Available online at: www.ijmrhs.com DOI: 10.5958/2319-5886.2016.00017.5
Research article Open Access

EVALUATION OF CORTICOSTEROID USE PATTERN IN STEROID RESPONSIVE DERMATOLOGICAL CONDITIONS

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ARTICLE INFO

Received: 12th Dec 2015
Revised: 29th Dec 2015
Accepted: 31st Dec 2015

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Keywords: Adverse Drug Reactions, Corticosteroid Drugs, Dermatology, Drug Utilization

ABSTRACT

Background: Skin diseases account for 2% of the Out Patient Department based consultations in general practice worldwide, which includes diseases like, Dermatitis, Eczema, Acne, Urticaria, Psoriasis, skin allergy etc. Corticosteroids are one of the most commonly prescribed drugs in the skin diseases. Collection of data on the utilization of drugs at the hospital out-patient level has been shown to be an effective tool to constitute guidelines for improving utilization patterns. **Objectives:** Present study was designed to study utilization pattern of corticosteroid drugs with special emphasis on their adverse effects in a tertiary care teaching hospital. **Materials and Methods:** Prescriptions from department of dermatology were evaluated to know current trends. **Results:** Out of total 756 patients, 56.34% were male and 43.65 % were females. Corticosteroids were most commonly prescribed for Eczema (27.38%). 28.43 % of the drugs were prescribed from WHO essential drugs list. Corticosteroids were most commonly prescribed by topical route (86.48%). Diagnosis was included in 92.72 % of the prescriptions, while strength of the topical corticosteroidal was mentioned in 84.78 % of the prescriptions. Strength of the topical corticosteroidal was mentioned in 84.78 % of prescriptions. High potency topical corticosteroids were prescribed most frequently (63.72%). Total 32 steroid related adverse drug reactions were reported, Prednisolone was most commonly associated with adverse drug reactions. **Conclusions:** Present study reports use of High potency corticosteroids more frequently than others and emphasizes need of rational and complete prescribing of steroids in dermatology.

INTRODUCTION

Skin diseases are one of the commonly encountered medical conditions in outpatient department. Commonly encountered skin conditions in India are eczema, dermatitis, Urticaria, fungal skin infections, acne etc. It has been estimated that worldwide OPD based consultations for skin related diseases account for up to 2% cases[1]. Skin diseases have a serious impact on people's quality of life in developing countries, more so in India where climate, socioeconomic status, religions and customs are widely varied in different parts of the country.[1] Commonly used drugs for treatment of dermatological conditions include antibiotics, antiseptics, corticosteroids, antifungals, antivirals, antihistaminics, local anesthetics, emollients, keratolytics, antiparasitics, vitamins. The topical corticosteroids are among the most commonly prescribed medication in dermatology settings since they were first introduced in early 1950s.[2] 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 reasonable cost. Therefore, prescribing of drugs needs to be continuously assessed and refined suitably and it reflects the dermatologist's skill in diagnosis and attitude towards selecting the most appropriate cost effective treatment. For successful treatment with corticosteroids (topical and to a less extent systemic) key factors to be considered are accurate diagnosis, selecting the correct drug, keeping in mind the potency, delivery vehicle, frequency of application, duration of treatment and adverse effects, and proper patient profiling.[3] Collection of data on the utilization of drugs at the hospital out-patient level has been shown to be an effective tool to constitute guidelines for improving utilization patterns. This will result in more effective and rational therapy as well as economic benefits in the use of drugs and also identification of problems related to drug use such as polypharmacy, drug–drug interaction and adverse drug reactions. [4]

Objectives: Present study was planned to analyze the prescribing pattern of steroids used in the department of dermatology (inpatient and outpatient) and their adverse effect profile.

MATERIALS AND METHODS

Study design: A prospective and observational study
Place of research& time frame: The study was carried out to analyze prescriptions from outpatient and inpatient department of dermatology at B. J. Govt. Medical College, Pune from 1 August 2013 to 30 July 2014.
Ethical approval: The study was started after approval from Institutional Ethics Committee and informed consent was taken from the participants.

Inclusion criteria: Patients of either sex attending dermatology department, receiving corticosteroids in any form were included in the study.

Exclusion criteria: HIV patients, Severely ill patients, cancer chemotherapy patients.

Sample size: Total 756 patients visiting department of Skin and Venereology,

Methodology: They were interviewed and necessary information regarding their diseases and therapy was collected as per case record form. Patients form In Patient. Department were followed up till their hospital stay. During visits, patients were asked about any adverse drug reactions they had developed. Their case record files were also seen to detect any adverse drug reaction if recorded. For information regarding adverse drug reactions, a check-list was used. Causality analysis as per Naranjo criteria was performed.[5] The data gathered was tabulated in different parameters like age, sex, diagnosis, no. of drugs/formulations prescribed, and Adverse Drug reactions due to glucocorticoid drugs observed.

