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PROSPECTIVE STUDY OF TOPICAL CORTICOSTEROIDS IN DEPARTMENT OF DERMATOLOGY IN TERTIARY CARE CENTRE IN BIHAR

Dermatology

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ABSTRACT

BACKGROUND: Drug utilization studies aims to evaluate the factors related to prescription, dispensing, administration, consumption of medications and its associated events (either beneficial or adverse). The present study was designed to study the prescription pattern, rationality of usage and also to study and assess the adverse drug reaction of topical corticosteroids in Dermatology department. **MATERIAL AND METHODS:** This is prospective, observational study was conducted in department of Dermatology, JNKTMCH, Madhepura Bihar. All age group patients of either sex prescribed with topical corticosteroids were included in the study. The study was duration one year. A total of 1030 prescriptions were analysed in the study. **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.

KEYWORDS

Topical corticosteroids; drug utilization study.

INTRODUCTION

Their scope is to evaluate the present state and future trends of drug usage, estimate crude disease prevalence, drug expenditures, appropriateness of prescriptions and adherence to evidence-based recommendations. Inappropriate drug use may lead to increased cost of medical care, antimicrobial resistance, adverse effects and patient mortality. The development of drug utilization as a research field has made it possible to study drug prescription and drug usage in a scientific and formal manner.

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. Drug use is a complex process, in any country a large number of social, cultural and various other factors contribute to the ways the drugs are being used. various factors includes national drug policy, illiteracy, poverty, use of multiple health care systems, drug advertising and promotion, sale of prescription drugs without prescription, competition in the medical and pharmaceutical market place and limited availability of independent unbiased drug information. Inappropriate drug use may lead to increased cost of medical care, antimicrobial resistance, adverse effects and patient mortality. Hence in recent years drug utilization study has become a potential for the evaluation of health systems. Dermatological conditions account for upto 2% of consultations in general practice worldwide and 10-20% in India . In developing countries, irrational use of drugs/non specific use of drugs is responsible for the scarcity of drug resources leading to an increase in the expenditure and burden to the government/patients, Corticosteroids have an important role in the treatment of many diseases including skin diseases. Their application is immense in the field of dermatology. 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. One of the steps to achieve this is to monitor, evaluate and therapeutically analyse the prescriptions of dermatological drugs. Such analysis will not only improve the standards of medical treatment at all levels in the health system but, will also help in the identification of problems related to drug use such as polypharmacy, drug interactions and adverse drug reactions, Dermatology is one of the few disciplines in which we are able to apply therapy directly to the target site. Concentration, vehicle and the frequency of application can all be altered according to the response, which can easily be monitored. The drugs commonly used in dermatology are vitamins/minerals, antibiotics, antiseptics, antifungal, antiviral, antihistamines, emollients, keratolytics, antiparasitics and corticosteroids. In dermatology, corticosteroids (Cs) are widely prescribed either in topical or systemic formulations in various potencies to tailor therapy according to the severity of the underlying condition, anatomic location of application, area of involvement and patient age. Topical corticosteroids (TCs) are some of the most frequently used agents in modern topical therapy. They exhibit anti-proliferative, immunosuppressive and hormonal activities. Almost 6 decades after their introduction, they continue to be used extensively both as over-the-counter as well as in prescriptions in treatment of a wide variety of inflammatory diseases, Collection of data on utilization of drugs at the hospital level is an effective tool to constitute guidelines for improving drug utilization patterns. This has resulted in a more effective rational therapy and an economic benefit in the use of drugs.

OBJECTIVES

To evaluate the rationality of topical corticosteroids usage in dermatology department. To study and assess the adverse drug reactions to topical corticosteroids.

Review of Literature

The World Health Organization (WHO) in 1997 defined drug utilization as the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social and economic consequences. The interest in drug utilization studies began in the early 1960s and its importance has increased since then, because of increase in the marketing of new drugs, wide variation in the pattern of drug prescription and consumption, growing concern about delayed adverse effects and increase in concern regarding the cost of drugs. the major source of data on drug utilization are several private companies that specialize in collecting these data and then selling them to the pharmaceutical manufacturers for its use in marketing studies. Studies on the process of drug utilization focus on factors related to prescribing, dispensing, administration, consumption of medications and its associated events , covering the medical and non medical determinants of drug utilization, the effects of drug utilization, as well as studies of how drug utilization relates to the effects of drug use in a beneficial or an adverse way. Different types of drug usage information are required depending on the problems being evaluated. It includes information about the overall drug use or usage of drug groups, individual generic compounds or specific products. Often information about the condition being treated, about the patient and about the prescriber is also required. In addition data on drug costs are required to ensure that drugs are used efficiently and economically. Corticosteroids have been used as a drug therapy for more than six decades. Corticotherapy was born in the late 1940s, at a time when steroid chemistry was beginning to offer new therapeutic pathways. The isolation and identification of the adrenal steroids by Reichstein and Kendall and the effects of these compounds on carbohydrate metabolism (hence the term *glucocorticoids*) culminated with the synthesis of *cortisone* - the first pharmacologically effective glucocorticoid to become readily available. Subsequently, Tait and colleagues isolated and characterized a distinct corticosteroid – *aldosterone* which affected fluid and electrolyte balance and therefore was termed as *mineralocorticoid*. The isolation of distinct corticosteroids that regulated carbohydrate metabolism or fluid and electrolyte balance led to the concept that the adrenal cortex comprises two largely independent units: an outer zone that produces mineralocorticoids and an inner region that synthesizes glucocorticoids and androgen precursor, Corticosteroids or glucocorticoids, which were introduced in the late 1950s, led to a revolution in the treatment of dermatological diseases and even to this

day they constitute one of the largest and commonly used groups of drugs in dermatological practice. Corticosteroids are prescribed frequently for their immunosuppressive and anti-inflammatory properties. They are administered locally through topical and intralesional routes, systemically through intramuscular, intravenous and oral routes.

