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Original Research Article

Analysis of individual case safety reports of spontaneous reporting in adverse drug reaction monitoring centre at a tertiary care hospital

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ABSTRACT

Background: In developing countries like India, the increased economic burden in healthcare system is due to adverse drug reactions (ADRs) related hospitalizations which in turn are related to polypharmacy associated with increased potential of ADRs. World Health Organization (WHO) started the program for international drug monitoring (WHO PIDM) in the year 1968. India is one of the member countries under WHO PIDM using the Vigibase for analysis of individual case safety reports (ICSRs). Aim of the study was to analyse the ICSRs by spontaneous reporting at ADR monitoring centre.
Methods: The present study was focused on analyzing the ICSRs of spontaneous reporting using Vigiflow data from the ADR monitoring centre (AMC), Madras Medical College, Chennai.
Results: A total of 541 ICSRs from the period between July 2017 and June 2018 were analysed. Among 541 ICSRs, 814 ADRs were analysed and found that the majority of the ADRs belonged to SOC of gastrointestinal disorders and the most of the ADRs were implicated by antimicrobial agents followed by non-steroidal anti-inflammatory drugs (NSAIDs). Among all the ICSRs, majority of the ADRs occurred in males (n=292) and the maximum number of ADRs were in the age group of 45-60 years (n=197). Of the 541 ICSRs, 313 were found to be of "serious" category and majority of the ICSRs outcome was found to be "recovered" (n=262). The causality assessment of the ICSRs were anlysed and found that the maximum number of ICSRs were under "probable" category as per WHO-UMC scale.
Conclusions: Robust pharmacovigilance activities plays important role in minimizing the ADRs for better patient safety.

Keywords: Individual case safety reports, Vigiflow, Adverse drug reactions, Pharmacovigilance

INTRODUCTION

Medicines are tested for quality, safety and efficacy before their approval. Clinical trials are the evidence for safety and efficacy of drugs to get marketing approval from the regulatory agencies. However, these clinical trials have limitations and the information collected during pre-marketing phase is incomplete when it comes to possible adverse drug reactions (ADRs) which is because of the small sample size and limited duration of study. The conditions of use of drug(s) in clinical practice differ from clinical trials and information about rare and delayed ADRs, chronic toxicity and use in special groups such as children, elderly and pregnant women are usually unavailable.[1]

An ADR is defined as "any response to a drug which is noxious and unintended that occurs at doses normally used in human beings for prophylaxis, diagnosis, therapy of disease, or for the modification of physiological functions. ADRs can result in life-threatening illness, permanent disabilities and even death. Detection of such reactions predicts a hazard for the future use of a specific drug(s) and may result in the initiation of preventive measures,

specific treatments, alteration of drug dosages, or even withdrawal of a given drug from the market.[2]

One of the major causes of morbidity is ADRs. In developing countries like India, the increased economic burden in healthcare is due to ADR related hospitalizations. In United States of America (USA), ADRs are responsible for 3.4-7.0% of hospital admissions. Studies from overseas as well as India have demonstrated that polypharmacy is associated with increased potential for ADRs.[3]

Considering the importance of ADRs, the World Health Organization (WHO) set up an international program for drug monitoring. To date, there are 152 full member countries and 23 associate member countries that share their safety data with Vigibase, the WHO global database of individual case safety reports (ICSRs).[4] An ICSR includes information on adverse events/ADRs, problems related to drugs, and complaints filed by consumers with respect to any given drug. Vigibase is maintained by the Uppsala monitoring center, a WHO collaborating center for international drug monitoring based in Sweden.

Vigibase is the single largest drug safety repository in the world. At the national level of pharmacovigilance, Vigiflow-an online safety data management system facilitates the standardized collection, processing, and sharing of ICSR data for analysis.[5]

Aim and objectives

The aim of the study was to analyze the ICSRs obtained by spontaneous reporting using Vigiflow data from the AMC of our institution under pharmacovigilance programme of India (PvPI).

