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Pattern of Adverse Drug Reactions and Their Economic Impact on Admitted Patients in Medicine Wards of a Tertiary Care Hospital

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ABSTRACT:

Objective: Adverse drug reactions (ADRs) have recently emerged as a leading cause of illness and death, as well as a significant strain on the healthcare system. The important objectives of the research were to identify and assess the pattern of ADRs, analyse the ADRs based on their causality, severity, and preventability and also find out the economic impact of ADRs.

Method: A prospective observational study was carried out for six months in three hospital wards specifically designated for general medicine. The definition of ADR by the World Health Organization was adopted. The severity, preventability, and causality of each adverse drug reaction (ADR) were evaluated using Naranjo's scale, the Hartwig *et al.* criteria, and the modified Shumock and Thornton's criteria. The medication cost induced by ADR was estimated using the available resources at the study site.

Result: 31 patients were removed from the 540 patients' data set because of incomplete information and medical-legal cases (MLC) that were recorded throughout the study duration. 509 patients' data were analysed and 52 ADRs were detected in 49 patients across three hospital

medical wards of the 49 patients suffering from 52 ADRs, only 3 patients had two ADRs and 46 patients had only one ADR, respectively. It was noted that the occurrence of ADRs was 10.2% (52/509). Based on the Rawlins and Thompson system, the greatest number of ADRs (86.54%) were identified as type A reactions. As per the Anatomical and Therapeutic Classification (ATC) system, the drug class typically linked with ADRs was anti-infectives for systemic use (26.92%) followed by cardiovascular systems (25%). MedDRA terminology was used for ADR coding and the most frequently existing reactions were constipation (25%), Skin Rash (10%), and cough (8%). As per Naranjo's causality assessment scale, the maximum percentage of ADRs was probable (61%), followed by possible (37%). Based on the Hartwig *et al*. severity scale, ADRs were evaluated and approximately 50% of ADRs were of the moderate type, followed by 48% of ADRs of mild type ADRs and according to modified Shumock and Thornton's criteria, Most ADRs (94%) were not preventable. The economic burden per patient due to ADRs was ₹102.31 and the average drug cost induced in mild, moderate, and severe reactions was ₹75.9, ₹89.4, ₹658, respectively.

Conclusion: The outcomes of this study will minimize costs to the healthcare system and improve patient safety.

Keywords: ADR patterns, Economic Burden, Risk Factors, Causality, Severity.

1. INTRODUCTION

Medication extensively benefits human health, but ADRs to medicines are also negative aspects of human health [1]. Additionally, ADRs are considered a double-edged sword with great potential to harm people worldwide [2]. Significant ADRs account for 6.7% of hospitalized patient cases in the United State (US), where they constitute a significant contributor to morbidity and mortality and the fourth or sixth most common cause of death [3,4]. ADRs are quite expensive and greatly influence people's health, quality of life, and healthcare costs in society. Furthermore, they may cause patients to lose faith in the medical system, harming medicine adherence and therapeutic outcomes [5]. In Australia, a Study determined that medications contributed to 5.7 % of all admissions; and 4.9 % of them were attributed to ADRs, and the study assessed that each patient incurred an expense of more than € 2 million. As per the German Study, the cost of ADRs was individually estimated at between US $2000 and US $4000 and the annual direct cost of ADRs was estimated to be 0.4 billion dollars according to the US study [6,7,8]. In the US and Canada, ADRs make up 4.2-20% of hospitalized patients., 5.7–18.8% in Australia, and 2.5–10.6% in Europe, per a study of the

literature [9,10,11]. The frequency of ADRs in hospital admissions was 3.2% in England, 4.8% in Germany, and 5.6 % in the United States [11]. The incidence of ADRs in India ranges from 5.9 to 22.3%, however, 1.8% of deaths are attributable to ADRs. ADR-related hospital admissions made up 0.7% of all admissions, with patients paying an average of INR 690 for ADRs [8,12]. As reported by Ramesh *et al*. all reported ADR treatment costs were US$1595, and per patient, the ADR treatment costs were US$15 [13]. The major risk factors responsible for adverse drug reactions (ADRs), which have been extensively studied, were age, sex, co-morbidities, poly-pharmacy, inappropriate medication use, disease severity, poor cognitive function, alcohol Intake, length of stay and depression [14,15]. A literature review found that risk factors were divided into five main groups: patient, disease, therapy, healthcare, and genetics-related. Of the five, the two most reported in the scientific literature were medicine-related and disease-related. Polypharmacy, older age, length of hospital stays, comorbidities, inappropriate medication use, cardiovascular agents and anti-infective medications were particularly connected risk factors for ADRs [16,17]. In the public teaching hospitals in the Uttarakhand region, very little research has examined the financial impact of ADRs. Therefore, the current objective of the present study is to ascertain the incidence rate and pattern of ADRs. The secondary objective is to determine the economic burden of ADRs in tertiary care public sector hospitals.

