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Drug Utilization Evaluation of Corticosteroids Indicated for Psoriasis and Dermatitis by Clinical Pharmacists at a Tertiary Care Teaching Hospital of Northcoastal Andhra Pradesh-A Prospective Observational Case Study

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ABSTRACT

Background of the Study: The current focus of research is on corticosteroids that can improve skin conditions with its anti-inflammatory and immunosuppressive action.

Objectives: To obtain information on number of drugs prescribed, their prescribing patterns, duration of treatment and rationality of drug use and side effects of corticosteroids.

Study Design, Study Period & Study Site: A prospective observational case series study was conducted from July-2019 to February-2020 at MIMS (Maharaja Institute of Medical Sciences) Nellimarla, Vizianagaram.

Methodology: A total of 280 patients the study is being conducted in the department of dermatology. The participants enrolled in the study involve inpatients and outpatients only after filling a properly written informed consent. The data is collected in a pre-designed data collection form.

Results: A total 280 prescriptions were analyzed having 275 corticosteroids and among them 32.1% were male and 67.9% were females. Majority of patients were between the range of 21-30 years (25.71%) and 31-40 years (14.2%) and 41-50 years (11.7%). Clobetasol was found to be the most prescribed drug (86%) followed by betamethasone (68%). Most drugs were prescribed rationally some factors like drug administration time were deviating from rationality.

Conclusion: Although most of the drugs were prescribed rationally, involvement of clinical pharmacists in patient care can help in more rational prescribing along with prevention and early detection of side effects which can directly promote drug safety and better patient outcomes.

Key words:

Drug utilization evaluation, Corticosteroid, immunosuppressive, clobetasol, betamethasone.

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INTRODUCTION

Drug Utilization Evaluation (DUE) is defined as an authorized, structured, ongoing review of practitioner prescribing, pharmacist dispensing, and patient use of medications. 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 consequences¹. DUE is an ongoing, systematic process designed to maintain the appropriate and effective use of drugs. It involves a comprehensive review of patient's prescription and medication data before, during, and after dispensing in order to assure appropriate therapeutic decision making and positive patient outcomes². Pharmacists participating in DUE programs can directly improve the quality of care for patients, individually and as populations, by preventing the use of unnecessary or inappropriate drug therapy and by preventing adverse drug reactions. The purpose of a DUE is to ensure that drugs are used appropriately, safely, and effectively to improve patient health status. In addition, continual improvement in the appropriate and effective use of drugs has the potential to lower the overall cost of care. DUE allows the pharmacist to document and substantiate the benefit of pharmacy intervention in improving therapeutic and economic

outcomes. Drug use is a complex process. In any country a large number of socio-cultural factors contribute to the ways.

Drugs are used. In India, these include 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. The complexity of drug use means that optimal benefits of drug therapy in patient care may not be achieved because of underuse, overuse or misuse of drugs. Inappropriate drug use may also lead to increased cost of medical care, antimicrobial resistance, adverse effects and patient mortality. Hence in recent year studies on drug utilization have become a potential tool to be used in the evaluation of health system. Acute increases in antibiotic resistance may be due to antibiotic selection pressures, overcrowding and other environmental changes, all of which are present in our setting. The most resistant organisms are found in units where patients are immune-compromised, are subject to invasive procedures or remain for long periods institutions elsewhere in the world have enhanced patient care through therapeutic optimization of the use of antimicrobial agents through the use of antibiotic restriction Policies implemented widely throughout the hospital³. Appropriate use of antibiotics is central to limiting the development and the spread of

Research Article

resistant bacteria in hospitals and communities. Thus DUE plays a key role in helping the health care system to understand, interpret and improve the prescribing, administration and use of medications. The principal aim of DU research is to facilitate rational use of drugs, which implies the prescription of a Well-documented drug in an optimal dose on the right indication, with correct information and at an affordable price. It also provides insight into the efficacy of drug use *i.e.* Whether a certain drug therapy provides value for money. DU research can thus help to set priorities for the rational allocation of health care budgets.

