



Drug Use Assessment of Immunomodulators Drugs Prescribed in Dermatology Out Patient Department of A Tertiary Care Teaching Hospital

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ABSTRACT

The present study is a Cross-sectional, Single centre, Prospective & Observational study conducted in dermatology outpatient department in a Tertiary Care Teaching Hospital (THTC). The study aims to observe the pattern of immunomodulator drugs (IMDs) prescribed in dermatology outpatient department of a Tertiary Care Teaching Hospital. **Primary Objective** was to find out the prescription pattern of IMDs in dermatology OPD of a Tertiary Care Teaching Hospital and **Secondary Objective** was 1) to see the most commonly prescribed IMDs & their indications, 2) to determine percentage of prescribed IMDs available on Hospital Drug Formulary (HDF), & 3) to evaluate use of Corticosteroids (CS) as IMDs in various dermatological conditions.

KEYWORDS

Drug Use Assessment, Immunomodulator drugs (IMDs), Corticosteroids (CS), Dermatology department, Hospital Drug Formulary (HDF).

Introduction:

Immunomodulator drug (IMD) is defined as a substance, biological or synthetic that stimulates, suppresses or modulates any of the components of immune system including innate & adaptive arms of the immune response.

Topical IMDs regulate local immune response of the skin. They are now emerging as treatment of choice for immune mediated disorders like Vitiligo, Psoriasis, Contact allergic dermatitis, Alopecia areata, Atopic dermatitis, Lupus erythematosus, Pemphigus vulgaris & Pemphigus foliaceus. Also used for treating Keratinisation disorders and Skin tumors.

Drug utilization study (DUS) on continuous basis is essential to help clinicians to appropriately review & make adequate revision in management of their patients.

Developing countries have limited funds for health care & drugs hence it becomes very important to prescribe drugs rationally so that these funds can be used properly for treating large number of patients.

Drug Use Evaluation also referred to as **Drug Utilization Study / Review (DUS/ DUR)** is the system of continuous, systematic & criteria-based drug evaluation that ensures appropriate drug usage. Prescriptions are a good source of drug use. Trends in utilization for specific drugs & diseases can also be established by doing such studies. Collection of data for utilization of drugs at Hospital OPD level has been shown to be an effective tool to constitute guidelines for improving DUS patterns, thus resulting therefore in more effective & rational therapy.

Few studies done specifically targeted towards use of Corticosteroids (CS) in dermatology set up. The literature pertaining to prescription pattern studies of IMDs use in dermatology was lacking, so we have designed the present study to bridge this gap in the knowledge.

The study aims to observe the pattern of immunomodulator drugs (IMDs) prescribed in dermatology outpatient department of a Tertiary Care Teaching Hospital (TCTH). The study will also focus on percentage of drugs prescribed from the Hospital Drug Formulary (HDF), so that it will provide knowledge regarding health facility of our institute.

Materials & Method:

The study was conducted from 1st Jan 2013 to 30th September 2013 i.e for a period of 9mths. It was a Cross sectional, Single centre, Prospective & Observational study.

It was done in Dermatology OPD setting in a Tertiary Care Teaching Hospital (TCTH). Approval of Institutional Ethics Committee (IEC) was sought prior to starting the study.

The department of dermatology runs a Special clinic for Immunological skin / cutaneous conditions. All patients visiting this clinic were screened by observing their prescriptions and those meeting the inclusion criteria were enrolled in our study.

The **Inclusion criteria** were 1) Patients whose treatment contains one or more IMDs, 2) Patients giving written informed consent, 3) All new & old cases prescribed with IMDs.

The Patients or Legally Acceptable Representative (LAR) were informed their role in the study in the language they understand. They were enrolled only after they gave valid written informed consent after reading Patient Information Sheet (PIS) and by signing the Informed Consent Form (ICF). Data was extracted pertaining to the particulars of the patients & IMDs from the patients prescription.

Enrollment data was collected as follows:

1. General particulars like Patients Name, Initials, sex, age & weight.
2. Patients symptomatology & diagnosis (definitive & presumptive)
3. Drugs details noted like drug route, duration of treatment, brand or generic name, doses, frequency of administration & availability on hospital formulary.