2. MATERIALS AND METHODS

A prospective observational study was conducted in the three medicine wards of a Government Doon Medical College and Hospital, Dehradun, Uttarakhand. The time duration for the study was six months.

Government Doon Medical College and Hospital (GDMCH) and its Research Review Board (RRB) and Institutional Ethics Committee (IEC) evaluated and approved the study protocol. Government Doon Medical College and Hospital (GDMCH) under Dehradun Municipality was established as a dispensary in 1854. In 1860, the dispensary began admitting patients to its wards, and in 1910, it began performing surgeries. About 350 beds have already been added, and the hospital is being expanded to 750 beds, including departments dedicated to neurosurgery and plastic surgery, apart from other super specialties.

2.1. Inclusion criteria

- Patients who experienced ADRs while admitted to medicine wards of tertiary care hospitals.
- Furthermore, ADRs found in patient records as revealed by healthcare providers

2.2 Exclusion criteria

- ADRs that take place outside the medicine wards.
- Incomplete lab results, unfinished prescriptions, and daily notes found in patient files
- Victims of drug misuse, as well as those who have experienced poisoning, whether deliberate or unintentional.

3. DATA COLLECTION PROCEDURE

In the context of the study, patients admitted to the wards were identified. Patients' prescription schedules, medical histories, and nursing notes were accessed daily by visiting the wards. Patients' data that satisfied the inclusion-exclusion criteria were moved to a standard "data collection form" that was suitably created. All pertinent information was recorded, including the patient's allergy status to the medications, previous drug use past, prominent symptoms, co-morbidities, mode of administration, appropriate dosage, frequency, and date on which the patient's ADRs first manifested. Until they were released from the wards or moved to the intensive care unit, the patients were observed. ADRs were found using a combination of subjective, objective, and spontaneous reporting. The ADR was discussed and confirmed with the head of the medicine department of the hospital.

4. DRUGS CLASSIFICATION AND ADRS CODE

The Anatomical Therapeutic and Chemical (ATC) system was used for drug classification and the MedDRA terminology was used for ADR coding.

5. ANALYSIS OF ADRs

5.1 ADRs Classification

The Rawlins and Thompson approach serves as the foundation for the ADR classification. This method classifies ADRs as either type B (idiosyncratic, lacking a clear dose-response relationship, and not predictable from the known pharmacology) or type A (dose-dependent and predictable from the known pharmacology) [18].

5.2 Evaluation of ADRs Causality based on Algorithm

The causality of suspected ADRs was evaluated using Naranjo's ADR probability scale. Every ADR in Naranjo's ADR likelihood scale was asked ten distinct questions.

The answers to these questions could be yes, no, and do not know. Every answer got a score. The score ranges from (- 4 to +13). The reaction was considered definite if the score was 9 or higher, probable if 5 to 8, possible if 1 to 4, and doubtful if 0 or less [19].

5.3 Severity of ADRs

Using the modified Hartwig *et al*. criteria, there were three categories for the severity assessment of ADRs: mild, moderate, and severe reactions. ADRs are categorized as mild (score = 1-2), moderate (score = 3-4), and severe (score = 5-7b) on this scale. [20].

5.4 Preventability of ADRs

The ADR preventability assessment criteria were outlined using modified Schumock and Thornton criteria. These criteria will be used to classify ADRs into three categories: definitely preventable, maybe preventable, and not preventable [21].

5.5 Risk elements for ADR incidence

Predisposing factors and adverse drug reactions (ADRs) were also examined. These were separated into subsequent groups.

Age: Based on age classifications, the patients have been split into adult and geriatric groups. The adult (18–60 years old) and geriatric (beyond 60 years old) age groups.

Gender: Male and female patients have been separated.

