

**Original Article**

**ANALYSIS OF ADVERSE DRUG EVENTS REPORTED AT PERIPHERAL ADR MONITORING CENTRE IN GUJARAT**

**RHYTHM, ALPA PRAGNESH GOR\*, BHARAT GAJJAR, ZALAK DALWADI, ANJALI GOYAL**

Department of Pharmacology, Pramukhswami Medical College, Karamsad, Gujarat, India, 388325

Email: alpapor15@gmail.com

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**ABSTRACT**

**Objective:** Hospital-based ADR (Adverse drug reaction) monitoring and reporting programmes are useful for identifying and minimizing preventable ADRs and may enhance the ability of prescribers to manage ADRs more effectively. The objective of this study was to evaluate and analyze the spontaneously reported adverse drug events from various departments of Shree Krishna Hospital, Karamsad.

**Methods:** This was a retrospective study and data was analyzed for adverse drug events reported during the period of April 2018 to March 2019 from various departments of Shree Krishna Hospital, Karamsad. Analysis was done on the basis of the demographic profile of patients, health care professionals who have reported and drugs causing ADRs, with their causality assessment using WHO probability scale.

**Results:** Out of 36 patients, 20 (55.55%) were males and 16 (44.44%) were females. Antibiotics were the most common culprit group of drugs for reported ADRs in 21 patients. The number of ADRs related to the skin was 21 (58.33%) followed by GIT 11 (30.55%), cardiovascular 2(5.55%) and neuronal 2(5.55%). According to WHO causality assessment scale 01 (2.77%) of the suspected ADR was certain, 27(75%) were probable and 8 (22.22%) were possible.

**Conclusion:** Our study concluded that the most commonly reported ADRs were dermatological reactions like itching and rashes. Antimicrobials were the most common drug group involved in causing ADRs. Even though there were continuous efforts for adverse drug event reporting awareness, still there is need to sensitize health care professionals to improve reporting.

**Keywords:** Adverse Drug reaction monitoring, Causality Assessment, Health Care Professional

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**INTRODUCTION**

Adverse drug reactions (ADRs) are one of the leading causes of mortality and morbidity in health care and entail a significant burden on healthcare facilities. ADRs can also lead to an increase in the length of hospital stay and sometimes requiring additional investigations and drug therapies for the treatment of symptoms and diseases caused to the patient [1, 2]. Pharmacovigilance programme of India was introduced in 2010 with the vision to improve patient safety and welfare of Indian population by monitoring the safety of medicines and thereby reducing the risk associated with their use [3]. Hospital-based ADR monitoring and reporting programmes are useful for identifying and minimizing preventable ADRs and may enhance the ability of prescribers to manage ADRs more effectively [4]. The study site is Shree Krishna Hospital, Karamsad, which is attached to MCI recognized medical college and is one of the peripheral ADR monitoring centers of India. The objective of this study was to evaluate and analyze the spontaneously reported adverse drug events from the various departments of Shree Krishna Hospital, Karamsad.

**MATERIALS AND METHODS**

This was a retrospective study which was approved by the institutional ethics committee (IEC: Cr.33/196/19). The data were analyzed for adverse drug events reported during the period of April 2018 to March 2019 from various departments of Shree Krishna Hospital, Karamsad. Analysis was done on the basis of demographic profile of patients, drugs causing ADRs with their causality assessment using WHO probability scale. ADRs were also analyzed

on the basis of health care professionals who have reported. Descriptive statistics were used for the data analysis.

**RESULTS**

A total of 36 ADRs were reported in this study. Out of 36 patients, 20 (55.55%) were males and 16 (44.44%) were females. All the reported ADRs were confirmed by treating physicians. Seventeen ADRs were reported from age group below 18 y, followed by fifteen ADRs from age group 18-60 y and four ADRs were reported from age group above 60 y. Age and gender-wise distribution of ADRs are shown in table 1. Total 31(86.11%) ADRs were reported from inpatient departments and 5 (13.88%) were from outpatient departments. Most of the ADRs were reported from pediatrics 15 (41.66%) followed by medicine 06 (16.66%), skin 05 (13.88%) and surgery 04 (11.11%) departments, as shown in fig. 1. Majority of ADRs 30 (83.33%) were reported by prescribers themselves. Six (16.66%) ADRs were reported by other health care professionals as shown in fig. 2.

