Publisher
MEDRESEARCH
www.medresearch.in

International Journal of Medical Research and Review

2019 Volume 7 Number 3 May-June

E-ISSN:2320-8686
P-ISSN:2321-127X

Research Article
Evaluation

Evaluation of corticosteroid use in outpatient department of dermatology of a tertiary care teaching hospital: a prospective observational study

J. Sheth H.[1], G. Chaudhary R.[2*], D. Malhotra S.[3]

DOI: https://doi.org/10.17511/ijmrr.2019.i03.16

[1] Haiya J. Sheth, Resident, Department of Pharmacology, Smt. N.H.L. Municipal Medical College, Ahmedabad, Gujarat, India.

[2*] Raju G. Chaudhary, Professor & Head, Department of Dermatology, Smt. N.H.L. Municipal Medical College, Ahmedabad, Gujarat, India.

[3] Supriya D. Malhotra, Professor & Head, Department of Pharmacology, Smt. N.H.L. Municipal Medical College, Ahmedabad, Gujarat, India.

Background: Corticosteroids are widely prescribed drugs in dermatology. Rational prescribing of steroids is important for best therapeutic outcome at lowest possible dose. A study was carried out at a tertiary care teaching hospital in order to evaluate the use of corticosteroids which provided a picture of trends in the usage of corticosteroids in dermatology at that set-up. **Materials and Methods:** This prospective, observational study was carried out in department of dermatology for 1 year after ethical approval. Data was analysed for parameters related to corticosteroids, their potency, WHO drug prescribing indicators, effectiveness as well as effects of corticosteroids on quality of life of patients. Statistical analysis was done using Microsoft Excel Office 365. **Results:** In the 223 patients, 44.84% patients belonged to 21-40 years age group. Mostcommon indication was eczema in 29.15% cases. Topical betamethasone (25.11%) and oral prednisolone (20.17%) were most frequently prescribed. 95/140 topical steroids prescribed were super highly potent. Among concomitant drugs, a majority of 38% were antihistaminics. Degree of polypharmacy showed 04 drugs in a majority (43.15%) of prescriptions. Only 6.27% drugs were prescribed by generic name. **Conclusion:** Corticosteroids were beneficial to a large no. of patients. Initial usage of low potency steroids topically wherever possible can be emphasized. WHO drug prescribing indicators analysis indicated the need to adhere to WHO guidelines as well as prescribing drugs by generic name. To maintain a balance between judicious use and frequent abuse with corticosteroid is important along with physician's vigilance and patient education.

Keywords: Betamethasone, Corticosteroids, Dermatology, Potency, Topical, WHO drug prescribing indicators

Corresponding Author

Raju G. Chaudhary, Professor & Head, Department of Dermatology, Smt. N.H.L. Municipal Medical College, Ahmedabad, Gujarat, India.
Email: drdermaraju@yahoo.com

How to Cite this Article

Sheth HJ, Chaudhary RG, Malhotra SD. Evaluation of corticosteroid use in outpatient department of dermatology of a tertiary care teaching hospital: a prospective observational study. Int J Med Res Rev. 2019;7(3):243-252.
Available From https://ijmrr.medresearch.in/index.php/ijmrr/article/view/1066

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Manuscript Received	Review Round 1	Review Round 2	Review Round 3	Accepted
2019-05-30	2019-06-08	2019-06-16		2019-06-20

Conflict of Interest	Funding	Ethical Approval	Plagiarism X-checker	Note
No	Nil	Yes	6%	

Introduction

Skin is the largest organ in the body. Prevalence of skin diseases varies from 7.86% to 11.16% [1]. They account for up to 2% of consultations in general practice worldwide [2]. Amongst several drugs that are employed for the treatment of various dermatological conditions, corticosteroids are widely prescribed ones. This is due to their extra-ordinary anti-inflammatory as well as immunosuppressive actions. They can be administered by local or systemic route. They are chosen on the basis of few factors that are decided by the treating clinicians. It is important to use the safest and least number of steroids to obtain the best possible effects at their lowest possible therapeutic dose for the shortest period at a reasonable cost and with lesser side-effects [3]. It is also important to stick to the standard treatment guidelines at the time of treatment with corticosteroids. This will allow its rational use of drugs.