TYPES OF DUE STUDIES

DUE STUDIES ARE EITHER QUALITATIVE OR QUANTITATIVE

QUALITATIVE

DU studies are multi-disciplinary operations which collect, organize, analyse and report information on actual drug use. They usually examine use of specific drugs or specific conditions. Qualitative DU studies include the concept of criteria. Criteria are predetermined elements against which aspect of the quality, medical necessity and appropriateness of medical care may be compared. Drug use criteria may be based upon indications for use, dose, dosing frequency and duration of therapy. Qualitative studies assess the appropriateness of drug utilization and generally link prescribing data to reasons (indications) for prescribing. Such studies are referred to as DU review or DU Evaluation. The process is a "therapeutic audit" based on defined criteria and has the purpose of improving the quality of therapeutic care.

QUANTITATIVE

DU studies involve the collection, organization and display of estimates or measurements of drug use. This information is generally used for making purchase decisions or preparing drug budgets. But data from quantitative drug use studies are generally considered suggestive, not conclusive with respect to quality of drug use. It is possible to combine both quantitative and qualitative DU studies, which will yield information about pattern and amount of drug use as well as quality of drug use.

AIM & OBJECTIVES

AIM

To study the drug use evaluation of corticosteroids in psoriasis and dermatitis in the department of dermatology of MIMS hospital at Nellimarla.

OBJECTIVES

- To conduct a prospective study on drug utilization of corticosteroids in the psoriasis and dermatitis.
- To evaluate rational use of corticosteroids.
- To check the most common route of administration of corticosteroids.
- To identify the potency of corticosteroid prescribed.
- To evaluate the percentage of corticosteroid per prescription.
- To evaluate the side effects associated with corticosteroids.
- To find the age group distribution of patients.

- To check the type of skin diseases.
- To check the pattern of corticosteroids prescribed.

PLAN OF WORK

The entire study was planned to be carried out for the period of 8 months. The proposed protocol was designed as given below:

PHASE 1

- Obtaining consent from hospital authorities.
- Obtaining ethical clearance from institutional research & ethics committee.
- Literature survey.
- Designing of data entry format.
- Data collection: Collection of patient data, treatment chart from patient's case sheet of in-patients & out-patients.

PHASE II

- To evaluate rational use of corticosteroids.
- To check the most common route of administration of corticosteroids.
- To identify the potency of corticosteroid prescribed.
- To evaluate the percentage of corticosteroid per prescription.
- To evaluate the side effects associated with corticosteroids.
- To find the age group distribution of patients.

METHODOLOGY

Research Design

Type of Study: Prospective observational case study

Sample Size: 280 patients.

Data Collection: Data was collected from dermatology ward using structured data entry format.

Study Duration: 8 months

Inclusion Criteria: Patients in dermatology ward prescribed with corticosteroids.

Exclusion Criteria: Patients from other departments (general medicine, general surgery, orthopedics, OBG and pediatrics ward).

Study site: The study was conducted in dermatology department of maharaja institute of medicinal sciences – nellimarla, vizianagarm.

Phase 1

A pilot study was carried out for a period of 2 weeks in the department of dermatology to find the scope of study. All the prescriptions containing corticosteroid were monitored to know the dose, dosage form, route of administration and extent of corticosteroid use, and also for conditions in which it has been prescribed.

Literature will support the study were collected and reviewed, for study on importance of corticosteroid prescribing pattern in dermatology.

OBTAINING CONSENT FROM THE HOSPITAL AUTHORITY

The study was carried out in the hospital by department of pharmacy practice. So it has to be approved by medical superintendent (MS) and same should be informed to all physicians and surgeons of the hospital. For obtaining the consent, a study protocol has been prepared which include proposed title, study site, inclusion and exclusion criteria, objective and methodology about the work to be carried out.

