

Analysis of spontaneous individual case safety reports reported at adverse drug reaction monitoring centre: tertiary care teaching hospital in South India

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ABSTRACT

Background: Drugs are double edged weapons, they are used in treatment of the patients but in return can harm as well. The safety of drug prescribing has become a need of the hour topic in medicine. Safety monitoring of patients via Pharmacovigilance tool has become an integral part of pharmacotherapy. This study has been undertaken to analyze the various individual case safety reports including the Special situation cases of medication error and over dose and to promote the reporting of adverse drug reactions (ADRs) among the healthcare professionals (HCPs).

Methods: A retrospective non-interventional observational study was done for indexed period of six months at AMC-PvPI under Osmania Medical College and General Hospital. The reported individual case safety reports (ICSRs) are evaluated on basis of demographics of age and gender, seriousness criteria, outcome parameters and causality assessment of suspected drug (s) and suspected ADR/AE (s) as per the ICH guidelines and WHO causality assessment scale.

Results: A total of 177 ICSRs are reported out of that 137 were ADRs, 36-medication error cases and 4-cases of over dose. The incidence of ADRs in females are high compared with males was identical. The occurrence of ADRs in adult patients (61%) was significantly higher than other age groups. Of total ADRs, most of them were with analgesics (26%) and highly reported system organ classification was CNS. Overall, 79% patients were recovered from ADRs.

Conclusions: The results depicted an insight to the HCPs on the importance of monitoring and reporting of ICSRs. Our study results emphasized need to roll out a pharmacovigilance practice tool to ensure the safe use of drugs for better Pharmacotherapy and development of pharmacogenomic studies.

Keywords: Health care professionals, Individual Case safety report, System organ classification, Adverse drug reaction, Adverse event, Toxic epidermal necrolysis

INTRODUCTION

In the past few decades there has been an exponential growth in the global human population and India accounts as 17.4% (1.37 billion population till August-2019) in the world.¹ With the increasing population the disease rate is also directly proportional to the mortality of the people globally. So in order to improve the patient

health and decrease the mortality rate related with diseases new therapeutics are introduced into the market along with the existing once as an ongoing life cycle. These medicines play a crucial role in increasing the human life span and reducing the morbidity which inversely decreases the mortality rate. However pharmaceuticals could also be potentially hazardous. By use of medicines the recipients of the prescribed

pharmaceutical drugs may lead them to adverse drug reactions (ADRs) and adverse events (AEs) unfortunately. 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 and dosed. Each and every drug and the excipients has its own differences in metabolic rate and genetic variations among patients when administered ending up with either positive effect or ADRs/AEs. Sufferings from the disease and disorder conditions are mainly intervened by the medical treatment. But in the past itself it has been detected that drug themselves can prove fatal; as the saying rightly goes “drugs are double edged weapons”.² So it’s always every ones responsibility to report ADRs and monitor the benefits outweighing the risks as still future is in our hands to improve.

A drug or medicine is a pharmaceutical product of chemical substance used in the prevention, treatment, cure of disease or for the modification of physiological function or pathological state in the benefit of the recipient”.^{3,4} Drugs may be used for a limited duration, or on a regular basis for chronic disorders. Apart from all the benefits of the drugs, the adverse reactions and adverse events associated with them are most common. Adverse drug reaction can be defined as “an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product”.³ They are usually preventable, cause of illness, which may require modifying the dosage regimen or discontinuing a medication or prolongation of hospitalization. But sometimes it results in disability or can be life-threatening even cause death.³

At global level as well drug toxicity is playing as a major limitation in providing a good health care to patients by affecting health and economic burden.² The safety of drug prescribing has become a need of the hour topic in medicine because most of the important ADRs/AEs are caused by routinely prescribed and used medications.

