Original Article

Study of cutaneous adverse drug reaction in tertiary care hospital – A prospective study

Vishal M Ubale[1*], Punam A Gosavi[2]

[1]Assistant Professor, Department of Pharmacology, Government Medical College, Nagpur, Maharashtra, INDIA.
[2]Assistant Professor, Department of Pharmacology, Government Medical College, Latur, Maharashtra, INDIA.
Email: vmubale2@gmail.com

Abstract

Introduction: Cutaneous adverse drug reactions (ADR) are most common types of adverse reaction to drug therapy, almost any drug can induce skin reactions. Cutaneous ADR is any undesirable change in the structure or function of the skin, its appendages or mucous membranes and encompass all adverse event related to drug eruption, regardless of etiology. **Aims and objectives:** To Study cutaneous adverse drug reaction at tertiary care hospital. **Material and Method:** Study was conducted after obtaining permission from Institutional ethical committee. The study was carried out in the Department of Dermatology at tertiary care hospital from July to Jan 2015 **Result :**The most common suspected drug was found were Oral Antimicrobials - 23.14% followed by Injectable Antimicrobials - 20.25%, NSAID'S- 18.60% , Topical Steroids - 15.70%, Anti-epileptics - 7.02%, Anti- Tubercular - 4.55%, Topical clobetasole with Gentamicin - 3.72%, Oral steroids - 2.89%, Iron with Multivitamins - 2.07%, Blood and its products - 1.24% , Anti-cancer - 0.83 % respectively. Prevalence of Various cutaneous adverse drug reactions i.e. Maculopapular Rashes were found in 21.49% followed by Acute Urticaria in 17.36%, Fixed drug eruption in 14.46%, Alopecia in 12.81 %, Steven Johnson syndrome in 8.68%, Erythema Multiforme-7.85, Facial swelling with itching in 6.20%, Toxic epidermal necrolysis in 3.72%, Steroid induced purpura in 2.89, Acneform eruptions in 1.65%, Steroid induced Cushing syndrome in 1.24%, Angioedema in 0.83%, Miscellaneous in 0.83 Respectively. **Conclusion:** The most common suspected drug forcutaneous adverse drug reaction were Oral Antimicrobials, Injectable Antimicrobials, NSAID'S, Topical Steroids, Anti-epileptics, Anti- Tubercular and the most common cutaneous adverse drug reactions were Maculopapular Rashes, Acute Urticaria, Fixed drug eruption , Alopecia, Steven Johnson syndrome respectively.

Key Words: Cutaneous adverse drug reaction, Maculopapular Rashes, Acute Urticaria, Steven Johnson syndrome.

[*]**Address for Correspondence:**
Dr. Vishal M Ubale, Department of Pharmacology, Government Medical College, Nagpur, Maharashtra, INDIA.
Email: vmubale2@gmail.com

Received Date: 17/12/2016 Revised Date: 04/01/2017 Accepted Date: 10/02/2017

Access this article online

Quick Response Code:

Website: www.medpulse.in

DOI: 12 February 2017

INTRODUCTION

Cutaneous adverse drug reactions (ADR) are most common types of adverse reaction to drug therapy, almost any drug can induce skin reactions. Cutaneous ADR is any undesirable change in the structure or function of the skin, its appendages or mucous membranes and encompass all adverse event related to drug eruption, regardless of etiology.[1] It affect 2-3% of hospitalized patient.[2] These reactions arises as a result of immunological non-immunological mechanism.[3] The severity of the cutaneous ADR may be varies from mild itching to a life threatening Stevens-Johnson syndrome (SJS). There are various predisposing factors for the occurrence of an cutaneous ADR like extremes of age like in neonates and elderly, the liver and kidney enzymes necessary for drug metabolism and elimination are not optimally functional. Women are expected to have a higher incidence of ADRs than men. Patients with past history of ADRs are more likely to develop an ADR. Genetic factors also play a role for pre-disposition to ADR.[4]According to WHO, an adverse drug reaction is defined as "a response to a drug that is noxious and unintended and occurs at doses, used in man for prophylaxis, diagnosis, or therapy of a disease or for modification of physiological function [5]. Cutaneous ADRs are the most common ADRs and have become

How to site this article: Vishal M Ubale, Punam A Gosavi. Study of cutaneous adverse drug reaction in tertiary care hospital – A prospective study. *MedPulse – International Medical Journal.* February 2017; 4(2): 201-203. http://www.medpulse.in (accessed 14 February 2017).

very common in recent times [6]. They are thought to occur up to 3% of medical inpatients [7]. There are several important predisposing factors for ADRs. Genetic factors may have an important role and patients who have a reliable history of drug allergy always need to be carefully monitored on the initiation of any drug, but particularly, those drugs which are commonly implicated in skin reaction. Hepatic disease, renal disease, systemic lupus erythematosus (SLE) and acute immunodeficiency syndrome (AIDS) are some of the disease states, associated with an increased risk of skin reactions [8].

