

Prescription pattern and adverse drug reaction profile of drugs prescribed in dermatology out-patient department at a tertiary care teaching hospital

V.M. Motghare^{1,*}, C.S. Bajait², A. Turnakar³, S.D. Sontakke⁴, S. Chavan⁵

¹Professor & Head, ²Assistant Professor, ^{3,4}Associate Professor, Gov. Medical College Nagpur, ⁵MBBS 3rd yr. Student, Dept. of Pharmacology, SRTR GMC Ambejogai

***Corresponding Author:**

Email: vm.motghare@gmail.com

Abstract

Introduction: Skin diseases are chronic in nature and they require lifetime treatment. Prescription pattern reflects health professional attitude towards the disease and role of drugs in its treatment. The study of prescription pattern is important to make medical care rational and cost effective.

Objective: To evaluate drug prescribing pattern and adverse drug reaction profile in Dermatology department of tertiary care hospital.

Results: 410 prescriptions were analyzed which include 1696 drugs. Majority of drugs prescribed were antihistaminic (20.99%), antibacterial (16.05%), antifungal (9.08%), and corticosteroids (7.78%). Eighteen patients were reported with ADR. Most of ADRs are reported with Antimicrobials (50%) & common ADR was Maculopapular rash (50%), On severity assessment by modified Hartwig and Siegel's scale, out of 18 ADRs, 8 (44.44%) were mild, 8 (44.44%) were moderate and 2 (11.11) were severe in nature.

Conclusion: The present study showed antihistaminic were commonly prescribed class & antibiotics were responsible from majority of ADR. Maculopapular rash was most common ADR.

Keywords: ADR, DU study, Skin diseases.

Introduction

Dermatological conditions are common in clinical practice accounting for up to 2% of consultations in general practice worldwide.⁽¹⁾ The pattern of skin disease varies from one country to another and across different parts within the same country.⁽²⁾

In India the most prevalent dermatological condition include scabies, pyoderma, dermatitis, urticaria, fungal skin infection, acne, alopecia and less common are eczematous disorder like psoriasis, skin cancer and cutaneous adverse drug reaction.⁽³⁾ Most of skin diseases are chronic in nature and they require lifetime treatment hence appropriate diagnosis by physician using clinical experience and various diagnostic test and rational prescription of drugs based on physician understanding of both risk and benefit of drugs is important component of drug therapy.

The International Network for the Rational Use of Drugs (INRUD) was established in 1989 to promote the rational use of drugs in developing countries. World Health Organization (WHO) has defines 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"⁽⁴⁾

Drug utilization study is an important component of Pharmacoepidemiology. World Health Organization (2003) defines Drug utilization as "The marketing, distribution, prescribing and use of drug in society, with special emphasis on medical, economical and social consequences"⁽⁵⁾

Prescription pattern reflects health professional

attitude 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 needed for evaluating proper utilization of drugs for efficacy, safety, convenience and economic aspects.

Despite advances in control of drug regulations and as the market is flooded with large number of pharmaceutical preparation with innumerable trade names available often at unaffordable price the irrational drug prescribing is still worldwide concern.

An 'adverse drug reaction', as defined by the World Health Organization, 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.⁽⁶⁾ It has been estimated that the incidence of ADRs throughout the world is 5% and 5-6% of all the hospital admissions which are caused by drug - induced problems⁽⁷⁾ Cutaneous drug eruptions are most common types of adverse reaction to drug therapy, with an overall incidence rate of 2%–3% in hospitalized patients.⁽⁸⁾

The irrational use of drugs is a major problem of present day medical practice and its consequences include ineffective treatment, unnecessary prescription of drug leading to Adverse Drug Reactions (ADR) and economic burden on patients and society.⁽⁹⁾ Therefore periodic auditing of prescriptions and pharmacovigilance is essential to increase the therapeutic efficacy, decrease adverse effects and provide feedback to prescribers, also set-up Hospital formulary depending on geographic profile of disease

and availability of drugs.^(10,11)

Very few systematically analyzed data are available on the drug utilization pattern and adverse drug reaction profile in dermatology Outpatient department (OPD) in India.

Keeping these facts in consideration the present study was planned to evaluate drug prescribing pattern and adverse drug reaction profile in Dermatology department of tertiary care hospital.

