|| ISSN(online): 2589-8698 || ISSN(print): 2589-868X ||
International Journal of Medical and Biomedical Studies
Available Online at www.ijmbs.info
NLM (National Library of Medicine ID: 101738825)
Index Copernicus Value 2019: 79.34
Original Research Article
Volume 5, Issue 11; November: 2021; Page No. 151-154

CUTANEOUS ADVERSE DRUG REACTIONS IN TERTIARY HOSPITAL (ADVERSE DRUG REACTION OF CUTANEOUS IN TERTIARY CARE HOSPITAL: A RETROSPECTIVE STUDY.)

Dr. Samkit Shah[1], Dr Atul Giri[2]
[1] Assistant Professor Dept of Dermatology, Vedantaa Institute of Medical Sciences, Saswand, Dhundalwadi, Palgahr, Maharashtra
[2] Assistant Professor Dept of Dermatology, Vedantaa Institute of Medical Sciences, Saswand, Dhundalwadi, Palgahr (Maharashtra)

Article Info: Received 04 October 2021; Accepted 03 November 2021
DOI: https://doi.org/10.32553/ijmbs.v5i11.1928
Corresponding author: Dr Atul Giri
Conflict of interest: No conflict of interest.

Abstract

Introduction: The term “adverse drug reaction" is defined as the noxious response that occurs due to administration of a drug and this response is resulted when the drug is administered within the permissible dose intended for prophylactic, therapeutic or diagnostic purpose of a disease. About 30% of adverse drug reactions (ADR) appear as cutaneous form. The developed countries (in-patient incidence 1-3%) in comparison developing nations (2-5% in same category) report lesser cases of cutaneous ADR.

Objectives: The study intends to find incidence of cutaneous adverse drug reactions in a tertiary care hospital and the responsible classes of drug.

Materials and Methods: This retrospective study has considered 50 patients. the records of the patients were obtained from the hospital record and the type of ADR and the drugs each patient used, were obtained and evaluated.

Result: the study has found that most common ADR is maculopapular rash, contributing to 32% of the total patients which is followed by other cutaneous ADR like are to urticaria, exfoliative dermatitis and eczematous eruption. The study has also found that the most common cutaneous ADR causing classes of drug is the anti-microbials, followed by NSAIDs and steroids.

Conclusion: Cutaneous ADR should be well known by the clinicians, it can be tackled at right time and hence can be minimized. Antimicribials, NSAIDs and steroid managements should be taken care as they cause ADR the most often. Swift detection and appropriate response are essential to minimize the burden of the management.

Keywords: adr, cutaneous, drug reactions, antimicrobials

Introduction

According to World Health Organization, the term “adverse drug reaction" is defined as the noxious response that occurs due to administration of a drug and this response is resulted when the drug is administered within the permissible dose intended for prophylactic, therapeutic or diagnostic purpose of a disease. Traditionally, there are two types of adverse reaction, Type A and Type B. Type A refers to the side effects which are dose dependent while Type B refers to allergic reaction which is not dose dependent and also occurs unpredictably.There are many kinds of drugs that can cause a drug reaction, some common classes of such drugs are sulfonamides, NSAIDs, fluoroquinolones, antibiotics, angiotensin converting enzyme inhibitors, etc.[1]. Type A constitutes about 90% of all adverse drug reaction cases while Type B contributes about 15% of all cases. Again, about 30% ADRs are of cutaneous nature. [2]. ADRs are many a times harmless and also self-limited but in several cases they can be fatal for e.g. in toxic epidermal necrolysis [3]. The market is flooding with new types of drugs and this when accompanied with self-medication and easy availability of drugs over the counter has increased the chances of ADRs manifold than it was previously [4]. Dermatologists now-a-days have a frequent encounter with CADR (cutaneous adverse drug reactions). Few important causes of CADRs are: Atopy, genetic makeup of the patient in which the drug is acting *in-vivo,* HLA variation, comorbidities, current immunity level, presence of any ongoing viral infection, interaction of that drug with other drugs taken by the patient; some drugs prescribed as a treatment for tuberculosis are known to have severe CADRs [4]. The success rate of detecting drug reactions of new drugs prior-launch is nearly 50% only [4]. The developed countries (in-patient incidence 1-3%) in comparison developing nations (2-5% in same category) report lesser cases of CADRs [5]. The geriatric population fall an easy victim to ADRs as they are on multiple drugs and according to a study about 75% such patients faced this after discharge from hospital to a preliminary health care shelter [6, 7].