MATERIAL AND METHODS:

This is prospective, observational study was conducted in department of Dermatology, JNKTMCH, Madhepura Bihar. All age group patients of either sex prescribed with topical corticosteroids were included in the study. The study was done over a period of 12 months, All the patients prescribed with topical corticosteroids in their prescription attending dermatology department.

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 which do not contain Topical corticosteroids.

Sample Size

A total of 1030 prescriptions were analysed in the study. The data was collected prospectively by direct observation in a specially designed proforma containing relevant details such as demographic data, disease and drug history. Data was collected from the outpatient and inpatient prescriptions containing topical corticosteroids. Prescriptions were collected twice weekly for a period of 1 year.

Statistical Analysis

The data collected were analyzed by using descriptive statistics, namely mean and standard deviation for quantitative variables. To evaluate the appropriateness of prescribing, standard treatment guidelines and essential medicine list was used.

RESULTS

Age Distribution .A total of 1030 patients prescription data were collected. Out of 1030 patients 252 (24.4%) of them belonged to the age group of 31-40 years.

Age distribution of study participants

Age group (years)	Number	Percentage
0-10	19	1.8
11-20	94	9.1
21-30	171	16.6
31-40	252	24.4
41-50	169	16.4
51-60	186	18.1
61-70	113	11.0
71-80	20	1.9
>80	6	0.6
Total	**1030**	**100**

The common disease conditions encountered 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, Out of 1030 patients, 979 of them had no associated co-morbidities. 21(2%) patients were suffering from BL Hansen's disease, HIV positive 14(1.4%) and others. Out of 1030 patients 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%), 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, 101 patients were not prescribed with any concomitant drug. In the remaining 929 patients a total of 1497 drugs were prescribed. Each prescription contained 1.6 concomitant drug per prescription.

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 in our study was skin atropy 30(2.9%), striae and purpura in 23 (2.2%) patients.

DISCUSSION

Glucocorticoids are used topically for a large variety of dermatological conditions. The intensity of action depends on the extent of absorption to the deeper layers, thus, lipophilicity of the compound determines potency to a great extent. Misuse or abuse of TCs appears to be a common problem in our country. This is reflected by the large proportion of patients who visit the Dermatology Department with adverse effects of these drugs. However, the real problem is even greater than what it appears, there are number of indications where topical corticosteroids are contraindicated, but if applied to bring about an initial relief it makes the disease very difficult to treat by a dermatologist as the clinical picture and response to the actual treatment gets modified significantly. In our study out of 1030 patients, 638 (61.9%) were males and 392 (38.1%) were females patients (fig 9) which is similar to the study done by aryal et al. . This denotes that skin disease can occur in all age groups and are more common in males. Most of the prescriptions in our study were outpatients as compared to inpatients. As per our study most common skin conditions diagnosed were eczematous diseases like allergic contact dermatitis 147(14.3%), chronic eczema 80(7.8%), dermatitis 46(4.5%), acute eczema 43(4.2%), varicose eczema 31(3.0%), irritant contact dermatitis 40(3.9%) and papillosquamous diseases like psoriasis vulgaris 126(12.2%), plaque psoriasis 60(5.8%), pustular psoriasis 45(4.4%), bullous dermatoses like pemphigus vulgaris 24(2.3%) and bullous pemphigoid 13(1.3%), auto immune skin diseases and other diseases. This disease pattern was 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 relies mostly on the geographic location, genetic makeup and other environmental factors, 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 almost all the prescriptions.

To compare our results with few similar studies on prescription patterns of topical corticosteroids in dermatology department, in a study by Mahar et al topical steroids were given in 28.4% of all the prescriptions where drug dose, quantity, frequency and duration were not mentioned. Clobetasol 680(60.6%) followed by Mometasone 120(10.7%), 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%), As per our study the concomitant drugs prescribed along with corticosteroids, showed antihistaminics 850(56.8%) were most commonly prescribed followed by liquid paraffin 127(8.5%), antacids 98(6.5%) and antibiotics 58(3.9%). A similar study by Padma L et al. showed Antihistaminic (34.69%) were more commonly prescribed systemic drugs along with corticosteroids as itching was the associated complaint. Other important concomitant drugs used were antacids to prevent gastric irritation, Calcium preparations to avoid osteoporosis, systemic antibiotics and antifungals because of the presence of secondary infections. Multivitamin, Iron preparation and other drugs were prescribed depending upon patient requirements. In our study it was observed that most of these 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. Remaining 952 drugs (34.7%) were to be purchased from outside. The adverse effects noted in our study. Out of 1030 patients, the adverse effects were noted in 118 patients. Most common adverse effect seen were skin atropy 30(2.9%), purpura 23(2.2%), striae 23(2.2%), weight gain 18(1.8%), weakness 9(0.9%), acne 8(0.8%) ,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 this study it is clear that majority of the dermatological prescriptions were written with a thorough knowledge of the recent guidelines. The pitfalls in prescribing pattern elsewhere might be because of non availability of

particular drugs in their hospital pharmacy or due to availability of drugs in particular brand names.

CONCLUSION

In our study topical corticosteroids like Clobetasol, Mometasone and Halobetasol were used most frequently, since they are moderate-high potent, more efficacious, once daily application with better patient compliance and reduced adverse drug reactions were seen. Common skin conditions encountered were allergic contact dermatitis, eczematous disease, psoriasis. The therapies provided in the above prescriptions were efficacious.

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