



PHARMACOEPIDEMIOLOGY OF DRUGS UTILIZED IN SKIN OUTPATIENT DEPARTMENT OF A TERTIARY CARE HOSPITAL

Pharmaceutical Science

**Dr. Puja Khanna
Malav**

Govt Medical College Kota.

Dr. Savita Saini

Govt Medical College Kota.

Dr. Arti Singh

Govt Medical College Kota.

ABSTRACT

Periodical auditing of drug utilization is vital for the purpose of promoting rational use of drugs. So, for pharmacoepidemiological analysis of the drugs, used in skin OPD, a study was held prospectively for 3 months, in the department of Skin and Pharmacology. Data were collected from prescription form of the patients in OPD. Various parameters of utilization pattern was evaluated. The maximum number of patients belonged to age group of -----years and lower middle class of socioeconomic status but there was no sex preponderance. Dosage, duration and frequency of therapy was recorded in more than 89% of prescriptions. the average number of drugs per prescription were 2.69 ; drugs prescribed with their generic names were 26.04% ; fixed dose combinations prescribed were 36.98% and polypharmacy found were 23.3% of prescription in the OPD. The commonest dosage form were ----- . More than 80% of drugs were prescribed from hospital pharmacy. Average total cost per prescription was -----INR in OPD; but was free of cost from hospital pharmacy.

KEYWORDS

Pharmacoepidemiology, Drug utilization study ,antifungal, opd, Antihistaminics, Cost analysis

INTRODUCTION

Skin is a part of integumentary system that constitutes the largest organ of human body and thus it is exposed to injury by various extrinsic factors like environmental, infectious, chemical agents as well as intrinsic factors such as metabolic, immunological and genetics. In addition to that, many systemic diseases are also identified by their dermatological manifestations therefore it is considered metaphorically as a mirror to various internal diseases [1,2].

Skin diseases are common and causes huge disease burden globally. overall skin is the 8th leading cause of health burden worldwide and it was 4th leading cause of non fatal health burden in 2010 worldwide [3]. The skin disorders constitute 2% of total Out Patient Department(OPD) consultations worldwide [4]. As such no data is available from India but still skin disorders in India are common and include pyoderma, urticaria,acne, dermatitis, scabies, fungal skin infections , alopecia etc [5].

The skin disorders have serious detrimental effects on quality of life of general population by increasing the physical, social, psychological sufferings as well as it increases financial burden as most of the skin diseases are chronic and needs longer duration of treatment[6].

In India, there are multiple problems in prescription pattern of drugs including irrational drug combinations, overuse of multivitamins, unwanted use of antibacterial in fungal conditions and prescribing drugs from same classes [7, 8]. It contributes to the emergence of antimicrobial resistance. Dermatologists account for nearly 5% of antibiotic prescriptions worldwide and most of the conditions requires prolonged treatment [9, 10]. Further, the skin conditions are wrongly diagnosed and managed. Thus continuous monitoring is required to evaluate pattern of drug use to find any changes from contemporary practices or available guidelines. hence in order to generate data, drug utilization studies are need of the hour.

Pharmacoepidemiology refers to the epidemiology methods for studying the clinical use and effects/side-effects of drugs in wide numbers of people with the motive of supporting the cost-effective and rational use of drugs in the population. this may be drug-oriented, emphasizing the safety and effectiveness of drugs as well as utilization-oriented in order to improve the quality of drug therapy via educational interventions. hence the drug utilization research or studies are the strong exploratory tools to ascertain the role of drugs in the society that refers to the marketing, distribution, prescription and use of drugs with emphasis on the medical, social and economic consequences. Thus drug utilization research have become an essential part of pharmacoepidemiology and together both provide the insights into varied aspects of drug prescribing and drug use like pattern of use, quality of use, determinants of use and its outcomes[11]. Therefore periodical auditing of drug utilization pattern is important for

promotion of rational use of drugs, for increasing the therapeutic efficacy and cost effectiveness, for reducing the adverse effects and to give feedback to the prescribers[12, 13]. Previous studies conducted in Australia suggest that academic detailing improves the quality of prescription and enhances the adherence of clinician to standard treatment guidelines[14]. Data regarding patterns of drugs used in India , particularly in dermatology department are too limited .