Thus, main purpose of using corticosteroids in dermatology is to relieve the patients from signs and symptoms of skin diseases and thus achieve improvements.A study was carried out at a tertiary care teaching hospital inorder to evaluate the use of corticosteroids which provided a picture of trends in the usage of corticosteroids in dermatology at that particular set-up. Here, main aim was - to study the prescribing pattern of corticosteroids in Outpatient Department (OPD) of Dermatology; to analyse use of corticosteroids according to WHO Drug Prescribing Indicators; to assess effects of corticosteroids on patient's Quality of Life (QoL) by using Dermatology Life Quality Index (DLQI) questionnaire.

Materials & Methods

This prospective, observational study began only after obtaining approval from Institutional Review Board. It was conducted from December 2016 to December 2017 at the Department of Dermatology of a Tertiary Care Teaching Hospital. The sample size was duration based. The data was collected on case record from and DLQI questionnaire. Patients fulfilling the criteria such as those of either gender and aged eighteen years or more, those willing to give their written informed consent, those attending Dermatology OPD and being prescribed corticosteroids as one of the drugs were included in the study.

Patients not willing to give their written informed consent, indoor patients, pregnant and lactating females, those with severe co-morbid conditions were excluded from the study.

The data was analysed for age groups and gender distribution, dermatological indications, commonly prescribed corticosteroids, their fixed dose combinations, dosage forms & route of administration, duration of action, potency of topical corticosteroids etc. Other parameters analysed were concomitant drugs, WHO drug prescribing indicators, effectiveness of corticosteroids using scoring systems, effects of corticosteroids on patient's quality of life using DLQI questionnaire.

Here, disease severity scores were calculated by the treating dermatologist. DLQI questionnaire was handed over to the patients who then filled the boxes and accordingly their scores were calculated before and after steroid treatment.

Patients were asked to come for a follow-up visit after 7 days inorder to calculate the effectiveness as well as effects of steroids on patient's quality of life. The statistical analysis was done using Microsoft Excel Office 365 and rechecked with SPSS (version 21.0).

Results

A total of 223 patients were included in the study. Only 46 patients turned up for follow-up.

Socio-Demographic Profile

Table-1: Age group wise gender distribution

Age groups (years)	Gender distribution				Total (n=223)	
	Males		Females			
	(n)	(%)	(n)	(%)	(n)	(%)
≤20	10	4.48	19	8.52	29	13.00
21-40	53	23.76	47	21.07	100	44.84
41-60	43	19.28	36	16.14	79	35.42
61-80	10	4.48	01	0.44	11	4.93
≥81	02	0.89	02	0.89	04	1.79
Total	118	52.91	105	47.08	223	
Mean age ±S.D.	39.42±15.91		39.32±15.92		39.37±15.89	

In the Age range of 18-90 years, mean age was 39.37±15.89 years. A majority of 100 (44.84%) patients belonged to the age group of young adults i.e. 21-40 years. Male: Female ratio was 1.21:1. Table 1 shows age group wise gender distribution.

Dermatological indications for corticosteroids

Table-2: Dermatological indications for corticosteroids

Dermatological indications	Total (n=223)	
	(n)	(%)
Eczema	65	29.15
Allergic contact dermatitis	39	17.48
Lichen planus	25	11.21
Psoriasis	15	6.72
Keloid	13	5.83
Fixed drug eruption	13	5.83
Pemphigus vulgaris	11	4.93
Acute rash	10	4.48
Angioedema	08	3.58
Acute urticaria	07	3.13
Discoid lupus erythematosus	07	3.13
Insect bite	06	2.69
Alopecia areata	04	1.71
Total	223	

A total of 13 indications were noted. Most common was Eczema i.e. 65 (29.15%) followed by allergic contact dermatitis 39 (17.48%) among 223. Refer Table 2.