Then the protocol of the study was submitted to medical superintendent, MS permitted to perform the study by ward round and utilize the hospital facilities through a letter. Obtaining Clearance Certificate from Institutional Ethical Committee For obtaining the clearance certificate and application along with study protocol which include the proposed title, study site, inclusion and exclusion criteria, objective and methodology about the work to be carried out was submitted to chairman of the institutional ethical committee if MIMS hospital. The study was approved by committee by issuing ethical clearance certificate. Data Entry Format or Proforma A separate data entry format for incorporating inpatient and outpatient details was designed it include demographic details, family history, medical history, diagnosis, categories of drug prescribed, and adverse drug reactions.

Phase 2

Collection of Data

The study was planned to investigate 280 patient record to increase the precision of the Parameters. Patient records from inpatient wards and outpatient wards of the selected dermatology of the hospital were obtained. Prescriptions were also collected. A total of 280 prescriptions written by qualified medical doctors were collected randomly from the wards and analysed. Latest edition of CIM'S drug manual was used to decode brand name of drugs to generic name for the purpose of analyzer.

Phase 3

Analysis of data: The prescriptions of the selected patients were collected from both inpatient and outpatient dermatology department, paying due attention to inclusion and exclusion criteria and were evaluated prospectively for the presence and fulfilment of the following variables- Personal data of patient- Name, age, sex and residency.

- Past medical history.
- Past medication history.
- Reason for admission.
- Drugs prescribed.
- Route of administration.
- Adverse drug reactions.

DATA EVALUATION

The data collected from all the prescriptions were evaluated using Micromedex software and information regarding the potency of corticosteroid in a prescription, their severity and management were summarized.

RESULTS

The clinical study was carried out with 250 patients who were prescribed with corticosteroids in the department of dermatology, Sangareddy.

GENDER DISTRIBUTION

In the study population of 250 patients, 116 were male patients and 134 were female patients. It indicates female patients were found to be comparatively more, when compared with male.

Table 1: Gender distribution of Study population

GENDER	NO. OF PATIENTS	PERCENTAGE (%)
Male	90	32.1
Female	190	67.9

GENDER

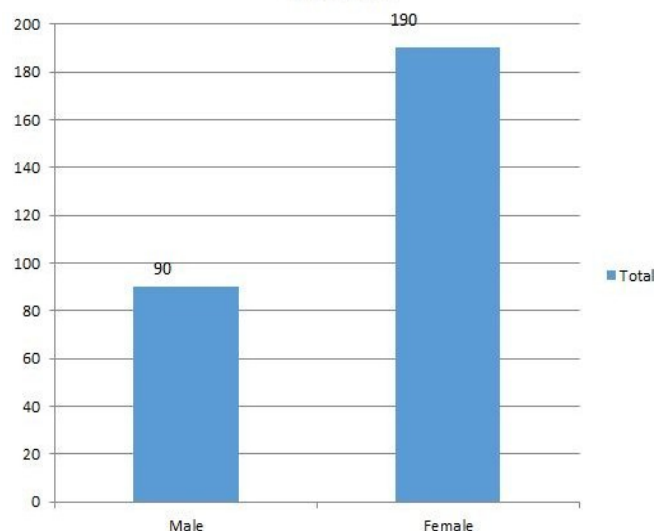


Fig 1: Gender distribution of Study population

AGE DISTRIBUTION

Out of 280 patients, 25.7% were between 21-30 years, 11.7% were 41-50 years, and 14.2% were 31-40 years

Table 2: Age distribution of study population

AGE GROUP (YRS)	NO. OF PATIENTS	PERCENTAGE (%)
0-10	19	6.7
11-20	49	13.6
21-30	72	25.71
31-40	40	14.2
41-50	33	11.7
51-60	37	16.4
≥61	30	12.4

