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ORIGINAL ARTICLE

Clinical Assessment of Adverse Drug Reactions in Patients with Prolonged Illness at a Tertiary Care Teaching Hospital

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ABSTRACT

The study primarily assesses the relationship between the development of adverse drug reactions (ADRs) and chronic disease patients from different departments of a teaching hospital that provides tertiary care, as well as the cause, severity, and preventability of ADRs. For two years, a prospective observational study was carried out in a teaching hospital for tertiary care in Hyderabad, India. Every patient was divided according on their socioeconomic status, gender, age, quantity of drugs taken, and illness condition. The WHO-UMC causality evaluation, Hartwig's Siegel's scale, and the modified Shumock and Thornton criteria were used to analyse the reported ADRs. Data analysis was done using descriptive statistics. 391 of the 691 participants that were enrolled in the trial reported having 510 adverse drug reactions. 62.9% of these are outpatients, while 37.0% are inpatients. The majority of patients (58.0%) are female, and adults (41–60 years old) account for 45.8% of all adverse drug reactions. 65.8% of patients do not take their prescribed drugs as directed. It has also been discovered that lifestyle choices, financial standing, and educational attainment are predictors of ADRs. According to WHO's ADR probability scale, 42.9% of ADRs were likely to occur. According to Hartwig and Siegel's severity rating scales, 40 percent of ADRs were preventable, 13.1% of ADRs were severe, and 33.7% were moderate. A database of ADRs caused by commonly used medications is provided by this study. Therefore, our study suggests that health care workers' reporting of adverse drug reactions has to be improved. In order to improve potential intervention options and lessen the burden and expense of ADRs, this study also recommends more research be done in India.

Key words: *Diabetes mellitus, Adverse drug reactions, Spontaneous reporting, Naranjo's and Hartwig's Siegel's Severity assessment.*

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INTRODUCTION

The WHO defines pharmacovigilance (PV) as the research and practices involved in identifying, evaluating, comprehending, and preventing side effects or any other issue associated to drugs. In reaction to the 1962 thalidomide tragedy, WHO launched the Programme for International Drug Monitoring [1]. Monitoring adverse drug reactions (ADRs) in the Indian population, educating medical professionals about the significance of ADR reporting in India, tracking the benefit-risk profile of medications, producing independent, evidence-based recommendations on medication safety, assisting the CDSCO in developing safety-related regulatory decisions for medications, sharing findings with all relevant parties, and establishing a national centre of excellence in line with international drug safety monitoring standards [2].

Following the recommendations relevant to each chronic ailment is generally advised. Polypharmacy will unavoidably result from following all recommendations for every medication a patient is taking, as the majority of clinical practice guidelines do not alter or address the applicability of their advice for older patients with several disorders [3]. An estimated 50.8 million persons in India had diabetes in 2010, and by 2030, that figure is predicted to increase to 87 million [4]. According to reports, both rural and urban areas of India are seeing a sharp rise in the prevalence of diabetes [5]. When managing diabetic mellitus, a prescriber's understanding of the pharmacokinetics and pharmacodynamics of medications and how they