Details of corticosteroids prescribed
Corticosteroids commonly prescribed

Most frequently prescribed corticosteroids were Betamethasone 56 (25.11%), Clobetasol 52 (23.31%) and Prednisolone 45 (20.17%). The least prescribed were Fluocinolone 05 (2.24%), Beclomethasone 04 (1.79%) and Halobetasol 01 (0.44%) (Figure 1).

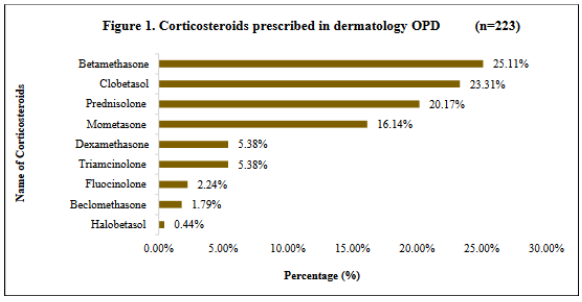

Fig 1: Corticosteroids commonly prescribed

Fixed dose combinations (FDCs) of corticosteroids

A total of 96 (43.04%) corticosteroids (topical formulations) were prescribed as FDCs. Majority FDCs were topical corticosteroid + anti-bacterial i.e. 71/96. The rest contained corticosteroid with anti-fungal (02/96), combination of anti-fungal and anti-bacterial (01/96) or other drugs (22/96).

Dosage form and route of administration for corticosteroids

Table-3: Dosage forms and routes for corticosteroid administration

Dosage forms		Route of administration	Total (n=223)	
			(n)	(%)
Topical	Cream, ointment, lotion, gel	Topical	140	62.78
Solid	Tablet	Oral	59	26.46
Liquid	Injection	Intra-muscular	12	5.38
		Intra-lesional	12	5.38
Total			223	

Overall 140 (62.78%) topical dosage forms of corticosteroids were prescribed whereas solid and liquid dosage forms constituted 59 (26.46%) and 24 (10.76%) respectively as shown in table 3. Accordingly, topical route was the most preferred followed by oral route for 26.46% cases.

Duration of action of corticosteroids

Table-4: Duration of action of corticosteroids prescribed

Duration of action (hours)	Total (n=223)	
	(n)	%
Long acting (36-55)	77	34.53
Intermediate acting (12-36)	146	65.47
Short acting (1-12)	0	0
Total	223	

146/223 were intermediately acting which included Clobetasol, Prednisolone, Mometasone, Triamcinolone and Halobetasol. Remaining 77 long acting corticosteroids were mainly Betamethasone, Dexamethasone (12/77), Fluocinolone (05/77) and Beclomethasone (04/77) (Table 4).

Potency of topical corticosteroids

Table-5: Potency wise topical corticosteroids for different sites

Sites for topical steroid application	No. of topical corticosteroids (n=140)	
	Super highly potent (n=95)	Moderately potent (n=45)
Upper Limb	Betamethasone (17) Clobetasol (14)	Mometasone (16) Beclomethasone (02)

	Halobetasol (01)	Fluocinolone (01)
Trunk	Betamethasone (13) Clobetasol (13)	Mometasone (09) Beclomethasone (01)
Lower Limb	Betamethasone (11) Clobetasol (10)	Mometasone (09) Fluocinolone (04) Beclomethasone (01)
Face	Clobetasol (05) Betamethasone (01)	-
Upper Limb + Lower Limb	Clobetasol (04)	Mometasone (02)
Scalp	Clobetasol (03)	-
Upper Limb + Lower Limb + Trunk	Clobetasol (02)	-
Shoulders	Clobetasol (01)	-

Out of 140 topical preparations, potency wise majority were super highly potent followed by moderate potency constituting 95/140 and 45/140 Respectively (Table 5).

