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Original Research Article

DRUG UTILIZATION STUDY OF TOPICAL CORTICOSTEROIDS IN THE DEPARTMENT OF DERMATOLOGY IN A TERTIARY CARE HOSPITAL

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Abstract

Background: The present study was designed to study the prescription pattern, rationality of usage and to assess the adverse drug reaction to topical corticosteroids in Dermatology department. **Materials and Methods:** After obtaining approval from the Institutional Ethics committee a prospective, observational study was conducted in department of Dermatology, at a tertiary care hospital in north Karnataka. Patients of all age group of either sex prescribed with topical corticosteroids were included. A total of 1030 prescriptions were analysed in the study. The data was collected in a specially designed proforma and the prescriptions were analysed for demographic data, disease data, drug data, number of drugs prescribed by generic names, drug combinations prescribed and number of drugs available from hospital pharmacy. Any adverse effects due to usage of topical corticosteroids were noted. **Result:** Out of 1030 prescriptions, 638 were males and 392 were females. Majority of the patients belonged to the age group of 31- 40 years. The most common disease condition-encountered was allergic contact dermatitis (14.3%). Out of 1030 prescriptions, 1122 were corticosteroids; which amounts to 1.09 steroid per prescription. Clobetasol was the most commonly used topical corticosteroid. Antihistaminics were the most common concomitant drugs prescribed. 70.8% of drugs were prescribed in generic names. 76.2% of the drugs were essential drugs. 65.3% of the drugs were available in hospital pharmacy. The most common adverse effect noted was skin atrophy (2.9%). **Conclusion:** Use of topical corticosteroids was found to be appropriate as per standard guidelines and the current protocol of prescribing topical corticosteroids, with a minimum number of adverse drug reactions.

INTRODUCTION

Drug utilization studies aim to evaluate the factors related to prescription, dispensing, administration, consumption of medications and the associated events which could be either beneficial or adverse. The purpose of drug utilization studies is to evaluate the present trends of drug usage, estimate drug expenditures, appropriateness of prescriptions and adherence to evidence-based guidelines. The World Health Organisation (WHO) defines drug utilization as the marketing, distribution, prescription and the use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences.[1] Inappropriate patterns of drug use may lead to increased cost of medical care, antimicrobial resistance, adverse effects and patient morbidity and mortality. Irrational prescription of drugs is a common occurrence in clinical practice. The cost of such irrational drug use is enormous in developing countries in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks but no objective benefits.[4-9] Analysis of prescriptions will help in improving the standards of medical treatment at all levels in the health system, and also help in identification of drug use related problems such as polypharmacy, drug interactions and adverse drug reactions [6].Hence drug utilization studies serve as a potential tool for the evaluation of health systems. Drug utilization studies done on regular basis are essential to provide the clinicians an opportunity to review and make appropriate changes in the management of their patients.[10]

Dermatological conditions account for up to 2% of consultations in general practice worldwide and 10-20% in India.[4,5] The ultimate goal in dermatological therapy is to use the safest and least number of drugs; in order to obtain the best possible effect in the shortest period at a reasonable cost. Corticosteroids play an important role in the treatment of many skin diseases. They exhibit anti-proliferative,

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immunosuppressive and hormonal activities. They are being used extensively both as over-the-counter as well as prescription medications in the treatment of a wide variety of inflammatory diseases.[8] In dermatology, corticosteroids are prescribed either in topical or systemic formulations in various potencies according to the severity of the condition, anatomic location, area of involvement and patient age. Topical corticosteroids, which were introduced in the late 1950s, have revolutionized the practice of dermatology and they still constitute one of the largest groups of drugs used in this discipline.[7] The choice of specific corticosteroid is determined by various factors such as accuracy of diagnosis, age, socioeconomic status of the patients and knowledge of the clinician.

The current study was planned to understand the pattern of corticosteroid use in dermatological conditions as there was a paucity of such studies in this region.

MATERIALS AND METHODS

This is a prospective, observational study which was conducted in department of Dermatology, in a tertiary care hospital in North Karnataka, after obtaining approval from the Institutional Ethics Committee. The study population included all the patients prescribed with topical corticosteroids in their prescription, attending dermatology department. A total of 1030 prescriptions were analysed in the study.

Inclusion Criteria

- All age group of either sex prescribed with topical corticosteroids in dermatology department during study period.
- Willingness to give consent and available for further follow up in case of any adverse effects.

Exclusion Criteria

Prescriptions that do not contain topical corticosteroids.

The data was collected prospectively in a specially designed proforma by direct observation. Data was collected from the outpatient and inpatient prescriptions containing topical corticosteroids. The prescription was analyzed for the following: Demographic data, disease data, co-morbidities, topical corticosteroid usage and other drugs per prescription, indication, duration of treatment, dosage form, frequency of administration, formulation, average number of drugs per prescription, number of drugs prescribed by generic names, number of drug combinations prescribed, number of drugs available from hospital pharmacy, and whether the patients were given instructions regarding usage, dose, frequency of application and adverse reactions.