The above data was recorded in the case record form (CRF).

Data analysis: Parameters (11) studied for data analysis were as follows:

1. Demographic parameters of the patients (Age & Sex)
2. Commonly diagnosed skin (immunological) conditions
3. Type of IMDs commonly prescribed
4. Percentage (%) of IMDs prescribed by generic & brand name
5. Recommended doses for each IMD

6. Route/s of IMD prescribed
7. Total number of Drugs / IMDs /CS prescribed per patient
8. Type of commonly given corticosteroid (CS)
9. Route of each steroid
10. Potency of topical steroid.
11. Percentage (%) of IMDs given from Hospital Drug formulary (HDF)

The doses given to the cases were compared with recommended doses. These were taken from:

Wolverton SE. Comprehensive dermatological drug therapy, 3rd edition, Edinburgh, Elsevier, 2013 & Valia AR, Valia R, IDA-VL, Textbook of dermatology, 3rd ed. Mumbai. BMP, 2013.

Statistical analysis: Observations related to baseline demographics & clinical profile of the patients were expressed as frequency percentages. Results of the parameters determining drug use pattern were expressed as frequency percentages (%). Age expressed as mean years as the data was skewed.

Results:

1a) Age: from an age range of **06 – 68 years**, median age was **35 years**. **80** cases (50%) were from **21 to 40 yrs**, 44 cases (27.5%) between 41 to 50 yrs, 27 cases (16.88%) of 1 to 20 yrs, 09 cases (5.62%) of 60 yrs & above & NO (zero) cases of 51 to 60 yrs. (1, 2, 3).

1b) Sex: Of the total 160 patients 96 (60%) were Females (F) & 64 (40%) were Males (M) with M: F ratio of 1: 1.5. (1, 2, 13, 14)

2) Commonly diagnosed skin (immunological) conditions: Pertaining to the clinical profile of the patients, following skin diseases were encountered:

Dermatological conditions	Number of cases & (%)
Vitiligo vulgaris	34 (21.25%) Ref (8)
Psoriasis vulgaris	27 (16.85%)
Pemphigus vulgaris	16 (10%)
Alopecia areata	15 (9.3%)
Allergic dermatitis	15 (9.3%)
Bullous pemphigoid	8 (5%)
Chronic urticaria	8 (5%)
Genital warts	7 (4.35%)
Contact dermatitis	6 (3.75%)
Pemphigus fallacious	6 (3.75%)
Systemic sclerosis	6 (3.75%)
Others *	12 (7.5%)
Total	160 cases / patients

* **Others** include, 4 cases of mixed connective tissue disorder, 3 of SLE, 2 for dermatomyositis, 2 of P. erythematoses & 1 of Bechet's disease. **3a)** Total **607** drugs were prescribed to **160** cases, out of which **317** were **the IMDs**.

3b) Various IMDs of different classes prescribed were as below:

IMD drug class	Prescribed drug class	% prescribed
Steroids	191	60.25
Methotrexate	43	13.69
Tacrolimus	30	9.4
Azathioprine	18	5.6
Levamisole	11	3.4
Cyclophosphamide	11	3.4
Imiquimod	7	2.2
Cyclosporin	5	1.57
Mycophenolate mofetil	1	0.3

4) 317 IMDs prescribed, **120 (38%)** were by **Generic name** & **197 (62%)** were by **Brand name** (9, 10).

5) for 93% encounters that got noted, IMDs were given in **recommended doses**.

6) Regarding the route of administration for Immunomodulator drugs (IMDs), 157 (49.52%)

IMDs were given by Local route & **160 (50.47%)** IMDs were by Systemic route.

Local route include Topical & Intra-lesional while **Systemic route** has Oral & IM (1)

7) Number of drugs given per patient was as follows (3,7,6)

Total Drugs (607) ==> 3.79 / patient
 Total IMDs (317) ==> 1.98 / patient
 Total Corticosteroids (CS) (191) ==> 1.19 / patient.