Duration: The stay could be anything from one to five days, six to ten days, eleven to fifteen days, sixteen to twenty days, twenty to twenty-six days, or longer than twenty-six days. A quantity of medications: The quantity of medications was divided into groups of 1, 5, 6, 10, 11, 15, 16, 20, 21, and 30.

5.6 Economic Impact of ADRs

ADR management cost was used to determine the costs associated with ADR management (from the start of the ADR to the conclusion of treatment).

5.7 Statistical analysis of ADRs

Every outcome was shown as a percentage and an average. The length of stay, number of medicines, and number of diagnoses were all expressed as an average. ADRs' frequency, seriousness, and causation were shown as percentages.

6. RESULT

6.1 General demographic characteristics of the study population.

There were 509 patients under close observation in the medicine wards of the hospital. Total of 509 patients, only 49 patients experienced 52 ADRs. The average number of ADRs for every single patient was 1.06, and the frequency of ADRs was determined to be 10.21%.

Table 1: Study Population's demographic features and ADR frequency				
Characteristics	**Patients without ADR**	**Patients with ADR**	**The sum of all participants in the study**	**ADRs Number (%)**
No. of patients n (%)	460 (90.37)	49 (9.6)	509 (100)	52 (10.2)
Gender				
Male n (%)	248 (91.17)	24(8.8)	272 (53.43)	26 (9.5)
Female n (%)	212 (89.45)	25 (10.54)	237 (46.56)	26 (11)
Age Categories				
19–59 years n (%)	344 (93.22)	25 (6.77)	369 (72.49)	25 (6.8)
>60 years n (%)	116 (82.85)	24(17.14)	140 (27.50)	27 (19.2)
No. of diagnosis				
1-3 n (%)	393 (90.97)	39 (9.02)	432 (84.87)	42 (9.7)
4-6 n (%)	62 (87.32)	9 (12.67)	71 (13.94)	09 (12.7)
7-9 n (%)	5 (83.33)	1(16.66)	6 (1.17)	01 (16.7)
No. of Medications taken				
1-5 n (%)	89 (96.73)	3 (3.26)	92 (18.07)	3 (3.3)
6-10 n (%)	285 (92.23)	24 (7.76)	309 (60.70)	25 (8.1)
11-15 n (%)	78 (80.41)	19 (19.58)	97 (19.05)	21 (21.6)
16-20 n (%)	7 (70)	3 (30)	10 (1.96)	3 (30)
21-25 n (%)	1 (100)	0	1 (0.196)	0 (0)
Hospital stays (days)				
1-5 n (%)	346 (92.02)	30 (7.97)	376 (74.45)	31 (8.2)
6-10 n (%)	103 (88.79)	13 (11.20)	116 (22.78)	14 (12.1)
11-15 n (%)	10 (66)	5 (33.33)	15 (2.94)	06 (40)
16-20 n (%)	1 (100)	0	1 (0.196)	0
21-25 n (%)	0	1 (100)	1 (0.196)	1 (100)

6.2 Anatomical and Therapeutic Classification (ATC) of drugs related to Adverse Drug Reactions

Anti-infective system (J) medications (n = 14, 26.92%) and Cardiovascular System (C) medications (n = 13, 25%) were the anatomical classes of medications that were often linked to the ADRs. The anti-infective systems' most often occurring adverse drug reactions (ADRs) were caused by anti-bacterial (J01) (n =12, 25%) and antimycobacterial (J04) (n =2, 3.84%) drugs.

Table 2: Anatomical and Therapeutic class of Medication implicated in ADRs

Anatomical Class [Code] (Number of ADRs, %)	Therapeutics Class [Code]	Number of ADRs (%)
Anti -infective for systematic use [J] (14, 26.92)	Antibacterial for systemic use [JO1]	12 (23.07)
	Antimycobacterials [J04]	2 (3.84)
Cardiovascular Drug [C] (13, 25)	Diuretics [C03]	8 (15.28)
	Calcium channel blockers [C08]	3 (5.76)
	Lipid modifiers [C10]	2 (3.84)
Alimentary Tract and Metabolism [A] (9, 17.30)	Drugs for acids related disorders [A02]	4 (7.69)
	Drugs for diabetes [A10]	4 (7.69)
	Antiemetics and Antinauseants [A04]	1 (1.92)
Nervous System [N] (5, 9.61)	Analgesics [N02]	4 (7.69)
	Antiepileptics [N03]	1 (1.92)
Blood and Blood Forming Organs [B] (4, 7.69)	Blood substitute and perfusion solution [B05]	3 (5.76)
	Antithrombotic Agent [B 01]	1 (1.92)
Systenic Hormonal Preparation, Excl Sex Hormones and Insulin [H] (3 , 5.76)	Systemic corticosteroids [H02]	3 (5.76)
Musculo-Skeletal System [M] (2 , 3.84)	Antirheumatic and anti-inflammatory goods [M01]	2 (3.84)
Breathing System [R] (1, 1.92)	Medication for obstructive respiratory disorders [R03]	1 (1.92)
V Various [V] (1, 1.92)	All other medicinal element [V03]	1 (1.92)

