Study of ADR (Adverse Drug Reactions) Reporting in Pravara Rural Hospital, Loni.

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Abstract

Background: Pharmacovigilance is essential for detection of adverse drug reactions and is helpful in generating data for drugs that is required for health care. The present study was undertaken to study the adverse drug reactions (ADRs) reported by Pravara Rural Hospital, Loni during the year 2019.

Materials and Methods: The present study was an observational cross sectional study, which was carried out between January 2018 and December 2018. All the suspected ADRs reported during the above mentioned period were recorded for the following parameters; Age, Sex of patients, the department from which ADR was reported, the drugs suspected, the Adverse drug reaction observed, severity of ADR and causality assessment of the ADR. The causality assessment was done using WHO-Uppsala Monitoring Center causality scale by the departmental causality assessment committee.

Results: 40 ADRs were reported during the year 2018. The number of females (30, 75%) was more as compared to males (10, 25%). The age group of 19-30 years (22, 55%) was most commonly affected with ADRs. Of the forty drugs suspected, 32 (80%) were given orally followed by 6 (15%) and 2 (5%) by oral and local route, respectively. The classes of drug showing ADRs most commonly were Antimicrobial agents (18, 45%) followed by blood and components (8, 20%). Highest percentage of ADRs were reported from Gynecology department (17, 42.5%) followed by Medicine Department (14, 35%). All the adverse drug reaction fell into either Possible (24, 60%) or Probable (16, 40%) category. ADRs related to skin and general reactions were more commonly observed. None of the ADRs were serious and all the patients recovered from the ADR.

Conclusions: The ADRs reported in the present study were sparse and stimulation of the health care providers regarding the importance of ADR reporting is the need of hour.

Keywords: Adverse drug reactions, Pharmacovigilance, Pharmacovigilance Programme of India, Causality assessment.

Introduction

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 problems, including herbal materials.[1] The drugs used in modern medicine are powerful and have been a boon for many diseases. Nevertheless, there have been incidences of mishaps due to rampant prescription of drugs to susceptible population in whom the drugs were either not tested. History also teaches us that use of drugs in wider population leads to unfolding of newer adverse drug reactions. Pharmacovigilance is an important activity to check such adverse drug reactions. In a review article by Onakpoya et al., the authors gives an account of 462 medicinal products that were withdrawn from market owing to their harmful effects observed after post-marketing surveillance[2]. Adverse drug reactions may also occur due to disease process and concurrently given medications that lead to drug interactions. These reactions are commonly observed in hospitals where multiple drugs are commonly prescribed[3].

The importance of Pharmacovigilance cannot be overemphasized. Therefore the Pharmacovigilance Programme of India (PvPI) is an important national programme that should be implemented through sensitization of Indian population[4]. Indian Pharmacopoeia Commission (IPC) is the National Coordination Centre (NCC) for PvPI. It collects data through suspected ADR form from ADR monitoring centers (AMCs) which included medical colleges & hospitals, institutes, private and corporate hospitals[5].

PvPI aims at improving and keeping vigilance on drugs to enhance safety of patients along with better health.Although the reporting of ADRs have been facilitated, it is not mandatory for the health care providers to report the ADRs[6, 7].

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Since the inception of the programme in 2011, underreporting is a challenge despite efficient organization for reporting of ADRs[8, 9]. The current was aimed to analyze the reporting of ADRs AMC of Pravara Rural Hospital, Loni, during the year 2018.

Materials and Methods

The present study was an observational cross sectional study, which was carried out between January 2018 and December 2018. The study was conducted in Pravara Rural Hospital Loni, which caters the rural population of Loni and nearby villages. The AMC in the institute was established in December 2017. The study was undertaken after the approval from the Pharmacovigilance Committee and the regulatory authority of the hospital.

All the suspected ADRs reported during the above mentioned period were recorded for the following parameters; Age, Sex of patients, the department from which ADR was reported, the drugs suspected, the Adverse drug reaction observed, severity of ADR and causality assessment of the ADR. The causality assessment was done using WHO-Uppsala Monitoring Center causality scale by the Causality Assessment Committee[10]. The information of the patients related to ADR was kept confidential. Serious ADRs were defined as those which required hospitalization or prolonged hospitalization, were permanently disabling, leading to congenital anomaly, were life threatening, or led to death. All the reported ADRs were reported online by Vigiflow, which is a online Indian Pharmacovigilance database. The ADR-related data were calculated as a percentage of the patient population.