METHODS

A prospective observational study was carried out using spontaneous ICSR data from Vigiflow- an online safety data management system from AMC, Madras Medical College, Chennai.

All the ICSRs during the period between July 2017 and June 2018 were included in the study. They were analyzed based on the patient age group, gender, seriousness of the ADRs, suspected drugs, ADRs grouped under system organ class (SOC), outcome of the reaction and the causality assessment (WHO-UMC scale) of the ADRs in relation to the suspected drugs.

RESULTS

A total of 541 ICSRs were analyzed during the study period. Of the 541 ICSRs, 292 were found to be males and 249 were found to be female patients. The age group in which the maximum number of ADRs implicated was 45-60 years (n=197) followed by 18-44 years (n=180), above 60 years (n=123), 3-17 years (n=40) and less than 3 years (n=1) (Figure 1).

Of the 541 ICSRs, 313 were categorized as “Serious” of which maximum numbers of ADRs belonged to “required intervention to prevent permanent damage” category (n=198) and “hospitalization/prolonged hospital stay” (n=91) and 228 were categorized as “non serious” (Table 1).

Table 1: Seriousness of the ADRs.

Seriousness criteria	Number of reports
Death	0
Life threatening	0
Hospitalization/prolonged hospital stay	91
Disability	12
Congenital anomaly	0
Required intervention to prevent permanent impairment or damage	198
Other	12
Non-serious ADRs	228

It was analysed from the 541 ICSRs, a total of 576 suspected drugs implicated the ADRs. Most of the implicated ADRs were with antibacterials (n=140) followed by NSAIDs (n=88), antihypertensives (n=63), antiepileptics (n=43), others (n=32), corticosteroids (n=29), hypoglycaemics (n=28), bronchodilators (n=24) and antineoplastics (n=23) (Figure 2).

A total of 814 ADRs were analysed from 541 ICSRs and were grouped in to SOC. The most implicated ADRs belonged to gastrointestinal disorders (n=332) followed by skin and appendages disorders (n=185), neurologic disorders (n=75), general disorders (n=73), respiratory disorders (n=38), metabolic and nutritional disorders (n=30), cardiovascular disorders (n=16), musculoskeletal disorders (n=16), liver and biliary disorders (n=11), renal and urinary disorders (n=11), blood disorders (n=7), application site disorders (n=5), psychiatric disorders (n=5), vision disorders (n=4), endocrine disorders (n=3) and bleeding and clotting disorders (n=3) (Table 2).

Among the 541 ICSRs, the outcome of the ADRs were analysed and maximum were “recovered” (n=262) followed by “recovering” (n=212), “continuing” (n=38), “unknown” (n=39) and none were found to be “fatal” (Figure 3).

The causality assessment was done using WHO-UMC scale and was found that maximum number of ICSRs were “probable (n=372) followed by “possible” (n=168) and “certain” (n=1) category (Figure 4).