8) 191 Corticosteroids (CS), different corticosteroids prescribed were as follows:

Corticosteroids	Number of CS prescribed
Prednisolone	44 #
Clobetasol	25
Halobetasol	40
Betamethasone	45 \$
Fluticasone	05
Mometasone	20
Flucinolone	02
Triamcinolone	10
TOTAL	191

9) Route of administration for 191corticosteroids (CS) prescribed, **121 (63.35%)** were by local route & **70 (36.65%)** were by Systemic route. Out of **121** locally used drugs **114** were used topically & **07** were used as intralesional injection. Of the **70** drugs used systemically, **67** were given by oral (PO) route & **03** were used as IM injection. (7, 5, 6)

Prednisolone was the Most common steroid prescribed **orally (PO)**. Out of **156** IMDs given orally (PO), **44 (28.20%)** were prescribed prednisolone; out of **191** total Corticosteroids (CS), **44 (23%)** & out of **67** orally(systemic) used CS, **44 (65.67%)** were given prednisolone.(4)

Betamethasone (BM) was the most common steroid used by both **Oral & Topical** routes. Of **191** CS, **45 (23.56%)** were given BM. We found **23 (32.85%)** BM prescriptions out of **70** systemic steroids & **23 (34.32%)** out of **67** Orally (PO) used systemic steroids. Similarly, **22 (18.18%)** BM prescriptions out of **121** local CS & **22 (19.29%)** BM out of Topical steroids was noted. (3)

10) Regarding the potency of steroids, out of **114** topical steroids prescribed, **80 (70.17%)** were of superpotent class, **64 (29.80%)** were of Mid strength class. No steroid of Potent, mild potent & least potency was given to the cases. (12, 4)

11) Out of 317 IMDs, **169 (51%)** were prescribed from **Hospital Drug Formulary (HDF) & 158 (49%)** were from outside the Hospital Formulary. (10)

Discussion:

The present study was conducted in dermatology outpatient department of tertiary care teaching hospital. The study was carried out to observe the prescription pattern of immunomodulator drugs (IMDs) and assess their use in dermatology.

The prescription data was collected from **160** patients over a period of **9 months**.

60 % of patients who visited the immunology clinic in our dermatology OPD were females. The female to male ratio in our study was **1.5 : 1**. Our study results correlates with the

findings of the study conducted by Sarkar C et. al in western Nepal, Yuwanate A in Wardha & Rathod SS et.al in Ambajogai which also showed more female patients in their respective studies. (1, 2, 13)

Most of the autoimmune diseases like SLE, Scleroderma etc. were found more commonly in female patients & the female gender is a risk factor for Polyautoimmunity. (14)

The median age of patients studied was **35 yrs** with the range of **06 to 68 yrs**. Out of **160 cases**, 50% were in the age group of **21 to 40 yrs**. Our study results also correlate with the study findings of Sarkar C et. al in Nepal, Yuwanate A et. al in Wardha & Javsen C et. al in Mumbai. (1,2,3).

Of 160 cases studied, maximum diagnosed cases were of Vitiligo vulgaris (**21.25%**) followed by Psoriasis vulgaris (**16.90%**). However various cross sectional studies conducted in other institutes in the dermatology OPD have different findings in this regard. As in study of Yuwanate A et.al (Wardha) showed that maximum number of patients diagnosed were of Acne vulgaris. Similarly in the study conducted by Bijoy KP in Pune, maximum number of patients diagnosed were of Fungal infection. (2,12)

In our study, **317** Immunomodulator drugs (IMDs) were prescribed to **160** patients. Corticosteroids (CS) were the most common group of IMDs prescribed. **191 CS** were prescribed to **160** patients, accounting for **60.25%** of all IMDs. This finding correlates well with the study conducted by Sarkar C et.al (Nepal). (1)

Prescribing under generic name is considered economical & rational. In our present study, **38%** IMDs were prescribed by Generic name & **62%** by Brand name. Our findings correlate well with study by Uppal et.al and Narwane SP et.al which showed **65%** & **83.4%** of drugs were prescribed by Brand name respectively. But this usually can result in expensive prescribing since branded drugs are costlier. Also in cases where polypharmacy is prescribed, it also can lead to confusion among drugs given by lookalike & sound alike brand names & further add to prescription errors. (9, 10)

In our study **93%** of drugs were given by their standard recommended doses. In a study by Sharma P et.al, **27%** of prescriptions the doses were not mentioned & those cases where doses were mentioned, **11%** prescriptions were found to be incorrect. It is very important to prescribe correct recommended dose of the drug since it helps to maximize benefits & reduce the side effects. (11).

