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Original Research Article

Evaluate the Adverse Drug Reactions Data Procured from in Patients of Internal Medicine Department in a Tertiary Care Hospital in West Rajasthan: A Prospective Study

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Background: This prospective study is carried out to evaluate the ADRs in inpatients of Internal medicine department of P.B.M. Hospital, attached to S.P. Medical College, Bikaner (Rajasthan).

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: The severity of ADR based on modified hartwig scale with gender distribution. Table shows majority of ADR (59%) comes in mild category followed by moderate category in 41% of study subjects. No subject shows severe ADR.

Conclusion: We concluded that ADR monitoring and reporting by pharmacovigilance programme is needed to provide the optimum patient care.

Keywords: ADR, Severity, Organ.

Introduction

ADRs are one among leading cause of death and the incidence of ADRs in Indian population ranges between 1.8-25.1% with 8% resulting in hospitalization. [1] Data on ADRs are poor and inadequate and upto 50% of ADRs are unrecognized by attending physicians. [2] Because of significant health and economic costs associated with ADEs, regulatory authorities invest significantly (eg. staff & resources) in evaluating the risk of treatments and in monitoring the safety of drug throughout the lifetime of their use. This occurs mainly through pharmacovigilance and post marketing surveillance (PMS). PMS, the continuous safety monitoring of all drug, plays a critical role in drug safety and drug therapy decision making. PMS monitors drug safety through collecting and analyzing voluntary spontaneous reports, submitted by healthcare professional (HCPs), pharmaceutical companies and patients. HCPs are encouraged to voluntarily report ADRs to drug regulatory authorities. [3]
Pharmacovigilance also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of

adverse effect with pharmaceutical products. [4]

National pharmacovigilance protocol, Ministry of Health and Family Welfare, Government of India, is the pharmacovigilance regulatory authority in India. [5] Spontaneous reporting system (SRS) by health care professional (HCP), a common method of ADR reporting, serves as the backbone for pharmacovigilance. The main drawback of spontaneous reporting system by HCP is under reporting and selective reporting. This can lead to false conclusion about drug risk. Therefore, including patients as reporters of ADRs may increase its early detection and reporting and provide useful added source of information as patients are found to perceive ADRs more rapidly and clearly than HCP. [6] With the existing limited and inconsistent ADR data, more studies at institutional level can generate valid ADR information. Hence this prospective study is carried out to identify and evaluate the ADRs in inpatients of Internal medicine department of P.B.M. Hospital, attached to S.P. Medical College, Bikaner (Rajasthan).

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

Table 1: Organ System Affected

Organ System	Male		Female		Total	
	No.	%	No	%	No.	%
Skin	24	57	7	59	31	57
Gastrointestinal	10	24	3	25	13	24
CNS	1	2	1	8	2	4
Musculoskeletal	4	10	0	0	4	8
Respiratory	2	5	1	8	3	5
Genito urinary	1	2	0	0	1	2
Total	42	100	12	100	54	100

The organ system affected due to ADRs with gender distribution. The commonest organ system involved in ADR was skin (Dermatological) accounting for 57% of total ADR. This was followed by involvement of G.I. system in 24%, musculoskeletal system in 8%, Respiratory system in 5% and genitourinary system in 2% of study subjects.

Table 2: Suspected Therapeutic Class of Drugs

Class of Drug	Male		Female		Total	
	No.	%	No	%	No.	%
Antimicrobial	25	60	9	75	34	63
PPIs	3	7	0	0	3	5
NSAIDS	3	7	1	8.3	4	8
Antiemetic	1	2.5	1	8.3	2	4
Corticosteroid	1	2.5	0	0	1	2
Antisera (ASV)	3	7	0	0	3	5
Opioid analgesics	2	5	1	8.3	3	5
Antidepressants	2	5	0	0	2	4
Antipsychotic	1	2.5	0	0	1	2
Antiepileptic	1	2.5	0	0	1	2
Total	42	100	12	100	54	100

The suspected therapeutic class of drugs causing ADR with gender distribution. The majority of the ADR were caused by antimicrobial agents (63%) followed by NSAIDS causing ADR in 8% of study subjects. PPIS, Antisera (ASV) and opioid analgesics each caused ADR in 5% subjects followed by antiemetic (4%), antidepressants (4%) corticosteriod (2%) Antipsychotic (2%) and antiepileptic drugs (2%).

Table 3: Causality Assessment

Causality	Male		Female		Total	
	No.	%	No	%	No.	%
Definite ADR	0	0	0	0	0	0
Probable ADR	30	71	7	58	37	69
Possible ADR	12	29	5	42	17	31
Doubtful ADR	0	0	0	0	0	0
Total	42	100	12	100	54	100

The majority of ADR comes in category of probable ADR (69%) followed by possible ADR in 31% subjects. No ADR comes in definite or doubtful ADR category.