Aims and Objectives

1. To evaluate prescription pattern of drugs prescribed in Dermatology Out Patient Department (OPD).
2. To evaluate adverse drug reaction profile of drugs prescribed in Dermatology OPD.

Materials and Methods

An observational cross-sectional study was conducted for 2 months in 410 patients after the approval of Institutional Ethics Committee at tertiary care teaching hospital. Written Informed Consent was taken from all patients visiting the Dermatology OPD who were willing to participate in study before their prescription were analyzed.

The case sheet of patients was analyzed for prescription pattern using WHO core drug use indicators. Simultaneously development of any ADR to drug prescribed was observed with present visit and follow-up visit after 3 days. ADR was analyzed using WHO-UMC causality assessment scale and Hartwig's Severity Assessment Scale.

Data was analyzed using descriptive statistics with Mean and percentages as applicable.

Results

A total 410 prescriptions were analyzed with male preponderance. (53.66%) The commonest age group suffering from skin diseases is 16-45 (57%). Total 1696 drugs were prescribed with an average number of drugs per prescription 4.13. (Table 1) Only 152 prescription have mentioned diagnosis of patient and scabies being the common reason for attending dermatology OPD (Fig 1) common classes of drugs prescribed were antihistaminic (20.99%), antibacterial (16.05%), antifungal (9.08%) and corticosteroids (7.78%). as shown in Fig. 2 Amoxicillin(76.76%) and ciprofloxacin(14.28%) were the most commonly used oral antibiotics while Framycetin sulfate(73.07%) was commonly used topically. Fluconazole (87.5%) was most commonly used oral antifungal agent while miconazole for topical application. Cetirizine (84.26%) was the most commonly used antihistaminics. Most of the drugs were prescribed by oral route (73.34%) followed by topical (24.66%) and parenteral (2%). Table

2 shows drugs classes & their routes of administration. Prescriptions were analysed for prescriptions format as shown in Table 3.

Out of 410 patients, 18 patients were reported with ADR. Most of ADRs are reported with Antimicrobials (50%), NSAIDs (22%), steroids (16%) and O.C. pills (11%). Adverse reaction reports with these drugs include: Maculopapular rash (50%), Fixed drug eruption (25%), Acne form eruption (18.75%), Urticaria (12.50%), Hyper pigmentation (6.25%). (Table 4) According to WHO-UMC causality assessment system, 01 ADR was certain (5.55%), 05 were probable (27.77) and 12(66.66%) were possible in nature. On severity assessment by modified Hartwig and Siegel's scale, 8 (44.44%) ADR were mild, 8 (44.44%) were moderate and 2 (11.11) were severe in nature.

Table 1: Analysis of prescriptions of patients attending skin OPD (n=410)

Parameter	Observation
Total no. of prescriptions	410
Total no. of drugs	1696
Average no. of drugs per prescription	4.13
% of drugs prescribed by generic name	38.7
% of drugs prescribed by brand name	61.3
Drugs from National essential drug list	1084(63.91%)

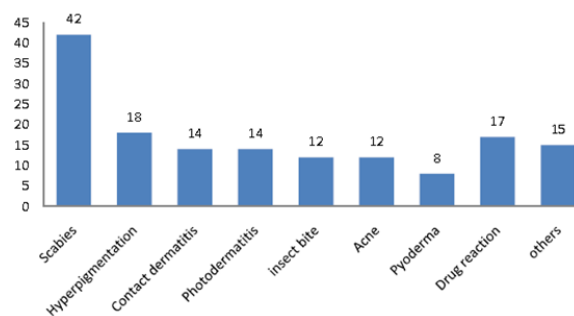


Fig. 1: Distribution of common skin diseases

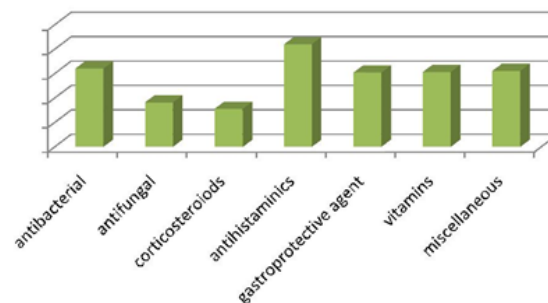


Fig. 2: Analysis of drug prescribed in Skin OPD.

