

## A PROSPECTIVE STUDY OF ADVERSE DRUG REACTIONS AND DRUG UTILIZATION PATTERN IN DERMATOLOGY DEPARTMENT

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### ABSTRACT

**Introduction:** Dermatological diseases are long-lasting in nature and they need lifelong treatment mostly. Prescription pattern echoes dermatologists' attitude towards the disease and part of drugs in its treatment. Hence the study of drug utilization pattern and related adverse effect profile is important to make medical management balanced. **Objective:** To evaluate drug prescribing pattern and adverse drug reaction profile in Dermatology department of tertiary care hospital. **Results:** In our study 350 patient's treatment were analyzed which include various drugs which account for around 1408. Majority of drugs prescribed were antihistamines (25.23%), antibacterial (18%), antifungal (12%), and corticosteroids (9%). Forty patients were reported with ADR. Most of ADRs are reported with Antimicrobials & common ADR was Maculopapular rash, on severity assessment by modified Hartwig and Siegel's scale, out of 40 ADRs, 22 (55%) were mild, 14 (35%) were moderate and 4 (10%) were severe in nature. Based on Naranjo scale analysis 32 were possible 7 was probable and one was definite. **Conclusion:** The present study showed antihistaminic were commonly prescribed class & antibiotics were responsible from majority of ADR. Maculopapular rash was most common ADR.

**KEYWORDS:** Adverse drug reaction, drug utilization, dermatology.

### INTRODUCTION

Dermatological diseases are very commonly encountered in daily clinical practice accounting for up to 2% of doctor appointments in general practice globally.<sup>[1]</sup> The form of skin disease differs from one country to another and across different parts within the same country.<sup>[2]</sup> In India the most widespread dermatological condition include scabies, pyoderma, dermatitis, urticaria, fungal skin infection, acne, alopecia and less frequently eczematous disorder like psoriasis, skin cancer and cutaneous adverse drug reaction.<sup>[3]</sup> Most of skin diseases are long-lasting in nature and they necessitate regular and prolonged treatment hence appropriate diagnosis by physician using clinical knowledge and various diagnostic test and rational prescription of drugs based on physician understanding of both risk and benefit of drugs is important element of pharmacological management.

The International Network for the Rational Use of Drugs (INRUD) was established in 1989 to encourage the rational use of drugs in developing countries. World Health Organization (WHO) has defined rational use of

drugs when "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".<sup>[4]</sup>

Drug utilization study is an important component of Pharmacology. WHO defines Drug utilization as "The marketing, distribution, prescribing and use of drug in society, with special emphasis on medical, economic and social consequences".

Prescription pattern reflects health professional defiance towards the disease and role of drugs in its treatment. The study of prescription pattern is important to monitor prescribing practices to make medical care rational and cost effective. Appropriate drug utilization studies are required for evaluating proper use of drugs for efficacy, safety, accessibility and economic aspects.

An 'adverse drug reaction', as defined by the WHO, is a noxious, unintended effect of a drug, which occurs at normal doses in humans for the prophylaxis, diagnosis, or the therapy of the disease or for the modification of its physiological function. It has been projected that the

prevalence of ADRs throughout the world is 5% and 5-6% of all the hospital admissions which are produced by drug - induced problems,<sup>[5]</sup> Cutaneous drug eruptions are most common types of adverse reaction to drug therapy, with an overall incidence rate of 2%–3% in hospitalized patients. Therefore periodic auditing of prescriptions and pharmacovigilance is vital to intensify the therapeutic efficacy, reduction of adverse effects and, also prepare Hospital formulary depending on geographic profile of disease and availability of drugs.<sup>[6]</sup>

Very few systematically analyzed data are available on the drug utilization pattern and adverse drug reaction in dermatology department in India. Keeping these facts in consideration the present study was planned to evaluate drug prescribing pattern and adverse drug effects in Dermatology department of tertiary care teaching hospital

## MATERIALS AND METHODS

An observational cross-sectional study was conducted for three months in 350 patients after the approval of Institutional Ethics Committee at Government Dharmapuri Medical College. Written Informed Consent was taken from all patients visiting the Dermatology department who were willing to participate in study before their prescription were analyzed.

