

Prevalence of Adverse Drug Reactions in Patients of Internal Medicine Department in a Tertiary Care Hospital in West Rajasthan: A Prospective Study

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Conflict of interest: Nil

Background: To study the prevalence of adverse drug reaction in internal medicine department.

Methods: This prospective observational study was conducted for the duration of six months from June 2014 to November 2014 to analyse the occurrence of ADRs in hospitalized patients of internal medicine department at PBM hospital associated with Sardar Patel Medical College, a tertiary care teaching hospital in Bikaner, Rajasthan.

Results: A total of 3892 patients were hospitalized in the study period of six months in the medicine department. Out of which a total of 54 patients experienced an ADR, giving an incidence rate of 1.4%.

Conclusion: Hospital based monitoring of ADR and reporting is an important programme to identify and quantify the risks associated with the use of drugs. This information may be useful in identifying and minimizing ADRs.

Keywords: ADR, Prevalence, Medicine.

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Introduction

Adverse drug reactions (ADRs) are common and often preventable cause of hospital admission. Detection and monitoring of ADRs is of vital importance for patient safety, as more than 50% of approved drugs are associated with some type of adverse effects that are not detected prior to their approval for clinical use. [1] A landmark study by Lazarou and colleagues found that ADRs to be the fourth to sixth leading cause of death in united states and serious ADRs accounted for 6.7% of hospitalized admission. [2] ADRs are a significant problem in health care that reduces the quality of care received by

patients and increases the total costs of healthcare. Not surprisingly, prevention is the most efficient and human strategy. Research suggested that as many as 50% of ADRs are preventable. [3]

Material and Methods

This prospective observational study was conducted for the duration of six months from June 2014 to November 2014 to analyse the occurrence of ADRs in hospitalized patients of Internal Medicine Department at PBM hospital associated with Sardar Patel Medical College, a tertiary care teaching hospital in Bikaner,

Rajasthan. This institute has been recently approved as a regional pharmacovigilance centre in year 2013.

All the patients who were admitted in medicine department and developed an ADR were included in study.

Inclusion Criteria:

- Patients receiving new drug or established drugs.
- Patients age between 6 to 70 years.
- Hospitalized patient
- Negative urine pregnancy test
- Exposure to other agent

Exclusion Criteria:

- Pregnant women
- Serious ill/moribund patients
- Drug abuse or addiction
- Severe psychiatric disorder (eg. schizophrenia)
- Inability to function independently
- Non cooperative patients
- Patients (<6 year and >70 year)

Study Procedure:

54 patients with suspected ADR were included in the study.

ADR data were collected by spontaneous reporting by health care professionals (Residents, Nurses, Physicians) through suspected ADR reporting form made available at medicine department. For each

patients with suspected ADR, a detailed history including drug history, personal history, family history, present and past medical history were documented. Any untoward event was labeled as adverse drug reaction after discussion with the treating physician.

Regular awareness and motivational programme for the patients to report any suspected ADR was conducted. They were motivated to report the suspected ADR verbally.

A thorough clinical evaluation and scrutiny of data was done to assess severity, to detect any predisposing factors, to assess the probability that reaction was drug related.

Observation and Results

This prospective observational study was conducted for the duration of six months to analyse the occurrence of ADRs in hospitalized patients of internal medicine department at PBM hospital associated with Sardar Patel Medical College, a tertiary care teaching hospital in Bikaner, Rajasthan. This institute has been recently approved as a regional Pharmacovigilance center in year 2013.

A total of 3892 patients were hospitalized in the study period of six months in the medicine department. Out of which a total of 54 patients experienced an ADR, giving an incidence rate of 1.4%.

Table I Gender Distribution

Male		Female		Total	
No.	%	No.	%	No.	%
42	78	12	22	54	100

The demographic characteristics for age of total 54 subjects enrolled in the study with gender distribution. Majority of the study subjects (70%) having a suspected ADR, comes in the adults age group (19-60 years.) followed by elderly subjects (61-70 years) 24%. Paediatric age group (6-18 years) constitute 6% of the subjects having an ADR.

Table II Age Distribution

Age in Year	Male		Female		Total	
	No.	%	No.	%	No.	%
6-18 (Paediatric Age Group)	1	2	2	16.6	3	6
19-60 (Adult Age Group)	29	69	9	75	38	70
61-70 (Elderly)	12	29	1	8.3	13	24
Total	42	100	12	100	54	100

The socioeconomic status of study subjects, assessed based on the modified Kuppuswamy scale of socioeconomic status. Majority of subjects (44%) falls in the category of upper-lower class followed by 39% from lower middle class and 17% from upper middle class.

