

A COMPREHENSIVE COST ANALYSIS OF ADVERSE DRUG REACTIONS AMONG HOSPITALISED PATIENTS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Objective: To analyse the incremental cost of preventing and managing ADRs among hospitalised patients.

Methods: A 6-month retrospective and prospective study was conducted at a tertiary care hospital in Perinthalmanna. Direct medical costs related to ADR prevention and management were collected from patients' case files, along with data on causative drugs and reactions. **Results:** Of 121 case sheets reviewed, 55 ADR cases were identified (55% female, 45% male). The 65–75 age group was most affected (23.64%). Anti-diabetic drugs were the most common cause (16 cases), and gastric irritation was the most frequent reaction (10 cases). The total additional treatment cost was ₹26,243.23, averaging ₹477.15 per patient. Average management cost per ADR was ₹287.93, and average prevention cost was ₹497.71. **Conclusion:** Elderly patients are most susceptible to ADRs, with gastric irritation being the most common reaction. ADRs significantly increase the financial burden on patients through both prevention and management costs.

KEYWORDS: ADR, Prevention of ADR, Management of ADR, Economic Burden, Antibiotics, Causality, Severity, Preventability.

INTRODUCTION

According to WHO, “An adverse drug reaction (ADR) is a response to a medicine which is noxious or unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function”.^[1]

ADRs are detected using several methods, such as pre-marketing surveillance, post-marketing surveillance, followed by causality assessment, documentation of ADRs, and lastly reporting of adverse drug reactions.^[2] ADRs are reported if

the case involves any life-threatening event, death, congenital abnormalities, medically significant events deemed serious by the physician, and all known and unknown adverse reactions. All adverse drug reactions must be reported within 10 to 30 days. ADRs are reported in a standardized format that includes all the information and should be submitted to the nearest AMC. Several assessment scales have been used to evaluate ADRs, such as the Naranjo scale^[3] and the WHO-UMC scale^[4] for the causality assessment, the Modified Schumock and Thornton scale^[5] for preventability assessment and Hartwig and Siegel's scale^[6] for severity assessment.

Adverse drug reactions can be prevented by appropriate prescribing, monitoring and proper patient assessment. WHO estimated that at least 60% of ADRs are preventable. Studies show 20% to 80% of ADEs are preventable, with the most research indicating 60-70% preventability.^[7] For the management of observed ADRs, patients must be closely observed. The drug that caused the reaction should be stopped or withheld immediately, followed by supportive care such as IV fluids, analgesics, antihistamines, corticosteroids, or other therapies if the case is severe. The approaches for the management of Adrs include early detection, assessment, treatment, prevention and management.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) defines pharmacoeconomics as "the field of study that evaluates the behaviour of individuals, firms and markets relevant to the use of pharmaceutical products, services and programs that frequently focus on the costs (inputs) and consequences (outcomes) of that use".^[8] Costs are mainly about two types: direct costs (refer to the immediate medical expenses incurred in diagnosing, managing and treating the reactions)^[9] and indirect costs (refer to the loss of income or productivity that occurs when a person is unable to work or perform normal activities due to ADR).^[10]

Pharmacoeconomics analyses are classified into four different methodologies: i) Cost-minimization analysis (CMA) to find the least priced solution among many technologies that yield comparable clinical results, such as safety and effectiveness, ii) Cost-effectiveness analysis (CEA) involves comparing interventions by assessing their monetary costs alongside health outcomes measured in quantitative, iii) Cost-utility analysis (CUA) evaluates financial expenses in connection to health outcomes as determined by survival and utility, which are reported as quality-adjusted life years (QALYs) and iv) Cost-benefit analysis (CBA) converts all advantages and disadvantages into monetary terms, it assess both costs and health outcomes enabling direct comparison of solutions.^[11]

Rising healthcare costs and financial constraints have increased the role of pharmacists in patient care. Pharmacoeconomics helps evaluate the clinical and economic value of healthcare interventions, and Health Technology Assessment (HTA) help improve healthcare decisions by ensuring safe, effective and cost-efficient use of medicines.^[12]

Here, the direct cost of the medication for the management and prevention of adverse drug reactions has been analyzed. As there is a gap in this field of research, this study focuses on the additional costs associated with the management and prevention of adverse drug reactions among hospitalised patients in a tertiary care hospital.

MATERIALS AND METHODS

This was a prospective and retrospective study, which was carried out for about six months from September 2025 to February 2026. This was an observational study of the hospitalised patients admitted at KIMS Al Shifa Super Speciality Hospital, Perinthalmanna, Malappuram district, Kerala. The study included patients who had developed adverse drug reactions during their period of hospital stay. Any case sheets with adverse drug reactions, patients of all age groups

who have been admitted at all the departments have been included in the study. Case sheets with incomplete information and patients in the emergency departments have been excluded from the study.

