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RESEARCH ARTICLE

Evaluation of Adverse Drug Reactions in General Medicine Department of a Tertiary Care Hospital: A Cross-sectional study

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ABSTRACT

Background: In hospital settings, Adverse Drug Reactions (ADRs) are the major cause for the increased length of hospital stay, cost, morbidity and mortality. The study aim to evaluate the incidence, risk factors, prevalence of the ADRs in Hospital. **Materials and methods:** This is prospective, cross-sectional study conducted in general medicine department of a tertiary care referral hospital located in Hyderabad, Telangana, India. All patient related data was collected by using a suitably designed data collection form. Any untoward event after administration of the drug was labeled as adverse drug reaction after discussing with concerned physician. Descriptive statistics were used to represent socio-demographic, clinical, and ADR profile of the study participants. **Results and Discussion:** A total of 412 patients were recruited from the general medicine department of the hospital, among these patients 114 ADRs are observed and documented. Age more than 60 years was strongly associated to develop ADRs. The major organ system affected due to ADRs are as follows, skin (37; 32.4%), gastro intestinal tract (26; 22.8%), and cardiovascular system (10; 8.7%). ADRs are also affected other organ system like Liver, blood, central nervous system, kidney, respiratory system and body. The most common drugs involved are Antibiotics and NSAIDs. **Conclusion:** The study concludes that, the ADRs appeared in this study are moderate in nature where there is no harm to the patient. This study had improved the acceptance of ADRs caused by the drugs and also given interventions on case to case basis.

Keywords: Icariin, Partial sciatic nerve ligation, Neuropathic Pain

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CONTENTS

1. Introduction

According to World Health Organization (WHO) Adverse Drug Reaction means (ADR) "any noxious or unintended effect produced by the drug when it will be used in a doses for prophylactic, therapeutic, diagnostic and prevention of disease or alteration of physiological function". [1] ADRs in hospital patients were divided into two broad categories, one is patients admitted into hospital due to ADR and another one is, after admission into hospital the patient may develop ADR. [2] ADR oriented hospital admission rate is 5%, whereas ADRs developed after admission was 10-20%. [3]. ADRs are one of the major cause for morbidity and mortality. Early detection of ADRs is essential to save life and to improve quality of life. [4] ADRs are also associated with raise in length of hospital stay, risk of infections, costs and prevents progression of the disease. [5] Previous studies shows that spontaneous reporting and active surveillance system play a vital role in the detection of ADRs and to give appropriate management strategies. [6] Most of the studies relation to ADR reporting were conducted in well developed countries. The reasons may be availability of electronic health records, and patients are insured for their health care. [7]. In developing countries like India, reporting of ADRs is still infant stage. The major reasons are, healthcare professional are unaware, stigma among public, flexible regulatory system, and ADR reporting is not mandatory. [8] The current study aims to evaluate the ADRs in a general medicine department, where there will be high scope to use various types of drugs and combinations.

2. Materials and Methods

This is prospective, cross-sectional study conducted in general medicine department of a tertiary care referral hospital located in Hyderabad, Telangana, India. The study was conducted for a period of one year from February 2016 to January 2017. During this study period all in-patients age more than 18 years, irrespective of gender who are willing to participate in to the study were enrolled. Pediatrics, out-patients, and in-patients stayed less than 24 hours were excluded from the study.

Ethical considerations:

The study was conducted after getting ethical approval from the institutional ethics committee. The information collected from patients was kept confidential throughout the study. All serious adverse events and events require any type therapeutic intervention was communicated to concerned physician.

Sample size:

The sample size was calculated by using Epi-Info 7 statistical software given center for disease control. The estimated sample size was 384 by assuming 95% confidence interval, 80% power, 5% margin of error, and 50% of expected frequency from previous study. By assuming 20% dropout rate the final sample size was calculated as 460.

Data collection:

All patient related data was collected by using a suitably designed data collection form. The major data sources used are patient case sheet, laboratory data, medication charts and nursing notes. Any untoward event after administration of the drug was labeled as adverse drug reaction after discussing with concerned physician. The study was not imposed any type of modifications in treatment, diagnosis, and laboratory advices. The patient will follow the medical care given by the hospital.

