kakkar A. Physician's guide to Pharmacovigilance: terminology and causality assessment. *Eur J InterMed*. 2009;20:3–8.
21. Asawari LR, Palak P, Chintan P, Atmaram P. Preventability, predictability, and seriousness of adverse drug reactions amongst medicine inpatients in a teaching hospital: a prospective observational study. *Int J Pharma Chem Sci*. 2012;1:1293–1299.
22. Vijayakumar TM, Dhanaraju MD. Description of adverse drug reactions in a multi-specialty teaching hospital. *Int J Integr Med*. 2013;1:1–6.
23. Kiran R, Divya S, Prathiba N, Bhanu P. Monitoring and analysis of drug reactions in a private tertiary care teaching hospital. *Asian J Pharm Clin Res*. 2015;8:335–337.
24. Sangeetha R, Jamuna R, Kala P. Pattern of adverse drug reactions in a tertiary care teaching hospital: a cross-sectional study. *Asian J Pharm Clin Res*.. 2017;10:170–173.
25. Marcia GAdeAL, Sandra MBP, Jose GD, Valeria GM, Maria CSP. Adverse drug reaction monitoring: support for Pharmacovigilance at a tertiary care hospital in northern Brazil. *BMC Pharmacol Toxicol*. 2013;14:5.
26. Pankaj G, Aaditya U. Adverse drug reaction reporting and Pharmacovigilance: knowledge, attitudes, and perceptions amongst resident doctors. *J Pharma Sci Res*. 2011;3:1064–1069.
27. Shamma M, Dilip C, Ajmal M, et al.. A prospective study on adverse drug reactions of antibiotics in a tertiary care hospital. *Saudi Pharma J*. 2014;22:303–308.
28. Palanisamy S, Arul KG, Aiyalu R. A study on adverse drug reactions at a tertiary care teaching hospital. *Int J Pharm Teach Pract*. 2011;2:96–101.
29. Sivanandy P, Arul KSG, Aiyalu R. A study on assessment, monitoring, and reporting of adverse drug reactions in Indian hospital. *Asian J Pharm Clin Res*. 2011;4:112–116.
30. Mohamed MM, Abdel L, Basel AAW. Knowledge and awareness of adverse drug reactions and pharmacovigilance practices among healthcare professionals in Al-Madinah Al-Munawwarah, Kingdom of Saudi Arabia. *Saudi Pharma J*. 2015;23:154–161.