Aims and Objectives

The study intends to find the overall incidence of cutaneous adverse drug reactions in a tertiary care hospital in northern part of India. This study has considered ADR arising from

any drug and also intends to find the ADR occurring in each of the class of drugs.

Materials and Methods

This study is retrospective design. It was conducted between June 2021 and September 2021. The study has considered patients who visited the OPD of the Dermatology Department. The chief complaint of all the patients was cutaneous manifestation with a history of drug administration. The inclusion criteria followed were the patient's confirmed drug history, patients were between 5 years and 75 years old, the patient who came to Dermatology Department (OPD), the patients who had only cutaneous manifestations. The exclusion criteria followed were the incomplete patient record, the patient with other existing chronic diseases and the patient who was not confirmed ADR due to discontinuation of diagnosis. Applying all the inclusion and exclusion criteria, the study considered 50 patients.

The records of the patients were obtained from the hospital and were analysed. The drugs due to which the ADR occurred and the type of ADR that occurred in each patient was evaluated.

Result

After inclusion and exclusion criteria applied, the study finally considered 50 patients. The study has found that most of the patients belong to 26-35 years of age category. The male and female ratio is almost same (1.2:1). Figure 1 shows the age distribution of the patients considered for this study.

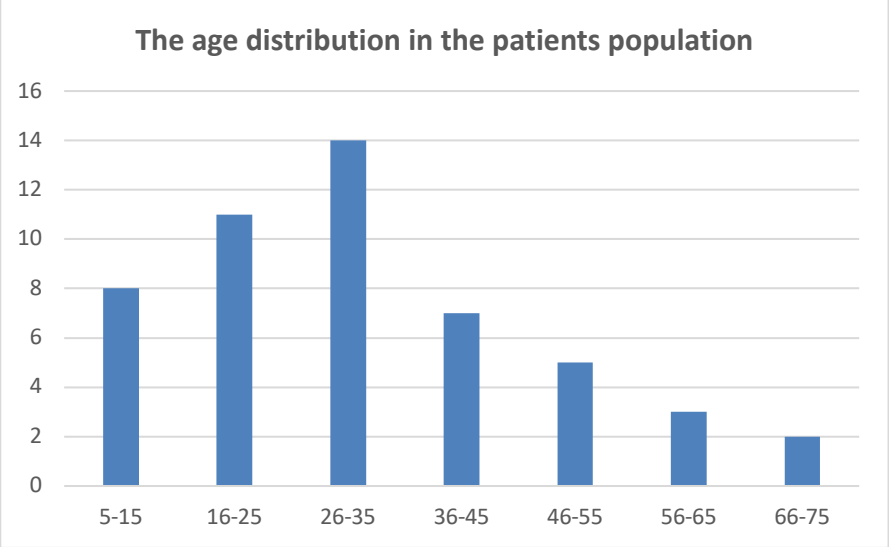

Figure 1: The distribution of age of the patients in this study

The authors recorded the cutaneous adverse reaction arised from drugs in each patient. It was found that the Maculopapular rash (32%) was the most common ADR found in this patient population. This was followed by urticaria (24%), exfoliative dermatitis (12%), eczematous eruption (10%) and many others. All the cutaneous ADR were evauated with number of patients and their percentages (Refer to Table 1).