This study did not involve direct patient interaction; only the patients' case files were analyzed from the MRD and from the nurses' station.

METHODOLOGY

The method that was used for this study is given in Figure 1.

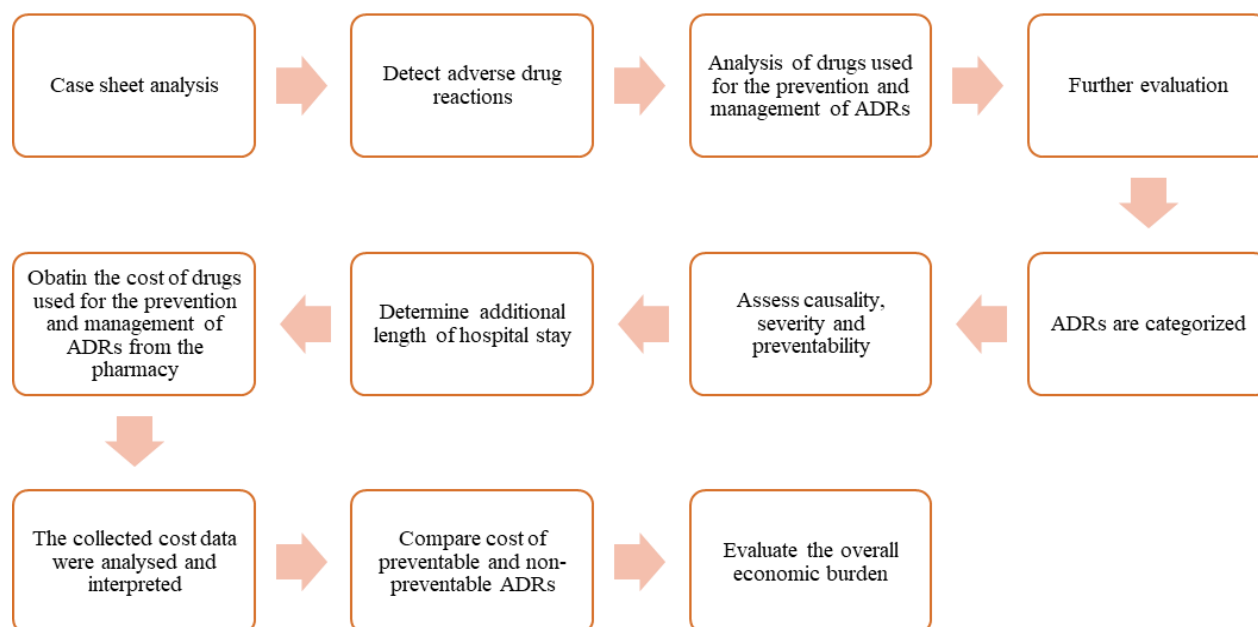


Figure 1: Study Procedure.

RESULTS

A total of 121 patients were analyzed during the study period. Of these 55 patients, 30 (55%) were female patients and 25 (45%) were male patients, as shown in Table no. 1.

Table 1: Gender-wise Distribution.

GENDER	NUMBER OF PATIENTS (N=55)	PERCENTAGE (%)
FEMALE	30	55%
MALE	25	45%

The distribution of patients by age is shown in Figure 2. Among which 13 patients (23.64%) belonged to the 65-75 age group, 10 patients (18.18%) were in the 55-65 age group, 9 patients (16.63%) were in the 75-85 age group, 8 patients (14.55%) were in the 25-35 age group, 4 patients (7.27%) were in 85-95 age, 3 patients (5.45%) were in 15-25 age, 2 patients (3.64%) were in 35-45 age and one patient (1.82%) was in 0-15 age.

Table no.2. shows that the most common class of drug that causes adverse reactions are antibiotics (16 nos), antibiotic drugs (14 nos), analgesics/ anti-pyretics (10 nos), cardiovascular drugs (7 nos), anti-epileptics drugs (6 nos), steroids (4 nos), gastrointestinal drugs (3 nos), psychiatric drugs (2 nos), bronchodilators, anesthetics, IV fluids, vitamins and minerals one each.

Table 2: Suspected Drug Class.