AGE

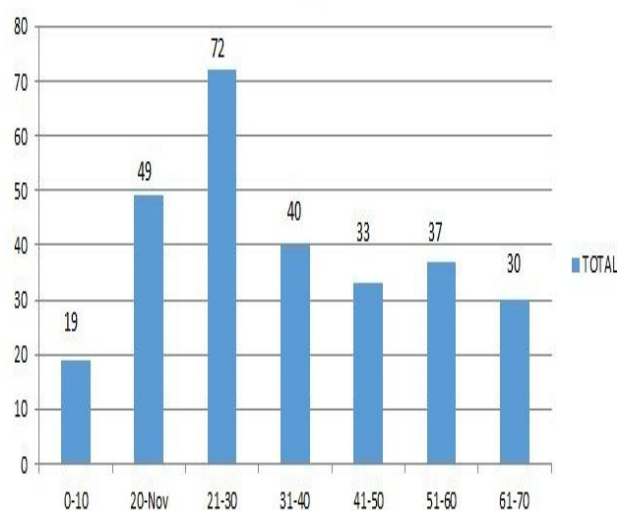


Fig 2: Age distribution of study population

DISEASE PATTERN AMONG STUDY SUBJECTS RECEIVING CORTICOSTEROIDS

In our study, psoriasis was found to be the major clinical complaint of the patients (19.2%), followed by dermatitis (17.6%) and eczema (14%).

Table 3: Disease Pattern among study subjects receiving corticosteroids

DISEASE	NO OF PATIENTS	PERCENTAGE%
PSORIASIS	170	67.9
DERMATITIS	90	32.1

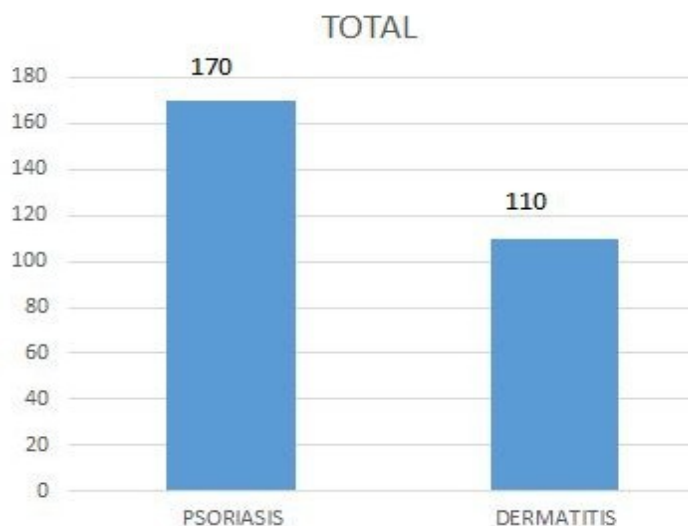


Fig 3: Disease Pattern among study subjects receiving corticosteroids

NUMBER OF CORTICOSTEROIDS PER PRESCRIPTION:

Out of 280 patients, one corticosteroid was prescribed for 230 patients 82.1%, 2 for 13.9% whereas 3 drugs were prescribed less (3.9%).

Table 4: Number of corticosteroids per prescription

NO. OF DRUGS PER PRESCRIPTION	NO. OF PATIENTS	PERCENTAGE (%)
Single corticosteroid	230	82.1
Two corticosteroids	39	13.9
Multiple corticosteroids	11	3.9

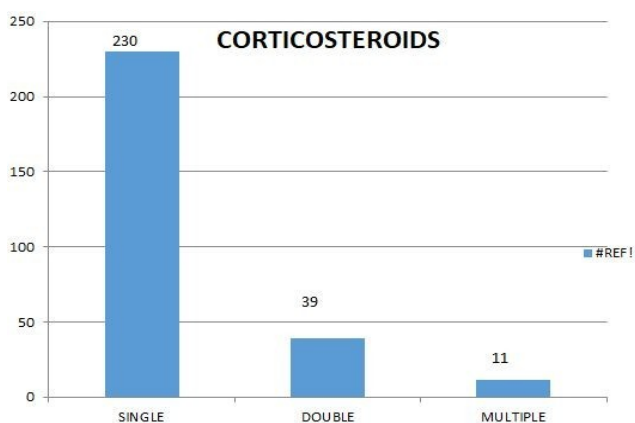


Fig 4: Number of corticosteroids per prescription

PATTERN OF CORTICOSTEROID PRESCRIBED FOR THE STUDY POPULATION

In our study out of 280 cases, 28.4% patients were prescribed with clobetasol, 16.8% with betamethasone followed by mometasone and halobetasol (13.2%).