When a study was conducted at South Indian tertiary care hospital, it was reported that 3.7% of the total hospitalized patients were suffering from ADR, among which 1.3% were fatal and 0.7% of the hospital admissions were due to ADRs.³ ADRs can be reported either with single medication or with the multiple drug therapy and with each additional medication taken by the patient the harmful incidences of an ADR episode gets multiplied by 1.14 thereby increasing hospital admission and prolonged stay.⁴

Hence, to counterfeit all the safety and economic challenges with use of drugs on health care system WHO as established “International Drug Monitoring Program”

via a safety monitoring tool as pharmacovigilance.^{5,6} This acts as active surveillance in the post-marketed pharmaceuticals.

WHO defines pharmacovigilance (Pv) 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.⁷ When it comes to India particularly because of the idiosyncratic methods of treating patients many pros and cons arise effecting the safety of patients while treating with the pharmaceuticals. To monitor and report the cons of these pharmaceuticals as in-house set up of good pharmacovigilance system is essential. Such that evidence based data is generated to win the public confidence and trust on use of drugs.

In the year 2010 the Ministry of Health and Family Welfare (MoHFW), launched the nationwide Pharmacovigilance Program of India (PvPI) under the umbrella of Indian Pharmacopoeia Commission (IPC) and it has been functioning as the National Coordination Centre (NCC) for PvPI from April 2011.⁸ Currently PvPI has recognized 270-Adverse drug reaction monitoring centers (AMCs) across the India, so that a good in-house set up of monitoring and reporting of ADRs and AEs by the healthcare professionals is observed.⁹ PvPI receive individual case safety reports (ICSRs) through various reporting methods established and through this data PvPI regularly recommends the drug regulatory authorities for regulatory interventions and suggests the healthcare professionals (HCPs) in improving the safe use of drugs by raising and circulating drug safety alerts.

In spite of these, still there is a huge demand for awareness regarding the detection, management, prevention and reporting of ADRs/AEs is most important in improving patient safety by reducing the economic burden. This present study was aimed to strengthen the analysis of reporting of ADRs/AEs of current trends, special situation and to improve the reporting culture among HCPs and common public.

METHODS

A retrospective non-interventional observational study was done for indexed period of six months from January 2019 to June 2019. The data of spontaneous suspected ICSR was collected and reported using the prescribed “Suspected Adverse Drug Reaction Reporting Form” for health care professionals (red form) and also the “Medicines Side Effect Reporting Form” for consumers (blue form) provided by PvPI-IPC.^{10,11} The HCPs and consumers or the patient caretakers were briefed about the recording information on the concerned forms and reporting to AMC under PvPI in the “Osmania Medical College and General Hospital” of a tertiary care teaching hospital. The “Patient Safety Pharmacovigilance Associate” appointed by the PvPI-IPC at AMC also

visited all departments regularly to observe the ADRs/AEs and collected data.

Inclusion criteria

ADR/AE reports of patients of all ages and both genders. ADR/AE reports of patients having complete data, from in-patient and out-patient, consumer reporting, from public- health program, medication errors, over-dose cases were also considered in the study.

Exclusion criteria

ADR/AE reports of patients with incomplete data and Ayush medications were excluded.

Study procedure

At the time of admission, all the patients past medical history, previous allergic reactions and history of consumption of alcohol and smoking were noted in the case sheets. The symptoms and signs observed through the clinical review process were assessed for their casual 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 with 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/AEs reported by the HCPs and consumer or the patient caretakers are analyzed for their completeness, credibility and correctness. Suspected ADRs/AEs that meet PvPI and ICH guidelines reporting valid criteria were separated and reported via said forms. The reported ICSRs are carefully evaluated for quality based on the following ICH guidelines of valid criteria and also essential elements information which acts as supporting basis for causality assessment such as date of reaction (onset), description of the reaction or problem, suspected medication (s), indications for use or prescribed for, therapy dates, dosage regimen, concomitant medications including self-medication and herbal remedies, de-challenge, re-challenge, seriousness criteria, relevant lab investigations/tests, relevant medical history, outcomes and additional information.

After receipt of the initial report of a spontaneous suspected ADR/AE, follow up was done for missing information, ADR management, outcome and other details necessary for evaluation through direct contact with the reporter, patients and/or evaluation of patient medical records.