Table 2: Analysis of prescribed drug according to routes of administration

Drug Groups	Oral	Topical	Parenteral	Total
	No (%)	No (%)	No (%)	No (%)
Antibacterial	168(61.76)	104(38.24)	-	272(16.05)
Antifungal	32(20.77)	122(79.23)	-	154(9.08)
Corticosteroids	6(4.54)	122(92.42)	4(3.04)	132(7.78)
Antihistaminics	330(92.69)	-	26(7.31)	356(20.99)
Vitamins	260	-	-	260(15.33)
Gastroprotective agents	258	-	-	258(15.21)
Miscellaneous	190(71.96)	70(26.51)	4(1.53)	264(15.56)

Table 3: Analysis of prescriptions format (n =410)

Parameters	No.	% of prescription
Diagnosis not mentioned	258	62.92
Chief complaints not mentioned	378	92.19
Duration not mentioned	8	1.95
Route not mentioned	288	70.24
Frequency not mentioned	170	41.46

Table 4: Adverse drug reactions and drug responsible

Type of reaction	No. of patients	Drug responsible
Maculopapular rash	03	Amoxicillin
	02	Co-trimoxazole
	01	Diclofenac sodium
	01	Phenytoin
	01	Ibuprofen
Fixed drug eruption	02	Cotrimoxazole
	01	Metronidazole
	01	Paracetamol
Urticaria	01	Diclofenac injection
	01	Ampicillin
Acneform eruption	03	Clobetasol
Hyperpigmentation	01	O.C pills
Total	18	

Discussion

A large number of drug utilization studies have been carried out in developed countries. Quantitative and qualitative geographical differences do exist in patterns of drug consumption and hence results of studies conducted in developed countries cannot be applied to developing countries.

Average number of drugs is an important index of prescription analysis and in the present study it was 4.13 which indicates the trend of polypharmacy. Polypharmacy has been reported to be the one of the cause of adverse drug reactions, drug-drug interaction, poor compliance towards treatment, increases cost of therapy^(9,12) Average number of drugs per prescription

was quite higher than previously conducted studies by Minocha KB. et al. and Badar VA, Shrivastava M. et al. which showed 2-3 drugs per prescription.^(13,14)

In our study most Prescriptions were inadequate in terms of documentation of diagnosis, dose, duration and frequency of drug administrations the dose and dosage schedule were poorly mentioned in majority of the prescriptions and this can also lead to an increase in the overall cost of treatment due to inappropriate use of drugs by the patient. Similar finding in-terms of adequacy of superscription, route of administration and duration of therapy were reported by Sharma P et al.⁽¹⁵⁾

The most commonly prescribed drug group in our study were Antihistaminics (20.59%) followed by antibacterials (16%) and antifungals. Higher use of antihistaminics were also reported by Tikoo D et al.⁽¹⁶⁾ while use of higher number of antibiotics was reported by Sajith M. et al.⁽¹⁾ Patients with symptoms of itching due to infectious or inflammatory disease was the common reason for greater use of antihistamines.

Among the total number of drugs prescribed, most of them were prescribed by the oral route (73%) followed by topical (24%) and injectable (2%) routes. While use of topical route was reported by Tikoo D et al.⁽¹⁶⁾ (topical route 60.2%).and Maini R. et al.⁽¹⁷⁾ (Topical 60%) The reason for high percentage of oral drugs being prescribed is that oral route is convenient and acceptable to patients.

Prescribing under a generic name is considered economical and rational but very few patients in the present study were prescribed by generic drugs (38.7%) as compared to branded drugs (61.3%). Our results were consistent with studies done by Maini R. et al.⁽¹⁷⁾ & Narwane SP et al.⁽¹⁸⁾

Drugs prescribed by generic names were cheaper compared to branded drugs, produces less chances of medication error. Poor prescribing of generic drugs can be because of concern about their quality.

Drugs from National Essential Drug List (EDL)⁽¹⁹⁾ constituted 63.91% in our study, while it was reported as 23% by Maini R. et al.⁽¹⁷⁾ 15.4% by Tikoo D et al⁽¹⁶⁾ and 51% by Georgekutty et al.⁽²⁰⁾ Use of essential drug list or hospital formulary based on National essential drug list helpful satisfying majority of health need of population in geographical area of tertiary care hospital which was

satisfactory in our study.