Statistical analysis:

Descriptive statistics were used to represent socio-demographic, clinical, and ADR profile of the study participants. Inferential statistics like chi-square test was used to associate the factors for development of ADRs.

3. Results and Discussion

A total of 412 patients were recruited from the general medicine department of the hospital, among these patients 114 ADRs are observed and documented. Age more than 60 years was strongly associated to develop ADRs. Most of the participants were belongs to female gender (51.9%), and literate (51.2%). All levels of socio-economic status group patients were present in the study. Most of the patients were comprise more than two drugs. The socio-demographic profile and ADR profile of the participants were represented in Table 1.

The causality assessment of the observed ADRs revealed that, nearly 80% of the ADRs are probable according to Narinjo scale. Nearly 50% of the ADRs are not preventable according to preventability scale. Most of the ADRs were moderate (77.2%) according severity scale. The results of the causality, preventability, and severity were represented in Table 2.

The major organ system affected due to ADRs are as follows, skin (37; 32.4%), gastro intestinal tract (26; 22.8%), and cardiovascular system (10; 8.7%). ADRs are also affected other organ system like Liver, blood, central nervous system, kidney, respiratory system and body. All the findings of the ADRs in various body system were represented in Table 3. The study findings relates to drugs involved and observed ADRs were represented in Table 4 and 5. The most common drugs involved are Antibiotics and NSAIDs.

Discussion

Adverse drug reaction (ADR) rates in clinical trials often understate those in practice. Post Marketing surveillance is employed to help overcome the limitations in ADR identification in clinical trials. This arises from many factors including: inadequate sample size, limited trial duration, restricted range of assessed outcomes, and relative exclusion of precisely those patients most likely to experience adverse effects, such as the elderly and those with poly pharmacy and co-morbidities.

The prevalence of ADRs in this study was 27.6%. Worldwide various studies reported the incidence rate ADRs was 6-20%. [10] The study shows that most of the ADRs are observed in elderly people than young people. The similar type of findings are also observed in the study conducted by Gor*et al*. [11] The causality assessment of the observed ADRs revealed that, nearly 80% of the ADRs are probable according to Narinjo scale. Nearly 50% of the ADRs are not preventable according to preventability scale. Most of the ADRs were moderate (77.2%) according severity scale. These findings are slightly contrast with Peter *et al*. [12]. The major organ system affected due to ADRs are as follows, skin (37; 32.4%), gastro intestinal tract (26; 22.8%), and cardiovascular system (10; 8.7%). The similar type of findings are also observed in the study conducted by Venkatasubbaiah *et al*. (9)

Strengths and weaknesses:

This study gives an evidence of the most common ADRs appearing in the hospital. This information is helpful for the healthcare professionals working in the hospital to combat ADRs. This study promotes the culture of ADR reporting by the healthcare providers. The study gives only evidence in in-patient department. This may not apply for the OP and ambulatory patient.

Table 1: Socio-demographic characteristics and ADR characteristics in study population (n=412)

Variable	Frequency (%)	ADRs No. (%)	Chi-square value	P-value
Age in years (Mean ± SD)				
18-30	96(23.30)	17(14.9)	81.5311	0.0021
31-40	110(26.69)	19(16.6)		
41-50	100(24.27)	16(14.03)		
51-60	49(11.89)	25(21.9)		
>60	57(13.83)	37(32.4)		
Gender				
Male	198(48.05)	53(46.4)	0.1546	0.6941
Female	214(51.94)	61(53.5)		
Education status				
Illiterate	201(48.78)	53(46.4)	0.3315	0.5647
Literate	211(51.21)	61(53.5)		
Socio-economic status				
Upper	107(25.97)	31(27.1)		
Middle	101(24.51)	27(23.6)	1.3793	0.2402
Lower middle	106(25.72)	33(28.9)		
Lower	98(23.78)	23(20.1)		
Length of hospital stay (days) (Mean ±SD)				
1-2				
3-4	97(23.54)	9(7.8)		
5-6	110(26.69)	26(22.8)	1.6739	0.4875
>6 days	104(25.24)	37(32.4)		
	101(24.51)	42(36.8)		
Number of drugs in a prescription (Mean ±SD)				
1-2	85(20.63)	11(9.6)		
3-4	101(24.51)	22(19.2)	2.6566	0.1031
5-6	115(27.91)	39(34.2)		
>6 drugs	111(26.94)	42(36.8)		