In the present study WHO causality assessment scale recommended by Uppsala Monitoring Centre (UMC) and PvPI was used for assessing the reported ICSRs causality.

The ICSRs are then uploaded in Vigiflow software and committed to NCC-PvPI, IPC Ghaziabad, which further sends the reports after analyzing to Uppsala Monitoring Centre, Sweden for maintaining global Pv data base.

RESULTS

Data reported was analyzed using descriptive statistics and percentage calculations are expressed.

ICSRs evaluation based on reporter details

During the indexed period a total no of ICSRs processed from OMC-Adverse drug reaction Monitoring center to NCC-PvPI and WHO global data base (through VigiFlow software) were 177 cases. Out of that 151 were collected and reported from HCPs (such as doctors, nurses, pharmacists) and 26 cases were reported directly by patients and or their caretakers using consumer reporting forms (Figure 1).

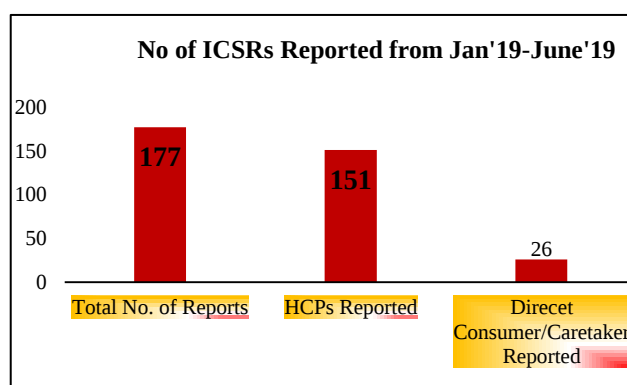


Figure 1: Number of adverse drug reaction/adverse event cases reported by healthcare professionals and direct consumers.

ICSRs analysis based on ADR/AE classification

Out of 177 ICSRs reported 78% (n=137 cases) are classified as spontaneous suspected ADRs/AEs and 20% (n=36 cases) medication error sub category-dispensing error as wrong drug dispensed and product-a-look like confusion with harmful adverse events and 2% (n=4 cases) intentional over-dose leading to adverse events (Figure 2).

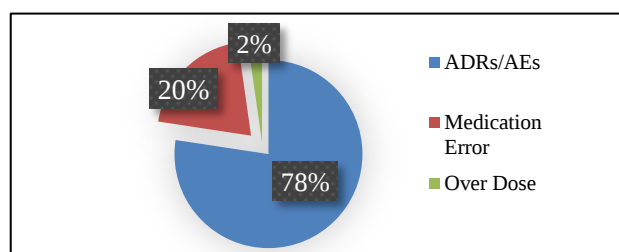


Figure 2: Categories of individual case safety reports distribution according to WHO safety monitoring.

Patient demographics

Age and gender evaluation

According to WHO-UMC vigiflow software age groups are classified into 1-day to 4-years infants; 05-11 years children; 12-17 years adolescents; 18-69 years adults; 70 years and above elderly people.

Among them 177 ICSRs reported in the present study, 20% (n=36 cases) are defined as infants, 10% (n=18 cases) children, 6% (n=10 cases) adolescences, 61% (n=108 cases) adults and 3% (n=5 cases) elderly people. The most commonly and highly effected defined age was adults compared with other age-group (Figure 3). Gender demographics reported are 45% (n=80 cases) males, 54% (n=90 cases) females and 1% (n=2 cases). Other account for transgender (Figure 4).

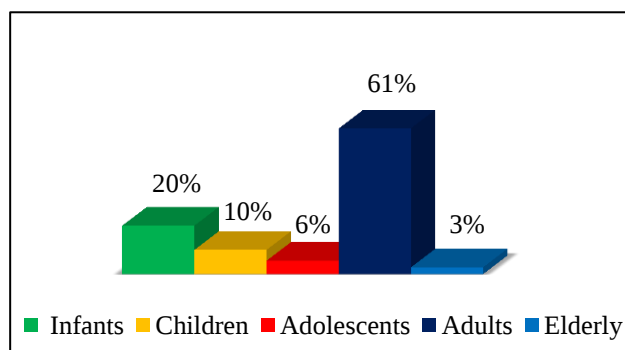


Figure 3: Individual case safety reports based on age-group classification.