In some cases, determination of serum or blood levels of drug may be useful to confirm the over dose of drug, at the time of ADR. Dechallenge (improvement after stopping of drug) and rechallenge (recurrence or exacerbation of reaction after reexposure to the offending drug) are also important to document. If no ADR occurs upon rechallenge, the drug can be continued, if clinically indicated. If an ADR does occur, both the severity of reaction and the need for the drug use should be assessed before a decision is made about its continuation or discontinuation [9,10].

A wide clinical spectrum of cutaneous ADRs, ranging from mild purpura to serious Stevens Johnson syndrome (SJS) can be produced by many drugs. The incidence of developing cutaneous ADR increases with the number of drugs taken and some drug interactions may also contribute to the development of skin eruptions [11]. ADRs can also occur with herbal drugs. The use of herbal supplements has increased dramatically in recent years [12]. The centre for disease control and prevention reported that in 1999, 10% of adults used herbal medicines [13].

MATERIAL AND METHOD

Study was conducted after obtaining permission from Institutional ethical committee. Informed consent was taken from study subjects. Information regarding the etiological agent, drug history, temporal correlation with the drug, duration of the reaction, associated mucosal or systemic involvement, improvement of the lesion on withdrawal of drug and laboratory investigations were recorded in a carefully pre-designed proforma and by using CDSCO WHO ADR reporting form

Suspected ADR reporting form: The diagnosis of the cutaneous ADRs was in accordance with the definition of ADR provided by the WHO, A plausible time relationship between the introduction of the drug and the onset of a reaction, Improvement in the condition of the patient after dechallenge/withdrawal of the suspected drug, Ayurvedic, herbal, homeopathic medicines, All age groups , Gender-male and female were included into study while Cases associated with vaccines, Drug over dosage, Cutaneous manifestation of systemic diseases, were excluded from study. The study was carried out in the Department of Dermatology at tertiary care hospital from July to Jan 2015 During one year period Total 242 patients were included into the study.

RESULT

Table 1: Showing suspected drug for Cutaneous ADR

Causative Drug	Number of cases	Percentage
Oral Antimicrobials	56	23.14
Injectable Antimicrobials	49	20.25
NSAID'S	45	18.60
Topical Steroids	38	15.70
Anti-epileptics	17	7.02
Anti- Tubercular	11	4.55
Topical clobetasole with Gentamicin	9	3.72
Oral steroids	7	2.89
Iron with Multivitamins	5	2.07
Blood and its products	3	1.24
Anti-cancer	2	0.83
Total	**242**	**100.00**

The most common suspected drug was found were Oral Antimicrobials - 23.14% followed by Injectable Antimicrobials - 20.25%, NSAID'S- 18.60%, Topical Steroids - 15.70%, Anti-epileptics - 7.02%, Anti-Tubercular - 4.55%, Topical clobetasole with Gentamicin - 3.72%, Oral steroids - 2.89%, Iron with Multivitamins - 2.07%, Blood and its products - 1.24% , Anti-cancer - 0.83 % respectively.

Table 2: Prevalence of Various cutaneous adverse drug reactions

Maculopapular Rashes	52	21.49
Acute Urticaria	42	17.36
Fixed drug eruption	35	14.46
Alopecia	31	12.81
Steven Johnson syndrome	21	8.68
Erythema Multiforme	19	7.85
Facial swelling with itching	15	6.20
Toxic epidermal necrolysis	9	3.72
Steroid induced purpura	7	2.89
Acneform eruptions	4	1.65
Steroid induced Cushing syndrome	3	1.24
Angioedema	2	0.83
Miscellaneous	2	0.83
Total	**242**	**100.00**

Prevalence of Various cutaneous adverse drug reactions i.e. Maculopapular Rashes were found in 21.49% followed by Acute Urticaria in 17.36% , Fixed drug eruption in 14.46%, Alopecia in 12.81 %, Steven Johnson syndrome in 8.68%, Erythema Multiforme-7.85, Facial swelling with itching in 6.20%, Toxic epidermal necrolysis in 3.72% , Steroid induced purpura in 2.89, Acneform eruptions in 1.65%, Steroid induced Cushing syndrome in 1.24% ,Angioedema in 0.83%, Miscellaneous in 0.83 Respectively.