Drugs prescribed concomitantly with corticosteroids

Table-6: Drugs prescribed concomitantly with corticosteroids

Drug class	Drugs	Total(n=521)	
		(n)	%
Anti-histaminics	Chlorpheniramine maleate (75); Cetirizine (73); Levocetirizine (46); Hydroxyzine (04)	198	38.00
Dermatologicals	Liquid paraffin (140); Lactocalamine (06); Propylene glycol (05); Glycerine (01)	152	29.17
Drugs for Peptic Ulcer	Pantoprazole (34); Ranitidine (34)	68	13.00
Anti-infectives	Anti-bacterials (45) = Fusidic Acid (15); Azithromycin (14); Cefixime (13); Minocycline (03) Anti-fungals (03) = Ketoconazole (03) Anti-protozoals (01) = Metronidazole (01)	49	9.40
Nutritional Agents	B-complex (17); Vit. C (09); Vit. A (08); Calcium (01)	35	6.71
Immunosuppressants	Tacrolimus (12); Azathioprine (01)	13	2.49
NSAIDS	Paracetamol (04); Ibuprofen (02)	06	1.15
Total		521	

In 223 prescriptions, concomitant drugs were 521. Most frequently prescribed were Anti-histaminics 198 (38%) and Dermatologicals 152 (29.17%). Others included Drugs for Peptic ulcer, Anti-infectives, Nutritional agents, Immunosuppressants and NSAIDs Table 6.

WHO drug prescribing indicators

Average number of drugs per encounter

Total no. of drugs prescribed were 744 leading to an average of 3.34±0.91 drugs per encounter. Total no. of corticosteroids and concomitant drugs prescribed were 223 and 521 respectively making an average of 01 and 2.34±0.91 per encounter respectively. Total no. of drugs per prescription ranged from 01-06. Majority i.e. 94 (42.15%) prescriptions had 04 drugs prescribed followed by 74 (33.18%) prescriptions with 03 drugs.

Only 05 (2.24%) prescriptions out of 223 had corticosteroid prescribed. A maximum of 06 drugs were prescribed in 02 (0.89%) cases only.

Percentage of drugs prescribed by generic name

Overall percentage of drugs prescribed by generic name was 50.26%. Total no. of corticosteroids and concomitant drugs prescribed by generic name were 14/223 and 360/521 with a percentage of 6.27% and 69.09% respectively.

Percentage of encounters with an antibiotic prescribed

Total no. of encounters with an antibiotic prescribed were 103. This included 72 FDCs of corticosteroids with antibiotics + 45 antibiotics being prescribed as concomitant drugs with corticosteroids making a total of 117.

But almost 14 cases had co-existence of antibiotic in FDC as well as concomitant drugs. So, 14 cases were considered as a single encounter. Thus, percentage of encounter with an antibiotic prescribed was 46.18%.

Percentage of encounters with an injection prescribed

Total no. of encounters with an injection prescribed were 24 making it 10.76%.

Percentage of drugs prescribed from essential drugs list or formulary Total no. of drugs prescribed from Essential Drugs List (Hospital Formulary) were 481/744 leading to 64.65%.

Effectiveness of corticosteroids prescribed

Table-7: Mean score of scoring system for effectiveness of corticosteroids

Scoring Systems	Total no. of Patients (n=46)		Mean score ±S.D.	
	(n)	%	At Baseline	After Treatment
EASI	25	54.34	8.81±2.35	3.66±0.88
PASI	06	13.04	17.38±7.05	10.14±4.13
PAAS	05	10.86	13.84±0.65	10.06±0.93
POSAS	04	8.69	21.23±2.75	20.5±2.51
UAS	04	8.69	5±0.81	1.5±0.57
SALT	02	4.34	28.3±6.08	21.25±6.01
Total	46			

* Here, EASI = Eczema Area and Severity Index, PASI = Psoriasis Area and Severity Index, PAAS = Pemphigus Area and Activity Score, POSAS = Patient and Observer Scar Assessment Scale, UAS = Urticaria Activity Score, SALT = Severity of Alopecia Total score46 patients were subjected to 06 scoring systems.