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 (44.44%) followed by fixed drug eruption (22.22%) and acneform eruption (16.66%). Study by Saha A. et al.⁽²¹⁾ reported commonest cutaneous ADRs were morbilliform eruption (30.18%), followed by fixed drug eruption (24.52%). Another study conducted by Shah SP. et al.⁽²²⁾ reported FDEs (27.3 %) were the commonest presentation followed by maculopapular rashes (24.5 %).

ADR findings in present study suggest that antimicrobials (50%), NSAIDs (22%), were responsible for most of ADRs. Similar findings also reported by study conducted by Shah SP. et al.⁽²²⁾ they reported, antibiotics (39%) were the most commonly suspected drugs followed by unknown medicines (29%) for cutaneous ADR. Saha A. et al.⁽²¹⁾ reported 17%, cutaneous ADRs due to Sulfa group followed by fluoroquinolones (11.30%)

As per WHO-UMC causality scale and majority of ADRs were 12(66.66%) possible and 05(27.77%) were probable in nature. Similar finding also reported by Shah SP. et al.⁽²²⁾

On severity assessment by modified Hartwig and Siegel's scale, out of 18 ADRs, 08(44.44%) were mild, 08 (44.44%) were moderate in nature. Study conducted by Achayra T et al.⁽²³⁾ reported 83% moderate 15% mild in nature on Hartwig and Siegel's scale.

Conclusion

The present study showed polypharmacy, more use of non-essential medicines and non-Generic (Branded) drugs. Hence there is a need to emphasize prescribers to adhere to the prescription guidelines and encourage use of the essential drug list which should be updated regularly and made available to all the physicians.

There is a clear need for development of standard treatment guidelines and educational initiatives like continued medical education (CME) 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. Hence, further ADRs due to particular drugs can be reduced in other patients with rational prescription.

References

1. Sajith M, Lokhande KD, Padma S, Pawar AP. Prevalence of various skin disorders and prescribing pattern of antihistamines 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/. Accessed: September 2014.
5. World Health Organization: Introduction to drug utilization research: Available at: http://www.whocc.no/filearchive/publications/drug_utilization_research.pdf accessed: September 2014.
6. Edwards IR, Arosen JK. Adverse drug reactions: Definitions, diagnosis and management. Lancet 2000;356:1255-56.
7. 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.p.102-04.
8. Lauraence DR, Bennett PN, Brown MJ. Unwanted effects and adverse drug reactions. Clinical Pharmacology. 8th edn. Churchill Livingstone 1997:121-37.
9. Uppal R, Nayak P, Sharma PL. Prescribing trends in internal medicine. Int J Clin Pharm Ther Toxicol 1984;22:373-76.
10. Bijoy KP, Vidyadhar RS, Palak P, Chintan SP, Atmaram PP. Drug prescribing and economic analysis for skin diseases in dermatology OPD of an Indian tertiary care teaching hospital. Indian J Pharm Pract. 2012;5(1):28-33.
11. Gupta N, Sharma D, Garg SK, Bhargava VK. Auditing of prescriptions to study antimicrobials in a tertiary hospital, 1997. 29(6):411-415.
12. 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.
13. Minocha KB, Bajaj S, Gupta K. A clinic pharmacological study of out-patient prescribing pattern of dermatological drugs in an Indian tertiary hospital. Indian J Pharmacol 2000;32:384-85.
14. Badar VA, Shrivastava MP, Badwaik RT. Surveillance of drug prescribing trends in skin OPD of IGMC. Indian J Pharmacol 2002; 34:150.
15. Sharma P, Kapoor B. Study of prescribing pattern for Rational Drug Therapy. JK Science 2003;5(3):107-09.
16. 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.
17. 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.
18. Narwane SP, Patel TC., Shetty YC, Chikhalkar SB. Drug Utilization and Cost Analysis for Common Skin Diseases in Dermatology OPD of an Indian Tertiary Care Hospital - A Prescription Survey British Journal of Pharmaceutical Research 2011;1(1):9-18.
19. Tripathi KD. In: Tripathi M (eds.) List of Essential Drugs. Essentials of Medical Pharmacology. 7th Edn.: Jaypee Brothers Medical Publishers Ltd., New Delhi, 2013; pp.957-61.
20. Georgekutty KV, Sambasivam N, Nagarajan M. A study on drug prescribing pattern in Madurai city. Indian J Pharmacol 2002;34:361-62.
21. 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.
22. 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.
 23. 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.