CLASS OF DRUGS	QUANTITY	CLASS OF DRUGS	QUANTITY
Antibiotics	16	Gastrointestinal drugs	3
Anti-diabetic drugs	14	Psychiatric Drugs	2
Analgesic/ Antipyretics	10	Bronchodilators	2
Cardiovascular Drugs	7	Anaesthetics	1
Anti-epileptic Drugs	6	IV fluids	1
Steroids	4	Vitamins & Minerals	1

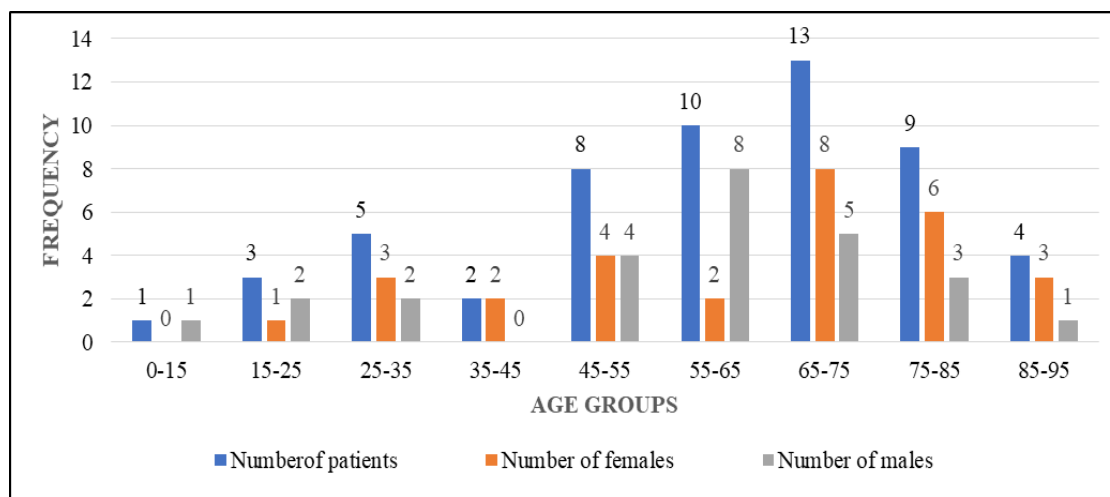
**Figure 2: Age-wise Distribution.**

Table no.3. shows the observed reactions that have occurred in patients, such as gastric irritations (10 cases), itching (8 cases), hypoglycemia (8 cases), constipation (7 cases) and many more reactions like rashes, hyponatremia, redness, breathlessness and so on.

Table no 3: Observed Adverse Reactions.

REACTION SEEN	NUMBER OF CASES
Gastric Irritation	10
Hypoglycaemia	8
Itching	8
Constipation	7
Rashes	3
Hyponatremia	3
Redness	2
Breathlessness	2

Table no.4. shows the quantity of the drugs that were used for the management of the adverse drug reaction, tablet loperamide (19 nos) was the most commonly used drug, followed by injection glucose powder (17 nos), tablet pantop (13 nos), pheniramine (12 nos), hydroxyzine (10 nos), amikacin (8 nos), ondansetron (7 nos), cremaffin (5 nos) and so on for the management of ADR.

Table no 4: ADR Management Drugs.

MANAGEMENT DRUGS	TOTAL QUANTITY	MANAGEMENT DRUGS	TOTAL QUANTITY
Loperamide	19	Hydroxyzine	10
Glucose Powder	17	Amikacin	8
Pantoprazole	13	Ondansetron	7
Pheniramine	12	Cremaffin	5

Table no.5. shows the commonly used drugs that were used for the prevention of ADRs, drug pantoprazole of 40mg dose was administered to 30 patients with a total quantity of 228, drug pantoprazole in combination with domperidone, of a combination dose 40/30mg, was administered to two patients with a total quantity of 6, syrup cremaffin with a dose of 10ml was administered to two patients with a total quantity of 2 and lastly drug ondansetron of 4mg dose was administered to one patient with total quantity of on.

Table no 5: ADR Prevention Drugs.

PREVENTION DRUGS	DOSE	QUANTITY	NUMBER OF PATIENTS
Pantoprazole	40 mg	228	30
Pantoprazole + Domperidone	40/30 mg	6	2
Syrup Cremaffin	10 ml	2	2
Ondansetron	4 mg	1	1

Table no. 6. shows the causality of adverse drug reactions was systematically assessed using the standard WHO-UMC causality assessment scale. From the table, it is evident that among the 55 ADR cases, the majority were classified as probable (43 cases), followed by possible ADRs (11 cases), with only one case categorised as certain.

Table no 6: Causality Assessment.