Table 1: Cutaneous ADR found in the patient population and their percentages of total patients for each ADR

Cutaneous ADR	Number of patients	Percentage of total patients
Maculopapular rash	19	32
Urticaria	11	24
Exfoliative dermatitis	9	12
Eczematous eruption	5	10
Fixed Drug Eruption	5	8
Erythema nodosum	3	4
Photosensitivity	2	4
Lichenoid eruption	1	4
Toxic Epidermal Necrolysis	2	2

The study also evaluated the class of drug that each patient was given. It was seen that 42% of the patients had antimicrobials followed by NSAIDs (26%) and steroids (18%). The findings of this study is depicted in Figure 2.

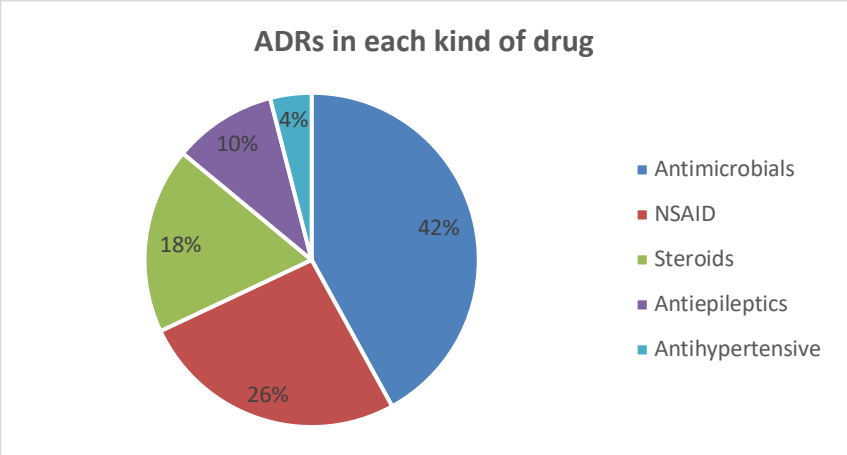

Figure 2: The cutaneous ADR found in each class of drug in this study

Discussion

Study by Hoetzenecker reveals that ADRs of cutaneous type are an immense and un-necessary burden on any nation. Results from the study reveal that most ADRs are manageable and can be controlled but nearly 2% are fatal; few important ones under this category are : "acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN)" [8].

ADRs are the un-fateful consequences of medication which were given with an intention to cure and ease the suffering of the patient. According to the results of this study most type of adverse events were related to drugs and allergies. There was no frequency seen of idiosyncratic adverse reactions. Most often found ARDs were related to CNS, gut & cardiovascular system and numerous type of medication were found to be the causative agents [9].

An Indian study revealed that among 258 patients studied for drug induced CADR the most common was exanthematous drug eruption (42.63%) which was followed urticaria (21.32%). It was also observed that in 64.73% of patients, the causative agent was antibiotics of several types and it was non-steroidal anti-inflammatory drugs (NSAIDs) in another 15.50% patients. About 12 patients (4.65%) faced severe cutaneous adverse drug reactions and 'Stevens–Johnson syndrome & Toxic epidermal necrolysis' alone constituted about 50% severe reactions and the drugs responsible for the same were antituberculous drugs. [4,8-9]

An Italian study specifically focused on Allopurinol and concluded that it is potent enough to cause severe cutaneous adverse reactions which included 'Drug Reaction with Eosinophilia

and Systemic Symptoms syndrome, toxic epidermal necrolysis &Stevens–Johnson syndrome'. Results revealed that out of 108 cases in 52% cases allopurinol caused serious cutaneous ADRs; these patients either had to be hospitalized or it increased their hospital stay; and about half of these had to face an unfavorable result [10].

A German study on paediatric in-patients concluded that drug Metamizole which is widely used as analgesic and antipyretic can induce ADR in patients taking it. Although, ADRs in severe form were rarely found. About 90% of the studied population had received Metamizole parenterally and results revealed: three incidences showing agranulocytosis, one had allergic shock and yet another had a rash. There was total recovery in all cases and no serious harm [11].