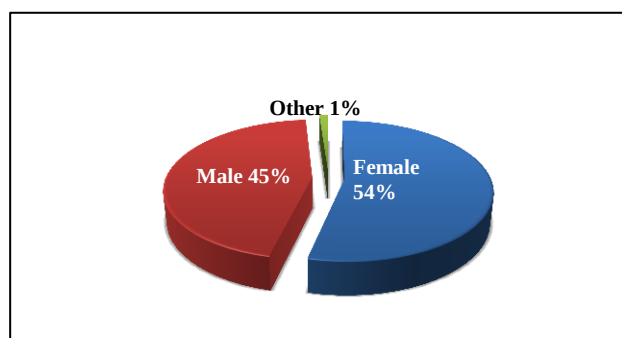


Figure 4: Individual case safety reports based on gender.

ICSRs based on seriousness criteria and outcomes parameters evaluation

According to the ICSR seriousness criteria ICH-guidelines, 39% (n=69 cases) serious and 61% (n=108 cases) non-serious are reported during the index period (Figure 5).

While, the outcome of reported ICSRs are 79% (n=140 cases) recovered, 13% (n=23 cases) recovering at the

time of report received at AMC, 7% (n=13 cases) continuing/not recovered and 1% (n=1 case) fatal (Table 1). Most of the cases got recovered after the positive de-challenge observed and with treatment management.

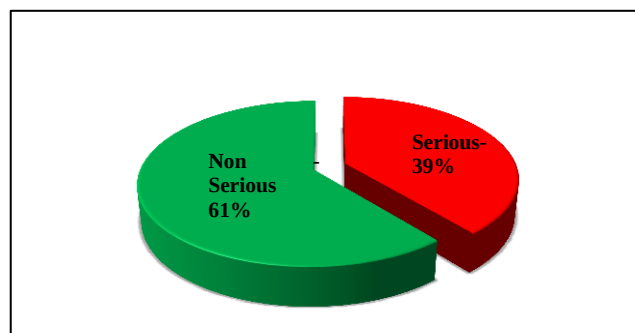


Figure 5: Classification of individual case safety reports based on seriousness criteria of ICH guidelines.

Table 1: Outcome parameter of the individual case safety reports.

S. No.	Outcome parameter	No. of ICSRs	%
1	Recovered	140	79
2	Recovering	23	13
3	Continuing/not-recovered	13	7
4	Fatal	1	1

Causality assessment analysis

Causality assessment is defined as the onset of temporal relation (time- related) with the suspected drug (s)/ medicine (s) to the suspected adverse reaction (s)/ event (s). The parameters considered while assessing the causality are dosage regimen, therapy dates, laboratory tests, concomitant medication (s), pre-existing medical conditions, de-challenge and the re-challenge data. PvPI follows the WHO causality assessment scale to analyze the reported suspected ICSRs. 50% (n=89 cases) deemed to be probable, 48% (n=84 cases) possible and 2% (n=4 cases) certain are reported (Figure 6).

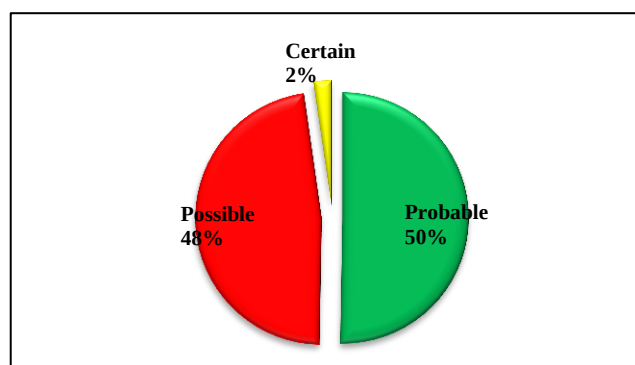


Figure 6: Causality assessment distribution according to WHO-UMC scale.