AIM

Considering these facts, the present study was planned with the purpose of pharmacoepidemiological analysis of the drugs to explain the pattern of use, their availability in the hospital and to evaluate their cost analysis in every prescription of skin OPD of tertiary care hospitals attached to GMC, Kota.

MATERIAL AND METHODS

The present study was conducted in the skin department in collaboration with department of Pharmacology and approval from Institutional Ethics Committee was taken before the initiating the study. Data were collected in a specially designed form to record the required information.

Analysis of prescriptions were done prospectively in outdoor patient department(OPD) visiting the OPD, thrice weekly or daily for 3 months.(November 2019 to January 2020)after taking the informed written consent from all the patients.

The variables evaluated from the prescriptions included the demographic profile(female/male, age, socioeconomic status as per Kuppuswamy scale indications for which the drug were prescribed, drugs prescribed by their generic or brand name, doses prescribed, dosage forms, frequency and routes of administration, duration of treatment,average number of drugs prescribed per prescription, number of fixed-dose combinations versus single agent, average number of drugs prescribed from hospital pharmacy and cost analysis for every prescription.

RESULTS

After screening the three months prescriptions of the patients, it was seen that a total of 752 prescriptions were analysed in OPD, among those -354(47.07%)--- were males and -398 (52.93%)-----were females. Thus female patients outnumbered the male in this view and male to female ratio was 0.88. Distribution of patients in OPD as per their age is shown in Table.1 where more than 50% of the patients were in the age group of 21 to 40 years and of which highest number of patients belonged to age group of 31-40 years (26.99%), followed by 21-30 year age groups(23.94%). Number of patients at two extreme of ages were much less i.e above 61 years only 3.06% followed by 6.91% at 0-10 years. It was seen that there was progressive increase in number of patients as the age of the patient increases upto 40 years and after

that there was a decrease in number of patient.

Table 1: Age Distribution

Age Distribution	No. Of patient	Percentage
0-10	52	6.91
11-20	83	11.04
21-30	180	23.94
31-40	203	26.99
41-50	143	19.02
51-60	68	9.04
61 & above	23	3.06
Total	752	100.00

The study population was also classified as per Kuppuswamy scale taking into account their education, type of profession and family income per month. In OPD, 59% of the patients belonged to the lower middle class, 18.33% to upper middle class, and the remaining 7.01% was of lower class. (Figure 1).

In the skin OPD, like in table -2 acne with (17.95 %) was most common dermatological disorder closely followed by eczema (16.62%) and dermatophytosis (14.89%). less percentage of patients had scabies (7.57%) particularly in paediatric age groups. Alopecia (4.12%) and psoriasis (3.06 %) were other diseases but these were comparatively uncommon. Pigmentation disorders including both hypo and hyper-pigmentation was 3.47%.

Table 2: Disease distribution(%)

Acne	17.95
Eczema	16.62
Dermatophytosis	14.98
Dermatitis	13.96
Pyoderma	12.37
Scabies	7.57
Alopecia	4.12
Pigmentation	3.47
Psoriasis	3.06
Others	5.98

As per table 3, antihistaminics (24.13%) were the most frequently prescribed class of drugs in OPD. Among antihistaminics 2nd generation antihistaminics levocetirizine (41.22%), fexofenadine (17.85%) and cetirizine (19.17%) were common while highly sedative hydroxyzine (11.77%) was used less frequently.

Table no -3 Drugs used (%)

Antihistaminics	24.13
Antifungals	21.02
Antibiotics	15.91
Steroids & combinations	13.01
Antacids	10.99
Others	5.91
Vitamins	4.95
Antiparasites	4.07

Antifungals (21.02%) were the 2nd most common prescribed drug class. Among oral antifungals, fluconazole (53.12%), itraconazole (21.73%) were used and amid topical agents clotrimazole, ketoconazole were used in form of powders, shampoos and soaps. Terbinafine (15.2%) was also used in both oral and cream form for dermatophytosis treatment.

Antibiotic (15.91%) were used in both oral (39.27%) and topical (60.73 %) route. Among oral antibiotics, azithromycin, amoxicillin-clavulanic acid and cefadroxil were used and amid topical antibiotics, clindamycin for acne treatment was very common, other than this mupirocin and fusidic acid and other fixed dose combination of 2 or more antibiotics or along with steroids were used very commonly.