Table 4: Severity

Severity	Male		Female		Total	
	No.	%	No	%	No.	%
Mild	24	57	8	67	32	59
Moderate	18	43	4	33	22	41
Severe	0	0	0	0	0	0
Total	42	100	12	100	54	100

The severity of ADR based on modified Hartwig scale with gender distribution. Table shows majority of ADR (59%) comes in mild category followed by moderate category in 41% of study subjects. No subject shows severe ADR

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.

The present study showed that majority of ADR comes in category of probable ADR (69%), which are in accordance with study conducted by Arulmani R *et al* [7] in which about two thirds of reactions(62.2%) were classified as probable. It is corresponds to the study conducted by Harsha R et al [8] in South Indian hospital, regarding causality assessment done by using Naranjo's scale revealed that majority (52%) of ADRs were evaluated as being probable, followed by possible(45%) and 3% of ADRs belonged to definite category.

Causality assessment done by using Naranjo's scale in a study [9] which revealed that out of 103 ADRs, majority of ADRs 41(39.80%) were definite, it is followed by 36(34.95%) were probable, 23(22.33%) were possible and 3(2.91%) were unlikely related to drug.

In our study no ADR comes in definite or doubtful ADR category.

While considering the severity of ADR based on modified Hartwig scale with gender distribution in our study majority of ADRs (59%) comes in mild category. It is accordance with the study [10] in which majority of reactions(53.7%) were also mild. In our study no subject showed severe ADR.

The analysis of the fate of the suspected drugs showed that the drug was withdrawn in many of the cases and the dose altered in the some while no change was made with suspected drug in others because of considering the risk benefit ratio in specific patients. Drug re-challenge was not done in any of the cases. [11]

In our study vast majority of the patients were recovered from ADR because none of the reported reactions was fatal. Most of the cases needed treatment for recovery from reactions in which many of them were treated symptomatically.

The results provided insight to the health care providers on the importance of monitoring and reporting of ADRs.

Monitoring of ADRs is an ongoing ceaseless and continuing process. Though pharmacovigilance is still in its infancy in India, this is likely to expand in the times to come. This is because, as the newer and newer drugs hit the market, the need for pharmacovigilance grows more than ever before. Therefore, monitoring of the adverse effects of newer drugs particularly of serious nature is mandatory.

Although present study has some limitations like enrollment of only indoor patients, inability to assess outcome after de-challenge and re-challenge, inability to perform logistic regression on the number

of drugs administered as a parameter, this study would definitely give an insight into the pattern of ADR in the medicine department in a tertiary care hospital and may help to increase awareness for further pharmacovigilance studies.

Conclusion

We concluded that ADR monitoring and reporting by pharmacovigilance programme is needed to provide the optimum patient care.

References

1. Sriram S, Ghasemi A, Ramaswamy R, Devi M, Balasubramanian R, Ravi TK, Sabzghabaee AM: Prevalence of ADR at a private tertiary care hospital in South India. JRMS. 2011; 16(1): 16-25.
2. Fracas A, Bojita M, Adverse drug reactions in clinical practice. A causality assessment of a case of drug induced pancreatitis. J Gastrointestin Liver Dis. 2009; 18 (3): 353-58.
3. Belton KJ, The European pharmacovigilance research group Attitude survey of adverse drug reaction reporting by health care professional across the European Union. European journal of clinical pharmacology. 1997; 52(6): 424-427.
4. Mc Gettigan P, Golden J, Conroy RM, Arthur N, Feely J. Reporting of adverse drug reactions by hospital doctors and the response to intervention. Br J clin pharmacol. 1997; 44:98-100.
5. Phatak, Abimanyu, Nagari BG. Safety of medicines. Pharma Times. 2003;35: 19-21.
6. Fitzgerald P. Pharmacovigilance inspections Indian J Pharmacol. 2008; 40:28-30
7. 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.
8. Harsha. A study assessment, monitoring and documentation of adverse drug reactions. IJPTP. 2012;3 (2):253-256.
9. Rabbur RSM, Emmerton L: An introduction to adverse drug reporting system in different countries. Int J Pharm Prac. 2005; 13(1): 91-100.
10. 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.
11. Tamubango Kitoko H. Accouchement prématuré aux cliniques universitaires de Lubumbashi de 2011-2019: fréquence et prise en charge. Journal of Medical Research and Health Sciences, 2023;6(2): 2457–2470.