ADVERSE DRUG REACTIONS AND PHARMACOECONOMIC IMPACT ON PATIENTS ADMITTED IN MEDICINE DEPARTMENT OF A TEITARY CARE TEACHING HOSPITAL

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Abstract

To analyze adverse drug reactions and their Pharmacoeconomic impact. To increase a listing of signs for figuring out destructive drug activities in hospitalized patients. To compare the frequency, severity and preventability of destructive drug reactions stated from a medication department. To Development and compare predictors for the value control of destructive drug reactions. To Development and validation of a Predictor version for severity of destructive drug reactions in hospitalized patients. An ambispective observational have a look at become carried out in a tertiary care Teaching sanatorium of Medicine department. The information become labeled primarily based totally on numerous parameters like age, gender, co morbidities, medication utilization in Patients admitted with destructive drug reactions and sufferers recognized with destructive drug reactions after admission within side the sanatorium and their monetary burden at the sufferers have been amassed and analyzed. The occurrence of ADRs documented on this examine turned into better than the ones research mentioned from comparable examine set up. Many of the mentioned research used spontaneous reporting technique which turned into normally related to decrease charges of reporting. Use of extensive tracking technique primarily based totally on energetic surveillance of statistics is probably useful in higher detection and documentation of ADRs. This version will assist to expect the severity of a response for the duration of preliminary levels of growing ADR, thereby probably supporting in identifying control approach for a selected patient.

Keywords:- Adverse Drug Reactions, Pharmacoeconomic, medication department, Demographic, Management.

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INTRODUCTION

In India, Pharmacovigilance application become initiated most effective in early eighties. Under the management of Drug Controller General of India, 5 facilities have been concerned in tracking and reporting. In the early 1990s, Drugs Controller General of India (DCGI) has set up ADR reporting and tracking application with six nearby facilities for reporting and tracking of ADRs. Since its inception, the country wide Pharmacovigilance center, positioned in All India Institute of Medical Sciences (AIIMS), New Delhi, amassed reviews of ADRs from all of the six nearby Pharmacovigilance facilities. Later, Indian Council of Medical Research (ICMR), thru its studies application, had diagnosed and supported twelve coaching hospitals throughout the United States for few years for reporting and tracking of ADRs.

Definitions

Adverse reactions to pills are described as 'a reaction to a drug that's noxious and unintentional and which happens at doses typically utilized in man' Adverse drug event (ADE) is described because the damage due to the usage of drug. In a feel ADRs also are destructive occasions with causal hyperlink to pills. Normally ADEs don't have set up causal courting to the destructive incident suspected of a drug.

Incidence of ADRs in hospitalized sufferers:

The occurrence fees of ADRs vary broadly throughout special Studies. ADRs in health center in- sufferers are typically divided into sorts viz: Those who broaden ADRs all through hospitalization duration and people who're admitted to health center because of ADRs. There are reviews on each companies of sufferers from throughout the sector. Many of such research are from advanced nations like US and UK.

1. Age

Age is taken into consideration as chance aspect for evaluation, pediatric institution become targeted due to their immaturity of enzyme structures and aged institution become taken into consideration due to aggregate of physiologic and pharmacokinetic elements which makes them prone for ADRs.

2. Gender

Studies have suggested a distinction in ADR frequencies among adult males and girls. Findings of many research have cautioned a propensity for girls to revel in extra reactions.

3. Polypharmacy

In exercise polypharmacy has been described as the usage of extra than a positive variety of medicine regardless of the appropriateness of drug use .Some to be had research did now no longer locate affiliation among polypharmacy and ADR. But there are variety of research which cautioned the viable affiliation among expanded pills and destructive occasions.

4. Multiple pathologies as a chance aspect for ADRs

Multiple disorder situations have been diagnosed as an unbiased chance aspect for drug headaches. In a file the variety of scientific troubles become diagnosed as extensive medical correlates of affected person-suggested drug headaches in a unilabiate analyses.