Table 5: Pattern of corticosteroids prescribed for the study population

DRUGS	NO. OF PATIENTS	PERCENTAGE (%)
Clobetasol	86	30.7
Betamethasone	68	24.2
Halobetasol	36	12.8
Prednisolone	28	10
Montelukast	36	12.8
Dexamethasone	6	2.1
Desonide	8	2.8
Hydrocortisone acetate	4	1.4

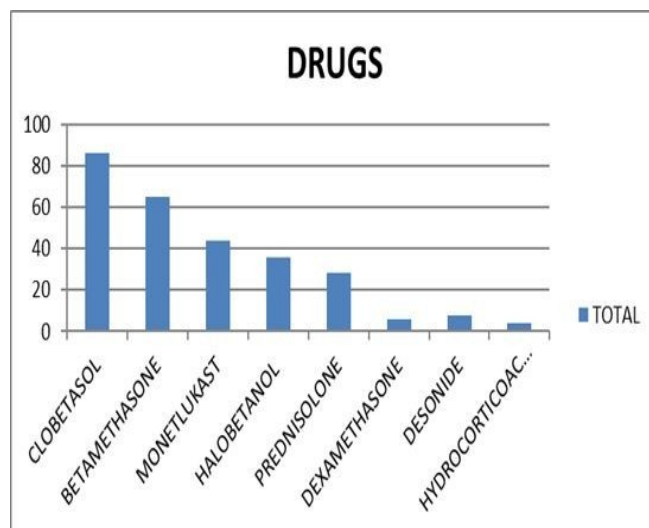


Fig 5: Pattern of corticosteroids prescribed for the study population

POTENCY OF CORTICOSTEROID PRESCRIBED

In our study, potent corticosteroids were prescribed for 58.2%, followed by very potent (27.8%), mild (10.7%), moderate (4.2%). The potent corticosteroids are recommended for short term use only and required for areas like palms and soles, Low to moderate potent steroids are useful for acute inflammatory lesions in face and inter triginous areas and can be used for long term.

Table 6: Pattern of corticosteroids prescribed for the study population

POTENCY	NO. OF PATIENTS	PERCENTAGE (%)
Potent	163	58.2
Very potent	78	27.8
Mild	30	10.7
Moderately potent	12	4.2