interact with normal ageing physiology is essential. The information is necessary to reduce and even prevent the negative consequences of hypoglycaemia and the side effects of anti-diabetic drugs. [6].
According to estimates, there were 1 billion hypertensive individuals worldwide in 2020, and by 2025, that number is expected to rise to 1.56 billion [7]. Adverse drug reactions are common with antihypertensive drugs, which can restrict treatment options and decrease patient compliance, both of which can make it more difficult to control blood pressure. It was thought that the varying frequencies of unpleasant symptoms for different classes of antihypertensive drugs were likely connected to their disparate discontinuation rates [8,9]. Anti-tubercular drugs that are costly and toxic and administered for an extended period of time are necessary for the treatment of tuberculosis [10,11]. Beginning in August 2007 [12], India's Revised National Tuberculosis Control Program (RNTCP) treats TB in accordance with the internationally accepted directly observed treatments (DOTS) guidelines.
Important risk factors for adverse drug reactions (ADRs) include the following: female gender, age (very young and very old), multiple drugs and co-occurring medical disorders, socioeconomic position, educational attainment, and lifestyle choices. [13].
Individuals who have diabetes are more likely to experience several major health issues. Serious conditions affecting the heart, blood vessels, eyes, kidneys, nerves, and teeth can result from persistently elevated blood glucose levels. Individuals who have diabetes are also more susceptible to infections. According to reports, 70% of diabetes patients worldwide also have hypertension, and diabetic individuals are twice as likely to acquire hypertension as euglycemic people. Patients with type 2 diabetes have been found to have a significant prevalence of DRPs. [14-16].
The current study was conducted at Hyderabad's Bhaskar Medical College and General Hospital, a teaching facility for tertiary care. ADRs in chronic conditions were evaluated for causality, severity, and preventability. The study also assessed the frequency of adverse drug reactions (ADRs) linked to patients' socioeconomic level, occupation, medication adherence, and educational attainment. Our organisation is an approved ADR monitoring centre (AMC) under the "Indian Pharmacovigilance Program." Physicians, clinical pharmacy interns, postgraduate medical students, and surrounding teaching hospitals provide suspected adverse drug reactions (ADRs) to the AMC. For the worldwide monitoring of ADRs, we send information to the WHO's "VigiFlow software," which is supplied by the Indian Pharmacopoeia Commission in Ghaziabad, India.

MATERIAL AND METHODS

Study design:

Pharmacovigilance reporting system that is engaged in a prospective observational longitudinal trial.

Study period:

The study was conducted over a period of 2 years from May 2023 to April 2024.

Ethics committee approval:

The Institutional Human Ethical Committee of Bhaskar Medical College and General Hospital authorities examined and approved the study protocol before it started.

Study criteria:

Inclusion criteria

- • Patients who are 18 years of age or older, of both sexes, and who are both inpatient and outpatient.
- Patients with co-occurring medical conditions and any chronic illness.

Exclusion criteria

- Children’s and pregnant women.
- Patients receiving medicines other than allopathic.
- Patients who experienced adverse event to vaccines, blood and /or blood products.
- Adverse event to poisoning/drug abuse and dependence.

Statistical analysis:

Data analysis was done using descriptive statistics. Tables and charts were used to illustrate each statistic, which was expressed as a percentage. Age, gender, quantity of medicines used, drug class, medication adherence, habits, economic position, education, and occupation were the categories utilised to separate the data.

RESULTS AND DISCUSSION

Study population

688 patients met the study criteria were included in the study. Of which 37.0% (n=255) were inpatients and 62.9% (n=434) were outpatients.

Characteristics of the study population

Out of 688 study patients, 41.9% (n=286) and 58.0% (n=402) were male and female respectively. Majority of the patients were in the age group of 40-65 (45.7%). 45% of patients using drugs between 1-2 drugs. 65% of patients are non-adherent to their medication. 31% of patients are both alcoholic and smokers.

45.5% patients are not educated. 21.6% of patients are unemployed followed by 23.4% patients are formers and 31.5% of patients are economically lower in class. The demographic details of the study population are given in Table1.