5. Multiple physicians as a chance aspect for ADRs

Number of research has proven that with growing variety of prescriber will increase the hazard of irrelevant aggregate of medicine main to in addition headaches.

Methods for Identifying ADRs

Number of strategies is to be had to gather records on ADRs. Method of ADR identity approach impacts the cap potential to carry out causality evaluation and calculation of occurrence.

- Spontaneous voluntary and solicited reporting
- Chart overview
- Diagnostic coding
- Screening of laboratory tests
- Integrated automatic surveillance
- Patient self-reporting.

Pharmacoeconomic effect of ADRs

ADR influences the fitness care gadget and sufferers in lots of methods like: problem of current therapy, prolongation of health center live and expanded monetary burden. ADR adversely influences the pleasant of lifestyles of sufferers and outcomes in direct and oblique fee to the fitness care gadget and society.[1,2,3]

Number of research has assessed the fee of ADRs in kind of fitness care settings like number one to tertiary stage fitness care facilities and in popular remedy to uniqueness care settings. The fee predicted for ADR relies upon upon the united states in which it's miles studied to the extent of care and 12 months of have a look at The expenses suggested with the aid of using variety of research estimate few million bucks on the institutional stage to billions of bucks on the country wide

stage. ADRs constitute extensive burden to the fitness care structures round the sector in phrases of the assets it consumes to control the situation and oblique expenses related to it

Predicting fee of ADRs

There is a want to apprehend ADRs and examine it so one can lessen the fee of ADRs. Cost evaluation of ADR increases crucial problem like angle to be followed in reading the ADRs. Social angle is desired in a Pharmacoeconomic assessment because it consists of all of the applicable expenses (4).

Heath care expenses related to ADR has been suggested in variety of research. These expenses are basically health center expenses, in especially bobbing up from an boom in period of live due to an ADR. Usually fee of immoderate health center remains become used to calculate the extra fee of ADR control for coverage organizations or the fitness care gadget (5;6).

A have a look at from European have a look at predicted that the prevalence of an ADR all through hospitalization or main to hospitalization is chargeable for a median fee of € 2800. In research suggested from US, the fee of character ADRs have been with inside the variety of US$ 2000 to 4000 in step with affected person (7). Depending at the occurrence and severity of ADRs, the fee in step with destructive impact averted ranged from US$ 215 to US$ 35459 (7;8;9).

At the National stage it's been suggested that in-residence ADEs on my own were predicted to be US$ 2 million with inside the US for departments of inner remedy health center admissions and in Germany it's been predicted that ADR outcomes in direct fee of 0.four billion marks annually (10).

In a have a look at with the aid of using Ramesh et al from India confirmed that the common fee concerned in treating ADRs become Rs. 690/- (US$ 15) in step with affected person. The fee seems low to the affected person as maximum of fitness care expenses withinside the have a look at health center have been protected beneath Neath a charity fund and most effective minimum expenses have been at once borne with the aid of using the sufferers. (11)

In some other have a look at at the ADRs in an extensive care unit of a personal health center in India, it become suggested that the control of a mean ADR led to US$ 1537 (12). In some other have a look at wherein admissions because of ADRs have been studied and those hospitalizations led to a mean of US$ a hundred and fifty in step with admission (13).

Thus ADRs impose extensive monetary burden to fitness care structures with inside the advanced nations and in addition to growing nations like India. Use of modeling strategies in Pharmacoeconomic is turning into an increasing number of famous amongst fitness care organizations. The use of modeling strategies can help decision- makers in making extra knowledgeable medical, policy, and remedy selections in real-international scenario. Traditionally linear regression has been the approach of preference for growing fashions in predicting expenses related to fitness care (14).

Generalized linear fashions (GLM) are suggested to be appealing for the regression of fee records due to the fact they offer parametric strategies of evaluation in which a number of non-regular distributions may be unique and the manner covariates act may be altered. Unlike the usage of records transformation in regular least-squares regression, GLM make inferences approximately the imply fee at once (15,16,17,18).

