DOI: 10.55522/jmpas.v7i3.0174 ISSN NO. 2320 – 7418

International peer reviewed open access journal

Journal of Medical Pharmaceutical and Allied Sciences

Journal homepage: www.jmpas.com CODEN: JMPACO

Research article

A study of adverse drug reactions in a tertiary care hospital of Pune

Steffi Jerry Mammen*

Clinical Pharmacist, Inamdar Multispecialty Hospital, Pune, Maharashtra, India

Corresponding author: Steffi Jerry Mammen, ✉ steffi.thomas@ymail.com

Clinical Pharmacist, Inamdar Multispecialty Hospital, Pune, Maharashtra, India

Received – 25 March 2018**, Revised** - 04 April 2018, **Accepted** – 28 April 2018 **(DD-MM-YYYY)**

Refer This Article

Steffi Jerry Mammen, 2018. A study of adverse drug reactions in a tertiary care hospital of Pune. Journal of medical pharmaceutical and allied sciences, V 7 - I 3, Pages -667 – 669. Doi: https://doi.org/10.55522/jmpas.V7I3.0174.

ABSTRACT

To study the adverse drug reactions reported from wards and critical units in a tertiary care hospital of Pune. The adverse drug reactions were analyzed by Naranjo's algorithm scale and Hart wig severity assessment scale and the outcomes were studied. This observational and cross-sectional study was conducted for 6 months from November 2016-May 2017 in an inpatient setting of a tertiary care hospital of Pune. Patients of all age groups and either sex were included in this study. The adverse drug reactions were checked for their causality and severity by performing the Naranjo's algorithm scale and Hart wig's scale respectively. Data analysis was done by descriptive statistics. Total 50 adverse drug reactions were reported from wards and critical units. 21-30 years age group was reported to have more adverse drug reactions. The most common organ affected is the Skin 32 (71.11%), followed by Respiratory system 3 (6.66%) and nervous system 3 (6.66%). Vancomycin 5 (20%) was the drug having majority of the ADR's. The commonly reported ADR in this study was rash and itching 29 (64.44%). According to Naranjo's algorithm scale, 23 (51.11%) suspected ADR's were probable, 17 (37.77%) ADR's were possible and 5(11.11%) were definite. As per Hart wig's severity assessment scale, majority of the ADR's were mild 21 (46.66%), followed by moderate 20 (44.44%) and severe 4 (8.88%). The outcome of the ADR's was all recovered 38 (84.44%) during the study period. Study was conducted only in wards and critical units not in all departments of the hospital.

Keywords: Pharmacovigilance, chemotherapy, Adverse drug reactions, Oncology Tertiary, Care hospital.

INTRODUCTION

Drugs have primarily used for diagnosis, prevention, treatment of various diseases and to alleviate pain. But it is sometimes observed, that these drugs have been proved fatal. This could be due to variable person-to-person response towards a drug. Even at therapeutic doses, people develop adverse effects. World health organization (WHO) defines an adverse drug reaction (ADR)," As a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function" According to epidemiological studies, ADR's account to 5% of hospital admissions and occur in 10-20% of hospitalized patients. It is the 7th leading cause of death. ADR's are a leading cause of morbidity and mortality in many countries. It is a great concern for public, medical professionals, pharmaceutical industry and regulatory authorities.

India is a country which has supported the WHO program for global monitoring of ADR's that wholly depends on spontaneous reporting. Spontaneous reporting is a very cost effective and affordable system which can identify rare adverse reactions and generate early signals for new drugs.

Objective

To study the adverse drug reactions reported from wards and critical units in a tertiary care hospital of Pune.

To analyze the adverse drug reactions by Naranjo's algorithm scale and Hart wig severity assessment scale and determine the outcome [1, 2].

METHODOLOGY

This observational and cross-sectional study was conducted for 6months from November 2016-May 2017 in an inpatient setting of a tertiary care hospital in Pune. The data was captured only in wards

and critical units. Patients of all age groups and either sex were included in this study. The Adverse Drug Reaction form filled by Resident MedicalOfficer was considered. The documentation of the adverse drug reaction form was maintained by the clinical pharmacist for evaluation and further study. The adverse drug reactions were checked for their causality and severity by performing the Naranjo's algorithm scale and Hart wig's scale respectively. The outcomes were studied. Data analysis was done by descriptive statistics.

Exclusion criteria: Known allergies or previous history given by patients regarding drug allergies are excluded from this study. OPD patients are also excluded. The use of alternative system of medicines such as Ayurveda, Homeopathy, Unani. As well as over dosage, excess consumption, was excluded. Patients who are mentally retarded, drug addicted, suicidal tendencies or consumption of a drug in the influence of alcohol was also excluded [3-7].

Statistics: Description statistics were used for data analysis.

RESULTS AND DISCUSSION

In this study, 50patients were reported to experience an ADR during the study. 5 ADR cases were discarded as more than one suspected drug was documented. Out of 45patients, 24 (53.33%) were females and 21 (46.66%) were males. The median age of the patients was 25. The patient who documented an ADR was as young as 9months and the oldest was of 84years. Majority of the patients experiencing an ADR were belonging in the age group of 21-30years (Table 1). It was also found that, the most common route of administration for suspected drugs was Intravenous 30 (66.66%), followed by oral 5(11.11%) and then topical 4 (8.88%) (Table-2). As shown in the (Table-3) the most common organ affected is the Skin 32 (71.11%), followed by Respiratory system 3 (6.66%) and nervous system 3 (6.66%).