RESULTS

Total 756 prescriptions were reviewed during the period of 1 August 2013 to 30 July 2014.

Demographic details:

Age wise classification: Highest number of patients (523 (69.17%)) were belonging to 21-60-year age group. 127 (16.79 %) and 25 (3.30 %) patients were > 60 years and < 20 years respectively. 47.75 % (361) patients were in the reproductive age group (15-49 years of age).

Sex wise classification: Among 756 patients, 426 (56.34%) were males while, 330 (43.65%) were females.

Classification based on diagnosis: 42 skin conditions in 756 patients were noted in which corticosteroids were prescribed. Corticosteroids were most commonly prescribed for Eczema (207 patients) followed by various types of psoriasis (166 patients). Table no. 1 shows common indications for corticosteroids.

Table 1: Common indications for corticosteroids

Name of Disease	No. of Cases	%
Eczema	207	27.38
Psoriasis	166	21.95
Dermatitis	73	9.65
Lichen Planus	41	5.42
Alopecia areata	35	4.62
Vitiligo	34	4.49
Urticaria	26	3.43
Hansen's disease	16	2.11
Prurigo Simplex	11	1.45
Amyloidosis	9	1.19
Others	138	18.25

Indications for steroid prescription: Steroids were mostly commonly prescribed for Eczema (27.38 %) followed by various forms of psoriasis (21.95 %) followed by various forms of dermatitis 9.65 %. Corticosteroids were prescribed less frequently for diseases like Keloid (0.92%), Melasma (0.92%), Stevens Johnson syndrome (0.79%), Erythema (0.66%), Discoid Lupus Erythematosus (0.66%), Xerosis (0.66%), Behcet's disease (0.52 %), Atopic diesthesis (0.52%), Tinea corporis (0.52 %), Pemphigus vulgaris (0.39%), Gianotti Crosti syndrome (0.26%), Hand foot mouth disease (0.26%), Pityriasis lichenoid chronica (0.26%), Acanthosis nigricans (0.13 %), Mycosis Fungoides (0.13%), Bullous pemphigoid (0.13%), Milria Rubra (0.13%), Dapsone sensitivity syndrome 0.13%) Intertrigo (0.13%) etc. table no.1 describes the common indications for corticosteroids.

Prescription details: The patient's name, age and sex were mentioned on 100 % of the prescriptions. Diagnosis was included in 92.72 % of the prescriptions. Average number of drugs prescribed per prescription were 3.64. Out of the 756 patients 661 patients were prescribed only one corticosteroid while 95 patients were given more than one corticosteroids like oral prednisolone along with topical corticosteroids. Strength of topical corticosteroid preparation was mentioned in 84.78 % of the prescriptions. None of the prescriptions carried instructions or special instructions to patient. All of the patients were given verbal instructions. **783 (28.43 %)** out of 2754 drugs prescribed belong to essential drug list published by World Health Organization (WHO) in April 2013.[6]

Route of administration of corticosteroids: Majority of the corticosteroid (86.48 %) were given by the topical route as shown in table no 2 while vary few corticosteroids (8.34 %) were given by oral route.

Table 2: Route of administration of corticosteroids

Route of administration of topical corticosteroids	OPD	IPD	No of prescriptions (%)
Oral: Prednisolone	26	45	71(8.34)
Parenteral: **Intralesional:** • Triamnicilone • acetonide **Intravenous:** Hydrocortisone Acetate	3	41	44(5.17)
Topical: Fluocinolone Acetonide, Halobetasol Propionate, Betamethasone Valerate, Clobetasol Butyrate	589	147	736(86.48)
Total	**618**	**233**	**851(100)**

Corticosteroids per prescription: 87.43 % of the patients were prescribed only one corticosteroid preparation while 12.56 % of the patients were given more than one corticosteroid as shown in figure no. 1.

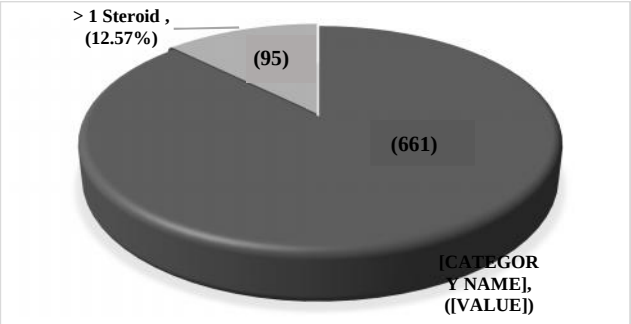

Fig 1:No. of corticosteroids per prescription

Details of topical corticosteroids prescribed: Frequency of application was mentioned in all the 100 % of the prescriptions while site of application was

mentioned in 70.89 % of the prescriptions. Strength of the corticosteroid preparation was mentioned in 84.78 % of the prescriptions. Quantity of the ointment/ cream/lotion to be applied was not mentioned in any of the prescriptions. Topical corticosteroids were most commonly prescribed in cream form (34.15 %) as shown in table no.3.