Statistical Analysis: The data was analyzed using descriptive statistics, namely mean and standard deviation for quantitative variables. To evaluate the appropriateness of prescription, standard treatment guidelines and essential medicine list was used. WHO drug use indicators for prescription patterns were also observed. Statistical analysis of the data, to generate graphs and tables were done using Microsoft Word and Excel.

RESULTS

Out of 1030 patients prescription 915 (88.8%) were outpatients (OP) and 115 (11.2%) were inpatients (IP). The common disease conditions where topical corticosteroids were prescribed were allergic contact dermatitis (ACD) 147(14.3%), Psoriasis 126(12.2%), Chronic eczema 80(7.8%), PLE 64 (6.2%), other papillosquamous diseases like Plaque psoriasis 60(5.8%) and bullous dermatoses which includes Pemphigus vulgaris 24(2.3%), Bullous pemphigoid 13(1.3%), autoimmune skin diseases and others. Out of 1030 patients, 979 (95%) of them had no associated co-morbidities. 21(2%) patients were suffering from BL Hansen's disease, 14(1.4%) were HIV positive. Other co-morbities included hypertension and diabetes.

Out of 1030 patient prescriptions 1122 corticosteroids preparations were prescribed. Each prescription contained 1.09 steroid prescribed in it. Clobetasol 680(60.6%) was the most common topical corticosteroid prescribed followed by Mometasone 120(10.7%). Others included Halobetasol + fusidic acid combination 101(9.0%), Betamethasone 81(7.2%), Dexamethasone 62(5.5%), Prednisolone 40(3.6%), Triamcinolone acetate 19(1.7%), Clobetasol + salicylic acid combination 10(0.9%), Clobetasol + fusidic acid 8(0.7%) and Mometasone + clotrimazole combination 1(0.1%). In our study ultra-high potent drug Clobetasol 680(60.6%) was prescribed most commonly followed by moderately potent Mometasone 120(10.7%) then ultra-high potent Halobetasol 101 (9.0%) then moderately potent Betamethasone 81(7.2%) and Triamcinolone 19 (1.7%).

Out of 1030 patients, 929 had concomitant medications. A total of 1497 concomitant drugs were prescribed which amounts to 1.6 concomitant drugs per prescription. Some of the most commonly prescribed concomitant medications were antihistaminic drugs (56.8%), Liquid Paraffin (8.5%), Ranitidine (6.5%), antimicrobial agents (3.9%) and others.

Prescription analysis: Among 1030 prescriptions, a total of 2741 drugs were prescribed. Out of these, 1941 (70.8%) were prescribed by their generic names, 2089 (76.2%) were essential drugs. On assessing drug combinations per prescription it was seen that in 54.8% prescriptions no combination therapy was used. Table 1 shows drug combination per prescription.

Out of 2741 drugs, 1789 (65.3%) were available in the pharmacy within the hospital. Remaining 952 drugs (34.7%) were to be purchased from outside. The dose as per finger tip unit, frequency and route

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of administration of topical corticosteroids were mentioned in all the prescriptions. ADVERSE DRUG REACTIONS: Out of 1030 patients, the adverse drug reactions were noted in 118 patients due to usage of corticosteroids. Most common adverse effect seen in our study was skin atrophy 30(2.9%), striae and purpura in 23 (2.2%) patients and others as shown in [Table 2].

Table 1: Combination of drugs per prescription.

Combination of drugs per prescription	Number	Percentage
0	565	54.85
1	408	39.61
2	36	3.50
3	18	1.75
4	2	0.19
5	1	0.10
Total	1030	100

Table 2: Adverse effects due to usage of corticosteroids

Adverse effect	Number	Percentage
No adverse effect	912	88.5
Skin atrophy	30	2.9
Purpura	23	2.2
Striae	23	2.2
Weight gain	18	1.8
Weakness	9	0.9
Acne	8	0.8
Cushing's Syndrome	3	0.3
Insomnia	2	0.2
Hyperglycemia	1	0.1
Osteoporosis	1	0.1
Total	1030	100

DISCUSSION

Glucocorticoids are used topically for a wide variety of dermatological conditions. The intensity of action depends on the extent of absorption into the deeper layers, thus, lipophilicity of the compound determines potency to a great extent.

As per our study most common skin conditions diagnosed were eczematous diseases like allergic contact dermatitis (14.3%), chronic eczema (7.8%), dermatitis (4.5%), acute eczema (4.2%), varicose eczema (3.0%), irritant contact dermatitis (3.9%) and papilla-squamous diseases like psoriasis vulgaris (12.2%), plaque psoriasis (5.8%), pustular psoriasis (4.4%), bullous dermatoses like pemphigus vulgaris (2.3%) and bullous pemphigoid (1.3%), auto immune skin diseases and others. This disease pattern is similar to the study conducted by Kumar MA et al and Kuruvilla et al, which showed eczematous diseases, were more common. This incidence of skin diseases depends mostly on the geographic location, genetic makeup and other environmental factors.[13]

