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EVALUATION AND ASSESSMENT OF ADVERSE DRUG REACTIONS DEVELOPED USING NEWLY PRESCRIBED DRUGS IN PATIENTS WITH ACUTE DISEASE

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ABSTRACT: The objective of current research is to assess the type of Adverse Drug Reactions (ADR) and associated risk factors, assess the prevalence, estimate the incidence of serious and fatal ADR and the severity of ADRs based on data collected from patients with ADRs caused by drug initially prescribed. Data of patients with acute diseases were collected and analyzed using SAS version 9.1. About 252 ADRs were identified among 183 patients. The majority of patients (70.49%) experienced one ADR reaction per patient. A higher risk of ADR was observed in the age group of 41-50 yrs (33.33%). The prevalence of ADR is predominant in adults (82.51%). ADR incidents were higher in gastrointestinal reactions (26.19%), with most of them identified by doctors or prescribers (44.41%). Suspected drug was withdrawn in 57.92% cases, specific and symptomatic treatment given to 45.23% followed by only symptiotic treatment for 30.95%. Definite improvement was predominant in challenged patients, whereas recurrence of symptoms was significantly observed among rechallenged patients with the respective suspected drug. According to the WHO probability scale and Naronj's scale, the causality assessment of ADRs indicates that possible and probable reactions were statistically significant. In 252 ADRs cases, 50% reactions predictable and 50% reactions were not-predictable. The study concluded that ADRs in patients with acute diseases are common and are preventable by spontaneous reporting of ADRs, proper documentation, and periodic reporting to regional pharmacovigilance centers to ensure drug safety.

INTRODUCTION: The WHO defines an ADR as "any response to a drug which is noxious and unintended and which occurs at doses used in man for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function". The incidence and severity of ADRs are influenced by patient characteristics such as age, gender, body weight, coexisting diseases, ethnicity, genetic or geographic factors and drug factors such as the type of drug, dosage, treatment duration, co-ingestion of other drugs, and route of administration [1,2].

ADRs can be grouped as one of the following; haematological (*e.g.* neutropenia, anaemia), dermatological (*e.g.* skin reactions), central nervous system (*e.g.* depression, epilepsy), metabolic (*e.g.* acidosis, diabetes, hyperkalaemia), reproductive (*e.g.* gynaecomastia, sexual dysfunction), gastrointestinal (*e.g.* nausea, vomiting, diarrhoea) bone disorders (*e.g.* osteopenia, osteoporosis), cardiovascular (e.*g.* arrhythmia, coronary angioplasty), hepatic (*e.g.* hepatitis, pancreatitis),

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neurological (*e.g*. peripheral neuropathy), renal (*e.g.* nephrotoxicity, renal failure) or other events [3-5]. The seriousness of ADRs can vary and may result in persistent or significant disability / incapacity, hospitalization, a medically important or life-threatening condition, or even death. They commonly occur as a result of pharmacokinetic interactions (*e.g*. drug absorption, drug excretion, enzyme induction, enzyme inhibition) or pharmacodynamics interactions (drug-drug interactions, e.g. synergistic interactions, opposing interactions) [6]. These occur due to the inability to know everything about a drug and its potential effects prior to it being marketed. However, some ADRs are caused, or perpetuated, by human practices. These comprise patient non-compliance with medication regimens as well as prescription and dispensing errors. Even though these complications seem inexorable, there are ways to curtail their occurrence and diminish their prevalence, such as focusing attention and study on particular groups of people who suffer more frequently from drug allergies and medication interactions [7, 8].

ADRs impact profoundly on our healthcare system, contributing significantly to patient morbidity, mortality, hospital admissions and healthcare costs. In attempt to closely monitor and help reduce the incidence of ADRs in the country, the National Department of Health has employed a Pharmacy and Therapeutics Pharmacovigilance committee to advise the Department of Health on issues relating to ADRs in order to promote the rational and cost-effective use of drugs in accordance with standard treatment guidelines [9-11].