Table 2: Individual case safety reports based on the system organ classification.

System organ classification	No. of ICSRs (%)
Injury, poisoning and procedural complications	47 (22)
Skin and subcutaneous tissue disorders	46 (21)
Gastro-intestinal system disorder	31 (14)
General disorders and administration site conditions	16 (7)
Nervous system disorder	51 (24)
Immune system disorders	5 (2)
Musculo-skeletal and connective tissue disorders	5 (2)
Respiratory, thoracic and mediastinal disorders	9 (4)
Cardiac disorders	3 (2)
Psychiatric disorders	3 (1)
Eye disorder	1 (1)

Analysis of ICSRs on classification of suspected drugs.

A higher number of ICSRs are reported for analgesic 26% (n=47 cases) followed by antiretroviral 23% (n=42 cases). Detailed list of suspected drugs is depicted (Figure 7). The others include antacids, bronchodilators, steroids, vitamin supplements, local-anesthetic, rabies-immunoglobulin vaccine, antidiuretic and organophosphorous compounds.

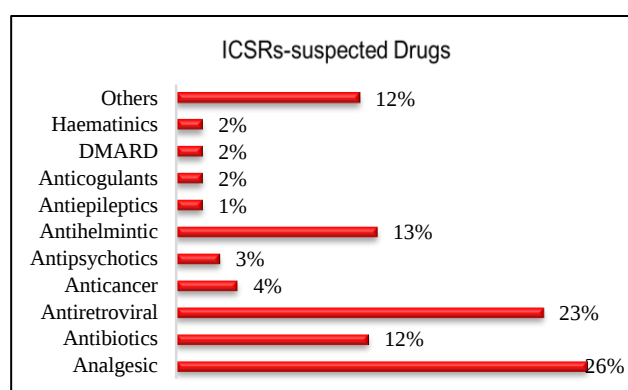


Figure 7: Individual case safety reports distribution based on classification of suspected drugs.

DISCUSSION

Drugs safety surveillance and ADRs/AEs reporting are acting as the backbone for the quality of healthcare treatment and it has become one of the vital national health programs globally as pharmacovigilance. ADR/AE could be considered as a differential diagnosis of heterogeneous conditions, as it is difficult to diagnose.¹² In general practice unexpected hospital admissions around 6% and consultations around 3% and were found to be due to ADRs/AEs.¹³ In the present study we have encouraged all the HCPs and direct consumer or patient caretakers for reporting ADRs/AEs in order to strengthen the patient safety contribution from each individual which plays a major role. We have considered and included the reports from special situations cases like medical errors and over-dose cases as these also play a

key role in monitoring patient safety. The reported ICSRs are evaluated on basis of demographics of age and gender, seriousness criteria, outcome parameters and causality assessment of suspected drug (s) and suspected ADR/AE(s).

In this study total 177 cases were reported out of which 137 cases (78%) accounts to ADRs/AEs which could have caused by the general prescription, administration conditions and because of the patient genetic variations, 36 cases (20%) AEs accounts to the medication error-dispensing error due to product-a-look confusion and wrong drug dispensed and led to the potential harm. Out of 36 cases, 35 were hospitalized and life-threatening and 1 case of fatal was reported. Present study is compared with the Alshakka et al study which was conducted in Yemen states that 4.5% of medication errors are due to wrong drug dispensed.¹⁴ In 2017 WHO has launched its “Medications without Harm Program” as part of its global safety challenges initiatives and U.S. Department of Health and Human Services through patient safety network has established preventing medication error strategies steps such that safety is ensured at each and every stage.^{15,16} To prevent the dispensing error with product-a-look problem they have implemented the use of “Tall man” lettering and automated cabins for the high risk medications.^{15,16} A study by Petrova et al states that incidence rate of poisoning, toxicity, overdosing and accidents is also quite high approximately 3.6% of the reported ADRs.¹⁷ About 13% of ADRs identified were directly linked to high costs and required hospital admission.¹⁷ In our study only 4 cases (2%) was reported with the overdose this was due to the short study period and is considered as the limitation.