Rationale to look

Indian council of Medical Research backed ADRs tracking application become performed with inside the have a look at health center. This have a look at become performed to pick out and gather ADR records of in-sufferers of Medicine and Specialty disciplines. (19,20,21,22). This have a look at become deliberate to gather the records on ADR and use the records for in addition evaluation of fee of ADRs and broaden prediction fashions for severity and fee. Since this have a look at become primarily based totally on chart overview process, it become envisaged to broaden a listing of indicator equipment for screening charts so that you can simplify the chart screening process. The uniqueness devices blanketed with inside the have a look at have been Cardiology and Dermatology.

Since there have been no suggested research on fee and severity prediction fashions in Indian settings, it become envisaged to perform such have a look at. It became concept such paintings may assist in drug protection studies on this United States withinside the route of modeling and prediction (23,24,25,26)..

METHODS:

An Ambispective observational study was conducted in a tertiary care Teaching hospital of Medicine department. The data was categorized based on various parameters like age, gender, co morbidities, medicine usage in Patients admitted with adverse drug reactions and patients diagnosed with adverse drug reactions after admission in the

hospital and their economic burden on the patients were collected and analyzed.

RESULTS:

The total number of admission in the male and female wards of the study unit of medicine department during the study period was 1056. These patients were intensively monitored by the investigator for ADRs. Over six months, a total of 214 ADRs from 230 patients (1.3 ADRs/patient) were identified and documented. Mean age (in years) of the patients was 45.92 .The occurrence ADRs were more in females when compared to males. Frequencies of ADRs among the age group of 31 to 45 years (32.24%) and 61 to 75 years (27.10%) were higher than other age groups (Table.1). Average number of drug taken by patients was 8 .The average length of stay of the patients was 5 days

Table 1. Demographic characteristic of patients

Characteristics	Number of patients with	Number of ADR related hospitalization, stay	ADR occurring during hospital stay,
		ADR (n=214)	(n=28)
Male	98(45.79%)	8 (4.47)	80 (44.19)
Female	116 (54.20%)	20 (10.57)	101 (55.80)
Age group			
16-30	32 (14.95)	1 (3.57)	21 (11.60)
31-45	69 (32.24)	6 (21.4)	64 (35.35)
46-60	53 (24.76)	8 (28.5)	46(25.41)
61-75	58 (27.10)	11 (39.2)	48 (28.17)

In the intensively followed group of 1056 patients (28) of patients were admitted due to ADRs. Incidence of ADRs during hospital stay was (181/1056). The overall incidence rate of ADR was 17.12% (214/1056). Type A Reactions accounted for 146 of the ADRs followed by Type B reactions 68 (Table 2)

Table.2 Classification and Assessment of ADRs

Parameters	**Number of ADRs(n=214)**
Type A	146 (68.22)
Type B	68 (31.77)
Causality	
Definite	5(2.33)
Probable	124 (57.94)
Possible	88 (41.12)
Onset ofADRs	
Acute (< 1 h)	15 (7.00)
Sub-acute (1 to 24 h)	101(4.19)
Latent (> 48 hrs)	98 (45.79)
Severity	
Mild	89 (41.58)
Moderate	117 (54.67)
Severe	8 (3.78)
Preventable	
Definitely preventable	67 (31.3.)
Probably preventable	18 (8.41)
Not preventable	129 (60.23)
Predisposing Factors	
Age	63 (29.43)
Gender (Female)	17 (7.94)
Multiple and inter-current disease	134 (62.61)
Polypharmacy	184 (85.98)
Minor	34 (18.47)
Moderate	28 (20.65)
Severe	112 (52.33)

Salbutamol produced the highest number of reactions (28; 8.83%) followed by Isoniazid, Rifampin, Pyrazinamide (52), and ceftriaxone (20). The organ systems affected due to ADRs are presented in (table 4).

Table 3. Drugs involved in ADRs.