6.3 Identification of ADRs

Based on data, 49 of 509 patients complained about ADRs. 3 patients had two ADRs and 46 patients had one ADR. (Table No.6). The system organ class most impacted was gastrointestinal disorders (38%) followed by Endocrine disorders (11%) and Skin and subcutaneous tissue disorders (10%). Most frequents ADRs were Constipations (25%) followed by skin rashes (10%).

Table No. 3: Commonly occurring ADRs with their frequency and percentage on Med RA terminology

ADR Hierarchy with (code) (%)	MedRA Code	ADR term	Frequency of ADRs (% of ADRs)
Gastrointestinal disorders (07) (38)	10010774	Constipation	13 (25)
	10012735	Diarrhoea	2(4)
	10013946	Dyspepsia	1(2)
	10028034	Mouth Ulcer	1(2)
	10033645	Pancreatitis	1(2)
	10068319	Throat pain	1(2)
	10000081	Abdominal Pain	1(2)
Endocrine disorders (05) (11)	10020993	Hypoglycemia	4 (8)
	10020635	Hyperglycemia,	2(4)
Skin and subcutaneous tissue disorders (23) (10)	10037844	Skin Rash	5 (10)
Respiratory, thoracic and mediastinal disorders (22) (8)	10011224	Cough	4 (8)
Nervous system disorders (17) (8)	10019211	Headache,	2(4)
	10022437	Insomnia	1(2)
	10038743	Restlessness	1(2)
Hepatobiliary disorders (09) (4)	10019851	Hepatotoxicity,	2(4)
Metabolism and nutrition disorders (14) (4)	10002649	Anorexia Nervosa	2(4)
Renal and urinary disorders (20) (2)	10069339	Acute Kidney Injury	1(2)

Ear and labyrinth disorders (04) (2)	10047340	Vertigo	1(2)
General disorders and administration site condition (8) (2)	10033371	Body Pain	1(2)
Metabolism and nutrition disorders (14) (2)	10021015	Hypokalemia	1(2)
Vascular disorders (24) (2)	10021097	Hypotension	1(2)
General disorders and administration site conditions (8) (2)	10033371	Neuropathic pain	1(2)
Investigations (13) (2)	10061878	occult blood	1(2)
Cardiac disorders (02) (2)	10033557	Palpitation	1(2)
Musculoskeletal and connective tissue disorders (15) (2)	10003988	Backache	1(2)

6.4 ADR frequency and incidence for individual drugs

Anti-tubercular medications (ATT) had the highest rate of adverse drug reactions (22.22%), followed by erythrocytes (14.29%) and glimepiride + metformin (14.29%) presented in Table no. 4 that Furesemide (7), Ceftriaxone (4), Pantoprazole (4), Amlodipin (3), and Metronidazole (3) were the top five medications causing the greatest number of ADRs.

Table No. 4: Frequency of ADRs for Individual drugs and their incidence

Drugs [ATC Code]	Patients exposed to drugs	Patients developed ADRs	Incidence (%)	Total No. of ADRs (%) (n=52)
Rifampicin, Pyrazinamide, Ethambutol, and Isoniazid [J04AM06]	9	2	22.22	2 (3.84)
Glimepiride (2mg) + Metformin (500mg) [A10BD02]	7	1	14.29	1 (1.92)
Erythrocytes [B05AX01]	14	2	14.29	2 (3.84)
Amikacin [J01GB06], Nimesulide [M01AX17], Metformin [A10BA02]	10 each	1 each	10.00 each	1 (1.92) each
Phenytoin [N03AB02]	14	1	7.14	1 (1.92)