This study from Korea revealed that, there the major causes of ADR were due to use of antibiotics (20.3%), antimycobacterials (5.4%) were next, and it was followed by analgesics (4.0%), & contrast media (1.9%). The antibiotic vancomycin caused most such events but was not fatal. The risk factor (even life threatening at times) due to ADRs was high for the following: male population; geriatric people; daily multi-medicine regime; antibiotics with piperacillin/β-lactamase inhibitor (especially cefotetan; ceftriaxone); combination of antibiotic and antifungals like rifampicin, isoniazid, pyrazinamide, and ethambutol; morphine; and iopromide' [12].

Conclusion

Cutaneous ADR needs to be avoided as it can sometimes be fatal. Due to ADR, the management of several diseases become more complex and the patient ends up with some

other problems. This makes the overall burden of the management difficult and time consuming for the clinician as well. But if the ADRs are well known by the clinicians, it can be tackled at right time and hence can be minimized. Antimicribials, NSAIDs and steroid managements should be taken care as they cause ADR the most often. For a dermatologist, the knowledge of ADR should be well known and the etiologies. Swift detection and appropriate response are essential to minimize the burden of the management by clinician and dermatologists.

References

1. Saha A, Das NK, Hazra A, Gharami RC, Chowdhury SN, Datta PK. Cutaneous adverse drug reaction profile in a tertiary care out patient setting in Eastern India. *Indian J Pharmacol.* 2012;44:792–7. [PMC free article] [PubMed] [Google Scholar]
2. Bhatia A, Kanish B, Ziauddin M, Badyal D, Kartik Cutaneous adverse drug reaction monitoring in a tertiary care teaching hospital. *Clin Res.* 2013;5:60–5. [Google Scholar]
3. Choon S, Lai N. An epidemiological and clinical analysis of cutaneous adverse drug reactions seen in a tertiary hospital in Johor, Malaysia. *Indian J Dermatol Venereol Leprol.* 2012;78:734–9. [PubMed] [Google Scholar]
4. Jha, N., Alexander, E., Kanish, B., & Badyal, D. K. (2018). A study of cutaneous adverse drug reactions in a tertiary care center in Punjab. *Indian dermatology online journal*, *9*(5), 299.
5. Sharma, S., Jayakumar, D., & Palappallil, D. S. (2019). Pharmacovigilance of cutaneous adverse drug reactions among patients attending dermatology department at a Tertiary Care Hospital. *Indian dermatology online journal*, *10*(5), 547.
6. Marcum ZA, Handler SM, Boyce R, Gellad W, Hanlon JT. Medication misadventures in the elderly: a year in review. Am J Geriatr Pharmacother. 2010;8(1):77–83.
7. Coxon J, Rees J. Avoiding medical errors in general practice. Trends Urol Men's Health. 2015;6(4):13–7.
8. Hoetzenecker, W., Nägeli, M., Mehra, E. T., Jensen, A. N., Saulite, I., Schmid-Grendelmeier, P., ... & French, L. E. (2016, January). Adverse cutaneous drug eruptions: current understanding. In *Seminars in immunopathology* (Vol. 38, No. 1, pp. 75-86). Springer Berlin Heidelberg.
9. Khalil, H., & Huang, C. (2020). Adverse drug reactions in primary care: a scoping review. *BMC health services research*, *20*(1), 1-13.
10. Scavone, C., Di Mauro, C., Ruggiero, R., Bernardi, F. F., Trama, U., Aiezza, M. L., ... & Capuano, A. (2020). Severe cutaneous adverse drug reactions associated with allopurinol: an analysis of spontaneous reporting system in Southern Italy. *Drugs-real world outcomes*, *7*(1), 41-51.
11. Zahn, J., Eberl, S., Rödle, W., Rascher, W., Neubert, A., & Toni, I. (2022). Metamizole Use in Children: Analysis of Drug Utilisation and Adverse Drug Reactions at a German University Hospital between 2015 and 2020. *Pediatric Drugs*, *24*(1), 45-56.
12. Jo, H. G., Jeong, K., Ryu, J. Y., Park, S., Choi, Y. S., Kwack, W. G., ... & Chung, E. K. (2022). Fatal Events Associated with Adverse Drug Reactions in the Korean National Pharmacovigilance Database *Journal of Personalized Medicine*, *12*(1), 5.