DRUG	No ofADRs(%)	ADRs (No)
Furosemide	59	Hypokalemia (29), Vomiting (30),
Isoniazid, Rifampin, Pyrazinamide	52	Hepatocellular damage(24), Allergic reaction (28),
Ceftriaxone	20	Rash (9), Diarrhea(3), Vomiting (6), Nausea(1),Pruritus (1)
Isoniazid, Rifampin, Pyrazinamide, Ethambutol	16	Hepatocellular damage (9) Hypotension(3),Dizziness (2), Headache(2)
Amlodipine	12	Oedema peripheral (4) Constipation(5) Anemia megaloblastic(3)
Phenytoin	6	Allergic reaction (2), Nystagmus(2), Gastric pain (2)
Piperacillin and enzyme inhibitor Chloroquine	5	Rash (3), Diarrhoea(1), Fever (1)
Prednisolone	4	Diabetes mellitus (2), Peptic ulcer (1), Hypertension (1)
Insulin (Human)	3	Hypoglycaemia (1), Hypokalaemia (1), Vomiting (1)
Warfarin	4	Prothrombin decreased (2),Oedema (1), Allergic reaction (1)

Table 4. Organ systems affected due to ADRs

SYSTEM ORGAN INVOLVED (N)	ADRS OBSERVED (N)
Central & peripheral nervous system disorders (45)	Tremor (16), Dizziness (12), Headache (6), Nystagmus (5), Convulsions (2), Drowsiness (2), Hypertonia (1),Neuroleptic malignancy syndrome (1)
Liver and Biliary system disorders (26)	Hepatocellular damage (26)
Body as whole - general disorders (12)	Oedema (6), Allergic reaction (3), Fatigue (2), Fever (1)
Gastro-intestinal system disorders (54)	Vomiting (28), Diarrhea (12), Constipation (6), Nausea (2), Gastritis (2), Peptic ulcer (2), Gastric pain (2).
Skin and appendages disorders (32)	Rash (14), Rash Maculopapular (4), Urticaria (2), Puritus(2) Angioedema (2), Stevens Johnson Syndrome (3), Pruritus (2),Rash Erythematous (1), Skin discoloration (2)
Heart rate and rhythm disorders (3)	Bradycardia (3)
Metabolic and nutritional disorders (42)	Hypokalaemia (23), Diabetes mellitus (6), Hypoglycaemia (9),Acidosis lactic (2), Hyperglycaemia (2)

Gastrointestinal system was the most common organ system affected (54). The most frequently reported reaction was vomiting (28) followed by hepatocellular damage (26), hypokalemia (23), tremors (16) and dizziness (12). In majority (109) of the cases, the suspected drug was withdrawn for the management of the ADR and an additional treatment for the reaction was instituted in (84) of cases. An improvement in the ADR was observed in majority (108) of the cases if there was dechallenge or dose reduction (Table 5). Two patient died due to hepatotoxicity caused by anti-tubercular drugs.

Mild and moderate reactions accounted for (89) and (117) of the reports respectively and only (8) of the reactions were classified to be severe. Outcome of patients who had ADRs was generally good with 101 patients recovered from ADRs (Table 5).

Table 5. Management and outcome of the ADRs

MANAGEMENT	Number (N=214)
Drug withdrawn	109
Dose altered	7
Additional treatment given	84
No change in drug regimen and no additional treatment	14
OUTCOME AFTER DECHALLENGE/DOSE ALTERATION	
Improved	108
Not improved	62
Unknown	8
After rechallenge	14
Recurrence of symptoms	8
No recurrence of symptoms	10
Unknown	4
FINAL OUTCOME	
Fatal	2
Recovered	101
Continuing	86
Unknown	9

The average cost of management of ADRs was Rs. 1,243,674/- (US$ 16,786). In the current set up cost of the management is usually borne by patients as most of them do not have health care insurance.