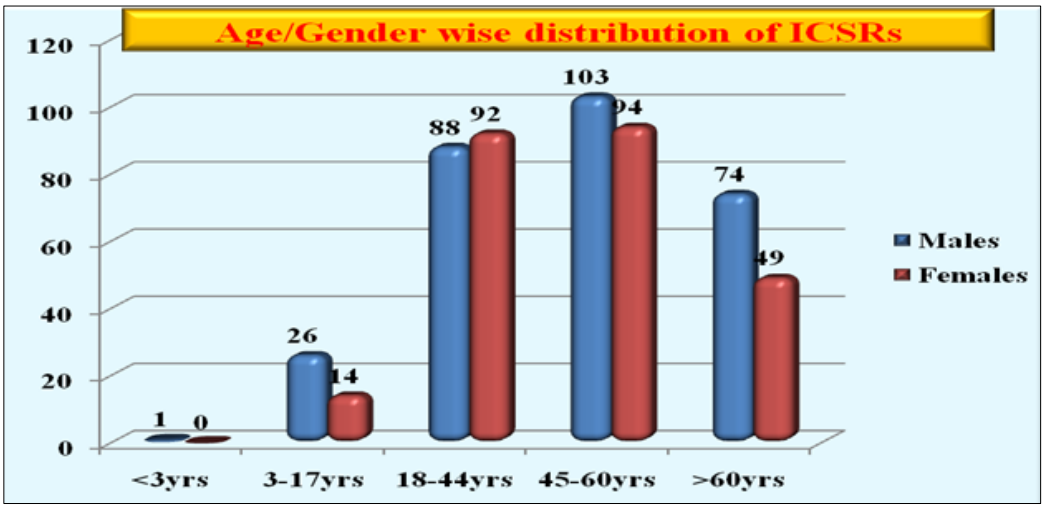

Figure 1: Distribution of ICSRs with respect to patient age/gender.

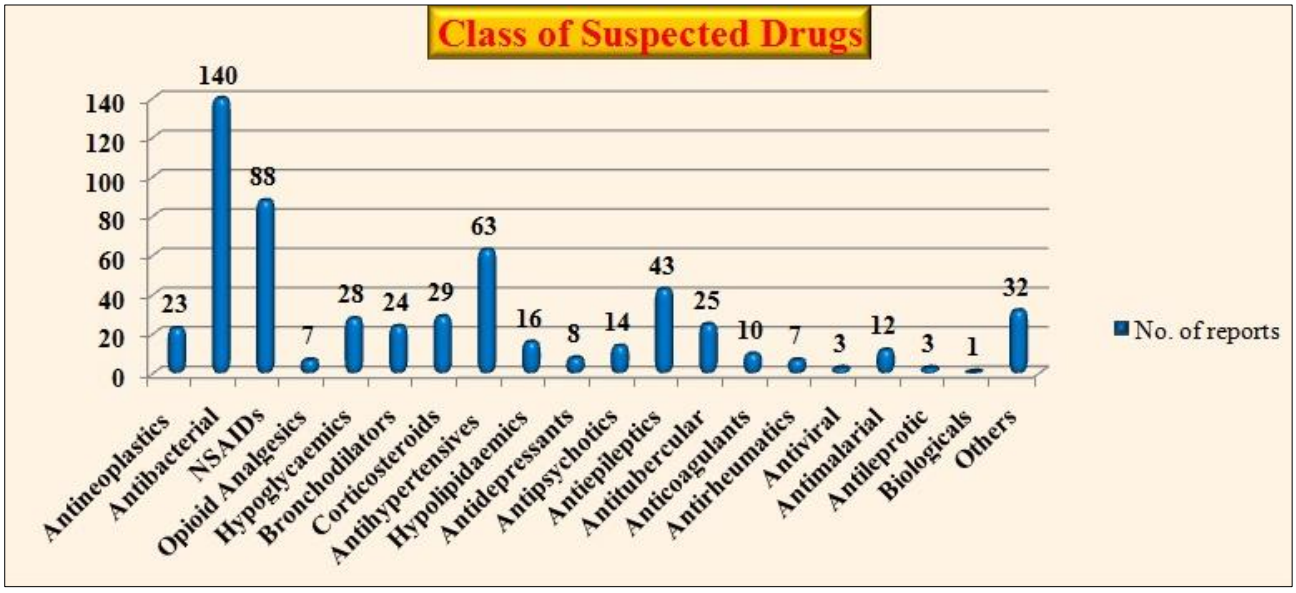

Figure 2: Class of suspected drugs.

