RESEARCH ARTICLE

Assessment of Adverse Drug Reactions Reported in a Tertiary Care Hospital in Northern India

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Abstract

Introduction: Periodic monitoring of ADRs in hospital settings is crucial to identifying risks associated with drug use, ensuring patient safety and public health.

Aim and Objectives: To evaluate the pattern of ADRs reported to the AMC GMC, Kathua.

Materials and Methods: The present retrospective observational study was conducted from May 2023 to May 2025. ADRs uploaded on Vigiflow were assessed based on patient demographics, drug class, route of administration, reaction, organ system affected, comorbidities, outcome, management, seriousness, causality assessment and reporter department. Patients of all ages and both genders with a history of drug consumption were included and incompletely filled ADRs were not included.

Results: A total of 66 ADRs were evaluated. The most affected group was females (59%) and the mean age was 45 years. Antimicrobials (27.2%) were the leading cause of ADRs, followed by analgesics (18.18%). Almost all the ADRs were contributed by clinicians of the institution (91%). The majority (36.2%) of cases were contributed by the Obstetrics and Gynecology department (22.7%), followed by the department of Psychiatry (18.18%).

Conclusion: The results of this study highlight the importance of conducting awareness programs and educating the general public, pharmacists and dentists regarding the spontaneous reporting of ADRs to promote rational prescribing of drugs.

Keywords: Adverse drug reaction, Pharmacovigilance, Causality, WHO- UMC scale

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Introduction

Adverse drug reactions (ADRs) are a major burden on health care facilities and cause significant mortality and morbidity. Adverse drug reactions also impact the economics of the country; they are expensive. Research has found that almost 10-20% of hospitalized patients suffer from drug induced issues.[1,2] ADRs are the 4th-6th leading cause of death. World Health Organization (WHO) defines ADRs as "any noxious and unintended response to a drug which occurs at doses used for prophylaxis, diagnosis, therapy or modification of physiologic function".[3] Adverse effects might develop suddenly, after chronic administration of medication or even after stopping the drug. ADR reporting is the foundation stone of the Pharmacovigilance program (PVPI) of our country, which aims to improve drug safety and public health. PVPI was established in 2010 under the aegis of the Central Drugs Standard Control Organization. (CDSCO). The Indian Pharmacopeia Commission (IPC) is the National Coordinating Center, located at Ghaziabad. Pharmacovigilance is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.[4] The pharmacovigilance program aims to educate and train healthcare professionals, paramedical staff, students and the general public about adverse drug effects and their reporting. It promotes rational use of drugs. Around 170 AMCs are there throughout India at present.[5] Spontaneous reporting is the most common type of reporting ADRs, and it is a voluntary type of reporting.

The rate of ADR reporting is 1% in India, whereas globally it is 5%, indicating under-reporting and a lack of awareness of ADR reporting in our nation.[6,7] PVPI is playing a major role in alleviating this major concern. It is of utmost importance to report adverse drug reactions (ADRs) as it helps to predict the ADR due to a drug in a particular population and further to address the problem. Further, there is a paucity of studies done to assess the pattern of Adverse drug reactions reported to the ADR monitoring center, GMC Kathua. Therefore, the present study was planned to study the patterns of reported ADRs in our institution.

Materials And Methods

The present retrospective, observational study was commenced after obtaining approval from the Institutional Ethics Committee of the institution vide no. IEC/GMCK/28 dated 28/05/2025. All suspected ADRs reported from May 2023 to May 2025 to the ADR Monitoring Center, GMC Kathua and submitted to the National Coordination Center – Pharmacovigilance Program of India were analyzed and evaluated.

The adverse drug reactions uploaded on the official web-based ICSR data management portal Vigiflow were assessed based on patient demographics (age and gender), drug characteristics (drug class, route of administration), ADR characteristics (reaction, organ system affected, comorbidities, outcome, management, seriousness of the reaction, causality assessment, and reporter department). World Health Organization- Uppsala Monitoring Center (WHO-UMC) causality assessment scale (classified as certain, probable, possible, unlikely) was used for evaluating the causality.

Inclusion Criteria

- ADRs occurring in the patients visiting the OPDs and IPDs of the various clinical
- Departments in the college were reported as ADR forms to the AMC, GMC Kathua.
- Patients of all ages and both genders with a definite history of consumption of drugs were included in the study.

Exclusion Criteria

- Adverse drug events due to vaccines, medical devices, blood products, and herbal products were not included.
- Incompletely filled ADR forms were rejected.

Statistical Analysis

The collected data was entered into MS Excel.

Descriptive statistics were used to analyze the data and values are expressed in numbers and percentages.

Table 1: Social-demographics profile of the patients

Age	*Frequency (n)*	*Percentage (%)*
< 20	3	4.5
21–40	27	41
41–60	27	41
≥ 61	9	13.5
Gender		
Male	27	41
Female	39	59
Outcome		
Recovered	42	63.6
Recovering	24	36.4

Results

The total number of ADRs reported to the AMC during the study duration of 2 years was 66, out of which males were 27 (41%), and females were 39 (59%) (Figure 1), which shows predominance of females in having ADRs. The overall mean age of patients reporting ADRs in our study was 45 years. It was also observed that the majority of the patients reporting ADRs recovered after the occurrence of ADR (63.6%) (Table 1).

The most commonly affected Organ system was Hypersensitivity reaction (n= 18), followed by the central nervous system (n= 12) (Table 2).

The most common drug group responsible for ADRs was antimicrobials (27.2%), among which antitubercular drug therapy (ATT) were the most common drugs causative of ADRs followed by analgesics (18.18%), antidepressant drugs (13.6%), hematinics which include intravenous iron and Vitamin B12 (13.6%), antipsychotic drugs (4.5%), anticonvulsants (4.5%), corticosteroids & antiallergic combination (4.5%), minerals like calcium (4.5%), antidiuretics (4.5%) and nutritional supplements (4.5%) (Table 3).