Considering the economic conditions of an average patient, the cost of management of ADRs is a significant burden to many patients. Using the Naranjo algorithm, 124 ADRs were defined as 'probable' whereas 88 were defined as 'possible' and 5 were classified as 'Definite' in relation to the suspected drug. In 85 of cases, the reaction was considered to be preventable (definitely or probably preventable). The results are represented in Table 2. Based on the occurrence of the reaction with respect to the time of administration, 101 reactions were classified as sub-acute, followed by 98 reactions as late onset and 16 as acute (Table 6)

Table 6. Cost of ADRs based on organ system involved

SYSTEM ORGAN INVOLVED†	NO OF ADR (N = 214)	TOTAL COST (US$)	COST/ADR (US$)
Gastro-intestinal system disorders	54	2694	49.88
Central & peripheral nervous system disorders	45	986	21.91
Skin and appendages disorders	32	3892	121.62
Metabolic and nutritional disorders	41	2438	59.46
Liver and biliary system disorders	26	4420	170
Body as whole - general disorders	10	1009	100.9
Platelet, bleeding & clotting disorders	2	259	129.5
Respiratory system disorders	1	312	312
Cardiovascular disorders, general	2	289	144.5
Urinary system disorders	1	487	487
Total cost	214	16786	1596.7

Predisposing factors

At least one predisposing factor was present in all of these reports. Common predisposing factors like female gender, poly pharmacy and multiple disease state were noticed in 134, 63 and 17 of the cases respectively (Table 2). Incidence of ADRs among females was significantly higher than males. Among the reports with poly pharmacy mild (2-3 drugs), moderate (4-5 drugs) and major (>5 drugs) categories were present in 112, 34 and 28 of the reports, respectively. On average each patient had 3 coded diagnoses thus making multiple diseases as underlying risk factor for most of the patients.

Table 7 Cost of ADRs

ADR†	NO OF ADR	TOTAL COST (US$)	COST/ADR (US$)
Hepatocellular damage	34	6225	197.90
Hypokalemia	30	1935	73.71
Renal failure acute	2	1542	964.87
Rash	13	1412	69.91
Stevens Johnson Syndrome	1	1301	805.37
Vomiting	38	1520	46.11
Pancytopenia	5	1423	478.19
Diabetes Mellitus	2	1261	192.85
Prothrombin decreased	2	1192	331.17
Anemia megaloblastic	3	972	1016.09
Allergic reaction	31	1059	241.72
Leucopenia	2	852	185.60
Oedema peripheral	4	658	178.35
Others	47	3471	

1 US$ ~ Rs 74.09; †-Classification based on WHO-ART

Table 8 Cost based on severity of ADRs

Severity	Level	No of ADR	Total cost (US$)
Mild	Level 1	11	118.36
	Level 2	78	3642.39
Moderate	Level 3	65	3345.25
	Level 4 (a)	34	**6315.31**
	Level 4 (b)	18	**3212.21**
Severe	Level 5	5	1204.35
	Level 6	2	**1217.4**
	Level 7	1	**625.34**

1 US$ ~ Rs74.09

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VELOPMENT AND EVALUATION ADVERSE DRUG REACTIONS FOR THE COST OF MANAGEMENT OF ADRS.

The median hospital stay of patients with ADRs was 5 days (95%) and the average cost per patient hospitalized with an ADR was Rs. 5811.5/- (US$ 79). The total cost to the hospital due to ADRs was found to be Rs. 1,243,674/- (US$ 16,786). The cost of ADR was studied based on the organ system involved. The cost per ADR was the highest with liver and biliary system disorder with US$ 4420/- (Table 6). The individual ADRs that led to the highest cost for management was studied (Table 7). The cost of management of ADRs based on the severity of ADRs was assessed (Table 8). The important components of the overall cost of management of ADRs were studied to identify the component which contributes to the overall cost. It was identified that the Drugs and surgical supply is the cost component along with lab investigations which contributes significantly to the overall cost of management (9). 1 US$ ~ Rs 74.09; † classification based on WHO-ART