Topical steroids and their combinations were prescribed more frequently as compared to oral or parenteral forms of steroids. This may be because of various systemic side effects of oral or parenteral steroids.

Ranitidine and pantoprazole were the two antacids prescribed frequently. Among antiparasites permethrin, ivermectin for scabies and albendazole, mebendazole as anthelmintics were prescribed in very few cases. Other drugs used in treating skin diseases were some anti-herpes drugs, antimetabolites such as methotrexate, keratolytic, emollients and antileprotic agents etc. As the number of new cases with

these diseases were very less, therefore we grouped all these drugs as other drugs and contribute 5.91 % of the prescriptions.

Dosage form of the drugs:

Table 4 depicts the drugs used in different dosage forms and route of administration for treatment of skin disease. It includes oral form i.e tablets (47.11%), parenteral (0.96%) and various topical (51.93%) route of administration. Usage of parenteral forms were very much limited and usually given for severe forms of infections, those resistant to oral antibiotics, intralesional steroids, and systemic fungal infections. Various anti-fungal and antibacterial agents were prescribed in topical dosage forms as cotrimazole powder, ketoconazole shampoo, mupirocin ointment, fusidic acid ointment, lotion, cream, gel. Also, various corticosteroids and their combinations in ointment and gel formulation were also available and prescribed. Tablets were prescribed most commonly (35.04%) that included antihistaminics, antifungal and antacids preparations. Some antibacterial, antacids and multivitamins were also prescribed in capsule form (4.07%). In topical agents, ointments were the most common formulation prescribed (21.00%) with different composition of steroids and their combinations.

Some parameters of pharmacoepidemiology that showed the dosage and frequency were recorded in more than 98% of prescriptions but the duration of treatment was recorded only in 89.4% of OPD prescriptions. The average number of drugs per prescription was 2.69% in OPD. Similarly, drugs prescribed by generic names were 26.04% in OPD and more than 60% of the drugs were prescribed by the brand names. The percentage of drugs dispensed from the hospital pharmacy was more than 80% while the percentage of fixed-dose combinations prescribed was 36.98% in OPD. The polypharmacy seen in the prescriptions were 23.3% in OPD. Regarding the dosage forms (Figure 2), it was seen that the most common dosage form of drug prescribed in OPD was ----- (81.92%) followed by ointment (17.63%), capsules (3.00%), tablets (5.33%) and syrups (0.75%).

Pharmaco economic datas of the prescriptions in OPD are presented in

DISCUSSION

Drug prescription forms an integral contact between the health care provider and the user (Nehru et al, 2005). It gives an insight into the nature of health care delivery system and is a contemplation of physicians attitude towards the disease and the role of drug in its treatment (Shanker et al, 2010). Datedly the pharmaceutical and medical professions have devoted considerable efforts and time for the development and rational utilization of safe and effective drugs for the treatment and prevention of diseases. There have been development of many new therapeutic agents which have made it attainable to cure or provide the symptomatic relief of many clinical disorders. though, in many circumstances drugs are not used rationally for optimum benefits and safety (Hussar et al, 1995).

Hence, pharmacoepidemiology can be a powerful tool that can benefit patient and public health but only if used appropriately by providing the insights into different aspects of drug prescribing and their uses. WHO organizes many drug utilization researches with the motive of rational prescription by various methods of auditing. The study was also a part of prescription audit.

After screening of 1200 OPD prescriptions, it was seen there was no preponderance {M:F= 1.3: 1} in the OPD amid the patients and the maximum number of patients belong to age group of ----- years. These findings manifested that the skin diseases are usually not sex linked but can be age related.

The economic status of the patients showed that most of the patient (59 % in OPD) belongs to the lower middle class (Figure 4) which was different with the result of the study conducted in psychiatry department, in which the most common class was upper lower class (Goyal et al, 2008). This high amount of lower middle class may be because of high prevalence of that community near the hospital or may be because of low registration and admission charges of the hospital.

Regarding the indications, we found the -----

The average number of drugs per prescription is prime criterion of the prescription audit. There has been recommendation that the limit of number of drugs prescribed per prescription should be two and justification for prescribing more than two drugs would be required

because of increased risk of drug interactions(Nies et al, 1990). In this study, the average number of drugs per prescription was 2.69% and that is more than the current recommendations. Other hospital based studies in India accounted 3-5 drugs per prescription is almost in same range or a little higher than our study (Maini et al, 2002, Kutty et al, 2002, Sharma et al 1990). Thus it is advisable to keep the number of drugs per prescription as low as possible since higher figures can lead to increased risk of drug interactions, higher hospital cost and errors of prescribing(Nies,1990, Atansova and Terzivanov, 1995, Pradhan et al, 1990).