Approximately 25/46 (54.34%) were assessed as per EASI whereas PASI, PAAS, POSAS, UAS and SALT were used in remaining 21/46 patients of psoriasis, pemphigus vulgaris, keloid, urticaria and alopecia areata respectively. Mean score ±S.D. at baseline and after corticosteroid treatment was calculated in these 46 patients. (Table 7)

Effects of corticosteroid use on patient's dermatology life quality index (DLQI)

Tabl-8: Analysis of DLQI score of patients

DLQI		Total no. of patients(n=46)			
Effects on Patient's QoL	DLQI Score (range)	At baseline		After corticosteroid therapy	
		(n)	%	(n)	%
No effect at all	0-1	0	0	0	0
Small effect	2-5	04	8.69	09	19.56
Moderate effect	6-10	10	21.73	35	76.08
Very large effect	11-20	32	69.56	02	4.34
Extremely large effect	21-30	0	0	0	0
Total		46		46	

* Here, DLQI = Dermatology Life Quality Index, QoL = Quality of Life

Table 8 shows analysis of DLQI score before & after giving corticosteroids. At baseline, majority patients (32/46) had very large effects on their QoL whereas after treatment, majority i.e. 35/46 had moderate effects on their QoL.

Table-9: Overall mean of patient's DLQI score at baseline and after corticosteroid treatment

DLQI Score	Mean (n=46)	Standard deviation	Standard error of mean	95% Confidence interval	t value	Degree of freedom	P value
(At baseline)	11	2.71	0.4	[10.22, 11.78]	20.87	45	<0.0001
(After Treatment)	6.85	2.21	0.33	[6.21, 7.48]			

*P value <0.0001 is statistically highly significant.

Here, DLQI = Dermatology Life Quality Index

As shown in Table 9, Mean DLQI score at baseline and after treatment was 11±2.71 and 6.85±2.21 respectively. It was highly significant statistically (P value <0.0001), calculated using Student's Paired 't' test.

Discussion

Since the introduction of corticosteroids in late 1950's, they have become readily available with a wide usage in the medical field. In dermatology, they have been commonly prescribed for acute urticaria, pemphigus vulgaris, keloid, fixed drug eruptions, eczema etc. This has led to dermatologists becoming one of the top most prescribers for corticosteroids [4].

Thus, corticosteroids have been frequently resorted as therapeutic modalities in modern dermatologic practice [5], mainly due to their palliative effect. However, care has to be taken at the time of selection as well as for dosage regimens. Accurate diagnosis before initiation of therapy is also very crucial. Its rational use can help reduce the incidence of adverse effects. Thus, drug use evaluation is designed to review drug use and prescribing patterns of drugs with current treatment guidelines for the treatment of a particular disease in concern. WHO along with the International Network for the rational use of drugs have given drug use indicators to evolve the standards of drug use [6].

Present study with 223 patients was undertaken in order to evaluate the usage of corticosteroids in commonly encountered dermatological disorders. During the study, appropriateness and completeness of prescriptions were analyzed along with those parameters as mentioned in methodology.

Analysis of socio-demographic characteristics showed that a large number of patients were young adults. This is comparable with the study by Bylappa BK et al [7]. This is probably because people at this age feel more conscious about their physical appearance cosmetically. Patients above 60 years of age being prescribed corticosteroids were only a handful in the present study.

Gender distribution showed male preponderance in the present study. Commonly encountered indications were eczema, allergic contact dermatitis, lichen planus and few more. Studies by Nerukar RP et al and Mukherjee S et al showed similar pattern [8, 9]. Life-threatening indications were pemphigus vulgaris and angioedema. Variations in pattern of indications observed in various studies is supposed to be due to environmental, genetic or drug factors, food-habits, influence of cosmetics and media on study population, etc.