CAUSALITY	FREQUENCY
Certain	1
Probable	43
Possible	11

Severity assessment of the 55 ADR cases was carried out by using Hartwig and Siegel's Severity Assessment. From table no. 7, among 55 cases, most were Mild (42), followed by moderate (13) and zero severe case.

Table no 7: Severity Assessment.

SEVERITY	NUMBER
Mild	42
Moderate	13
Severe	0

Table no. 8. presents the preventability assessment of adverse drug reactions using the Modified Schumock and Thornton scale. Out of 55 ADR cases, 4 were classified as definitely preventable, 48 as probably preventable, and 3 as not preventable.

Table no 8: Preventability Assessment.

PREVENTABILITY	FREQUENCY
Definitely Preventable	4
Probably Preventable	48
Not Preventable	3

Among 55 patients who experienced adverse drug reactions (ADRs), the total additional treatment cost was ₹26,243.23. The total cost incurred by patients for management of ADRs was ₹11,807.68, which included expenses for consumables such as syringes and cannulas.

The total prevention-related cost borne by patients was ₹14,433.55, including consumables.

The average total additional cost per patient was ₹477.15. The average management cost per ADR was ₹287.93, while the average prevention cost per ADR was ₹497.71.

DISCUSSION

This study evaluates the pattern and economic burden of adverse drug reactions among hospitalised patients in a tertiary care hospital. The discussion explains the main results of the study, compares them with previous studies, and highlights their importance in routine hospital practice. In this study, potential ADRs were observed in 45.45% of the medical records received.

In the present study, adverse drug reactions were found to be more common in female patients (55%) compared to male patients (45%). This higher incidence among females may be due to a higher proportion of females in the observed sample and a higher proportion of female inpatients during our study period at our study site, as well as differences in body composition, hormonal factors, and drug metabolism, which can influence drug response and susceptibility to adverse reactions. This observation is consistent with studies from Indian hospital settings conducted by Arulmani R et al., titled as Adverse drug reaction monitoring in a secondary care hospital in South India, which have reported a higher proportion of adverse drug reactions among female patients.^[13]

The present study included 55 patients, with females (52.7%) slightly outnumbering males (47.3%). Age-wise distribution showed that the majority of patients belonged to the elderly age groups, with the highest number observed in the 65–75 years group (23.64%), followed by the 55–65 years group (18.18%) and the 75–85 years group (16.36%). Younger age groups contributed fewer cases, with the 0–15 years group accounting for only 1.82%, indicating a lower incidence among paediatric patients. This suggests that advancing age may be an important factor, possibly due to increased comorbidities, polypharmacy, and frequent hospitalisation in older individuals. This age-wise distribution is comparable with findings reported by Lazarou et al., who demonstrated that increasing age is a significant risk factor due to polypharmacy, multiple comorbidities, and altered pharmacokinetics in the elderly.^[14,15]

In the present study, antibiotics were the most common drug class associated with adverse drug reactions (ADRs), followed by antidiabetic drugs and analgesic/antipyretics. This finding is consistent with several previous studies in which antibiotics were frequently implicated due to their widespread use and greater potential for hypersensitivity reactions. Antidiabetic drugs, particularly insulin and oral hypoglycaemic agents, are also commonly reported to cause ADRs, mainly due to dose-related effects and patient-related factors.^[16]

In the present study, gastric irritation was the most commonly observed adverse drug reaction in about 10 cases, followed by 8 cases with hypoglycaemia and itching and constipation in 7 cases. Other ADRs reported included rashes and hyponatremia (3 cases each), while redness and breathlessness were observed in 2 cases each. The predominance of gastrointestinal reactions such as gastric irritation and constipation, is comparable with the findings of Ramesh et al. and Patel et al., who identified gastrointestinal disturbances and cutaneous reactions as the leading ADRs among hospitalised patients. Cutaneous reactions such as itching, rashes and redness observed in the present study are also consistent with reports by Harugeri et al., who documented skin-related ADRs as one of the common reaction patterns. The occurrence of hypoglycaemia may be associated with the use of antidiabetic agents and insulin therapy mainly in elderly patients with multiple comorbidities.^[15,17,18]

The present study analysed the drugs used for the management of adverse drug reactions (ADRs) among the study population. Tablet loperamide (19 nos) was the most commonly used drug, indicating that gastrointestinal-related ADRs, such as diarrhoea, were frequently encountered. This was followed by glucose powder (17 nos) and tablet pantoprazole (13 nos), suggesting the need for glycaemic control and gastric protection during ADR management. Antihistamines such as injection Avil (11 nos) and tablet Atarax (10 nos) were commonly prescribed, reflecting the occurrence of allergic and hypersensitivity reactions. These findings are comparable with studies by Patel et al. and Pirmohamed et al., which reported that antihistamines, gastrointestinal agents, and supportive medications are the most commonly used drugs in ADR management.^[19,20]