Rosuvastatin [C10AA07], Ethanol [V03AZ01]	15 each	1 each	6.67 each	1 (1.92) each
Mannitol [B05BC01], Methylprednisolone [H02AB04]	16 each	1 each	6.25 each	1 (1.92) each
Furosemide [C03CA01]	106	6	5.66	7 (13.46)
Hydrocortisone (H02AB09)	37	2	5.41	2 (3.84)
Morphine [N02AA01], Torsemide [C03CA04], Acetylsalicylic acid [B01AC06]	20 each	1 each	5.00 each	1 (1.92) each
Amoxicillin and beta-lactamase inhibitor [J01CR02]	42	2	4.76	2 (3.84)
Tramadol [N02AX02]	45	2	4.44	2 (3.84)
Amlodipine [C08CA01]	70	3	4.29	3 (5.76)
Insulin [A10AE01]	54	2	3.70	2 (3.84)
Ciprofloxacin [J01MA02]	29	1	3.45	1 (1.92)
Budesonide [R03BA02]	33	1	3.03	1 (1.92)
Metronidazole [J01XD01]	108	3	2.78	3 (5.76)
Diclofenac [M02AA15]	58	1	1.72	1 (1.92)
Atorvastatin (C10AA05)	64	1	1.56	1 (1.92)
Ceftriaxone [J01DD04]	369	4	1.08	4 (7.69)
Pantoprazole [A02BC02]	457	4	0.88	4 (7.69)

6.5 Adverse Drug Reactions: Characteristics and Assessment

6.5.1 ADRs' classification

ADRs were categorized using the system that Rawlins and Thompson had developed. During research, 85.54% of ADRs were type A reactions, while 13.46% were type B reactions.

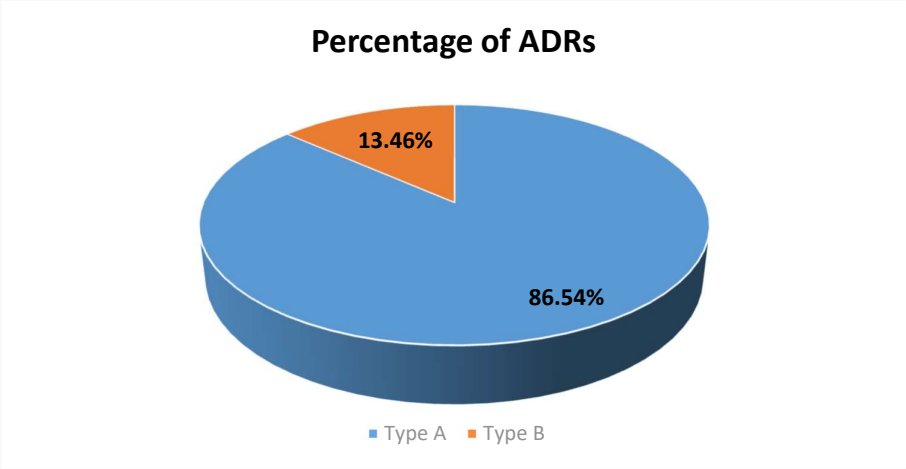

Figure No. 1: ADRs classification using Rawlins and Thompson

6.6 Assessment of Causality in ADRs

Using Naranjo's algorithm 61% (n=32) were probable, 37%. (n=19) were possible and 2% (n =1) was highly probable

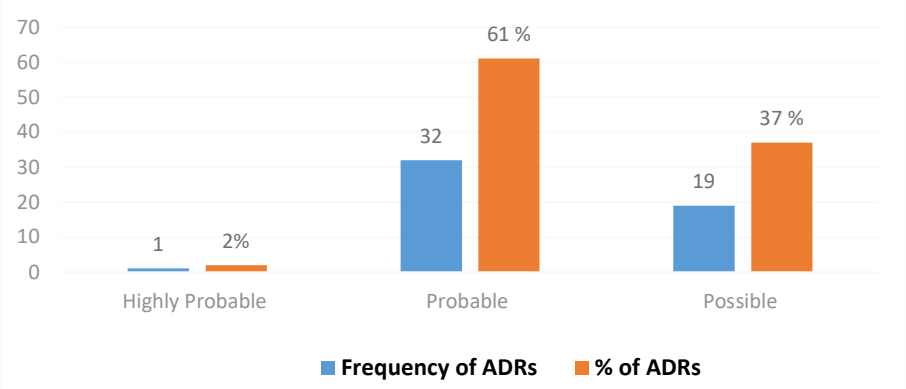

Figure No. 2: Assessment of Causality in ADRs by Using Naranjo's algorithm

6.7 ADRs Severity Grade

After mild 48% (n=25) (levels 1 and 2) and severe 2% (n=1) (levels 5 and 7), the majority 50% (n=26) of ADRs had moderate severity (levels 3, 4a, and 4b).