The objectives of this committee are to promote the safety of the patient, endorse the rational and cost effective use of drugs, inform healthcare institutions of policy and guideline changes, promote awareness of ADRs and the need to report all suspected ADRs [12-14]. Developing awareness of the potential risks of medicines, while also understanding the extent of their benefits, is critical to addressing the problem of drug-induced diseases. Failing to maintain constant vigilance when using medicines in patients can have devastating and even fatal consequences. This vigilance is required throughout the patient-practitioner relationship, *i.e.* when patients are being asked about their medication use and medical history, when diagnosing a disease condition and when prescribing, monitoring and reassessing management. When a new medicine is released into the market, there is still a substantial amount that is unknown about the safety of the medicinal product [15, 16]. The patients that are studied in the pre-marketing clinical trials of new medicines are usually limited to a small number and are studied for a short period of time. Hence, only the more common ADRs are detected during the clinical trials. Information about rare but serious ADRs, drug interactions, chronic toxicity, and risks in special patient groups (*e.g.* pediatric groups, geriatric groups, males, females, certain race groups, pregnant women) is often not available or incomplete at the time of marketing [17, 18].

MATERIALS AND METHODOLOGY: A prospective observational study was conducted in various departments of a tertiary care teaching hospital for a period of two year. Prior to the initiation of the study, ethical clearance was obtained from the hospital ethical committee (IHEC/DRSER:0738/2). Inclusion criterion of this study was an association between chief complaints on admission and the drug newly prescribed patient or patient caretaker being adequately communicable. Hospital admissions attributed to complaints unrelated to newly prescribed drugs for acute conditions, ADRs caused by drugs prescribed for chronic conditions; either newly prescribed or chronically used drugs are excluded from the study.

Data of the patients (demographic details, past medical history, past medication history, laboratory investigations, suspected drug, drug stopped, drug reinitiated, provisional and conformational diagnosis, results of assessment of ADRs by various scales/criterion, treatment, interviewing patient and patient caretakers) with ADRs, caused by the drug initially prescribed admitted in hospital during the study period were collected and analysed. Case sheets of patients who were initially prescribed with a new drug for an acute condition and revisited with complaints related to that drug are assessed for the impact of medication used in the past on the current complaints. Based on the information available, the type of ADR (based on various ADR assessment scales WHO probability scale, Naronj's scale) and associated risk factors

were identified. Data Analysis: The categorical variables were represented in number and percentage. Data were analyzed using SAS version 9.1.chi-square and p values were calculated using Medcalc's calculator [19, 20].

RESULTS: In this study, 252 ADRs were identified among 183 patients who implicate the probability of multiple ADRs in a single patient. 129 (70.49%) patients experienced one adverse drug reaction followed by 42 (22.95%) patients who developed two adverse drug reactions while 12 (5.99%) patients developed more than or equal to three. Statistically, chi-square value is 21.26 and P value is <0.0001, hence statistically significant number of ADRs per patient is one. The higher prevalence of adverse drug reactions was observed in patients of age 41-50 years (33.33%) followed by 31-40 years (28.41%), 21-30 years (11.47%), 51-60 years (9.28%) 61-70 years (6.01), 11-20 years (04.91), 71-80 years (3.82%), 1-10 years (1.63%) and 81-90 years (1.09%). Statistically, chi-square value is 18.86 and p value is <0.0001, hence age (31-50 years) is statistically significant for the incidence of ADR at circumstances of this study.