DISCUSSION

Drugs can be remarkably beneficial, lengthen life and improve its quality by reducing symptoms and improving well-being. However, all drugs have adverse effects and carry the potential for causing injury, even if used properly. WHO Defines an adverse drug reaction (ADR) is defined as "a response to a drug that is noxious and unintended and occurs at doses, used in man for prophylaxis, diagnosis or therapy of a disease or for modification of physiological function.[14] The skin and the mucosa are the commonest sites for initial presentation of many ADRs. Cutaneous ADRs affect 2-3% of hospitalized patients.[15] These reactions can arise, as a result, of immunologic or non-immunologic mechanisms. In addition to their human costs, ADRs are expensive to the health-care system. The severity of the cutaneous ADRs may vary from mild itching to a lifethreatening Stevens-Johnson syndrome (SJS). ADRs can also occur with herbal drugs. The use of herbal supplements has increased dramatically in recent years.[16] In our study we have found that The most common suspected drug was found were Oral Antimicrobials - 23.14% followed by Injectable Antimicrobials - 20.25%, NSAID'S- 18.60%, Topical Steroids - 15.70%, Anti-epileptics - 7.02%, Anti-Tubercular - 4.55%, Topical clobetasole with Gentamicin - 3.72%, Oral steroids - 2.89%, Iron with Multivitamins - 2.07%, Blood and its products - 1.24% , Anti-cancer - 0.83 % respectively. This was similar to Bharani Kalpana R *et al*[17] Amongst 231 cases observed, oral Antimicrobials-17.75%, Injectable Antimicrobials-17.32%, NSAID's- 17.32% and Topical Steroids (Betnovate)-15.58 %. were the leading cause. Antiepileptics- 7.79%, Anti-cancer drugs- 5.63%, Blood and its products 5.19% and Topical clobetasol with Gentamicin- 4.33%, Oral Steroid- 3.46% , Anti-tubercular drugs-3.46% and iron and multivitamins - 2.16% were responsible for remaining cases also similar C. Kumari Bai *et al*[18]. Prevalence of Various cutaneous adverse drug reactions i.e. Maculopapular Rashes were found in 21.49% followed by Acute Urticaria in 17.36% , Fixed drug eruption in 14.46%, Alopecia in 12.81 %, Steven Johnson syndrome in 8.68%, Erythema Multiforme-7.85, Facial swelling with itching in 6.20%, Toxic epidermal necrolysis in 3.72% , Steroid induced purpura in 2.89, Acneform eruptions in 1.65%, Steroid induced Cushing syndrome in 1.24% ,Angioedema in 0.83%, Miscellaneous in 0.83 Respectively. This was similar to Bharani Kalpana R *et al*. cutaneous drug reactions, 95 cases were of maculopapular rashes (41.12%), next being steroid damaged face in 42 (18.18%) followed by acute urticaria in 20 (8.65%) patients. Other reactions were fixed drug eruption in 18 (7.79%), Alopecia in 11 (4.76%) and Injection site redness and itching in 8 (3.46%) patients. 7 case were of Erythema multiforme constituting about (3.03%) of all cases, 4 of Stevens Johnson syndrome (1.73%), 3 each of facial swelling with itching (1.29%) and Acneform eruptions (1.29%). Toxic epidermal necrolysis, angioedema and steroid induced purpura each were seen in 2 cases (0.86%).Steroid induced Cushing syndrome was also observed in 2 of the cases (0.86%).

REFERENCES

1. Nayak S and Acharjya B (2008). IJD
2. Bigby M, Jick S, Jick H, Arndt K. Drug induced cutaneous reactions. A report from Boston collaborative drug surveillance program on 15,438 consecutive inpatients, 1975 to 1982. JAMA. 1986;256:357-62
3. Lee A, Thomson J. Drug induced skin reactions. Pharm J Lond. 1999;262:357-62.
4. Bai CK, Padma L, Mohan NTM, Veena DR. Drug induced cutaneous adverse drug reactions in dermatology in Dr. B.R. Ambedkar Medical College. Int J Basic Clin Pharmacol 2014;3:706-10.
5. Ralf I Edwards, Jaffery K Aronson. Lancet, 2000, 356, 1255-59.
6. Raksha MP, Marfatia YS. Indian J Dermatol venereal Leprol, 2008, 74, 80.
7. The Pharmaceutical Journal London 1999, 262, 357-362.
8. De Swarte RD. J Allergy Clin Immunol, 1984, 74, 209-21.
9. Rebecca S Gruchalla. Lancet, 2000, 356, 1505-1511.
10. Middleton E, Reed C, Ellis E, Adkinson NJ, Yunginger J, Busse W. Allergy: principles and practice. St. Louis: Mosby, 1998; vol II, 1212-24.
11. Naldi L, Conforti A, venegoni M, Trancon MG, Caputi A, Ghiotto E, *et al*. Br J Clin Pharmacol, 1999, 48, 839-46.
12. W Abebe. J Clin Pharmacy and Ther, 2002, 27, 391-401.
13. Stephen E Strauss. N Eng J Med, 2002, 347(25), 1997-1998.
14. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. Lancet. 2000 7;356:1255-9.
15. Bigby M, Jick S, Jick H, Arndt K. Drug-induced cutaneous reactions. A report from the Boston collaborative drug surveillance program on 15,438 consecutive inpatients, 1975 to 1982. JAMA. 1986; 256:3358-63.
16. Lee A, Thomson J. Drug induced skin reactions. Pharm J Lond. 1999; 262:357-62.
17. Bharani Kalpana R, Chandel Nitibhushansingh R, Goyal Chhaya. Dermatological Manifestations of Adverse Drug Reactions: An Observational Study from Tertiary Care Center of Central India. J Pharm Biomed Sci.2014; 04(03): 208-214.
18. C. Kumari Bai1, L. Padma1, N. T. Madan Mohan, D. R. Veena1. Drug-induced cutaneous adverse drug reactions in dermatology in Dr. B.R. Ambedkar Medical College.Int J Basic Clin Pharmacol. 2014 Aug;3(4):706-710.

Source of Support: None Declared
Conflict of Interest: None Declared