As shown in Table no. 5, pantoprazole 40 mg was the most commonly prescribed preventive drug, administered to 30 patients with a total quantity of 228. This indicates that gastrointestinal protection was a major preventive strategy, especially in patients receiving multiple drugs or drugs known to cause gastric irritation. The use of pantoprazole in combination with domperidone (40/30 mg) in a smaller number of patients suggests preventive management of acid-related symptoms along with nausea and gastric motility issues. The results of the present study are comparable with the findings of Gandhi et al., who reported that preventive use of proton pump inhibitors and antiemetics was commonly practised in hospitalised patients to reduce the occurrence of drug-induced gastrointestinal adverse effects. The study emphasised that patients receiving polypharmacy and long-term drug therapy were more likely to receive prophylactic medications, which is consistent with the predominant use of pantoprazole observed in the present study.^[21,22]

In the present study, the causality of 55 reported ADRs was assessed using the WHO–UMC causality assessment scale. The majority of ADRs were classified as probable (43 cases), followed by possible (11 cases), while only one case was categorised as certain. Most ADRs were therefore categorised as probable based on reasonable time relationships, improvement on drug withdrawal, and absence of alternative explanations. These findings are comparable with studies conducted by Saha et al. and Jose and Rao, where the majority of ADRs were classified as probable using the WHO–UMC scale, with fewer cases reported as certain. Similar patterns have also been reported in hospital-based pharmacovigilance studies, highlighting the practical applicability of the WHO–UMC scale in routine clinical settings. Overall, the results indicate that the WHO–UMC causality assessment scale is a reliable and practical tool for evaluating ADRs and supports its use in pharmacovigilance activities.^[23,24,25]

The severity of 55 ADRs was assessed using the Hartwig and Siegel severity assessment scale. Most ADRs were classified as mild (42 cases), followed by moderate (13 cases), while no severe ADRs were reported. This indicates that the majority of ADRs were manageable and did not require intensive medical intervention. The predominance of mild ADRs may be attributed to early detection, prompt management, and effective monitoring of patients during therapy. These findings are consistent with studies conducted by Belhekar et al., Chhabra et al., and Pirmohamed et al., which also reported that most ADRs were mild to moderate in severity, with fewer severe reactions observed in hospital settings. The absence of severe ADRs in the present study may reflect efficient pharmacovigilance practices and timely clinical intervention. Overall, the results emphasize the importance of continuous ADR monitoring and early identification to minimise the progression of ADRs and improve patient safety.^[26,27,28]

In the present study, preventability assessment using the Modified Schumock and Thornton scale revealed that the majority of adverse drug reactions (ADRs) were preventable. Out of 55 ADRs, 4 were definitely preventable and 48

were probably preventable, while only 3 were not preventable. These findings highlight that most ADRs occurred due to potentially avoidable factors such as inappropriate drug selection, lack of monitoring, or dosing issues. These findings are comparable with the study conducted by Bates et al., who reported that a significant proportion of ADRs in hospitalised patients were preventable and were often associated with prescribing errors and inadequate monitoring.^[29]

LIMITATIONS

The limited duration of the study restricted comprehensive data collection on adverse drug reactions in patients throughout time.

The sample size of patients included in the study was relatively small, which may limit the generalizability of the findings and may not accurately represent the true occurrence of ADRs in the population.

Incomplete or delayed reporting of ADRs by healthcare professionals may have affected the accuracy and reliability of the study findings.

The analysis was limited to direct medical costs, while indirect medical costs, like longer hospital stays, etc., were not included.

CONCLUSION

This study examined the additional costs incurred by patients due to adverse drug reactions. This six-month study sought to identify the adverse reactions among the inpatients, their prevention and management in a super-speciality hospital. The study included almost all age groups of patients admitted to the hospital during the study period. Elderly patients were most affected, with antibiotics and human insulin being the commonly implicated drugs, and gastric irritation as the frequent reaction. ADRs resulted in additional financial burden on patients due to both management and preventive measures. These findings emphasise the need for careful drug selection, monitoring, and preventive strategies to minimise ADR-related clinical and economic impact. From our study, it was understood that due to an adverse drug reaction, a patient may have an additional expense.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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None

ABBREVIATIONS

ADR- Adverse Drug Reactions; WHO- World Health Organization; UMC- Uppsala Monitoring Centre; AMC- ADR Monitoring Centre; MRD- Medical Record Department.

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