The case details and treatment profile of patients was analyzed for prescription pattern. Simultaneously development of any ADR to drug prescribed was observed with present visit and follow-up visit after 3 days. ADR was analyzed using Naranjo causality assessment scale and Hartwig's Severity Assessment Scale. Data was analyzed using descriptive statistics with Mean and percentages as applicable.

## RESULTS

A total 350 patients case sheet were analyzed, in our study we saw a male preponderance (59%). The commonest age group suffering from skin diseases is 20-40 (62%). Total 1408 drugs were prescribed with an average number of drugs per prescription in our study was 3.65. In our study common classes of drugs prescribed were antihistamines (25.23%), antibacterial (18%), antifungal (12%), and corticosteroids (9%). Amoxicillin (69%) and ciprofloxacin (18.6%) were the most commonly used oral antibiotics while Framycetin sulfate (71%) was commonly used topically. Fluconazole (85%) was most commonly used oral antifungal agent while miconazole for topical application. Cetirizine (89%) was the most commonly used antihistamines. Most of the drugs were prescribed by oral route (65%) followed by topical (33%) and parenteral (2%).

**Table 1: Analysis of prescribed drug according to routes of administration.**

Drug Groups	Oral No	Topical No	Parenteral No	Total No (%)
Antibacterial	175	78	-	253(18)
Antifungal	48	121	-	169(12)
Corticosteroids	10	111	5	126(9)
Antihistaminics	323	-	32	355(25.23)
Vitamins	239	-	-	239(17)
GIT drugs	169	-	-	169(12)
Miscellaneous	82	38	6	126(9)

Out of 350 patients, 40 patients were reported with ADR. Most of ADRs are reported with Antimicrobials which account for 70 percent (n=28), NSAIDs caused 8 ADRs, apart from this phenytoin in particular caused 4 ADR's. Adverse reaction reports with these drugs include: Maculopapular rash (n=25), Fixed drug eruption (25%), Urticaria (012.50%).

**Table 2: Adverse drug reactions and drug responsible.**

Type of reaction	No. of patients	Drug responsible
Maculopapular rash	10	Amoxycillin
	07	Co-trimoxazole
	03	Diclofenac sodium
	04	Phenytoin
	01	Ibuprofen
Fixed drug eruption	05	Cotrimoxazole
	03	Metronidazole
	02	Paracetamol
Urticaria	02	Diclofenac injection
	03	Ampicillin
Total	40	

On severity assessment by modified Hartwig and Siegel's scale, out of 40 ADRs, 22 (55%) were mild, 14 (35%) were moderate and 4 (10%) were severe in nature. Based on Naranjo scale analysis 32 were possible 7 was probable and one was definite.

## DISCUSSION

Multiple drug utilization studies have been done in developed countries. Quantitative and qualitative geographical differences do exist in patterns of drug consumption. Average number of drugs is an important index of prescription analysis and in the present study it was 3.65 which point to the trend of polypharmacy. Polypharmacy has been reported to be the one of the cause of adverse drug reactions, drug-drug interaction, poor compliance, increases cost of treatment,<sup>[7]</sup> Average number of drugs per prescription was quite higher than previously conducted studies by Minocha KB. et al. which showed 2-3 drugs per prescription.<sup>[8]</sup>

The most commonly prescribed drug group in our study were Antihistaminics followed by antibacterials

and antifungals. Higher use of antihistaminics were also reported by Tikoo D et al.<sup>[9]</sup> while use of higher number of antibiotics was reported by Sajith M. et al.<sup>[10]</sup> Patients with signs of itching due to infectious or inflammatory disease was the common motive for greater use of antihistaminics.

Among the total number of drugs prescribed, most of them were prescribed by the oral route followed by topical and injectable routes. While use of topical route was reported by Tikoo D et al.<sup>[9]</sup> and Maini R. et al.<sup>[11]</sup> The reason for high percentage of oral drugs being prescribed is that oral route is convenient and acceptable to patients.

Pharmacovigilance now become important component of drug treatment. Drug therapy and active pharmacovigilance goes hand in hand. In our study, most common ADR reported was Maculopapular rash followed by fixed drug eruption and urticaria, Studies by Saha A. et al.<sup>[12]</sup> reported commonest cutaneous ADRs were morbilliform eruption, followed by fixed drug eruption (24.52%). Another study conducted by Shah SP. et al.<sup>[13]</sup> reported fixed drug eruption were the commonest presentation followed by maculopapular rashes.