Table 1: Demographic details of the study population

		Inpatients (%)	Outpatients (%)	Total (%)
Characteristics		**(n=256)**	**(n=432)**	**(n=688)**
Gender	Male	104 (41.7)	183 (42.0)	287 (41.9)
	Female	149 (58.2)	252 (57.9)	401 (58.0)
Age	Young Adult	45 (17.4)	44 (10.2)	74 (12.5)
	(19-39)			
	Adult (40-60)	112 (43.5)	205 (47.5)	317 (45.5)
	Elderly (> 61)	99 (38.5)	186 (42.5)	285 (41.5)
No. of Drugs	1 – 3	116 (45.5)	202(46.0)	318 (45.0)
	3 – 4	89 (34.5)	169 (38.2)	258 (37.0)
	≥5	51 (19.5)	64 (14.2)	115 (16.4)
Medication	Adherence	89 (34.5)	147 (33.2)	236 (34.2)
adherence	Non	167 (65.5)	288 (66.4)	455 (65.5)
Social habits	Nil	39 (15.5)	80 (18.4)	119 (17.5)
	Alcoholic	57 (22.0)	110 (25.5)	167 (24.5)
	Smoker	59 (23.5)	93 (21.2)	152 (21.5)
	Alcoholic&	99 (38.5)	140 (32.5)	239 (34.2)
	Smoker			
	Abuse	02 (0.6)	12 (2.5)	14(2.2)
Education	Illiterate	141(55.5)	209 (48.2)	350 (50.4)
	Primary edu	66 (25.5)	102 (23.2)	168 (24.5)
	Secondary	32 (12.2)	75 (17.4)	107 (15.5)
	Pre university	13 (5.2)	34 (7.5)	52(6.5)
	university	04 (1.2)	15 (3.5)	19 14 (2.5)
Occupation	Student	17 (6.5)	22 (5.2)	39 36(5.4)
	Daily worker	55 (21.45	87 (20.2)	142 (20.4)
	Homemaker	32 (12.4)	85 (19.2)	117 (16.5)
	Agriculture	62 (24.5)	77 (3.6)	139 (20.3)
	Salaried/ Busin	29 (11.5)	49 (11.5)	11.4
	Unemployed	61 (23.5)	115 (26.4)	176 (25.2)
Socioeconomic	Upper	03 (1.2)	18 (4.2)	24 (3.2)
	Upper middle	12 (4.5)	54 (12.2)	65 (9.2)
	Middle Class	51(19.5)	98 (22.2)	149 (21.4)
	Lower Middle	91 (35.4)	129 (29.5)	220 (31.4)
	Lower Class	99 (38.8)	136(21.2)	235(34.2)

Adverse drug reaction

Out of 688 patients enrolled in the study 391 patients reported with 510 ADRs during the study period. The incidence of ADRs details is given in Table.

Table 2: Incidence of ADRs based on patient characteristics

Characteristics	Number of patients (n=688) with	Number of patients ADR (n=390)	Incidence	Number of ADRs (n=508)	Percentage of ADRs (%)
Category					
Inpatients	254	106	41.4	143	28.0
Out patients	434	285	65.5	367	71.9
Gender					
Male	288	190	65.5	239	46.8
Female	400	201	50.1	271	53.1
Age (years)					
Young Adults	88	31	34.8	48	9.4
Adults	316	187	58.9	258	50.5
Elderly (> 61)	284	173	60.7	204	40.0
Number of Medications					
1-2	317	218	68.5	261	51.1
3-4	257	108	41.8	159	31.1
>5	114	65	56.5	90	17.6
Medication Adherence					
Adherence	234	113	47.8	169	33.1
Non Adherence	454	278	61.0	341	66.8
Disease condition ICD-10					
(A00-B99)	128	107	82.9	176	34.5
(C00-D48)	1	1	100	1	0.1
(D50-D89)	18	9	50	13	2.5
(E00-E90)	286	145	50.3	152	29.8
(F00-F99)	7	4	57.1	6	1.1
(G00-G99)	29	17	58.6	24	4.7
(H00-H59)	2	1	50	1	0.1
(H60-H95)	2	1	50	1	0.1
(I00-I99)	44	23	52.2	26	5.0
(J00-J99)	22	16	72.7	21	4.1
(K00-K93)	23	11	47.8	13	2.5
(M00-M99)	18	6	33.3	9	1.7
(N00-N99)	10	4	40	7	1.3
(O00-O99)	15	8	53.3	12	2.3
(R00-R99)	75	34	45.3	42	8.2
(S00-T98)	1	1	100	1	0.1
(Z00-Z99)	7	3	42.8	5	0.9

Causality assessment of reported ADRs

Majority of the ADRs belonged to 'probable' in their causal relationship, as assessed by WHO probability Scale [n=219 (42.9%)], similar with study done by Rajeshreddy SGSV et al [17]. The causality categories of reported ADRs are presented in Figure.