The frequency of ADRs/AEs with age distribution of reported cases were predominant in adults followed by infants, children, adolescence and elderly. Similar results were observed in the studies conducted by various groups of researchers.¹⁸⁻²⁰ On other side few studies shown results from the elderly group were more, as age is considered for occurrence of the ADRs/AEs.^{21,22} There is no standard agreement among studies regarding the incidence of ADRs with respect to gender.²³ In the

present study females have shown higher prevalence ADRs/AEs compared to males, which is also similar to the studies conducted by Singh et al.¹⁸ This is because females are more susceptible to ADRs/AEs, possibly due to their high medication use, obstetric complications and metabolic alterations due to hormone levels.²³ Other studies has shown the incidence of ADRs/AEs is unrelated to gender i.e., no much significant difference in gender was reported.^{3,23} Various factors influence responding to drug metabolism of individuals which include differences in body mass index, genetic constitution, differences on the levels of various enzymes responsible for the drug metabolism.^{3,23}

Benefit-risk ratio of the post approval drugs mainly involves the consideration of seriousness criteria parameter. Majority of cases reported attributes to non-serious as compared to serious in this study, while in India other studies published also shown homogenous studies from Venkatasubbaiah et al, Sneha et al and Singh et al observed more number of serious ADRs/AEs.^{5,7,18,24,25} Considering the outcome parameter the end result of the reported cases in the indexed period are mostly recovered followed by recovering, not recovered and fortunately only one case of fatal was reported which where compared with similar to study conducted in India while studies done by Sneha et al and Hemavathy G et al reported cases with recovering outcome parameter were higher then recovered.^{5,7,12,26,27} In regards to the causality assessment it is to determine the relatedness or the likelihood of the drug (s) with reaction (s) establishing the reasonable time relationship and considering the comorbid factors. In the present study there is no much significant difference was observed between probable and possible criteria. Only 2% of certain cases were reported. Due to ethical considerations usually re-challenged is avoided and not practiced. So, this is considered as the other limitation of this study. But when compared with other studies they were varying trends reported, few studies reported more with possible followed by probable.^{5,27} And other studies probable were more.^{28,29}

In the present study a higher prevalence of ADRs/AEs are reported with nervous system SOC followed by the injury, poisoning and procedural complications, because of the medication error with harm related drug cases captured both the events and other drug related cases were also added. Skin and subcutaneous tissue disorder and GI disorders were mostly reported with anti-retroviral drugs, analgesics and antibiotics. Reactions ranging from mild to severe according to WHO toxicity grading and DV study protocol cases reported from itching to Steven Johnson syndrome and to toxic epidermal necrolysis. Cases of fixed drug eruptions with diclofenac, cefixime and metronidazole are reported. Two unlisted and unlabeled cases are reported in the indexed study period. One of Dolo induced eythema multi-forme and diclofenac induced Nicolau syndrome or embolia cutis medicamentosa is a rare iatrogenic complication

following after the intra-muscular injection, this was also a safety alert and signal contribution to NCC-PvPI signal review panel. With the increasing number of drugs for serious ADRs pharmacogenomic markers have been recognized and to prevent the incidents of some of these ADRs pharmacogenomic testing has been implemented.³⁰

CONCLUSION

The study pattern of ADRs and AEs reported to this ADR monitoring centre is comparable to the studies done in other parts of country and globally. Although the ADRs and AEs in the present study were included both serious and non-serious, preventable, monitoring and management of such ADRs through therapeutic interventions would be beneficial in better patient care. Risk and burned of ADRs is acting as the self-limiting for the successive therapeutics. Thus it can be concluded that all HCPs has to join hands to improve our health care system while creating more awareness of reporting ADRs to PV so that good pharmacotherapy can be achieved.

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