Prevalence was predominant among adults 151(82.51%) over geriatric 20 (10.92%) and children 12(6.55%), while males have the higher risk to develop ADRs among children and adults whereas in geriatrics both the genders have high risk in developing ADRs. In terms of organ system the ADR incidence higher in gastrointestinal system 66(26.19%) followed by dermatology 55(21.82%), central nervous system 28(11.11%), endocrine system 22(8.73%), hepatic system andhaematology 15(5.95%) reactions and the remaining details are mentioned in **Table 1 Fig. 1.**

TABLE 1: ADRS WERE DISTRIBUTED ACCORDING TO THE WHO ART SYSTEM CODES

S. no.	System	ART Codes	No. of ADRs	Percentage	Chi-Square Value / P-Value
1	Dermatology	(100)	55	21.82	
2	Muscular skeletal	(200)	05	1.98	
3	Central nervous	(410)	28	11.11	
4	Ophthalmic	(420)	03	1.19	
5	Otic system	(431)	10	3.96	205.33/
6	Gastrointestinal	(600)	66	26.19	<0.0001
7	Hepatic system	(700)	15	5.95	
8	Endocrine	(900)	22	8.73	
9	Cardiovascular	(1000)	11	4.36	
10	Heamatology	(1200)	15	5.95	
11	Renal system	(1300)	09	3.57	
12	General disorders	(1810)	13	5.15	
	Total		252	99.94	

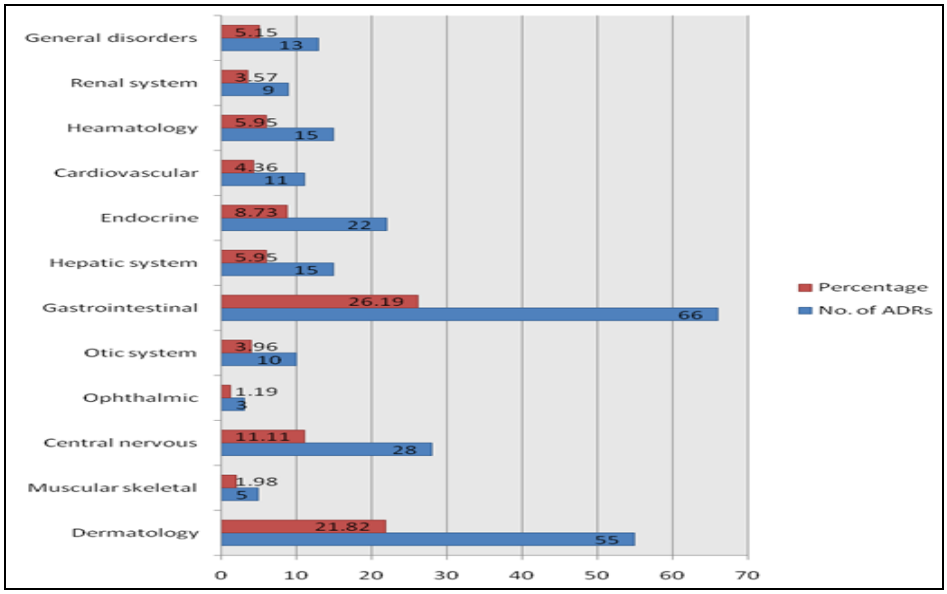

FIG. 1: ADRs WERE DISTRIBUTED ACCORDING TO THE WHO ART SYSTEM CODE

Statistically chi-square value is 205.33 and P-value as <0.0001, hence in gastrointestinal and dermatological systems are statistically significant. Categorisation of according to preferred term (WHO-ART) vs. suspected drug, for the drugs Ceftazidime, Fosfomycin, Rofecoxib, Ceftaroline Fosamil, Cephalothin, Meloxicam and Buprenorphine HCl was detailed in **Table 2.**