317 Immunomodulators (IMDs) in our study were near equally prescribed by Local (**157**) & Systemic (**160**) routes of drug administration. Local route included Topical & Intralesional injection. Systemic route involved Oral (Enteral) & Parenteral (IM inj.) routes. This correlates well with findings in the study conducted by Sarkar C et. al which showed drugs given by **50%** each systemic & local routes. (1).

Of total **607** drugs prescribed to 160 patients in our study, **317** were the **IMDs** accounting for **1.98** IMDs per prescription. (or 1.98 IMDs / patient). Regards use of **191** Corticosteroids (CS) as IMDs prescribed in dermatology OPD, it account for **1.19 CS** per prescription. In other studies conducted by Javsen C et.al, Mirshad PV et.al and Sweileh WM et.al it was found that use of Corticosteroids (CS) as IMDs in dermatology OPD account for **1.20, 1.29 & 1.48 CS** per prescription (per patient). (3,7,6).

Average drugs prescribed per patient should be kept as **low** as possible to avoid drug-drug interactions, minimize side effects, reduce cost of prescription & increase patient compliance to drug therapy.

Of **191 CS** given to **160 cases**, **70** (36.65%) & **121** (63.35%) were given by Systemic & Local route respectively. This finding correlates with the studies of Mirshad PV et.al (Kerala), Jena M et. al (Orissa) & Sweileh WM et.al noting **64%, 67% & 81%**

of CS given topically. Standard guidelines for giving topical steroids & their use need to be adhered to. (7, 5, 6)

Prednisolone was the Most common steroid prescribed **orally (PO)**. Out of **156 IMDs** given orally (PO), **44** (28.20%) were prescribed prednisolone; out of **191** total Corticosteroids (CS), **44** (23%) & out of **67** orally(systemic) used CS, **44** (65.67%) were given prednisolone. This finding correlates with the study of Divyashanthi CM et.al (4)

Betamethasone (BM) was the most common steroid used by both **Oral & Topical** routes. Of **191 CS**, **45** (23.56%) were given BM. We found **23** (32.85%) BM prescriptions out of **70** systemic steroids & **23** (34.32%) out of **67** Orally (PO) used systemic steroids. Similarly, **22** (18.18%) BM prescriptions out of **121** local CS & **22** (19.29%) BM out of Topical steroids was noted. Similar finding was noted in study of Javsen C et. al (Mumbai). (3).

Pertaining to Potency of steroids used, our study found **80 (70.17%)** out of **114 topical** steroids were super-potent, Rest 29.83% were of mid-strength. This was also seen in studies by Bijoy KP et. al & Divyashanthi CM et. al. (12, 4).

Our study noted that **51%** were from Hospital Drug Formulary (**HDF**) & **49%** of IMDs were out of Hospital Drug Formulary (**HDF**). In study by Narwane SP et. al it was seen that only **30%** drugs were dispensed from HDF. It is good to prescribe more drugs from HDF since it helps to reduce cost of medication & of treatment as most of IMDs & CS are to be given for long term. (10)

Conclusion:

The present study assessed the prescription pattern of Immunomodulator drugs

(IMDs) in Dermatology OPD of a Tertiary Care Teaching Hospital.

We encountered **317** immunomodulator drugs (IMDs) from the prescriptions to **160** patients enrolled in our study. Out of which **191** were Corticosteroids (CS) prescriptions.

Majority of the patients were from **2nd to 4th decade of age** with **Female** preponderance.

Vitiligo vulgaris & Psoriasis vulgaris were the common skin diseases we came across.

Corticosteroids, Methotrexate & Tacrolimus were the most common IMDs prescribed.

More drugs were prescribed by **Brand names** than Generic names in our study.

For most of the IMDs prescribed, **Standard Treatment Guidelines** (STGs) for doses & routes were followed.

Number of **IMDs prescribed per patient** were **1.98**, which were within limits recommended.

51% drugs were prescribed from **Hospital Drug Formulary** (**HDF**).

Use of **Super-potent** corticosteroids were on higher side in our study.

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