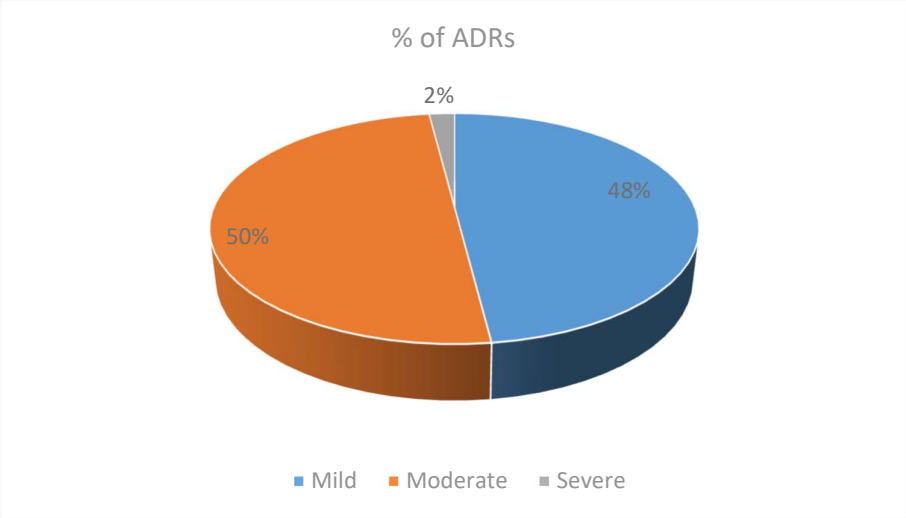

Figure No.3: Severity Analysis of ADRs by Using the Modified Hartwig et al, Criteria.

6.8 ADR' Preventability Analysis

The criteria set forth by Schumock and Thornton were applied here. There were three categories on the preventability scale: non-preventable, probably preventable, and definitely preventable. All 52 ADRs had their preventability evaluated; 3 (6%) were found to be "probably preventable," and 49 (94%) were found to be "non-preventable."

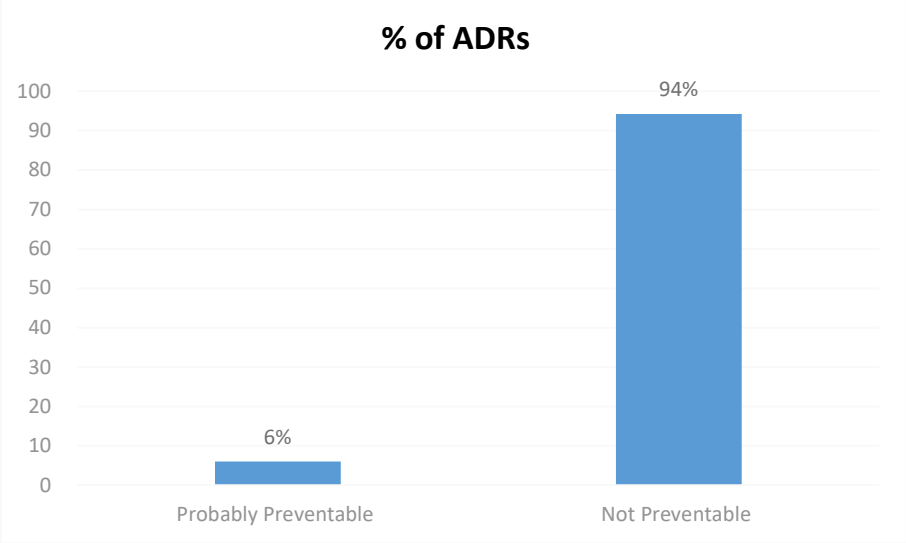

Figure No.4: Preventability Assessment of ADRs by Using Schumock and Thornton's criteria

Risk Factors for Adverse Drug Reactions to Occur

Gender, age, duration of stay, polypharmacy, and number of diagnoses were the five risk factors that were taken into consideration when analyzing the ADRs.

