IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 14, Issue 11 Ver. IX (Nov. 2015), PP 19-22
www.iosrjournals.org

Evaluation of cutaneous adverse drug reactions due to antimicrobial agents: A prospective study

Anuradha HV, Shivaswamy KN[1], Rachana PR
Department of Dermatology & Pharmacology, M S Ramaiah Medical College, Bangalore

Abstract:
Introduction*: Adverse drug reactions are global problems of major concern. Cutaneous drug eruptions are the most common among the various adverse drug reactions and can range from an asymptomatic rash to a life-threatening emergency. Hence, the present study was conducted with an objective to evaluate the cutaneous adverse reactions to antimicrobial drugs in a tertiary care hospital.*
Methodology*: A prospective study was conducted in tertiary care hospital in Bangalore. Patients suspected of having cutaneous adverse drug reactions after administering antimicrobial agents were included in the study. The WHO definition of adverse drug reaction was adopted. Causality assessment was done using WHO probability scale.*
Results*: Total of 59 cases were included in the study. The mean age of the patient was 36.89 years, with the male preponderance. Among the antimicrobial agents, the most common group which lead to causation of allergic reactions was beta lactams followed by fluoroquinolones. All the ADRs were mild to moderate in nature and manifested as erythematous rash and itching. As per the causality assessment of the ADRs done using WHO-UMC scale, 86.4 % were defined as probable, 8.5%aspossible and 5.1% as certain.*
Conclusion*: The cutaneous adverse drug reactions were commonly noticed for the antibacterial agent beta-lactams in our study followed by fluoroquinolones and were of mild to moderate severity in the form of erythematous rashes and pruritis.*
Key words*: Cutaneous adverse drug reaction; fluoroquinolones; beta lactams; erythematous rash*

I. Introduction

Adverse drug reaction (ADR) is a response to a medicine which is noxious, unintended and which occurs at a dose used in humans for prophylaxis, diagnosis, therapy or modification of physiological functions. Adverse drug reactions are global problems of major concern[1]. India is a developing country with large drug consuming population, producer of pharmaceuticals in the world with more than 6000 licensed drug manufacturers and over 60,000 branded formulations. Thus it is essential that the drug treatment be safe, efficacious and cost effective.[2]The enormity of the problem of ADR reporting and poor post marketing surveillance by pharmaceutical companies in India is well documented.

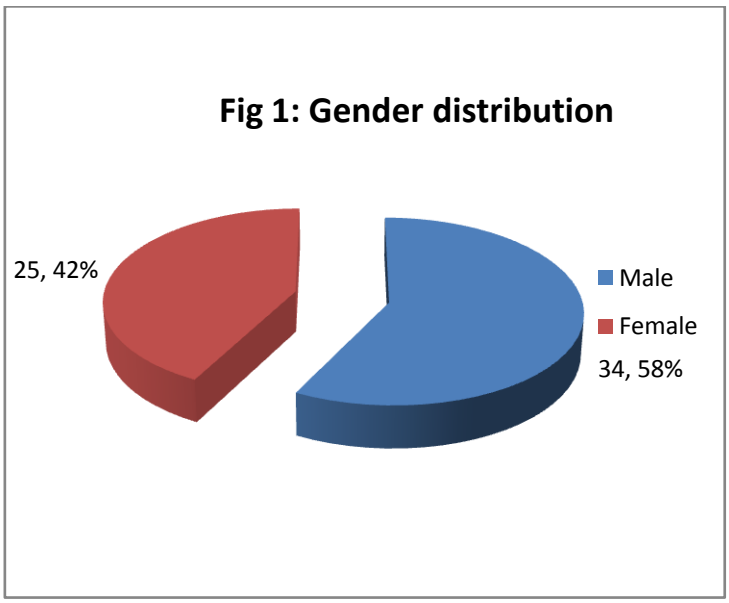
ADR reporting in India rates below 1% against the world rate of 5%. This clearly shows that the concept is still in its infancy here.[2,3]Cutaneous drug eruptions are the most common among the various adverse drug reactions and can range from an asymptomatic rash to a life-threatening emergency[4]. Many of the commonly used drugs have reaction rates over 1%. There is a wide spectrum of cutaneous adverse drug reactions varying from transient maculopapular rash to fatal toxic epidermal necrolysis (TEN). The pattern of cutaneous adverse drug eruptions and the drugs responsible for them keep changing every year.[5]However identifying true drug allergycan be challenging. Complicating factors of drug reactions include the myriad clinical symptoms and multiple mechanisms of drug-host interaction, many of which are poorly understood.[6] It is unclear if the increased risk is due to poly pharmacy alone or also due to changes in drug metabolism and/or excretion with age.[7, 8] Hence, the present study was conducted with an objective to evaluate the cutaneous adverse reactions to antimicrobial drugs in a tertiary care hospital.