Most of the ADRs with a single drug were attributed to ceftriaxone (9%) & iron sucrose (9%), followed by analgesics (Diclofenac 4.5%, Etoricoxib 4.5%, Mefenamic acid 4.5%). The drug combination most responsible for ADRs was found to be antitubercular therapy (18.1%).

Almost all the ADRs were contributed by clinicians of the institution (91%) and only a few were reported by medical officers of PHCs of the region (9%). None of the ADR reports were contributed by the nursing staff, dentists, and pharmacists. The

Causality assessment was done using the WHO-UMC scale, and it was found to be "Probable" for all (100%) cases.

Most of the patients who reported adverse effects had associated comorbidities (59%) and 41% of the patients had no associated comorbid conditions. 72.7% of ADRs were classified as non-serious and only 27.3% were classified as serious ADRs, which were life-threatening and were managed immediately using medical intervention.

Out of 66 ADRs, the majority of cases were contributed by the Obstetrics and Gynecology department (22.7%), followed by the department of Psychiatry (18.18%) & Chest diseases and Tuberculosis (18.18%) (Table 4). It was seen that majority of ADRs were observed when drugs were administered by oral route (63.6%), only 32% ADRs were observed with Intravenous route and 4.5% ADRs (bitter taste, burning sensation occurred due to the inhalational route of administration) were seen with inhalational route. ADRs seen with the intravenous route were most commonly anaphylactic reactions (9%), hypertension (5.7%), hypotension (5.7%), fever (5.7%) and DRESS, i.e., drug reaction with eosinophilia and systemic symptoms (5.7%).

Table 2: Distribution of ADRs according to organ system involved

Organ system affected	*Frequency (n)*	*Percentage (%)*
Skin & Subcutaneous tissue	9	13.6
Generalised disorder	3	4.54
CVS disorder	6	9
Liver disorder	12	18.1
GIT disorder	3	4.5
CNS disorder	12	18.1
Hypersensitivity reaction	18	27.2
Endocrine disorder	3	4.54

Table 3: Distribution of ADRs according to drug group involved

Drugs	*Frequency (n)*	*Percentage (%)*
Antimicrobials	18	27.2
Analgesics	12	18.18
Antidepressants	9	13.6
Hematinics	9	13.6
Antipsychotics	3	4.5
Anticonvulsants	3	4.5
Corticosteroids	3	4.5
Antiallergics	3	4.5
Minerals (Calcium)	3	4.5
Nutritional supplements (Alanine)	3	4.5

Table 4: Distribution of adverse drug reactions among departments

Department	*Percentage (%)*
Obstetrics & Gyanecology	22.7
Psychiatry	18.18
Chest diseases & TB	18.18
Dermatology	4.5
General medicine	10
Orthopedics	4.5
Emergency	8
Health department (PHCs)	13.6

Discussion

Adverse drug reactions (ADRs) result in a considerable increase in morbidity and sometimes even result in fatal outcomes in patients.[8] ADRs may also lead to prolonged hospitalization and considerable economic loss. Inappropriate medication, polypharmacy, self-medication, extreme age groups, smoking, and alcohol use are some risk factors for causing ADRs.

A retrospective study was undertaken to assess the ADR profile in our institution. Total number of 66 ADR reports recorded during the period of investigation were evaluated. Out of these 39 patients (59%) were females and the remaining 27 patients (41%) were males.

Many studies have shown females to be one of the risk factors for the causation of ADRs.[9,10]

Miller MA et al., in their study investigating gender based differences in toxicity of pharmaceuticals, have shown more ADRs and more serious adverse effects in females as compared to males.[11] Our results also reveal the increasing trend of ADRs in females as compared to males. Tharpe N et al has also reported two fold more ADRs risk in females than in males.[12] Most reports suggesting females as a risk factor of ADRs are in the elderly age group.[13,14]
However, a number of studies have shown no major gender differences in ADRs profile.[15,16] The discrepancy in our study could be because of the small sample size, as compared to other reports having voluminous data.

Most of the ADRs (82%) in the present study were in adults (19–60 years of age), followed by the elderly age group (13.5%) and the pediatric group (4.5%). Advancing age has been reported as a risk factor for ADRs.[9,17]

The current study reveals that antimicrobials (27.2%) were mostly responsible for ADRs, followed by analgesics (18%). Numerous studies show antimicrobials to be mostly responsible for ADRs, predominantly dermatological manifestations and these are in accordance with our results.[18,19]

The outcome is this because antimicrobials are frequently prescribed in clinical practice and are often misused as self-medication, resulting in irrational use and resistance, posing a big challenge to the treating physician.

Analgesics, as shown in the current trial, caused considerable ADRs following antimicrobials. This result is in accordance with other similar studies.[20]

A lesser number of serious ADRs were observed in our study as compared to other studies.[21] Causality of all the ADRs in our study was "probable," which is in concordance with some other studies.[22] It was also found that the majority of the ADRs were reported by physicians. There were no ADRs reported by the dentists, nursing staff and general public, highlighting the need to conduct educational programs and training for them.

Conclusion

Results of the present study depict that antimicrobials and analgesics were the most common drugs associated with the occurrence of ADRs and the majorly affected organ systems were the immune system and central nervous system. Thus, it highlights the importance of monitoring, reporting and managing ADRs to enhance patient care and safety. It is of paramount importance to conduct continuous educational and training programs, seminars and workshops on pharmacovigilance on a regular basis for all health care professionals. The general public, pharmacists, nursing staff, and dentists should also be made aware of the reporting of ADRs.

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Conflict of Interest

None declared

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