6.9 The Economic impacts of ADRs

52 ADRs emerged throughout the study. A total of 47 (90.38%) ADRs from 44 patients, and these ADRs cost money to manage. The cost of each ADR per patient was ₹102.31 (₹4502/44), and entire financial loss resulting from 44 patients was determined to be ₹4502.

Table 5: ADR – Severity-Based Costs Imposed

ADRs' Level of Severity	Total Number of ADRs	Cost of ADRs incurred in number	Average cost (total cost) (₹)
Mild	25	20	75.9 (1518)
Moderate	26	26	89.46 (2326)
Severe	1	1	658 (658)

7. DISCUSSION:

ADR during medication therapy has been recognized as a significant public health issue. It worsens the quality of life and drives up healthcare and society at large money both directly and indirectly [22].

In the present research study, the frequency of ADRs, approximately 10.2%, is compatible with the variety of observations from earlier prospective research studies conducted on hospitalized patients, which adopted the same methodology that was equivalent to the present research study [23]. However, the frequency of ADRs in this study was much higher than in the studies conducted by researchers [13], [24]. and the incidences were 3.7% and 6.9%, respectively, reported in prospective studies conducted in tertiary care hospitals in Mumbai and South India. Only 0.15 % of patients suffered from ADRs as mentioned in a study executed by Jose *et al*. (2006) [25]. The study conducted in Karnataka, India, relied on a spontaneous reporting system as the sole means of identifying ADRs. ADRs were systematically investigated in continuing study, using spontaneous reporting in addition to patient records as a source of evidence (medical notes, nursing notes, and laboratory data).

As per the ATC classification, anti-infective for systemic Use (26.92%) participated in the huge frequency of ADRs followed by Cardiovascular drugs (25%) and Alimentary tract and metabolism (17.30%). For individual drugs, furosemide was the leading cause of an ADR (13.46%) followed by ceftriaxone and pantoprazole (7.69% each). The study's findings are in line with a study by Ganesan et al. (2020), which found that the most frequently linked drug class for adverse drug reactions (ADRs) was anti-infective medications for systemic use.

[23,26] and Bergman *et al.* [27], found that drugs acting on cardiovascular were also the highest percentage of a class system for ADRs.

This study matches Davies EC *et al*. findings that loop diuretics and furosemide were most often associated with ADRs. In this study, diuretics are in the cardiovascular system per ATC [28].

Gastrointestinal disorders (38%) were the greatest suffering organ class system, followed by endocrine disorders (11%) and disorders of the skin and subcutaneous tissue (10%). The outcomes were similar to a study published in the USA that found the gastrointestinal and dermatological systems were the greatest severely impacted [46]. The finding of our research is also parallel with research from south India, which indicates that the neurological, gastrointestinal, and dermatological systems were the main organ classes implicated in adverse medication reactions [45, 47].

The most common ADRs in the study were constipation (25%), skin rash (10%), cough, and hypokalemia (8% each). Studies done by Yadesa *et al.* found that 40 % of ADRs affecting the gastro-intestinal tract were the most often recognized [17], Arulmani R *et al*. and Jose J *et al*. found the dermatological reaction to most frequently occurred [25, 29].

During the research, 86.54% of the ADRs were identified as type A and 13.46% of the ADRs have been determined as type B. Type-A reactions are pharmacologically predictable and type-B reactions are peculiar types and can't be anticipated pharmacologically. Benkirane R *et al.* found that 80.3% of ADRs were Type-A and 19.7% were Type-B in their research study.

[30]. According to Jose J *et al*., 72.5% of the ADRs were type-A [25]. Type-A reactions are found to be more common in all studies since most adverse drug reactions (ADRs) stem from a drug's pharmacology. Strange reactions are extremely uncommon and can be explained at a smaller level.

Since pharmacology causes most ADRs, type-A events are more common in all investigations. Very rare reactions can be explained at a smaller level.

The study concluded 37% of reactions were "possible", 62% of reactions were "probable" and 2% of reactions were "highly probable" or definite type. In their study, Ganesan *et al.* [23] observed that 66% of ADRs were classified as probable type, and approximately 29.3 % as possible type. According to their research study by Demissew *et al*. showed that nearly 71.9% of ADRs were categorized as probable, 26% as possible, and 2% as definite [31].