TABLE 2: ADRs WERE CATEGORIZED ACCORDING PREFERRED TERM (WHO-ART) VS. SUSPECTED DRUG

Drug	Preferred Term	No. of ADRs	Percentage
Ceftazidime 39	Loose stools	09	23.07
	Maculopapular Rashes	08	20.15
	Vomitings with food particles	04	10.25
	Hypokalemia	04	10.25
	Sweating	03	07.69
	Giddiness	03	07.69
	Ear pain	02	05.12
	Elevated serum Creatinine	02	05.12
	Tremor	02	05.12
	Tachycardia	02	05.12
Fosfomycin 44	Loose stools	11	25.00
	Rashes	10	22.27
	Hypokalemia	04	09.09
	Vomitings with food particles	03	06.81
	Increased AST/ALT levels	03	06.81
	Anemia	03	06.81
	Elevated serum Creatinine and BUN	03	06.81
	Tinnitus	03	06.81
Rofecoxib 39	General weakness	02	04.54
	Hypotension	02	04.54
	Erythematous	11	28.20
	Loose stools	08	20.51
	Hyperglycemia	05	12.82
	Vomitings with food particles	04	10.25
	Jaundice	03	07.69
	Fever with chills	02	05.12
	Ear pain and itching	02	05.12
	Elevated serum BUN	02	05.12
	Hypotension	02	05.12
Ceftaroline Fosamil 42	Rashes	09	21.42
	Loose stools	05	11.90
	Hepatitis	05	11.90
	Headache	04	09.52
	Hyperglycemia	03	07.14
	Giddiness	03	07.14
	Malaise	03	07.14
	Chills	03	07.14
	Hypernatremia	02	04.76
	Increased GGT levels	02	04.76
	Blurred vision	02	04.76
	Bradycardia	01	02.38
Cephalothin 21	Pruritis and Utricaria	07	33.33
	Abdominal pain	04	19.04
	Thrombocytopenia	03	14.28
	Fever with chills	03	14.28
	Hypoglycemia	02	09.52
	Hearing problem	02	09.52
Meloxicam 39	Burning sensation in abdomen region	11	28.20
	Dizziness and Headache	10	25.64
	Rashes	07	17.94
	Hemorrhage, Purpura	05	12.82
	Jaundice	02	05.12

	Nephritis	02	05.12
	Hearing problem	01	02.56
	Cardiac arrhythmias	01	02.56
Buprenorphine	Dizziness, Headache	08	42.10
Hydrochloride	Constipation	06	31.57
19	Hypotension	02	10.52
	Irritable skin	01	05.26
	Photosensitivity	01	05.26
	Hypoglycemia	01	05.26
Others	Anaemia	3	33.33
9	Rashes	2	22.22
	Blood vomiting	1	11.11
	Hyperkalemia	1	11.11
	Chest pain	1	11.11
	Hepatotoxicity	1	11.11

Most of ADRs were identified by doctors or prescribers 122(44.41%) followed by other health care professionals 72 (28.57%). Multiple drug therapy 67 (16.92%), Wrong time and administration 58(14.65%), Age 40(10.10%). The remaining details were mentioned in **Table 3 Fig. 2.**

TABLE 3: ADR's REPORTED PERSON

S. no.	ADR's reported Person	No. of ADRs	Percentage (%)	Chi-Square Value / P-Value
1	Doctors or Prescriber	122	44.41	
2	Other Health care Professionals	72	28.57	
3	Patient and patient care taker	36	14.28	94.79/
4	Pharmacist	22	8.73	<0.0001
	Total	252	99.99	