Suspected drugs with their formulations and reported ADRs are shown in table 2. Most of the ADRs were reported from injectable medications followed by medications given by oral route. Antibiotics were the most common culprit group of drugs for reported ADRs in 21 patients as shown in table 2. Among antibiotics, a fixed-dose combination of antitubercular drugs and single-dose formulation of vancomycin was reported in six patients each. The number of ADRs related to the skin were 21 (58.33%) followed by GIT 11 (30.55%), cardiovascular 2(5.55%) and neuronal 2(5.55%) as shown in fig. 3. According to WHO causality assessment scale 01(2.77%) of the suspected ADR was certain, 27(75%) were probable and 8 (22.22%) were possible as shown in fig. 4.

**Table 1: Demographic details**

| Age (Y) | Male (n) | Female (n) | Total (n) |
|---------|----------|------------|-----------|
| <18     | 10       | 07         | 17        |
| 18-60   | 08       | 07         | 15        |
| >60     | 02       | 02         | 4         |
|         | 20       | 16         | 36        |

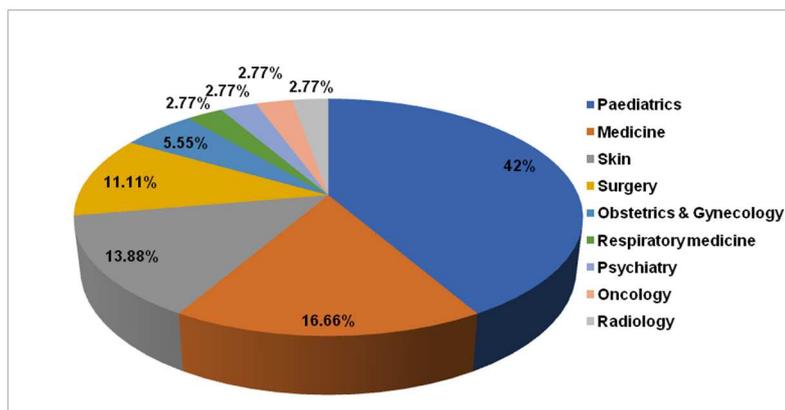


Fig. 1: Department wise reporting of ADR

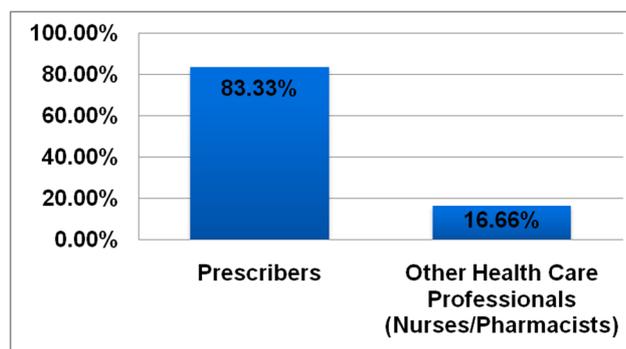


Fig. 2: Percentage of ADRs reported by different health care professionals

Table 2: Causative drugs and adverse drug reactions

| Dugs                                     | Single drug preparations | Fixed-dose combinations | Adverse drug reactions (frequency)                        |
|--|--------------------------|-------------------------|---|
| <b>Anticoagulants</b>                    |                          |                         |   |
| Injection Heparin                        | 01                       | 00                      | Haematoma and blackening of skin over injection site (01) |
| <b>Antispasmodic</b>                     |                          |                         |   |
| Injection Dicyclomine                    | 01                       | 00                      | Intussusception (01)                                      |
| <b>Antiemetics</b>                       |                          |                         |   |
| Injection Metoclopramide                 | 01                       | 00                      | Extrapyramidal side effects (01)                          |
| <b>Antibiotics</b>                       |                          |                         |   |
| Injection Vancomycin                     | 06                       | 00                      | Rashes (05), injection site redness (01)                  |
| Tablet Cefixime                          | 01                       | 00                      | Rashes and itching (01)                                   |
| Injection Ceftriaxone                    | 04                       | 00                      | Vomiting (03), Rashes (01)                                |