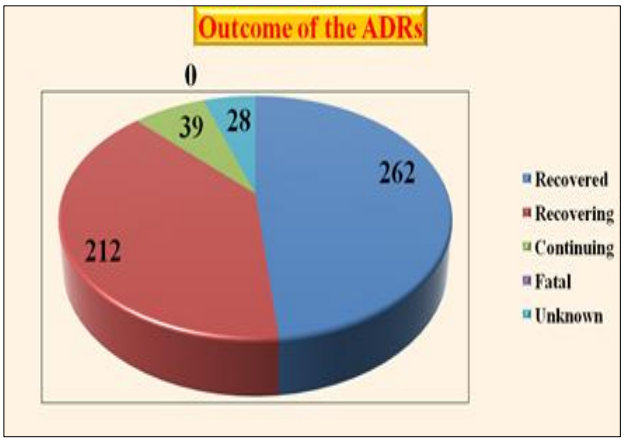

Figure 3: Outcome of ADRs.

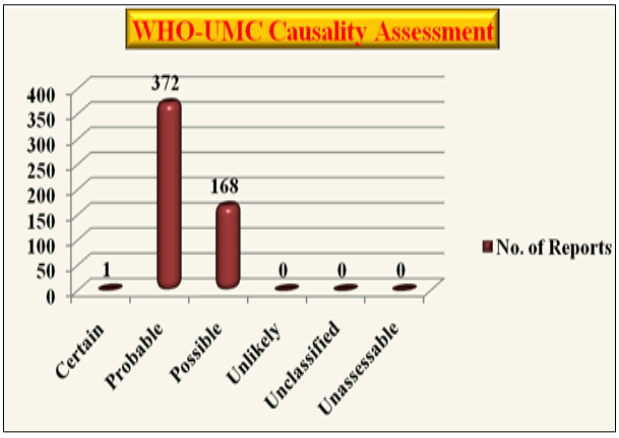

Figure 4: WHO-UMC causality assessment.

Table 2: System organ class (SOC) of implicated ADRs.

S. no.	System involved	No. of reports
1	Application site disorders	05
2	Blood disorders	07
3	Body as a whole – general disorders	73
4	Cardiovascular disorders	16
5	Endocrine disorders	03
6	Gastrointestinal disorders	332
7	Liver and biliary disorders	11
8	Metabolic and nutritional disorders	30
9	Musculoskeletal disorders	16
10	Neurologic disorders	75
11	Psychiatric disorders	05
12	Renal and urinary disorders	11
13	Respiratory disorders	38
14	Skin and appendages disorders	185
15	Bleeding and clotting disorders	03
16	Vision disorders	04
	Total	814

DISCUSSION

From our study it was found that the predominance of ADRs occurred in males than females and previous study by Mounika et al had shown similar finding but it was contrary to the findings of Bansod et al.[2,6]

The prevalence of ADRs was found in the age group of 45-60 years and similar findings were shown in Sen et al study.[7]

From our study it was found that most of the ADRs belonged to SOC of "gastrointestinal disorders" which is contrary to the study by Sen et al and Singh et al.[7,8]

Our study reveals that the most of the suspected class of drugs belonged to "antimicrobials" which is similar to Bansod et al study and Singh et al study.[6,8] Our study found that the most of the ICSRs were found to be "serious" which is contrary to the previous study by Swamy et al.[9]

From our study it was found that outcome of the most of the ADRs was "recovered" which is similar to the finding of Sen et al study.[7] The WHO-UMC causality assessment of ICSRs in our study revealed that most of the ICSRs belonged to "probable" category which is similar to the study by Bansod et al using Naranjo scale and is also similar to Ramakrishniah et al using WHO-UMC scale.[6,10]

Limitations

This was a non-interventional observational study using spontaneous reporting system data which is lacking the denominator data. The co-morbid conditions and other risk factors were not analysed in this study.

CONCLUSION

Our study revealed the valuable information regarding the prevalence of ADRs in relation to the patient demographics. Our study also found that the predominant ADRs were serious in nature and most implicated ADRs belonged to SOC of gastrointestinal disorders. Majority of the ADRs were implicated by antimicrobials followed by NSAIDs and our study also revealed that the majority of the outcome of the ADRs were recovered and the causality assessment as per WHO-UMC scale were found to be probable category. Hence robust pharmacovigilance activities are important to prevent these ADRs for establishing patient safety.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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