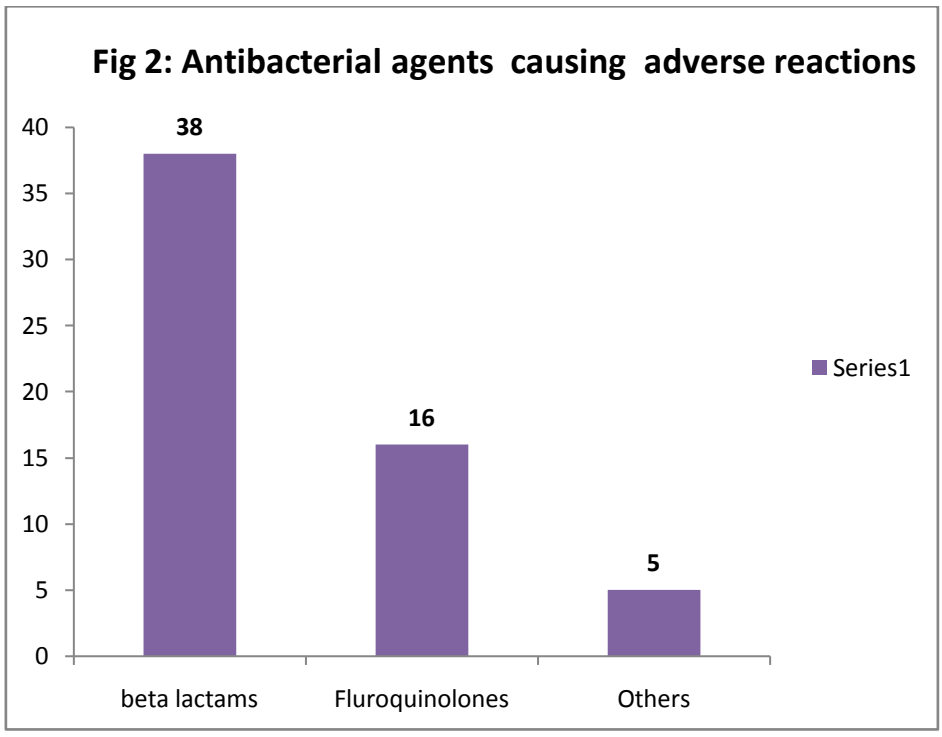
II. Methodology

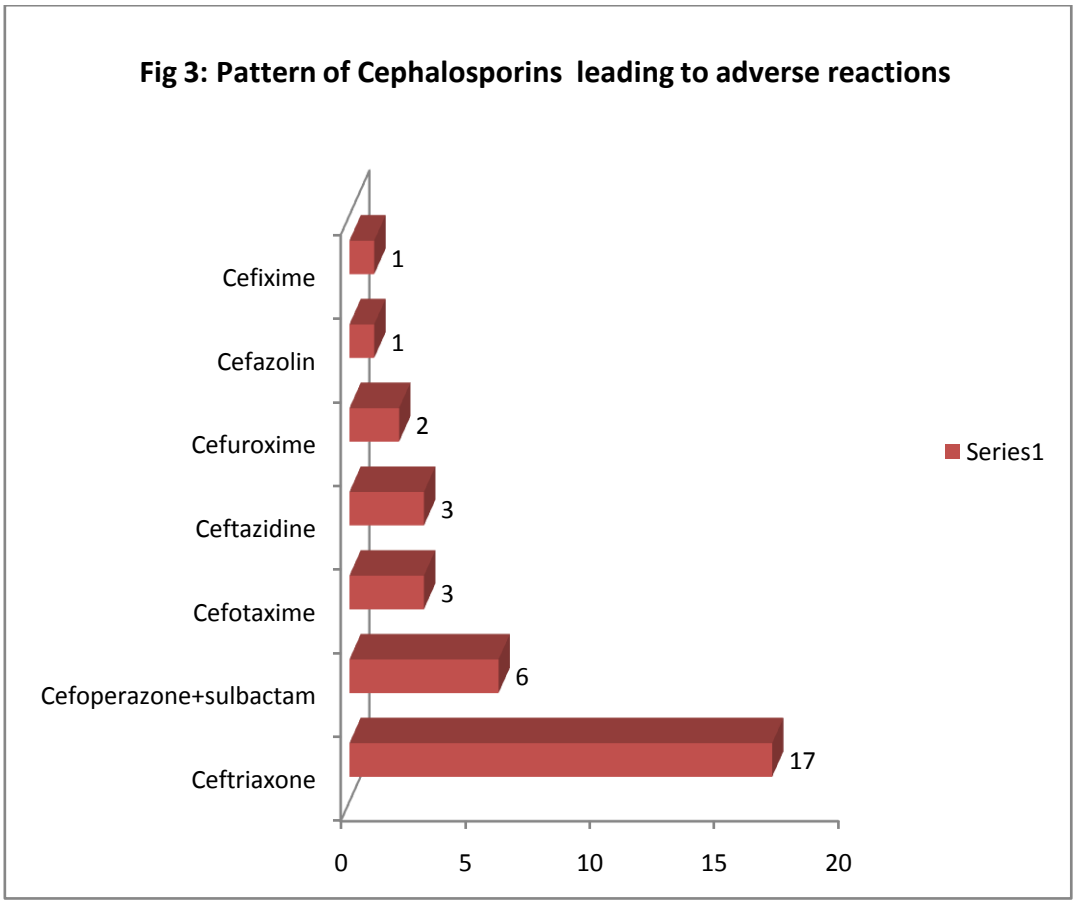
A prospective study was conducted in tertiary care hospital in Bangalore. Patients suspected of having cutaneous adverse drug reactions after administering antimicrobial agents were included in the study. The WHO definition of adverse drug reaction was adopted. Reporting was done according to CDSCO ADR Reporting Form. Causality assessment was done using WHO probability scale.[9]The detailed history including age, gender, duration of reaction, drugs responsible and associated complications were recorded in a specially designed proforma. All cutaneous adverse drug reactions were recorded and classified according to WHO scale. Total enumeration method of sampling method was adopted to calculate sample size. The cases were collected for a period of six months.