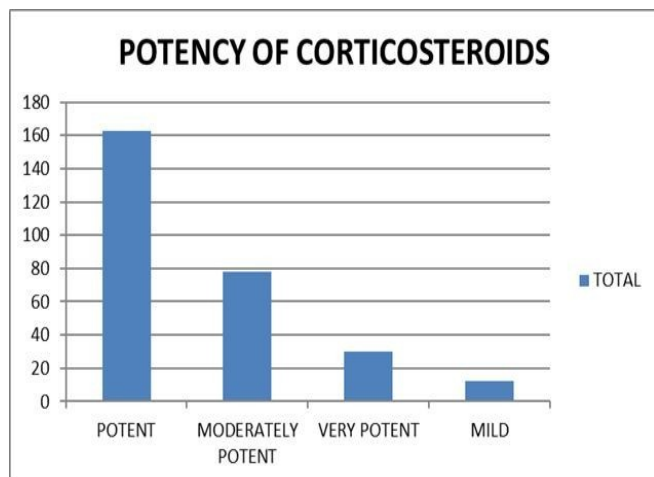


Fig 6: Potency of corticosteroids

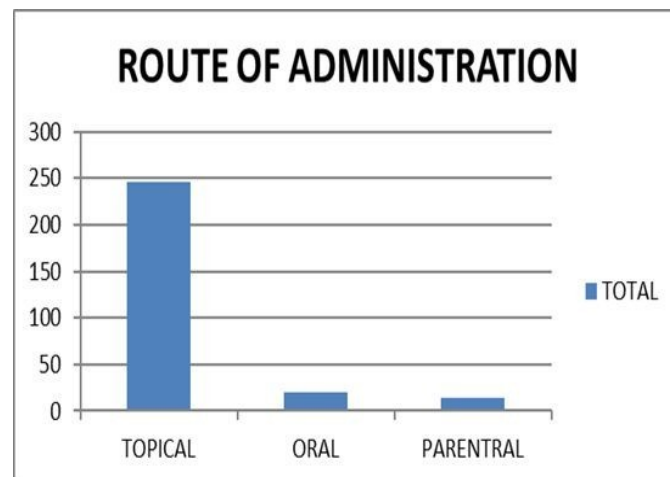


Fig 8: Route of administration

RATIONALITY OF CORTICOSTEROID PRESCRIBED

In our study, rational use of corticosteroids were 236 (84.2%) out of 280 cases and Irrational were 44 (15.7%) out of 280 cases. Rationality is assessed based on generic names used in the prescription, missed frequency, missed dose, and appropriate drug use.

Table 7: Rationality of corticosteroid prescribed

RATIONALITY	NO. OF PATIENTS	PERCENTAGE (%)
Rational	236	84.2
Irrational	44	15.7

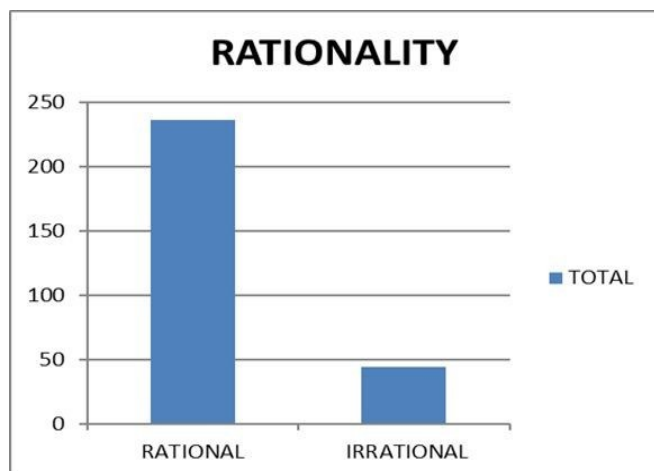


Fig 7: Rationality of corticosteroid prescribed

ROUTE OF ADMINISTRATION

In our study, topical corticosteroids were used majority 246 (87.8%), followed by oral of 20 (7.14%), and parenteral 14 (5%).

Table 8: Route of administration

Route of Administration	No of Patients	percentage
Topical	246	87.8
Oral	20	7.1
Parenteral	14	5

SIDE EFFECTS ASSOCIATED WITH CORTICOSTEROIDS

In our study, out of 280 cases 87 (34.8%) side effects were observed, Most commonly found side effect was acne (12.6%) followed by insomnia (4.59%).

Table 9: Side effects associated with corticosteroids

SIDE EFFECTS	NO OF PATIENTS	PERCENTAGE
Redness of skin	13	11.1
insomnia	6	5.1
blistering	8	6.8
tingling	9	7.6
burning	8	6.8
Hair bumps	7	5.9
Stretch marks	11	9.4
rashes	9	7.6
pimples	5	4.2
dryness	8	6.8
irritation	13	11.1
acne	15	12.8
Peeling of skin	5	4.2