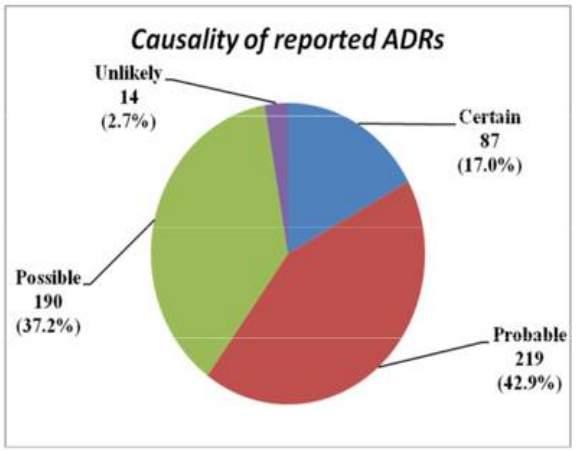

Figure 1: WHO-UMC Causality categories of reported ADRs

The WHO UMC proposed causality assessment is generally accepted method and most widely used method for causality assessment in clinical practice as they offered a simple methodology. Majority of the ADRs were assigned 'Probable' casual association between the adverse drug event and suspected drug.

Severity assessment of ADRs

Most of the reported ADRs were of 'Mild' in their severity and hence did not require withdrawal of the suspected drug especially when the benefits outweighed the risk. This finding coincides with Ponnusankar *et al*., Dindayal Patidar *et al* [18, 19]. The details of severity of ADRs are given in Figure.2

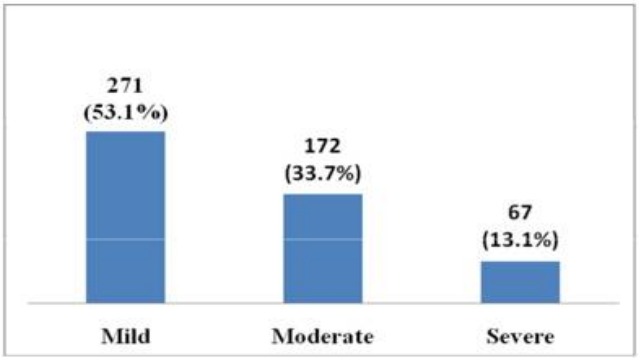

Figure 2: Severity of ADRs

Preventability of the ADRs

Of the 510 reported ADRs, 269 (52.7%) were classified as probable preventable, which is variance with the study done by Ponnusankar *et al* [18-21]. The details of the preventability of ADRs are presented in Figure.

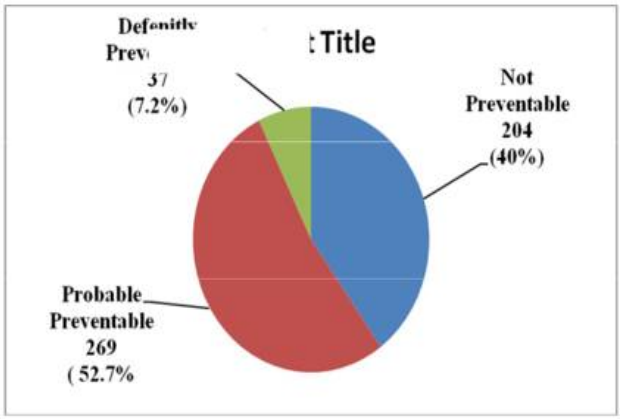

Figure 3: Preventability of ADRs

CONCLUSION

According to our research, the reports from the students were useful and contained information that was pertinent to clinical settings. By identifying novel, severe, and uncommon drug responses, ADR monitoring via spontaneous reporting systems contributes to patient safety. As future health care professionals, Pharm.D. Interns and postgraduate medical students should be exposed to ADR reporting during their clinical teaching placement. The current study focusses on the adverse drug reactions (ADRs) of antibiotics, cardiovascular, antidiabetic, and tubercular agents. It is crucial to observe the doctors who prescribe the most often prescribed medications in hospitals. Effective pharmacovigilance implementation would therefore lead to more stringent vigilance in the use of these medications and their safety evaluation, which would eventually improve patient care.

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