The drug class which encountered commonly with ADR's was Antimicrobials 22 (48.88%), followed by NSAID's 5 (11.11%) (Table-4). Vancomycin 5 (20%) was the drug having majority of the ADR's. The commonly reported ADR in this study was rash and itching 29 (64.44%). According to Naranjo's algorithm scale, 23 (51.11%) suspected ADR's were probable,

17 (37.77%) ADR's were possible and 5(11.11%) were definite (Table-5, 6). As per Hart wig's severity assessment scale, majority of the ADR's were mild 21 (46.66%), followed by moderate 20(44.44%) and severe 4 (8.88%) (Table7, 8). The outcome of the ADR's was all recovered 38 (84.44%) during the study period (Table-9) [8-12].

CONCLUSION

Adverse drug reactions is a drug related problem and if proper monitoring is done, it can contribute to drug safety. Rational use of antibiotics can help reduce the occurrence of ADR's to a great extent. In this study, 25 suspected drugs were reported to induce ADRs. After an ADR, the drug was withdrawn and recalling was not performed in any patient. Majority of ADRs experienced was, more in females than in males. This study mainly focused on ADRs admitted as Inpatients in wards and critical units. The most common route of administration was intravenous. ADR's were more in Antimicrobials, followed by NSAID's, and Vancomycin was the drug having majority of the ADR's. The commonly reported ADR in this study was rash and itching. Majority of the ADR's in this study were mild in nature and mostly all recovered during the study period. There is a need for more of spontaneous reporting by all health care professionals working in various departments in a tertiary care hospital. After an ADR occurrence, patient counseling in mandatory so that the patient is aware about it and can avoid further exposure to the drug in future. This can also help in reducing the length of stay of patients and also can be cost effective. The active involvement of clinical pharmacist to capture ADR's and awareness given via training to other health care professionals can help change the scenario in under-reported hospitals.

REFERENCES

1. M Shamna, C Dilip, M Ajmal, 2014. A prospective study on adverse drug reactions of antibiotics in a tertiary care hospital. Saudi P'ceutical Jou. 22, Pages 303–308. Doi: 10.1016/j.jsps.2013.06.004.

2. Hui li, Xiao Jing Guo, et al, 2014. Adverse drug reactions of spontaneous reports in Shangai pediatric population. PLoS ONE 9(2). Doi: https://doi.org/10.1371/journal.pone.0089829.

3. Lateef M. Khan, Sameer E. Al-Harthi, Omar I. Saadah 2013. Adverse drug reactions in hospitalized pediatric patients of Saudi Arabian University Hospital and impact of pharmacovigilance in reporting ADR. Saudi Pharmaceutical Journal. 21, Pages 261–266. Doi: 10.1016/j.jsps.2012.09.004.

4. Padmaja Uday Kumar, Prabha Adhikari, Pratibha Periera, 2009. A Prospective Analysis of Adverse Drug Reactions in a South Indian Hospital. Online Journal of Health and Allied Sciences. 8(3), Pages 1-6. Doi: http://www.ojhas.org/issue31/2009-3-12.htm.

5. Joel Thomas, Joshin Sara Cherian, Feba Susan Varghese, Shelina Hephzibah S, Vijay MC, Lijo James, 2018. Clinical Adverse Drug Reaction of Anti-Neoplastic Agents. JMPAS, jour. Of med. Phar and allied sci. V 7 - I 2, 755, 2018, 1000-1007.

6. Iwalewa EO, Iwalewa OJ, Adeboye JO, 2003. Analgesic, antipyretic, anti-inflammatory effects of methanol, chloroform and ether extracts Vernonia cinerea less leaf. J Ethnopharmacol; 8, Pages 229-34. Doi:10.1016/S0378-8741(03)00081-3.

7. Mazumder U, Gupta M, Manikandan L, 2003. Evaluation of Anti-inflammatory Activity of Vernonia cinerea Less. Extract in Rats. Phyto medicine. 10, Pages 185. Doi: 10.1078/094471103321659915.

8. Purnima A, 2009. Evaluation of Analgesic and Antipyretic Activities of Centratherum anthelminticum (L) Kuntze Seed,

Indian J. Pharm. Sci. 71(4), Pages 461-464. Doi: 10.4103/0250-474X.57302.

9. Akio M, Tomoki N, Tatsuo W, 1988. Pattern differences in experimental fevers induced by endotoxin endogenous pyrogens and prostaglandins. Am J Physiol. 254, Pages 633-640. Doi: 10.1152/ajpregu.1988.254.4.R633.

10. Singh o, 2012. Phytochemical investigation and antifungal activity of the seeds of centratherum anthelminticum; Kuntze, Acta Poloniae Pharmaceutical Drug Research. 69(6), Pages 1183-1187. Doi: 10.3923/ijp.2013.211.226.

11. Nyuyen DT, DP Orgill, GF Murphy, 2009. The Pathophysiologic Basis for Wound Healing and Cutaneous Regeneration. In: Biomaterial For Treating Skin Loss, Woodhead Publishing Ltd, USA. Pages 25-57. Doi: https://doi.org/10.1533/9781845695545.1.25.

12. Naranjo CA, Busto U, Sellers EM, 1981. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 80, Pages 289–95. Doi: 10.1038/clpt.1981.154.