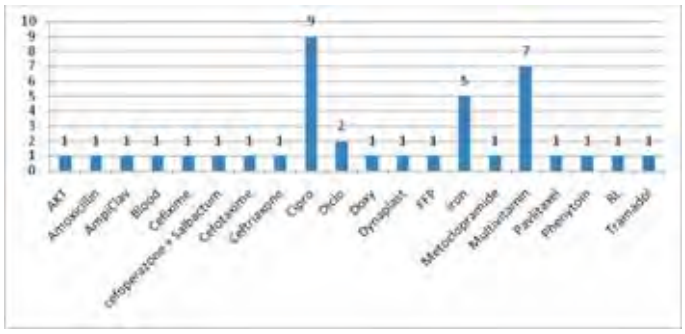
Results

Table no. 1. Month wise number of ADRs reported in the year 2018

S No.	Month	Number of ADRs
1	January	3
2	February	1
3	March	4
4	April	9
5	May	1
6	June	8
7	July	2
8	August	3
9	September	3
10	October	1
11	November	2
12	December	3
Total	40	

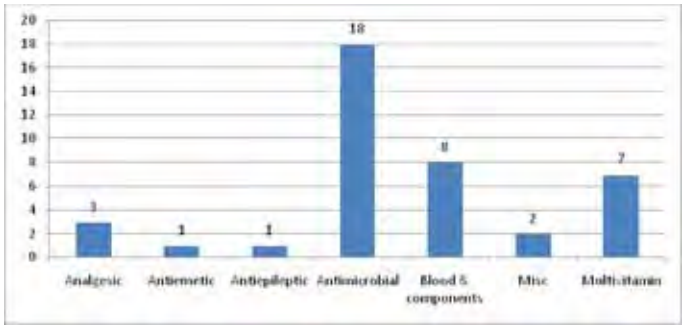
During our study period, 40 ADRs were reported. Monthly ADRs were analyzed as shown in Figure 1, which showed April (9, 22.5%) followed by June 2018 (8, 20%) with the highest number of ADRs. The total number of IPD admissions during the year 2018 was 95635. Therefore, the incidence rate of ADRs is 0.049%.

Figure no. 1. Distribution of ADRs according to the drug suspected



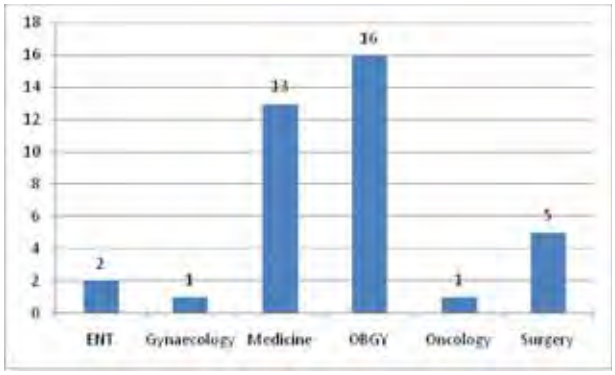
AKT- Anti Kochs Treatment, Cipro- Ciprofloxacin, Diclo- Diclofenac, Doxy- Doxycycline, FFP- Fresh Frozen Plasma, RL- Ringer lactate.

Figure no. 2. Number of ADRs according to the classes of drugs.



Numbers of ADRs by various pharmacological classes of drugs are summarized in Figure 2. The classes of drug showing ADRs most commonly were Antimicrobial agents (18, 45%) followed by blood and components (8, 20%).

Figure no. 3. Distribution of ADRs according to the reporting Department.



As depicted in Figure no. 3, the highest percentage of ADRs were reported from Gynecology department (17, 42.5%) followed by Medicine Department (14, 35%).

Table no. 2. Demographic, route of administration, and causality of adverse drug reactions

Demographic parameter	Number of ADRs (%)
Age wise distribution	
1-18	3 (7.5%)
19-30	22 (55%)
31-60	12 (30%)
>60	3 (7.5%)
Sex wise distribution	
Males	10 (25%)
Females	30 (75%)
Distribution according to Route of Administration	
Parenteral	32 (80%)
Oral	6 (15%)
Local	2 (5%)
Causality assessment	
Probable	16 (40%)
Possible	24 (60%)

ADR- Adverse drug reactions.