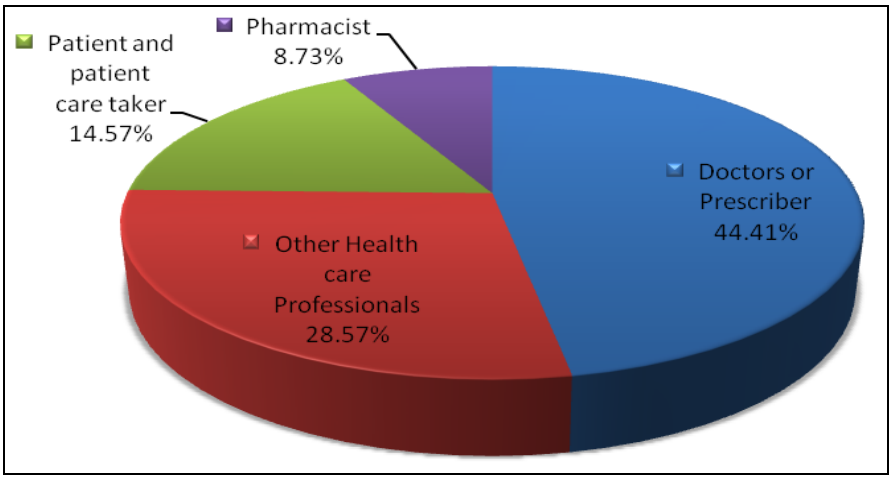

FIG. 2: ADRS REPORTED BY MANAGEMENT OF THE ADVERSE DRUG REACTION

Statistically chi-square value is 94.79 and p value is <0.0001, hence most of the reaction were reported by doctors or prescriber, it is statistically significant. Among 183 patients, suspected drug was withdrawn in 106(57.92%) patients followed by 48 (26.22%) patients dose were altered and no change in prescription in 29 (15.84) patients. The remaining details were mentioned in **Table 4 Fig. 3.**

TABLE 4: FATE OF THE SUSPECTED DRUG

S. no.	Fate of the suspected drug	No. of Patients	Percentage	Chi-Square Value / P-Value
1	Drug withdrawn	106	57.92	
2	Dose altered	48	26.22	52.75/
3	No change	29	15.84	<0.0001
	Total	183	99.99	

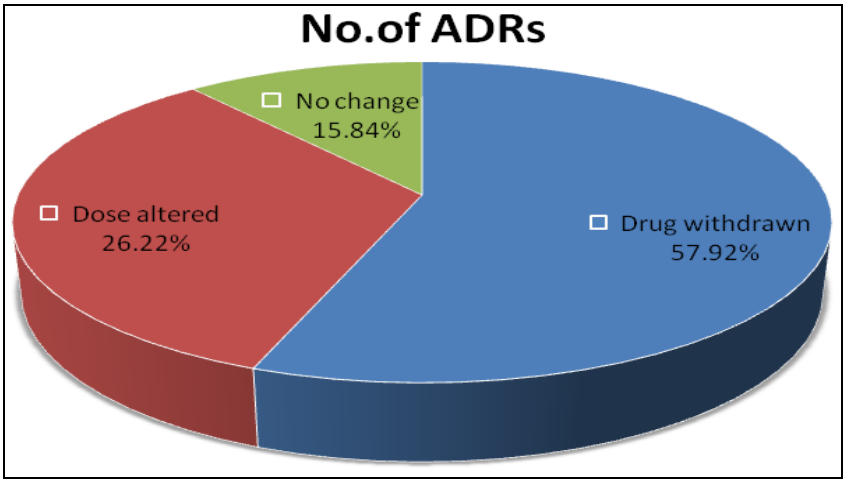

FIG. 3: FATE OF THE SUSPECTED DRUG

Statistically chi-square value is 52.75 and p value is <0.0001, hence most of cases where suspected drugs are withdrawn from treatment, its statistically significant. Among 252 ADRs, Specific and symptomatic treatment was given to 114 (45.23%) ADRs, followed by only symptomatic treatment was given to 78 (30.95%) ADRs. The remaining details were mentioned in **Table 5 Fig. 4.**

TABLE 5: TREATMENT FOR ADRs

S. no.	Treatment given	No. of ADRs	Percentage	Chi-Square Value / P-Value
1	Specific + Symptomatic	114	45.23	
2	Symptomatic	78	30.95	
3	Specific	42	16.66	84.00/
4	Nil	18	7.14	<0.0001
	Total	252	99.99	