Table 3: Details of topical corticosteroids prescribed

Contents of prescription	Mentioned	
	n	%
Generic name of the drug	698	82.02
Strength of the drug	624	84.78
Duration of treatment	736	100
Quantity to be used	0	0
Site of application	536	70.89
Frequency of application	736	100

Potency of prescribed corticosteroids: In Present study, high potency corticosteroids.[7] were prescribed most frequently (63.72 %) followed by moderate potency (15.03 %) as shown in figure no. 2.

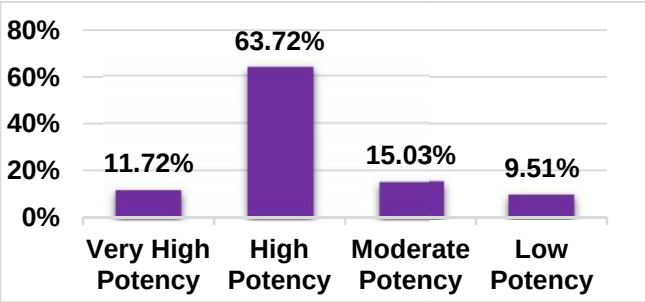

Fig 2: Formulations of topical corticosteroids prescribed

Fixed Drug Combination's (FDC) with corticosteroids: A Total of 8.83 % (65) topical corticosteroids out of 736 were prescribed as a Fixed Drug Combination (FDC) along with other drugs, the details of which have been elaborated in figure no. 3.

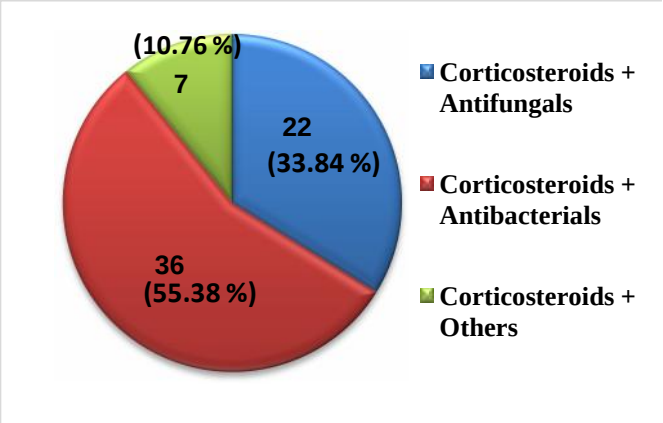

Fig 3. Fixed Drug Combination's (FDC) with corticosteroids

Adverse drug reactions encountered with corticosteroids: Total 32 steroid related adverse drug reactions were observed in present study. They were assessed using Naranjo's Algorithm. All **(100 %)** reactions were marked as **"Probable"** on Naranjo's scale.[5] Oral prednisolone was most commonly associated with adverse drug reactions (34.37 %) like moon facies, truncal obesity, gynecomastia, hirsutism etc. followed by Fluocinolone Acetonide (21.87 %) as described in table no. 04. Corticosteroid related Adverse Drug Reactions were treated by either stopping or tapering the dose of the suspected corticosteroid gradually. Patients were also given symptomatic treatment along with antihistaminics drugs (Hydroxyzine, Cetirizine.)

Table 4: Corticosteroids associated with Adverse Drug Reactions

Drug: Adverse Drug Reaction (ADR)	No. of ADR
Prednisolone: Moon Facies, Posterior sub capsular cataract, Hirsutism, Truncal obesity, Gynecomastia	**11**
Fluocinolone Acetonide: Rebound flare of psoriasis, Flaring of infection, Skin atrophy, Acneiform eruptions	**7**
Clobetasol : Thickened lichenified skin, Hyperpigmentation of forehead, Skin hypopigmentation, hyperpigmentation of skin	**5**
Halobetasol: Atrophy of skin, Perioral hyperpigmentation, Local irritation of skin, Hypersensitive reaction	**4**
Triamcinolone acetonide: Scarring of skin	**3**
Betamethasone: Scarring of skin, Hypersensitivity reaction.	**2**
Total	**32**

Drugs co-administered along with corticosteroids: Analysis of prescriptions showed that Antihistaminics drugs like cetirizine/levocetrizine, chlorpheneramine, hydroxyzine were most commonly co-prescribed along with corticosteroids (42.19 %), followed by Nutritional agents (Vitamin B Complex, Ferrous fumarate, Calcium) 15.86 %. Table no. 5 describes in details the commonly prescribed co-administered drugs along with corticosteroids.