| Tablet Amoxicillin                       | 01                       | 00                      | Maculopapular rash (01)                                   |
| Tablet Amoxicillin+Clavulanic acid       | 00                       | 01                      | Loose stools (01)   |
| Tablet Levofloxacin                      | 01                       | 00                      | Rashes over injection site (01)                           |
| Tablet Ofloxacin+Ornidazole              | 00                       | 01                      | Rashes and itching (01)                                   |
| Tablet Isoniazid+Rifampicin+Pyrazinamide | 00                       | 06                      | Raised SGPT, SGOT (04), Rashes and itching (02)           |
| <b>NSAIDs</b>                            |                          |                         |   |
| Tablet Ibuprofen                         | 01                       | 00                      | Bullous fixed drug eruptions (01)                         |
| <b>Vasopressors</b>                      |                          |                         |   |
| Injection Noradrenaline                  | 01                       | 00                      | Blackening of fingers and toes (01)                       |
| <b>Anticonvulsant</b>                    |                          |                         |   |
| Tablet Carbamazepine                     | 01                       | 00                      | Maculopapular rashes (01)                                 |
| <b>Vitamins and minerals</b>             |                          |                         |   |
| Injection B1B6B12                        | 00                       | 01                      | Rashes and itching (01)                                   |
| Injection Iron sucrose                   | 01                       | 00                      | Nausea and palpitations (01)                              |
| Injection Ferric carboxy maltose         | 02                       | 00                      | Hypersensitivity (02)                                     |
| <b>Others</b>                            |                          |                         |   |
| Injection Potassium chloride             | 01                       | 00                      | Injection site redness and itching (01)                   |
| Injection Crystalline amino acid         | 01                       | 00                      | Tachycardia (01)  |
| Injection Iohexol                        | 01                       | 00                      | Diarrhoea (01)  |
| Tablet Lithium                           | 01                       | 00                      | Cogwheel rigidity and hand tremors (01)                   |
| Injection Pentavalent vaccine            | 00                       | 01                      | Fever and rashes over injection site (01)                 |
| <b>Total</b>                             | <b>26</b>                | <b>10</b>               | <b>36</b>   |