The prescribing trend of corticosteroids in the present study was noted. Betamethasone, Clobetasol and Prednisolone were among the most frequently prescribed while Beclomethasone and Halobetasol were the least prescribed. In various studies across the country, results were similar to the present study with respect to commonly prescribed corticosteroids. However, in Adhikari K et al's study, the usage of Dexamethasone and Fluocinolone was higher [10].

In the present study, the fluorinated glucocorticoids were Betamethasone, Clobetasol, Triamcinolone, Dexamethasone, Fluocinolone and Halobetasol while non-fluorinated ones were Prednisolone, Mometasone and Beclomethasone. Fluorinated ones have higher lipid solubility & permeability through skin. So, non-fluorinated ones can be preferred for face, scalp, skin folds or groin. Halogenation actually stabilizes the corticosteroid molecule and renders it less liable to degradation and possible sensitization. Literature reports that fluorinated preparations can act as allergens rarely.

Rationality wise, use of FDCs of corticosteroids isn't correct but taking into consideration the infective nature of the indication, anti-bacterials or anti-fungals were added. The results obtained in Abraham MS et al study were similar but those from Jaiswal MK et al were contradictory [11, 12]. Topical steroid FDCs were preferred only if infection was limited to a smaller area of skin. In severe cases, short course of a suitable oral anti-infective was chosen.

With respect to dosage forms of corticosteroids preferred, it was topical in majority followed by solid and liquid ones in present study. Topical forms used were creams, ointments, lotions and gels whereas solid forms included tablets. Few cases had injections prescribed. Comparison with many studies had one constant finding that the topical formulations were used extensively in dermatology [13]. Accordingly, topical route was the most preferred route for drug administration.

The main reason behind using topical route for steroid administration was that it had minimum side effects, unless systemic administration was inevitable. Also, oral preparations should be given as short course with tapering doses unless the disease requires prolonged therapy. In such cases too, drug holidays and lowest possible therapeutic doses can be a boon for the patient. Data also revealed that intermediately acting corticosteroids such as Clobetasol, Prednisolone, Triamcinolone were higher prescribed compared to long acting ones. On comparing with other studies, variations were observed depending upon the location and severity of lesions.

Majority belonged to the category of super high potency such as Betamethasone and Clobetasol, whereas rest were moderately potent such as Beclomethasone, Mometasone etc.

Results from Aryal A et al, Bylappa BK et al and Abraham MS et al were matched and found to be similar [7, 11, 14]. Accordingly, super highly potent were mainly applied on upper limb, lower limbs in present study. Face or scalp should be exposed to low-moderate potent preparations to avoid its adverse effects. So, this result was as per the guidelines related to the selection of topical steroids for different sites on the basis of their potency.

All steroid prescriptions had concomitant drugs such as antihistaminics like chlorpheniramine maleate, cetirizine etc, dermatologicals like liquid paraffin, anti-ulcer drugs like pantoprazole etc. and NSAIDs were the least prescribed. This pattern varied in different studies depending upon the causative indications. In Purushotham et al study, anti-ulcer drugs were higher [15] whereas Thakur et al noted antibiotics as frequently prescribed concomitant drugs [16].

WHO Drug Prescribing Indicators from WHO Core Drug Use indicators were investigated for the use of corticosteroids and concomitant drugs in the present study. Average no. of drugs per encounter determines degree of polypharmacy which can contribute to non-compliance, DDIs, ADRs, complexity of therapy or economic burden on the patient. So, it should be kept minimal by taking care about the limit of two medicines per encounter as set by WHO.