ADR findings in present study suggest that antimicrobials, NSAIDs, were responsible for most of ADRs. Similar findings also reported by study conducted by Shah SP. et al.<sup>[13]</sup> They reported, antibiotics were the most commonly suspected drugs followed by unknown medicines for cutaneous ADR. Saha A. et al.<sup>[12]</sup> reported a high incidence of cutaneous ADRs due to Sulfa group followed by fluoroquinolones.

As per Naranjo causality scale and majority of ADRs were possible and few were probable in nature. Similar finding also reported by Shah SP. et al. On severity assessment by modified Hartwig and Siegel's scale, 22 (55%) were mild, 14 (35%) were moderate and 4 (10%) were severe in nature. Study conducted by Acharya T et al.<sup>[14]</sup> reported 83% moderate 15% mild in nature on Hartwig and Siegel's scale.

## CONCLUSION

The present study showed polypharmacy. Hence there is a need to emphasize prescribers to adhere to the prescription guidelines and encourage use of the essential drug list. There is a clear need for development of standard treatment guidelines and educational initiatives like continued medical education to encourage the rational and appropriate drug use. Educating, establishment and encouragement of Pharmacovigilance system among medical and non-health professionals including medical undergraduates improve ADRs identification and to identify the drugs causing it, therefore prolonged hospitalization, treatment cost, morbidity and mortalities can be minimized.

## REFERENCES

1. Sajith M, Lokhande KD, Padma S, Pawar AP. Prevalence of various skin disorders and prescribing pattern of antihistaminics in tertiary care hospital, pune. International Journal of Pharma Sciences and Research, 2014; 5(03): 73–77.
2. Juno J. Joel, Neethu Jose, Shastry C.S. Patterns of Skin Disease and Prescribing Trends in Rural India. Sch. Acad. J. Pharm., 2013; 2(4): 304-09.
3. Saravanakumar R. Study of prescribing pattern of topical corticosteroids in the department of dermatology in multi- speciality tertiary care teaching hospital in south India. Inj.J.Res. Pharm. Sci., 2012; 3(4): 685-87.
4. Rational use of medicine. World Health Organisation site. Available at: URL: [http://www.who.int/medicines/areas/rational\\_use/en/](http://www.who.int/medicines/areas/rational_use/en/). Accessed, September 2014.
5. Ramesh KV, Shenoy A, Chowta MN. Pharmacovigilance and adverse drug reaction monitoring. In: KV Ramesh, Ashok Shenoy, Mukta N Chowta editors. Practical Pharmacology for MBBS. 1st ed. New Delhi, Arya Publishing company, 2006; 102-04.
6. Gupta N, Sharma D, Garg SK, Bhargava VK. Auditing of prescriptions to study antimicrobials in a tertiary hospital, 1997; 29(6): 411-415.
7. Cork MJ, Timmins J, Holden C, Carr J, Berry V, Tazi Ahnini R. An audit of adverse drug reactions to aqueous cream in children with atopic eczema. The Pharmaceutical Journal, 2003; 271: 747-48.
8. Badar VA, Shrivastava MP, Badwaik RT. Surveillance of drug prescribing trends in skin OPD of IGMC. Indian J Pharmacol, 2002; 34: 150.
9. Tikoo D, Chopra SC, Kaushal S, Dogra A. Evaluation of Drug Use Pattern in Dermatology as a Tool to Promote Rational Prescribing. JK Science, 2011; 13(3): 128-31.
10. Sajith M, Lokhande KD, Padma S, Pawar AP. Prevalence of various skin disorders and prescribing pattern of antihistaminics in tertiary care hospital, Pune. Int J Phar Scien Resea, 2014; 5(03): 73-7.
11. Maini R, Verma K, Biswas NR, Agrawal S. Drug utilization study in dermatology in a tertiary hospital in Delhi. Indian J Physiol Pharmacol, 2002; 46(1): 107-10.
12. 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.
13. Shah SP, Desai MK, Dikshit RK. Analysis of Cutaneous Adverse Drug Reactions at a Tertiary Care Hospital– a Prospective Study Trop J Pharm Res, August, 2011; 10(4): 517-22.
14. Acharya T, Mehta D, Shah H, Dave J. Pharmacovigilance study of adverse cutaneous drug reactions in a Tertiary Care Hospital. Natl J Physiol Pharm Pharmacol, 2013; 3: 75- 81.