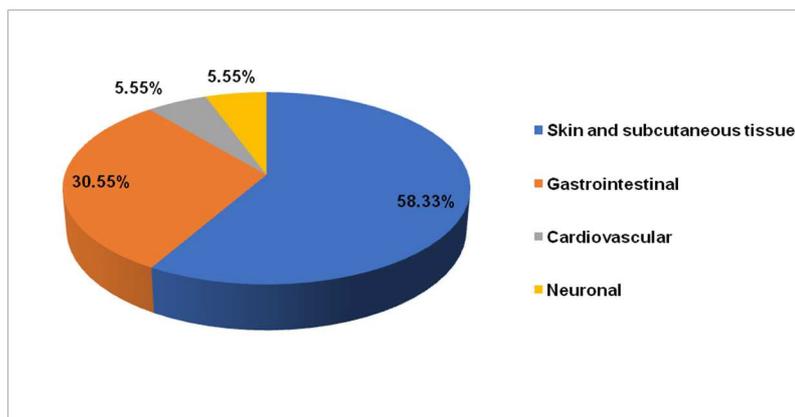


Fig. 3: Organ system involved

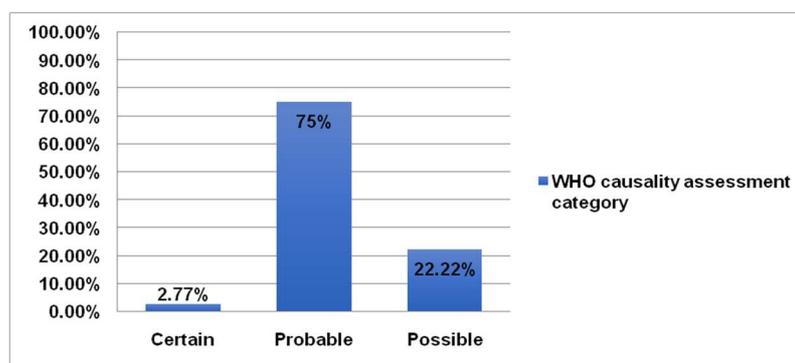


Fig. 4: WHO causality assessment

## DISCUSSION

It is universally accepted that no drug is absolutely free from side effects. From previous studies it is observed that 5% of all hospital admissions were due to drug-induced problems and 10-20% of hospitalized patients develop ADRs [5, 6]. There is under-reporting of these ADRs due to lack of awareness and communication, which needs to be improved to prevent the iatrogenic diseases in a hospital setup. Female patients have a greater risk of ADRs compared to male patients as they use various groups of medications than their counter partner, predominantly of drugs for oral contraception, menopause, and pregnancy [7]. In some previous studies by lihite *et al.*, patil *et al.*, bhabor *et al.*, james *et al.* most of the ADRs were reported in female patients [6, 8-10]. However, this study observed that the majority of ADRs were found in male, which is similar to findings by kharab *et al.* and sen *et al.* [12, 13]. In this study, most of the ADRs were reported from inpatient departments, which may be due to their presentation and spontaneous reporting by health care professionals during hospital stay. In this study, most of the ADRs were reported from pediatrics department, followed by skin department. This may be due to the reason that prescribers were more vigilant while prescribing to children and aware to report. Skin reactions are easily recognized and patients having this type of reaction are referred to skin department. In this study, most of the ADRs were reported from medications given by the parenteral route followed by medications given by the oral route, which is similar to another study by sen *et al.* [13]. Most of the ADRs were reported with an antimicrobial group of drugs in our study which is similar to studies by patil *et al.*, bhabor *et al.*, james *et al.*, ingale *et al.*, kharb *et al.* and patidar *et al.* [8-12, 14]. The organ system most commonly involved in this study was skin followed by the gastrointestinal system. The reason for the increased reporting of skin reactions could be due to the easy recognition of these reactions. A similar pattern was reported in studies by patil *et al.*, james *et al.*, ingale *et al.* and sen *et al.* [8, 10-11, 13]. Causality assessment using WHO UMC scale criteria [15] in this study showed that most of the reactions were of probable followed by possible. Similar findings were found in some

other studies by patil *et al.*, kharb *et al.* and sen *et al.* [8, 12-13]. A total of 36 ADRs were reported in this study and most of ADRs 83.33% were reported by prescribers. So there is a need to increase awareness among health care staff regarding ADR reporting by conducting training sessions. Our hospital formulary is based on WHO essential list of medicines, which may be the reason for less reporting of ADRs, however some of the ADRs may have been missed. Impact of rational use of medications based on WHO essential medicine list and less reporting of ADRs need to be further explored in our setup.

## CONCLUSION

Our study concluded that the most commonly reported ADRs were dermatological reactions like itching and rashes. Antimicrobials were the most common drug group involved in causing ADRs. Most of the responses in this study were probable according to WHO causality assessment scale. Even though there were continuous efforts for adverse drug event reporting awareness, there is still a need to sensitize health care professionals to improve reporting. This study has some limitations as it was an observational study carried over a short duration, and some of ADRs may not have been reported due to some reasons, however, still, it will give the information about current pattern of ADRs being reported by health care professionals at a tertiary care teaching hospital.

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## AUTHORS CONTRIBUTIONS

Bharat Gajjar and Alpa Gor developed concept. Rhythm, Zalak Dalwadi and Anjali Goyal did data collection. Data analysis was done

by Alpa Gor and Rhythm. Rhythm, Alpa Gor and Bharat Gajjar wrote the first draft of the manuscript. Rhythm communicated the manuscript to the journal. All authors reviewed and approved the final manuscript.

#### CONFLICT OF INTERESTS

Declared none

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