The majority (50%) of the ADRs were “moderate”, 48% ADRs were “mild” type, and 2. % of ADRs were “Severe” according to the Modified Hartwig's severity scale. The current study

results are in line with the results of the study conducted by Shegena *et al.* reported that 52.4% of ADRs are mild type [32]. Jose *et a*l. found 50.5% mild and 44% moderate ADRs [25]. Because more patients were surveyed, Sundaran *et al*. discovered 64% of ADRs were 'moderate' [33].

Using the Modified Schumock and Thornton criteria, about 6% of ADRs were likely preventable and the remaining 94% were not. It implies that about 30% of ADRs can be avoided if a suitable monitoring system is established in the research environment.

The study by Sneha *et al.* showed that about 87 % of ADRs were not preventable and probably preventable ADRs were 6% which is in line with the current study results [34].

ADR prevalence was 9.5% (26/272) in male patients and 11% (26/237) in female patients. Numerous studies conclude that gender is another element that contributes to ADRs [35]. Several other research mentioned higher ADR rates for women [36,37]. Given that individuals go through life stages including menarche, pregnancy, and other changes that alter the medication reaction, it might be warranted. The current study's findings don't support this because the sample size for women was slightly smaller than that of men; therefore, additional data is required to demonstrate a substantial correlation between gender and the incidence of ADRs.

In a recent study, the elderly patient group (19.2%) was more vulnerable to the frequency of adverse drug reactions (6.8%) than the adult patient groupIn a cross-sectional study with 1,332 inpatients 65 years of age or older, Marengony A *et al.* provided proof of it. Marengony A *et al*. further demonstrate that around 36.4% of those individuals experienced at least one unfavorable clinical event [38]. Saha *et al*. discovered that 42% of elderly patients had ADRs [39]. Numerous studies have shown that as people age, the prevalence of ADRs rises [40,41, 42]. The sample size for geriatric patients was one-third that of adult patients, therefore the study's findings don't hold up. More data is required to demonstrate a meaningful correlation between age and the prevalence of ADRs.

The duration of stay has a direct impact on the rate of ADRs. Longer hospital stays have been associated with more serious illnesses, more other medical conditions, and more prescribed pharmaceuticals, which increase the risk of ADRs. Several Studies reported that length of stay (LOS) is one of the risk factors for ADRs [25,28].

Furthermore, another significant risk factor for ADRs is polypharmacy. Because it is closely tied to sickness severity and multiple drug ADRs are more likely. Davies *et al*. discovered in prospective observational research that ADR patients took significantly more drugs than non-ADR patients. [28]. Many studies conducted that polypharmacy was a finding that is

comparable to the current research study and has also been identified as a significant contributing factor to ADRs [43,44].

The results showed that each patient's medicine cost increased by ₹102.31 as a result of ADR, and the total economic loss from 44 patients with ADR was ₹4502. Our analysis's findings were in line with an economic evaluation of ADRs conducted at a private hospital, which found that each patient in India exposed to an ADR typically paid Rs. 412.79 (US$ 9.30) indirect costs.

[45]. These variations might result from the research environment and other elements like private and public hospitals. According to a different Pune study, ₹441.86 was the medication-related cost borne by the admitted inpatient.

The medication cost per patient for each mild, moderate, and Severe ADR was ₹75.9, ₹89.4, and ₹658, respectively which was based on the research outcomes presented by Arulmani *et al.* [29]. Based on our research study, it was extremely important to minimize the ADRs. If possible, electronic prescribing may serve to minimize ADRs.

On average, medication expenses for mild, moderate, and severe ADRs were ₹75.9, ₹89.4, and ₹658, correspondingly. These results were consistent with the research presented by Arulmani *et al*. [29]. According to our research, minimization of the ADRs was critically important. If possible, computerized prescribing can be used to reduce adverse drug reactions.

10. CONCLUSION

The current study reported 10.2% ADRs, with constipation being the most common, followed by skin rash and cough, and furosemide being the most common medicine to produce ADRs. ADRs were generally Type - Reactions, probable types of ADRs were 62%, a majority (50%) of the ADRs were “moderate”, and 94% of the ADRs were not preventable. To manage the ADRs, the average cost for each patient was ₹102.31. The findings of this study will improve patient safety and reduce costs to the healthcare system.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

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