Table no. 2 displays the Demographic, route of administration, and causality of adverse drug reactions. The numbers of females (30, 75%) were more as compared to males (10, 25%). The observation is due to the fact that Gynecology department had been the second highest reporter of ADRs. The age group of 19-30 years (22, 55%) was most commonly affected with ADRs. Of the forty drugs suspected, 32 (80%) were given parentally followed by 6 (15%) and 2 (5%) by oral and local route, respectively. All the adverse drug reaction fell into either Possible (24, 60%) or Probable (16, 40%) category.

Table no. 3. System wise distribution of Adverse drug reactions.

Systems involved	Adverse drug reactions	No. of ADRs
CNS	Tingling in upper limb, Parasthesia.	3 (7.5%)
CVS	Burning chest pain, hypotension.	2 (5%)
General	Fever, Fever with chills, fever with rigors, chills, shivering.	10 (25%)
Immune system disorders	Itching, Breathlessness & Vomiting, Intense sweating, Heaviness in the chest & Breathlessness, Allergic reaction, Acute allergic reaction: Breathlessness.	5 (12.5%)
Skin	Itching and Redness, Generalized rash, Pruritic Rash, Vesicular rash, Pruritis, Itching at injection site, Rash and itching, Thrombophlebitis.	20 (50%)

As displayed in Table no. 3, ADRs related to skin (20, 50%) and general reactions were more commonly observed. None of the ADRs were serious and all the patients recovered from the ADR.

Discussion

During the period from January to December 2018, NCC-PvPI received a total of 71287 reports from 202 AMCs all over India[11]. While the data for the year 2018 is not yet available, if the same is compared with the ADRs reported by Pravara Rural Hospital is only 40 (0.056%). In a study by Singh P et al[12], their ADR monitoring committee reported 232 (0.352%) ADRs when compared to ADRs reported during the period of 2016-2017 (66056). Although, the sensitization programme regarding reporting of ADRs conducted had improved the practice of ADR reporting from 8 in 2016 and 2017 to 40 in 2018 respectively, the practice of reporting needs to be improved. The underreporting of ADRs may be due to over burdened health care providers.

ADRs were most commonly reported with Antimicrobials (45%) in the present study. The findings of our study are similar to that of Singh P et al[12], Leape LL[13] and Salvo F[14]. All the ADRs were reported by doctors and there was no report submitted by nurses. This was observed despite the nurses were sensitized for reporting ADRs. This observation was also supported by Rajesh R[15] and Singh P et al[12]. The probable reasons for this could be due to inattention or low confidence or undue fear regarding possible mistakes that could happen during ADR form filling.

The ADRs related to skin (20, 50%) were highest in the present study. Similar findings were seen in the studies done by Singh P et al[12] and Arulmani R[16]. All the ADRs were well known to be caused by the respective drugs and no new or unknown reaction was seen.

The total number of IPD admission during the period of January to December 2018 was 81030. Therefore, the incidence rate of ADRs in the present study was 0.049%. In the study by Singh etal12, the incidence rate of ADR was 0.044%, which is similar to that in our study. The occurrence rate of ADR in various studies all over the world is in the range of 6% to 20% 3. Gor and Desai3 had reported the incidence rate of 3% ADR in his study, whereas in another study, the incidence rate of ADR was 3.17% during 6 months of the period10. Thus, there is a low incidence of ADR reporting in our AMC.

With regards to the current situation of ADR monitoring, the underreporting of ADRs could have various reasons that remain unresolved. Most important of these could be sensitization of health care providers with due emphasis on the importance of Pharmacovigilance. As observed in the questionnaire based study done by Desai C K[17], the Health Care Providers have fear of litigation on occasions of wrong drug prescription; they feel it unnecessary to report ADRs that are already known; they do not believe in reporting when the certainty of ADRs due to drug prescribed is not established; they feel that reporting one ADR won't make the difference; they opine that only new ADRs and serious ADRs should only be reported; they do not have genuine interest in reporting. This occurs despite of the fact that it

has been mentioned in the ADR reporting forms that the information provided in it shall not be subjected to any litigation.

The ADR reporting is an important topic that is taught along with practice of filling ADR form during the Internship training program in the institute. Undergraduate and postgraduate students should be made aware of Pharmacovigilance and hands-on training for ADR form filling[8, 18].

Various approaches to improve the ADR reporting have been talked about. Establishment of ADR monitoring network in hospitals[19], education programmes for health care provider[20, 21], compulsion of ADR reporting[22] may be helpful methods to enhance reporting.

Conclusions

The ADRs reported in the present study were sparse and stimulation of the health care providers regarding the importance of ADR reporting is the need of hour.

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