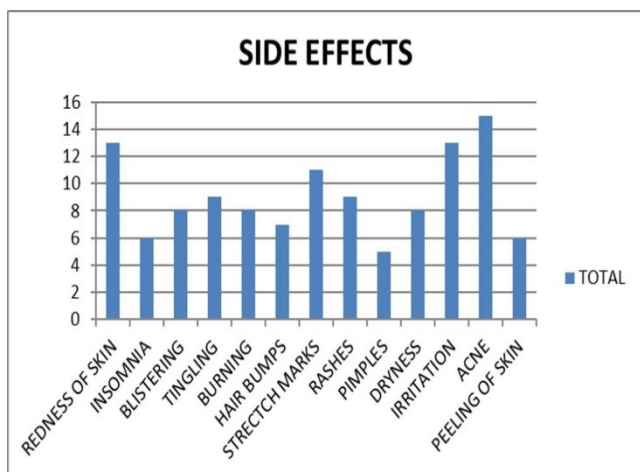


Fig 9: Side effects associated with corticosteroids

DISCUSSION

A prospective observational study, "Study on Drug Use Evaluation of Corticosteroids by Clinical Pharmacists in Dermatology Unit of a Tertiary Care Teaching Hospital of Northcoastal Andhra Pradesh" was conducted in a 500 bedded tertiary care teaching hospital including the inpatients and outpatients from dermatology department over a period of 6 months, from December 2019- May 2020. The data was collected from 280 inpatients and outpatients using specially designed data collection form. Most of the studies have shown that more female patients use corticosteroids than males, same as well the present study also showed that more females 190 (67.9%) are using corticosteroids than males 90 (32.1%) out of 280 patients. In this study, majority of patients using corticosteroids were between the ranges of 21-30 years (25.71%) and 41-50 years (11.7%) and 31-40 years (14.2%), it shows that corticosteroids were used mainly in younger and middle age groups. Out of 280 patients, only 69 patients were from inpatient and 211 patients from outpatients in department of dermatology. Psoriasis was the major clinical complication of patients (60.7%) besides dermatitis (39.3%). Out of 280 patients, 230 were prescribed with single drug therapy followed by 39 patients with 2 drugs, and 11 patients with multiple drugs per prescription, however most of the patients were prescribed with single corticosteroids. It is observed from the study that most of the patients (30.7%) were prescribed with Clobetasol and followed by betamethasone (23.2%). Although traditional corticosteroids include clobetasol and betamethasone associated with high rate of skin irritation, acne, dry skin but low risk of peeling of skin.

Out of 280 prescriptions 163 patients (58.2%) were found to be potent, 78 patients (27.85%) were found to be very potent whereas only 30 patients (10.7%) were found to be mild in our study, the use of corticosteroids were found to be rational, 236 (84.28%) and 44 (15.7%) were found to be irrational. In our study, most of the corticosteroids were prescribed via topical route, 246 (87.8%), oral 20 (7.1%) whereas parenteral 14 (5.6%) were least prescribed. Topical route causes a high local concentration in cutaneous and subcutaneous area of the body with low systemic delivery.

CONCLUSION

In present study corticosteroids were more prevalently used in younger and middle age group of female patients. The clobetasol and betamethasone were most frequently

prescribed for the management of skin diseases. The single drug mode of therapy with corticosteroids were preferred via topical and parenteral therapy. Corticosteroids are vital for clinical management of wide range of skin diseases and immunosuppressive actions, but it is mostly accompanied by skin irritations and complications. In the present study, the emollients were widely prescribed for prevention and healing of corticosteroids associated skin complications. In the present study, the prescription of corticosteroids is found to be rational. However to ensure safe, effective and well balanced therapeutic management of this corticosteroids, both patients and prescribers should be more aware of the appropriate dose, dosage regimen and overall indications. Drugs can be useful tools in the prevention and management of symptoms and disease, but if not used properly, they may be harmful and cause new symptoms or produce suboptimal effects. The drug utilization problems are common and have significant clinical and economic complications. Hence the support and involvement of pharmacist along with medical staff is essential for rational drug utilization.

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