The frequency, duration and dosage of drug therapy are the three vital parameters, if not clearly recorded, can result in indiscriminate and inappropriate use of drugs. In the present study we found that the dosage and frequency were recorded in more than 98% of prescriptions but the duration of drug therapy was recorded only in 89.4% OPD prescriptions. The same parameters were also eminent in a study in which the frequency of application was recorded in 93% and the duration of therapy was mentioned in 75% of all the prescriptions audited (Sharma et al, 1990). But few contrast results were also found in which the duration of treatment was not recorded for 73.26% of the drugs prescribed(Biswas et al,2001).

When the different dosage forms were compared it was viewed that ----were commonly prescribed in OPD followed by ointments, capsules, tablets and injections. The results of OPD were same to that of other studies in which the maximum number of drugs prescribed were in the form of ----- followed by -----(reference). These finding supports the use of topical formulations for treating skin diseases as they have site specific action, less systemic absorption and hence fewer side effects and more convenient for patient use.

Percentage of drugs prescribed by their generic names in our study was 26.04 % in OPD which was almost similar to one study (23%) as well as different (just over half i.e 53.6%) from some other studies(Ghosh et al,2003,Joshi et al, 1997). Few earlier studies have also reported to only 29.3% and 19% of drugs prescribed by the generic names(Rehana et al, 1998, Minocha et al,2000). this suggests the popularity of brand names amongst the medical practitioners of institutes and the influence of pharmaceutical companies. Prescriptions mentioning brand names could possibly result in prescribing (writing as well as reading) errors because brand names of many pharmacologically different drugs sound alike and spell similar. It can also lead to increase inside effects in turn increasing the cost of therapy(Rataboli and Garg 2005). In general, generic drugs are less costly as compared to the brand that consist the same active ingredient (Brady,2003). So the prescriptions of generic drugs must be emphasized to facilitate cheaper and better treatment for the patients.

The percentage of drugs given from the hospital pharmacy were more than 80% which was in contrast to other study(Narwane et al,2011). There were only some drugs which were not available in hospital pharmacy, therefore the hospital authorities should also make provisions for making these drugs at hand in the hospital pharmacy.

The fixed dose combinations(FDC) prescribed were 36.98% in OPD that was higher as compared to percentage of FDCs prescribed in another studies (Kshirsagar et al 1998, Narwane et al,2011)

Rational drug prescribing is described as the use of the least number of drugs to get the best possible effects in the shortest time duration and at a reasonable cost (Shanker et al, 2010). Since, WHO had recommended that average number of drugs per prescription must be two, result of our study reflects polypharmacy(Gross, 1981), it was 14% in OPD. The practice of polypharmacy must be restricted to conditions, as many a times they are unnecessary, rising the morbidity by pharmacokinetic and pharmacodynamic drug interactions and rising the cost of drug treatment.

As per our study , average total cost per prescription was 87.40 INR in OPD. The average hospital pharmacy cost per prescription was 0.00 INR. Due of free distribution of drugs in hospital pharmacy. hence the average cost borne by patient is always more as compared to the cost borne by hospital pharmacy.

The results were alike to the earlier studies where the cost paid by the patients was significantly more than that paid by the Hospital pharmacy (p< 0.0001)(Goyal et al,2008 and Narwane et al, 2011). The restraint of our study was that it was one cross sectional study and during calculating cost of treatment, we have not measured the actual

direct cost, cost of travelling, taking time off from work for the patient(Sharma and Das, 2006). among the direct costs , hospital and outpatient expenditure form the bulk (Swaminath,2008).