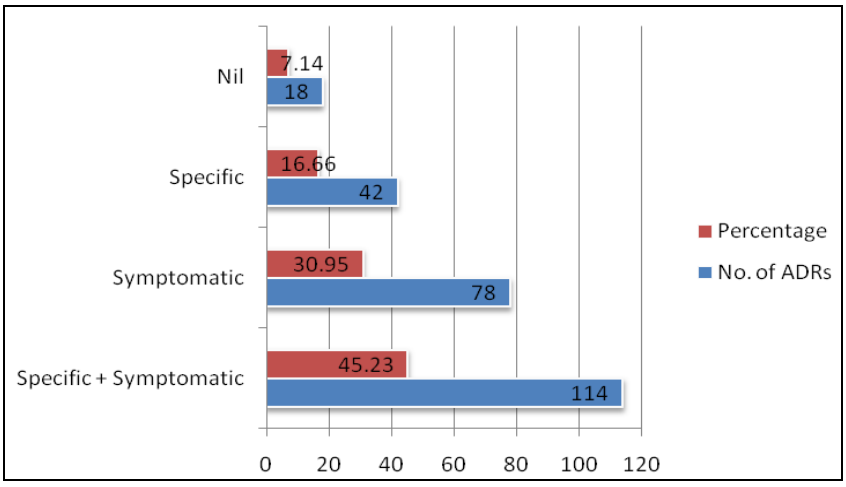

FIG. 4: TREATMENT FOR ADRs

Statistically chi-square value is 84.00 and P value is <0.0001, hence most of the patients were treated both specific and symptomatically, its statistically significant.

Dechallenge was done in 106 (57.92%) patients and the suspected drug was continued in 77 (42.07%) patients. Among 106 dechallenge patients drug was reinitiated in 36.79% and not reinitiated in 63.20% patients. Among 106 dechallenge patients the outcome of ADRs was definite improvement66 (62.26%) patients followed by no improvement was observed 19 (17.92%) patients and unknown information about in 21 (19.81%) patients. Drug withdrawal cases definite improvement was found to be statistically significant through chi-square value and p value.

Among 39 rechallenge patients the outcome of ADRs was as follows, recurrence of symptoms was

observed in 24 (61.53%) patients followed by no recurrence of symptoms in 10 (25.64%) patients and unknown patients are 5 (12.82%). Suspected drug withdraw cases, rechallenge cases Recurrence of symptoms were found to be statistically significant through chi-square value and P value. The remaining details were mentioned in **Table 6 Fig. 5.**

TABLE 6: DECHALLENGE AND RECHALLENGE INFORMATION

S. no.	Age group	ADR	Frequency	Percentage (%)	outcomes	Frequency	Percentage	Chi-Square Value / P-Value
1.	Dechallenge	Yes	106	57.92	Definite improvement	66	62.26	31.76/ <0.0001
					No improvement	19	17.92	
					Unknown	21	19.81	
					Chi-Square Value / P-Value	39.98/<0.0001		
		No	77	42.07				
2.	Rechallenge	Yes	39	36.79	Recurrence of symptoms	24	61.53	
					No recurrence of symptoms	10	25.64	
					Unknown	5	12.82	
					Chi-Square Value / P-Value	14.92/<0.0006		
		No	67	63.20				

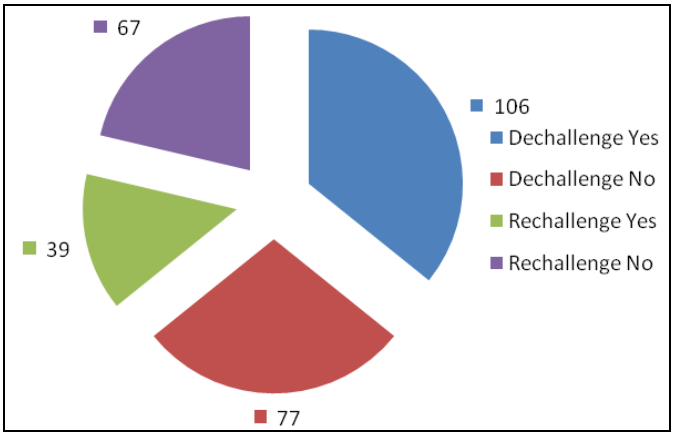

FIG. 5: DECHALLENGE AND RECHALLENGE INFORMATION

Among 252 ADRs, causality assessment of ADRs according to WHO probability scale was as follows, possible reactions in 112 (44.44%) patients followed by probable reactions in 98 (38.88%) patients, not assessable in 32 (12.69%) patients, unlikely reactions in 2 (0.79%) patients and conditional reactions in 2 (0.79%) in certain reactions in 6 (2.14%) patients. Possible and probable were found to be statistically significant through chi-square value and P value. Among 252 ADRs, assessment according to Naronj's scale was as follows, possible reactions in 135 (53.57%) patients followed by probable in 107 (42.46%) patients, unlikely in 5 (1.98%) and definite in 5 (1.98%) patients. Possible and probable were found to be statistically significant through chi-square value and P value.