Table 5: Drugs co-administered along with corticosteroids

Category of Drug	N	%
Antihistaminic Drugs • Cetrizine/Levocetrizine • Chlorpheneramine • Hydroxyzine Hydrochloride	803	42.19
Nutritional Drugs • Vitamin B Complex • Calcium • Ferrous fumarate	302	15.86
Dermal Protectant Agents • Octionoxate • Avobenzone	299	15.71
Antimicrobials **Antiviral Drugs** (Acyclovir)	19	1.00
Antifungal Drugs (Turbinafine HCL)	104	5.46
Antibacterial Drugs (Amoxicillin, Ampicillin, Azithromycin, Oflaxacin)	195	10.24
Immunosuppressant Agents • Tacrolimus • Methotrexete	76	3.99
Analgesic, Antipyretic Agents • Paracetamol, • Diclofenac Sodium, • Aceclofenac Sodium)	20	1.05
Other Drugs • Ranitidine • White petrolium jelly • Colchicine • Hydroxychloroquine Sulphate	85	4.46
Total	**1903**	**100**

DISCUSSION

Periodic reviewing of prescriptions is essential to increase the therapeutic efficacy, decrease adverse effects, provide feedback to prescribers and analyze the observance of standards of medical treatment.[8] Seven hundred fifty-six prescriptions containing 2754 drugs were audited in present study. Average number of drugs per prescription was found to be 3.64 in present study Padma L et al [9], reported average drugs prescribed per patient to be 3.65 which is similar to our study. Brand vs Generic Topical corticosteroids prescription was 82.02 % and 17.97 % in our study which is similar to the results obtained by Narwane SP et al.[10] who reported the same ratio to be 83.4 % and 16.6 % respectively. Only 8.83 % of the steroids were given as combination products containing antimicrobials, while majority (91.17 %) were given as single drug. Rathod SS et al.[11] found 88.74% and 11.26 % of the topical corticosteroids prescribed as single and combination product in their study which matches with our study. In present study high potency corticosteroids were prescribed most commonly (63.72 %). In a study carried out in USA in 1989 to 1991 by Stern RS et al.[12] it was observed that dermatologists were 3.9 times more likely to prescribe very high potency steroids than were other physicians. Corticosteroids were most commonly prescribed in cream form (94.15 %) in present study as compared to ointments (3.26 %) and lotions (2.58 %). The most commonly prescribed systemic agents were antihistaminic (42.19 %) which correlates with the finding of studies by Minocha et al.[13] who found 39.37 % of the antihistaminics prescribed in their study. The amount of the cream/ointment/lotion to be applied was not mentioned in any of the prescriptions which is very important regarding topical preparations as because the amount dispensed from prearation and actually used will have wide variation. Total 32 Steroid related adverse drug reactions were reported in present study. In present study most of the adverse drug reactions were due to chronic use of corticosteroids. Prednisolone was found to be the commonest drug associated with adverse drug reactions, similar with the study done by Ankit P. et al.[14] who also found prednisolone to be most commonly associated with adverse drug reactions. The Adverse Drug reactions observed in present study were chronically obvious type. Thus this study does not evaluate the immediate (early) ADRs associated with corticosteroid use, which is the limitation of present study.

Assessment of direct cost of the drug as well as the indirect costs like doctor's consultation fee, travel charges associated with the patient's visit was not done in present study which is major limitation of the present study. Being a prescription based analysis, total duration of the drug therapy was not taken into consideration in present study. Also, present study did not evaluate the benefits associated with the drug therapy like improvement in the disease condition/ cure.

In future, the study may be planned to carry out cost based analysis focusing on both direct and indirect cost associated the drug therapy. In addition to that the benefit accrued to the patient may be evaluated for cost - benefit analysis. Further specific studies may be planned in vulnerable population like subjects of child bearing age group and the elderly population Extensive focus on risk based analysis is also being considered which includes special emphasis on age group related adverse drug reactions like impact of corticosteroids on osteoporosis and its aggravation in elderly population. We also plan to evaluate the effect of corticosteroid therapy on fertility in females of childbearing age.

CONCLUSION

Present study reveals that topical corticosteroids of high potency are commonly used for the patients attending outpatient and inpatient department of skin in this tertiary care teaching hospital. In present study, use of corticosteroids was mostly appropriate and according to standard guidelines and current protocol of prescribing corticosteroid drugs.[15] This may explain relatively less number of adverse drug reactions observed in this study. However, the amount of drug to be dispensed and to be used by the patient should be mentioned in the prescriptions in clear terms. Further, studies to detect and monitor incipient Adverse Drug Reactions like osteoporosis and infertility are warranted.

ACKNOWLEDGEMENT: We are thankful to the by the professor and head, department of Skin and VD for allowing to conduct the study in their department. We are also grateful to the residents in department of Skin and VD for their help during the study period.

Conflict of interest: Conflict of interest declared none

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