Table 9. Cost generating components of the drug-related events

Components of charges	In Rs	In US$
Drugs & surgical supply	80250	1083.21
Lab investigations	10700	144.43
Professional charges	21400	288.86
Bed/hospital stay	123050	1660.93
Nursing charges	256800	3466.29
Administrative charges	263648	3558.72
Amenities	27820	375.51
Total	783668	10577.95

US$ ~ Rs 74.09

The general variety of admission within side the male and girl wards of the examine unit of drugs branch at some point of the examine length became 1056. These sufferers had been intensively monitored via way of means of the investigator for ADRs. Over six months, a complete of 214 ADRs from 230 sufferers had been diagnosed and documented Frequencies of ADRs some of the age organization of 31 to forty five years (32.24%) and sixty one to seventy five years (27.10%) had been better than different age groups. The median medical institution live of sufferers with ADRs became five days (95%) and the common value in line with affected person hospitalized with an ADR became Rs. 5811.five/- (US$ 79). The general value to the medical institution because of ADRs became discovered to be Rs. 1,243,674/- (US$ 16,786). The value of ADR became studied primarily based totally at the organ gadget involved. The value in line with ADR became the best with liver and biliary gadget sickness with US$ 4420/-. The man or woman ADRs that brought about the best value for control became studied

DISCUSSION:

The total number of admission in the male and female wards of the study unit of medicine department during the study period was 1056. These patients were intensively monitored by the investigator for ADRs. Over six months, a total of 214 ADRs from 230 patients (1.3 ADRs/patient) were identified and documented. Mean age (in years) of the patients was 45.92 .The occurrence ADRs were more in females when compared to males. Frequencies of ADRs among the age group of 31 to 45 years (32.24%) and 61 to 75 years (27.10%) were higher than other age groups (Table.1). Average number of drug taken by patients was 8 .The average length of stay of the patients was 5 days. In the intensively followed group of 1056 patients (28) of patients were admitted due to ADRs. Incidence of ADRs during hospital stay was (181/1056). The overall incidence rate of ADR was 17.12% (214/1056). Type A Reactions accounted for 146 of the ADRs followed by Type B reactions 68

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LIMITATIONS OF THE STUDY:

Random selection of patients was done in our study. So, the results cannot be generalized to all the patients admitted in the Hospital, as many cases might have been missed during night shifts. Rechallenge was not performed for many ADR cases and this might alter the causality if such information is available for all the cases. While polypharmacy was found to be a significant risk factor for ADR, the therapeutic rationale of individual prescriptions were not assessed thus any underlying problems with the prescriptions were not identified.

CONCLUSION

This study was aimed to review the amount of aspects on ADRs like development of indicators for ADEs, study the pattern, causality of ADRs in numerous departments like Medicine, Dermatology and Cardiology and develop prediction models for the severity and price of management of ADRs in certain departments. There are number of how much to watch ADEs and therefore use of ADE indictors to screen them provides an alternate method for detecting them.

Intensive monitoring was administered in one medicine unit of the study hospital. The aim of this work was to check the pattern, drugs involved, severity, outcomes and preventability of adverse drug reactions using intensive monitoring was disbursed. Prospective, intensive monitoring was carried out over a period of 6 months. The WHO definition of ADR was adopted. Use of intensive monitoring approach supported active surveillance of records could be helpful in better detection and documentation of ADRs.

The aim of the present work was to review the price related to documented adverse drug reactions within the medicine department of the study hospital. Data of intensive monitoring study was wont to assess the value of management of ADRs. Cost of management per adverse reaction was found to be Rs. 5811.5/- (US$ 79). The limitation of this model is that it absolutely developed supported the price pattern of the study hospital and it has to be tested in an exceedingly large dataset to reinforce its prediction. Once this model is validated using large datasets its potential application in predicting the cost of management of ADRs.

The collected data on ADRs from medicine and other departments gave an image on ADRs in these departments. The developed predictive models highlighted the potential applications of this approach during this discipline.

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