SD=Standard Deviation; ADR=Adverse Drug Reaction

Table 2: Causality, preventability, and severity of observed ADRs (n=114)

Causality	Frequency (%)
Highly probable	13(11.45)
Probable	91(79.82)
Possible	9(7.89)
Unlikely	1(0.87)
Preventability	Frequency (%)
Definitely preventable	9(7.89)
Probably preventable	51(44.73)
Not preventable	54(47.36)
Severity	Frequency (%)
Mild	16(14.03)
Moderate	88(77.19)

Severe	10(24.56)
Fatal	0(0)

ADR: Adverse Drug Reaction

Table 3: Distribution of ADRs according to Organ/System

Organ/System	Frequency (%)
Skin	37(32.45)
GI tract	26(22.80)
Hepatic (Liver)	4(3.50)
Cardiac	10(8.77)
Hematology	4(3.50)
CNS	8(7.50)
Renal (Kidney)	11(9.65)
Respiratory system	5(4.38)
Body	9(7.89)

ADR=Adverse Drug Reaction

Table 4: Distribution of ADRs according therapeutic class and Type

Drugs	Frequency (%)	Type A	Type B
Antibiotics	43(37.71)	15(13.15)	30(26.38)
NSAIDS	17(14.91)	13(11.40)	4(3.50)
Anti-epileptics	9(7.89)	0(0)	7(6.14)
ATT	7(6.14)	3(2.63)	4(3.50)
Anti-amoebic drugs	5(4.38)	6(5.26)	0(0)
Anti-platelet & Anti-coagulants	4(3.50)	5(4.38)	0(0)
Diuretics	8(7.01)	3(2.63)	1(0.87)
Anti-hypertensives	3(2.63)	5(4.38)	0
Anti- cancer drugs	2(1.75)	2(1.75)	1(0.87)
Diagnostic contrast	6(5.26)	0(0)	5(4.38)
media drugs	0(0)	0(0)	0(0)
Others	11(9.64)	5(4.38)	5(4.38)

ATT=Anti Tubercular Therapy; ADR=Adverse Drug Reaction; NSAID=Non-Steroidal Anti-Inflammatory Drugs

Table 5: Details of most commonly observed ADRs and their causative drugs

Observed ADRs	Causative Drug	Frequency
Acute upper GI bleeding (Duodenal Erosion)	L.M.W Heparin+aspirin+clopidogrel	2
Delusions, hallucinations	Inj.gentamycin+inj metronidazole	4
Hyponatremia	Cefeperazone +spironolactone	2
Severe constipation	Diclofenac+metronidazole	1
Edema of both upper limbs	Diclofenac. Inj +tramadol 50mg BD+ Inj.augmentin 1.2g	4
Acute gastritis, Induced Oesophageal, Ulcer, gastritis & upper GI Bleeding 2 episode of malena.	Digoxin + cefazolin	3
Gastritis (loose stools &vomiting)	Moxifloxacin + cefeperazone sulbactum	4
Increase in serum Creatinine	Inj.Diclofenac + Nimesulide 500mg BD	3
Tachycardia, cardiac arrest	Cefeperazone, sulbactam + spironolactone	4
Allergic reaction, Multiple rashes all over, the body	Ciprofloxacin+tinidazole	2
Allergic reaction, Allergic reaction over upper and lower limbs	ATT (Pyrazinamide, Rifampicin + isoniazid)	2
Increase in serum urea levels	ATT (Pyrazinamide, Rifampicin + isoniazid)	2
Visual Disturbances, loss of vision	ATT (Pyrazinamide, Rifampicin + isoniazid)	2
Urticaria and rashes all over the body	Phenytoin+carbamazepine	2
Hepatitis	ATT (Pyrazinamide, Rifampicin + isoniazid)	2
Anemia, Thrombocytopenia	Carbamazepine+ceftazidine	4

ADR=Adverse Drug Reaction

4. Conclusion

The study concludes that, the ADRs appeared in this study are moderate in nature where there is no harm to the patient. This study had improved the acceptance of ADRs caused by the drugs and also given interventions on case to case

basis. Most of the physicians are interested in reporting ADRs after completion of this study.

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6. Conflict of interest

All authors doesn't have any conflict of interest in publication of this study

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