Table III Socioeconomic Status

Socioeconomic Status	No.	%
I Upper	0	0
II Upper Middle	9	17
III Lower Middle	21	39
IV Upper Lower	24	44
V Lower Lower	0	0
Total	54	100

Discussion

This prospective observational study was conducted for the duration of six months from June 2014 to November 2014 to analyse the occurrence of ADRs in hospitalized patients of internal medicine department at PBM hospital associated with Sardar Patel Medical College, a tertiary care teaching hospital in Bikaner, Rajasthan.

Adverse drug reactions are a common occurrence, but are often not recognized. Even if they are recognized they are under reported as many physicians are unaware that clinically important ADRs should be reported to ADRs monitoring centres.

Adverse drug reactions have to be considered as one of the major causes of iatrogenic disease and are as old as medicine itself. They can have a detrimental effect on a patient's wellbeing and the overall health care system. A comprehensive ongoing ADR program in a hospital can help to complement organizational risk management activities, assess the safety of drug therapies, measure ADR incidence rates over time a educate health care professionals on drug effects and increase their level of awareness regarding ADRs. Further, periodic evaluation of ADR data for incidence and patterns is essential. Dissemination of this information to health care professionals helps in promoting drug safety in institutions. In general no drug is absolutely safe and an ADR can occur when

it is administrated alone or in combination. A continuously ongoing ADR program in a hospital can help to improve organizational risk management activities, assess the safety of drug therapies, measure ADR incidence rates over time and educate health care professional on drug effects and increase their level of awareness regarding ADRs. [4-6]

Furthermore, periodic evaluation of ADR data for incidence and patterns is essential. The accuracy of this information to the health care professionals helps in promoting drug safety and better patient care.

In our study the gender distribution of total 54 subjects enrolled in the study revealed that majority of study subjects (78%) are male having an ADR, indicating male dominance, which is in accordance with a previous prospective observational spontaneous reporting study [7] in which a total of 103 ADRs were identified out of which 55 (53.40%) patients were male and 48 (46.40%) were female patients which indicates that the prevalence of ADR is more in men than in women. Similar results were shown in an another study conducted by Harsha R (2012-2013) in south Indian hospital showed that in gender distribution, majority of study subjects were male (70%) indicating higher incidence of ADR in males. [8,9]

Similar results were also shown in an another prospective spontaneous reporting study on adverse drug reactions of

antibiotics in a tertiary care hospital conducted by Shamna M and his colleagues for a period of six months revealed that a total of 49 ADRs were reported among them male patients 26 (53.06%) predominated over females 23 (46.93%) in ADR occurrence similar results were shown in an another prospective study conducted by Palanisamy S *et al* [10] in 2009 at a multi-speciality tertiary care teaching hospital in South India revealed that out of 96 ADRs reported, nearly 59% were males indicating male dominance. [11]

Conclusion

Hospital based monitoring of ADR and reporting is an important programme to identify and quantify the risks associated with the use of drugs. This information may be useful in identifying and minimizing ADRs.

References

1. Rabbur RSM, Emmerton L: An introduction to adverse drug reporting system in different countries. *Int J Pharm Prac.* 2005; 13(1): 91-100.
2. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: A meta-analysis of prospective studies. *JAMA.* 1998; 279(15): 1200-1205.
3. Dorman H, Criegee – Rieck M, Neubert A, Egger T *et al.* Lack of awareness of community acquired adverse drug reaction upon hospital admission: Dimensions and consequences of a dilemma. *Drug safety.* 2003;26(5): 353-362.
4. Arulmani R, Rajendran SD and Suresh B. Adverse drug reaction monitoring in a secondary care hospital in South India. *Br J clin pharmacol.* 2008; 65(2): 210-216.
5. Chuenjid K, Peter RN, Darren MA. Hospital admission associated with adverse drug reaction: A systemic review of prospective observational studies. *Ann paharmacother* 2008; 7(8):1017-1025
6. Spyros PD, Demosthenes M and Thomas P. Adverse drug reactions as a cause of hospital admissions. A 6-months experience in a single centre in Greece. *European Journal of International Medicine* 2008; November: 505-510.
7. Gor AP and Desai SV. Adverse drug reaction in the in-patients of medicine department of a rural tertiary care teaching hospital and influence of pharmacovigilance in reporting ADR. *Indian J Pharmacol.* 2008;40 (1): 37-40.
8. Harsha. A study assessment, monitoring and documentation of adverse drug reactions. *IJPTP.* 2012; 3(2): 253-256.
9. M. Shamna *et al.* A prospective study on ADRs of antibiotics in a tertiary care hospital, *IJPCR,* 2012:3(2)
10. Palanisamy S, Kumaran AK, Rajasekaran A. A study on assessment, monitoring, documentation and reporting of adverse drug reaction at a multi-specialty tertiary care hospital in South India. *Int J Pharmatech Res.* 2009; 1(4): 1519-1522.
11. Syamsuddin, Edysyamsuddin. Maggot Development of Maggot: The development of *Hermetia Illucens* larvae as a life cycle balance of the Black Soldier Fly. *Current Science.* 2023; 3(2): 294–299.