Percentage of steroids prescribed by generic name was analysed. For steroids it was quite less as compared to concomitant drugs; probably because topical steroid preparations weren't available from the hospital pharmacy. However, Gambre R et al study showed a very good adherence to prescription by generic name [17]. WHO also recommends prescriptions with generic names of the drugs since it is an important part of rational prescribing. Percentage of encounters with an antibiotic in present study highly exceeded the recommended limit which isn't a good sign with respect to rational prescribing.

In case of percentage of encounters with an injection prescribed, it was almost similar to the WHO recommended limit. Hospital formulary was framed from National EML. Percentage of drugs prescribed from it were quite high in present study which was a positive sign since they are selected with due regard to disease prevalence and evidences of efficacy, safety and cost of medicines.

Evaluation of effectiveness of corticosteroid therapy before and after steroid treatment was done using respective disease severity scores in present study. Only a few patients turned up for follow-up visits which was a limiting factor here. Patients of eczema and allergic dermatitis, psoriasis, keloid, pemphigus vulgaris, urticaria and alopecia are ata were evaluated with EASI, PASI, POSAS, PAAS, UAS and SALT scoring systems respectively. Improvements i.e. effectiveness of steroid therapy was noted in mainly all patients. But few patients did not show satisfying improvements clinically requiring chronic steroid administration.

When drug therapy for the disease is taken in an appropriate manner, then QoL of patients may show a positive impact. During the present study, DLQI questionnaire tool helped to understand the impact of dermatological disease on patient's QoL at baseline and after steroid therapy. Here also, the limitation was 46 patients turning up for follow-up. Mean DLQI scores were calculated after subjecting patients to DLQI questionnaire before and after treatment. Analysis showed that before treatment, disease had very large effects on QoL of majority and after treatment shifted to moderate effects in a majority, thus showing improvements. For DLQI scoring, the dictum is higher the score, more is the impairment of QoL. Sung JY et al had analysed QoL in pemphigus patients and he found that DLQI score which was high during active disease was quite low during the disease remission phase because of treatment with steroids [18]. Using student's paired 't' test, it was also found that the mean difference between the two was highly significant (P value < 0.0001). This indicated the effectiveness as well as adherence to treatment with corticosteroids in those patients indirectly.

Since majority patients were lost on follow-up, adverse drug reactions to corticosteroid use couldn't be noted. FDCs of corticosteroids with anti-fungals in tinea patients can lead to tinea incognito [19]. One of the biggest limitations of the present study were exclusion of in-door patients of Dermatology Department. Another was lack of patients with multiple connective tissue disorders since they were all directed to Rheumatology OPD at the present set-up. Individual disease specific steroid therapy can be studied as well. For topical preparations, finger tip unit (FTU) method can be explained to patients. Follow-up of patients can also be carried out thoroughly. All these measures can help us obtain better results.

Conclusion

Corticosteroids were beneficial to a large no. of patients as the dermatologists stuck to more or less a rational prescribing method. Treatment schedule observed had therapeutic effects which was a good sign. However, initial usage of low potency steroids topically wherever possible can be emphasized upon.

WHO drug prescribing indicators brought an observation that the no. of prescribed drugs, antibiotics or injections per prescription can be reduced as per WHO guidelines. Need to prescribe them by generic name can be gradually implemented. The effectiveness of corticosteroids in disease remission as well as improving patient's quality of life was also in a positive direction.

Thus, main aim for any clinician while prescribing drugs should be quick therapeutic outcome with reduced economical, financial and mental stress to the patients. Careful consideration of various factors such as potency, formulation, responsiveness, adequate quantity to be applied (FTU method), treatment schedule, socio-demographic parameters, following standard treatment guidelines as well as the cost of corticosteroid therapy should be considered each time.

Thus, maintaining a balance between judicious use and frequent abuse with corticosteroid is important. Physician's vigilance, patient education during consultation is equally necessary for promoting rational corticosteroid prescribing pattern.

Acknowledgement

Authors would like to thank Department of Dermatology for their help and support during the study. Authors would also like to thank Dr. Pankaj R. Patel, Dean of this institute for his constant guidance and encouragement.

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