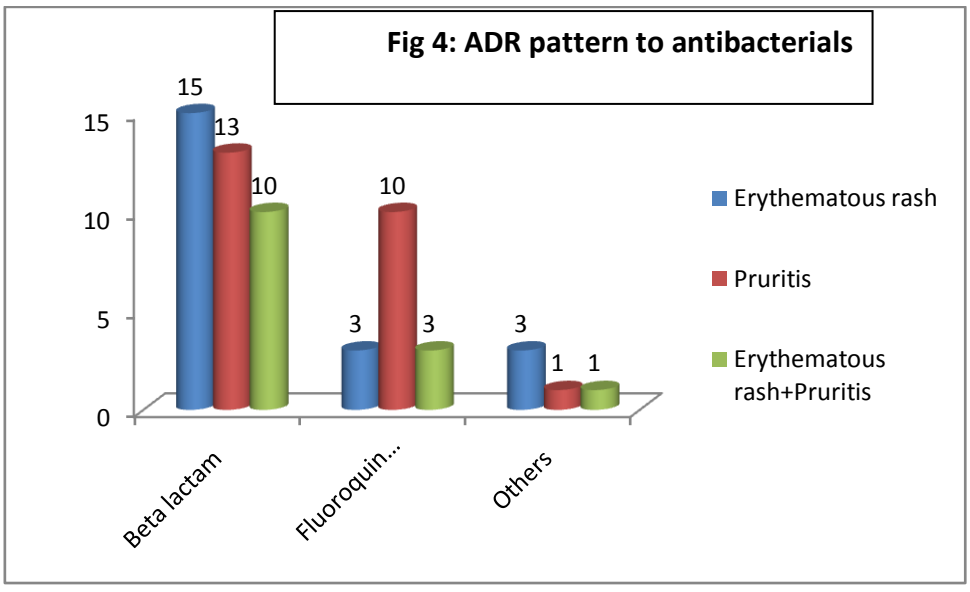
III. Results And Discussion

Total of 59 cases were included in the study. The mean age of the patient was 36.89 years, with the minimum of one year to a maximum of 85 year. Most of the patients were male (fig 1).Among the antimicrobial agents, the most common group which lead to causation of allergic reactions was betalactams followed by fluoroquinolones (fig 2). It was in contrast to the data of article by Patel et al[10]where sulfonamides were the commonest. This may be attributed to changing pattern of antibiotic usage.Among the beta lactams, incidence was more with cephalosporins as it is widely in practice. Pattern of cephalosporins leading to allergic reaction has been depicted in figure 3. Among fluoroquinolones commonest was ciprofloxacin, followed by levofloxacin and ofloxacin. Other antibiotics wereamikacin, azithromycin, metronidazole and vancomycin. The cutaneous reactions noted to antimicrobial agents were erythematous rashes with pruritis (23.6%), erythematous rashes (35.6%) and pruritis (40.7%). The pattern of adverse drug reactions to antibacterials has been shown in fig 4. All the ADRs were mild to moderate in nature and were treated symptomatically. The causality assessment of the ADRs was done using WHO-UMC scale and it was found that 51 cases (86.4%) were grouped under probable, 05(8.5%) cases under as possible and 03cases (5.1%) under certain.









IV. Conclusion

The cutaneous adverse drug reactions were commonly noticed for the antibacterial agent beta-lactams in our study followed by fluoroquinolones. Though the severity was mild to moderate, precaution needs to be taken with proper protocol of skin test dose as antibacterial administration can rarely lead to life threatening condition.

References

[1]. Rehan HS, Deepti C, Kakkar AK. Physician's guide to pharmacovigilance: Terminology and causality assessment. Eur J Intern Med. 2009;20:3-8.
[2]. Biswas P, Biswas AK. Setting standards for proactive pharmacovigilance in India: The way forward. Indian JPharmacol 2007;39:124-8.
[3]. Prakash S. Pharmacovigilance in India. Indian J Pharmacol 2007; 39: 123–123.
[4]. Chan HL, Stern RS, Arndt KA, Langlois J, Jick SS, Jick H et al. The incidence of erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis: a population based study with particular reference to reaction caused by drugs among outpatients.ArchDermatol 1990; 126:43–7.
[5]. Pudukadan D, Thappa DM. Adverse cutaneous drug reactions: Clinical pattern and causative agents in a tertiary care center in South India. Indian J DermatolVenereolLeprol 2004; 70:20-4.
[6]. Hernandez-Salazar A, Rosales SP, Rangel-Frausto S et al: Epidemiology of adverse cutaneous drug reactions. A prospective study in hospitalized patients. Arch Med Res 2006;37:899–902
[7]. Routledge PA, O'Mahony MS, Woodhouse KW. Adverse drug reactions in elderlypatients. Br J ClinPharmacol 2004; 57:121–6.
[8]. Gandhi TK, Weingart SN, Borus J,Seger AC, Peterson J, Burdick E et al. Adverse drug events in ambulatory care. N Engl J Med 2003; 348:1556–64.
[9]. The use of WHO-UMC system for standardised case causality assessment.(cited on 2014 Feb 2); Available from URL: http://www.Who-umc.org/Graphics/24734.pdf
[10]. Patel TK, Thakkar SH, Sharma DC. Cutaneous adverse drug reactions in Indian population:
[11]. A systematic review. Indian dermatology online Journal 2014;5(6): 76-86.