In our study out of 1030 patients, 1122 steroid preparations were prescribed. Each prescription contained 1.09 steroids prescribed. All the prescriptions contained minimum of one topical corticosteroid as monotherapy or in combination. The drug dose, quantity, frequency and duration were mentioned in all the prescriptions. To compare our results with few similar studies on prescription patterns of topical corticosteroids in dermatology department, a study by Mahar et al,[14] found that in 28.4% of all the prescriptions containing topical steroids, drug dose, quantity, frequency and duration were not mentioned. Another study done by Madarkar et al,[15] observed that out of all prescriptions studied, duration of application was not mentioned in 35.04% and the site of application was mentioned in 53.8% prescriptions. In comparison to the above quoted studies, our study did not show any prescription with incomplete information regarding use of medication. Not specifying the quantity can result in under-usage of the preparation causing subsequent sub-therapeutic outcome, at the same time excessive usage can result in unwanted effects. This highlights the need for proper patient instructions regarding the usage of medication in order to improve treatment outcomes and reduce adverse drug reactions.

In our study Clobetasol (60.6%) was most commonly prescribed corticosteroid followed by Mometasone (10.7%), Halobetasol (9.0%), Betamethasone (7.2%) and Triamcinolone (1.7%). This pattern of use is similar to a study conducted by Divyashanthi et al,[16] where Clobetasol (33.3%) was the most commonly prescribed topical corticosteroid followed by Halobetasol propionate (7.3%). In our study salicylic acid was most commonly combined with topical corticosteroids for its keratolytic action which promoted good penetration, which shows rational combination of drug therapy which is essential for improved drug response. This is similar to a study by Khan NA et al,[17] Divyashanthi et al,[18] and Sarvanakumar RT et al 4 where topical corticosteroids were combined with salicylic acid. Similar to our study, a study by Padma L et al showed Antihistaminic (34.69%) were more commonly prescribed systemic drugs along with corticosteroids

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as itching was the associated complaint. Other important concomitant drugs used in our study were antacids to prevent gastric irritation, Calcium preparations to avoid osteoporosis, systemic antibiotics and antifungals because of the presence of secondary infections.

Use of generic names usually provides flexibility to the dispensing pharmacist and generic drugs are less expensive than branded drugs. In our study out of 2741 drugs, 70.8% were prescribed by their generic names; however in a study conducted by Mirshad PV et al, all the prescriptions were prescribed by their brand names.

Average number of drugs per prescription is an important index of prescription audit. In our study out of 1030 patient prescriptions a total of 2741 drugs (2.7 drugs per prescription) were prescribed. 56.4% prescriptions contained 2 drugs per prescription and 20.7% prescriptions had 3 drugs per prescription. A study conducted by Nehru M et al, found 48.18% prescriptions had single drug per prescription and 30.9% prescriptions 2 drugs per prescription. This shows that there is a tendency towards polypharmacy in dermatological disorders. It is preferable to keep the number of drugs per prescription as low as possible since higher numbers lead to increased risk of drug interactions, adverse effects, development of bacterial resistance and increased cost to the patient. In our study, 76.2% drugs were prescribed from essential drug list. These drugs should be made available in the hospital pharmacy as they are cheaper in cost, it must be prescribed by all the doctors to reduce the cost burden on the patients. In our study, it was observed that most of the drugs were available and prescribed from the hospital pharmacy i.e. out of 2741 drugs, 1789 (65.3%) were available in the pharmacy within the hospital. Making the drugs available in the hospital pharmacy reduces the patients' efforts in procuring the medicines.

Out of 1030 patients, the adverse effects were noted in 118 patients. Some of the common adverse effect seen were skin atrophy 30(2.9%), purpura 23(2.2%), striae 23(2.2%), weight gain 18(1.8%), weakness 9(0.9%), acne 8(0.8%) and others. According to the study conducted by Patel H et al, cutaneous adverse effects of topically applied corticosteroids were observed in 36.7% patients. Fixed erythema and hypopigmentation were the most commonly reported ADR followed by striae and telangiectasia which differed from our study. From our study it is evident that majority of the dermatological prescriptions were written with a thorough knowledge of the recent prescribing guidelines. Even after several decades of introduction of topical corticosteroids they continue to be the first line therapy for various dermatological conditions. Though topical calcineurin inhibitors have become available, the value of topical corticosteroids has not diminished. However, maintaining balance between judicious use and frequent abuse of these compounds is a challenge which needs to be addressed. Hence, physician vigilance and patient education is an important way by which the issue of corticosteroid abuse can be tackled.

CONCLUSION

Prescription pattern studies help to generate data which can be of great value to researchers and policymakers. In our study common skin conditions encountered were allergic contact dermatitis, eczematous disease, psoriasis. We found that topical corticosteroids like Clobetasol, Mometasone and Halobetasol were used most frequently, since they have moderate to high potency, high efficacy with low incidence of adverse reactions. These drugs are used as once daily application and average number of drugs per prescription was as low as possible thereby reducing polypharmacy which in-turn helps in better patient compliance. The percentage of drugs prescribed by generic name and from essential drug list was high and efforts may be initiated to encourage the same. The key to safe use of topical steroid is the short term use of appropriate potency steroid. However, strict implementation of the existing regulations is the need of the hour to prevent their widespread abuse.

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