The 252 ADRs severity was assessed, most of the patients are at level-4a 94(37.30%) followed by level-4b 81 (32.14%), at level-5 32 (12.69%) of patients, 31 (12.30%) patients at level-3 and 13 patients severity at mild 7(02.77%) and 6 (02.98%) patients are at level-1 and level-2 respectively. One (00.39%) patient had permanent harm at level-6. Level 4a and level 4b ADRs were found to be statistically significant through chi-square value and P value. The remaining details were mentioned in **Table 7 Fig. 6, 7.**

TABLE 7: CAUSALITY ASSESSMENT ADVERSE DRUG REACTIONS ACCORDING TO VARIOUS SCALES

ADR assessment scale	Category	No. of ADRs	Percentage	Chi-Square Value / P-Value
WHO probability scale	Certain	06	2.38	300.76/ <0.0001
	Probable	98	38.88	
	Possible	112	44.44	
	Unassessable / Unclassifiable	32	12.69	
	Unlikely	02	0.79	

	Conditional/Unclassified		02	0.79	
	Total		252	99.98	
Naronjo's scale	Definite		05	1.98	
	Probable		107	42.46	219.08/
	Possible		135	53.57	<0.0001
	Unlikely		05	1.98	
	Total		252	99.99	
Modified Hartwig and Siegel scales.	Mild	Level 1	07	02.77	
		Level 2	06	02.98	233.22/
	Moderate	Level 3	31	12.30	<0.0001
		Level 4a	94	37.30	
		Level 4b	81	32.14	
	Severe	Level 5	32	12.69	
		Level 6	01	00.39	
		Level 7	00	00.00	
	Total		252	99.99	

In 252 ADRs, most of them are not-predictable adverse drug reactions 141 (55.95%) followed by predictable ADRs are 111 (44.04%). No category under this distribution is found to be statistically significant, 50% reactions predictable and 50% reactions not-predictable. In 252 ADRs definitely preventable adverse drug reaction are 129 (51.19%) followed by probably preventable adverse drug reactions are 98 (38.88%) and not preventable are 25 (09.92%).Statistically definitely preventable and probably preventable were found to be statistically significant through chi-square value and P value. The remaining details were mentioned in **Table 8 Fig. 6 & 7.**

TABLE 8: ASSESSMENT ADVERSE DRUG REACTIONS PREDICTABILITY AND PREVENTABILITY

	Category	No. of ADRs	Percentage	Chi-Square Value / P-Value
Predictability	Predictable	111	44.04	
	Not Predictable	141	55.95	2.06/<0.07
	Total	252	99.99	
Preventability	Definitely Preventable	129	51.19	
	Probably Preventable	98	38.88	67.88/<0.0001
	Not Preventable	25	09.92	
	Total	252	99.98	