CONCLUSION

The study concluded with overall impression of rational prescription at maximum places. However it needs some improvements as duration of therapy was missing in some cases. This was also combined with low generic prescribing and less number of fixed dose combinations in OPD that may result in less safe and more expensive prescribing. Therefore it is necessary to make doctors aware about the use of drugs, importance of prescribing drugs by their generic names and for patients point of view, the factor of cost effectiveness. Also, there is a need for formulation of prescribing guidelines and educational initiatives to motivate the rational and appropriate use of drugs. Improvement via continuous education is desired on the part of prescribers to ensure a good level of care. Drug information services including side effects and drug interactions for professionals and consumers at the hospital are highly required. The hospital administration should look into issues of hospital by continuous monitoring of the prescriptions and increasing the availability of the essential drugs . The actual direct costs and indirect costs was not included in the study, which is the limitation of this study. Thus it is advised to conduct more of such studies in other department as well, to audit large number of prescriptions and also to educate the prescribers by means of short term training sessions on rational drug treatment for benefit and safety of patients. The prescription could then be re-audited to measure the impact of intervention. This would not only help in rationalizing the prescription practices based on the feedback from these studies but also we can compare these practises among different institutions, regions and countries.

ACKNOWLEDGEMENT

Authors are thankful to Dr. Sardana, Principal & Controller of GMC ,Kota for his encouragement in research work as well as to all the patients for their valuable cooperation.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest to disclose.

REFERENCES:

- [1] Clark AF, Ghosh K, Tonnesan MG. Tissue Engineering for Cutaneous Wounds. *Journal of Investigative Dermatology*. 2007; 127:1018-29. [PubMed] [Google Scholar]
- [2] Engman MF. The Skin: A Mirror to the System. *JAMA*. 1919;73(21):1565-68. [Google Scholar]
- [3] Hay RJ, Johns NE, Williams HC, Bollinger IW, Dellavalle RP, Margolis DJ, et al. The Global Burden of Skin Disease in 2010: An Analysis of the Prevalence and Impact of Skin Conditions. *Journal of Investigative Dermatology*. 2014; 134: 1527-34. [PubMed] [Google Scholar]
- [4] Saravanakumar RT, Prasad GS, Ragul G, Mohanta GP, Manna PK, Moorthi C. Study of prescribing pattern of topical corticosteroids in the department of dermatology in multi-speciality tertiary care teaching hospital in south India. *Int J Res Pharm Sci*. 2012;3(4): 685-87. [Google Scholar]
- [5] Gangadharan C, Joseph A, Sarojini PA. Pattern of skin diseases in Kerala. *Indian J Dermatol Venereol Leprol*. 1976;42:49-51. [PubMed] [Google Scholar]
- [6] Joel JJ, Jose N, Shatry CS. Patterns of Skin Disease and Prescribing Trends in Rural India. *Sch Acad J Pharm*. 2013;2(4): 304-09. [Google Scholar]
- [7] Soumerai S. Factors influencing prescribing. *Aust J Hosp Pharm*. 1988; 18(suppl): 9-16. [Google Scholar]
- [8] Hogerzeil HV. Promoting rational prescribing: an international perspective. *Br J Clin Pharmacol*. 1995; 39: 1-6. [PMC free article] [PubMed] [Google Scholar]
- [9] Divyashanti CM, Nandhini A, Kumar SA. Study on drug utilization pattern of antibiotics among dermatology in-patients of a tertiary care teaching hospital, Karaikal, Puducherry. *Int J Basic Clin Pharmacol*. 2014; 3(6): 1072-77. [Google Scholar]
- [10] Chon SY, Doan HQ, Maya RM, Singh SM, Gordon RA, Tying SK. Antibiotic overuse and resistance in dermatology. *Dermatologic Therapy*. 2012; 25(1): 55-69. [PubMed] [Google Scholar]
- [11] Sjoqvist F, Birkett D. Introduction to Drug Utilization Research(WHO Booklet) New York: WHO Office of Publication;2003. Drug utilization. In: Bramley DW, editor ; pp.76-79.[Google Scholar]
- [12] Sweileh WM. Audit of prescribing practices of topical corticosteroids in outpatient dermatology clinics in north Palestine. *Eastern Mediterr Health J*. 2006;12(1/2):161-69. [PubMed] [Google Scholar]
- [13] Good CB. Polypharmacy in elderly patients with diabetes. *Diabetes Spectrum*. 2002; 15(4):240-48. [Google Scholar]
- [14] Markey P, Schattner P. Promoting evidence-based medicine in general practice- the impact of academic detailing. *Fam Pract*. 2001;18(4):364-66. [PubMed] [Google Scholar]