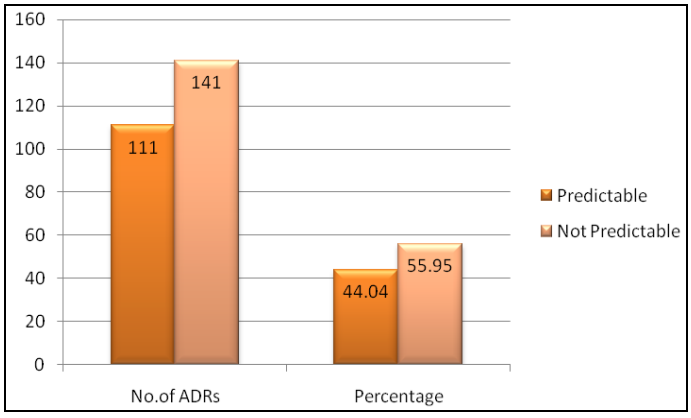

FIG. 6: ASSESSMENT ADVERSE DRUG REACTIONS PREDICTABILITY

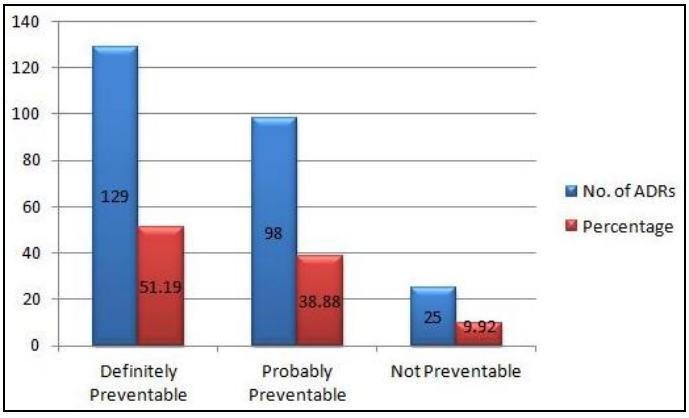

FIG. 7: ASSESSMENT ADVERSE DRUG REACTIONS PREVENTABILITY

DISCUSSION: During the study period total 6097 patients have newly prescribed medications among then 513(08.41%) patients have experienced at least one adverse drug reaction (ADR). Among the 513patients, 183(35.67%) patients were developed adverse drug reactions due to newly prescribed drugs which are used in diseases or acute diseases. Among the 183patients, 252 ADRs were identified, which shows the probability of multiple ADRs in a single patient. Adults (82.51%) were predominant over children and geriatric in terms of prevalence, while males have a higher risk to develop ADRs among children and adults whereas in geriatrics both the genders have a high risk in developing

ADRs. Among the 183 cases documented, males showed 1.61 times higher risk f to develop ADRs over females and patients from the urban area showed 1.57 times higher risk for ADRs over those from the rural area. Among 183 patients the higher prevalence of adverse drug reaction was observed in patients having a past medical history of CVS diseases and metabolic disease.

In this study gastrointestinal system (26.19%) was the most common organ system affected due to ADRs. The risk factors which are highly involved among ADRs are lack of knowledge (About ADRs) followed by poly pharmacy or multiple drug therapy. Most of ADRs were identified by doctors or prescribers. In 252 ADRs suspected drug was withdrawn and specific and symptomatic treatment was provided for most of the patients.

Among 106 dechallenge patients drug was reinitiated in 36.79% and not reinitiated in 63.20% patients. In 39 rechallenge patients, 61.53% patients have shown recurrence of symptoms whereas no recurrence of symptoms was observed 25.64% patients and recurrence is unknown in 12.82% patients.

Among 252 adverse drug reactions causality assessment of ADRs according to WHO probability scale, Naronj's scale and Karch & Lasagna's scale, most reactions are possible reactions. Most of the ADRs when assessed for severity were found to be at the level-4a and level-4b. Definitely preventable adverse drug reaction (51.19%) are found to be predominant followed by probably preventable adverse drug reaction (38.88%) and not preventable (09.92%).

CONCLUSION: Adverse drug reactions inflict a serious burden on hospitals through drag out patient stay and by increasing admission rates and the "direct costs" in ambulatory. The risk factors of ADRs need to be estimated and constrained in every patient to the possible extent.

Volunteer reporting of ADRs should be encouraged in order to avert avoidable ADRs in future especially in the urban areas where pharmacological management for every medical is readily available over the rural area. Much upgrading is needed in the interactions among pharmacokinetic, dynamic and genetic parameters to improve the therapy and to achieve drug safety, especially in female patients.

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