Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 13, (2024)
https://www.jneonatalsurg.com

OPEN ACCESS

Analysis Of Immunomodulator Drug Prescribing Practices In Dermatology: A Study On Trends, Dosage, And Formularies In A Tertiary Care Teaching Hospital

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Cite this paper as: Dr. Ashwak Ahmed, Dr.Ramakrishna Navaluri, (2024) Analysis Of Immunomodulator Drug Prescribing Practices In Dermatology: A Study On Trends, Dosage, And Formularies In A Tertiary Care Teaching Hospital. *Journal of Neonatal Surgery*, 13, 401-408.

ABSTRACT

This research aims to examine immunomodulator drugs (IMDs) prescribing patterns in a dermatology outpatient department of one of the Tertiary Care Teaching Hospitals. It targets the demographic distribution, prevalence of dermatological conditions and IMD trend distributions especially on the corticosteroids. The study noted that more than a half of prescribed drugs were IMDs, brand prescriptions (62%) were given preferably to generic names (38%). Most prescriptions used recommended doses, and there was equilibrium in the local and systemic administration route. Most common corticosteroids that were prescribed were prednisolone and betamethasone and most used super-potent topical steroids. Also, there was evidence on how the Hospital Drug Formulary (HDF) was used and 51 percent of the IMDs were ordered using the formulary showing that access to medication would be improved. In general, the research reveals that IMD prescription still needs to be continuously monitored to maximize the effect of treatment and enhance the use of drugs and support patients better in dermatological practices.

Keywords: *Immunomodulator drugs, corticosteroids, dermatology, prescription practices, drug utilization study*

1. INTRODUCTION

The term immunomodulation drugs (IMD) can be defined as a biological or a synthetic substance which can alter the activity of immune system either by activating or suppressing, different aspects of immune response, be it the innate or adaptive immune systems [1]. These medications have gained further significance in the cure of numerous immune-mediated disorders, specifically in the field of dermatology where a generous immune pathway capacity has made them invaluable in the treatment of chronic and complicated conditions [2].

Immunomodulators, specifically topical have drawn huge attraction within the field of dermatology. These medications act on the modification of local immune reaction in the skin and provide a restricted therapy method to the immune-mediated skin nuisances. Some of the disorders that IMDs have appeared to be of significant therapeutic value include vitiligo, psoriasis, contact allergic dermatitis, alopecia areata, atopic dermatitis, lupus erythematosus, pemphigus vulgaris and pemphigus foliaceus among others [3].

Moreover, the use of these drugs in the treatment of carcinomas and keratinization disorders of skin, as well as skin tumors, has been recorded, which further increases the range of their presence in dermatological practice [4]. The ineffectiveness and unsafe nature of dermatological treatments has necessitated the rise in the use of IMDs as a favorable treatment choice of these ailments. Nevertheless, ever increasing use of these drugs requires a constant review of their use. In this respect, drug utilization studies (DUS) are so significant due to offering good information about prescriber tendencies, drug performance, and drug safety. With the organizational gathering and examination of prescription information, the clinician can decide utilizing suitable information to enhance patient care and keeping medicine therapies appropriate to best practices and worldwide proofs [5].

The rational use of drugs is especially important in developing countries where funds and resources are sometimes constrained in the given fields of healthcare. Using IMDs properly would enable one to maximize the effectiveness of resources available and treat many more patients, not forgetting that the drugs the patient is prescribed must be both effective and affordable [6]. Drug utilization evaluation (DUE) or drug utilization review (DUR) refers to a programmed endeavor, which entails constant, criteria-based review of the use of drugs. This is critical in describing trends in drug use especially on special areas like dermatology [7].

Prescriptions are an excellent source of data to DUS because it helps in understanding the current practice in prescribing as well as the areas where things need to be corrected. Observation of the prescription trends gives a possibility to discover the areas of improvement in terms of effectiveness and rationality of therapy and, as a result, improving the outcome of the treatment in an ultimate state [8]. Although the crucial signficance of DUS may be acknowledged, the rather limited number of researches dealing with the use of IMDs in dermatology have been conducted. Though the use of corticosteroids, one of the most popular drug categories applied in dermatology, is well researched, few sources are available to describe the prescrption habits of IMDs [9].

The existence of such knowledge gap necessitated the design of the current study, which was envisaged to observe the trend of IMDs being prescribed under dermatology outpatient department of Tertiary Care Teaching Hospital (TCTH). The percentage of the drugs prescribed by the Hospital Drug Formulary (HDF) is another aspect emphasized in the study deducing its availability and accessibility in the healthcare facility [10]. Through analysis of this data, the proposed study will help to enhance the current prescribing behaviour to achieve better and effective treatment of dermatologic patients.

Drawing a conclusion, I can point out that the growing popularity of IMDs in dermatological practice is associated with the necessity of assessing the trend in their usage. A study on drug utilization like the one in the description is important in ensuring that the practice in the field of medicine is guided in the best manner, the best resources are directed, and that the patients are subjected to the best and apt medication regarding their conditions [11]. Such studies will be indispensable in the wake of the further development of IMDs, which are becoming increasingly popular among the population, and provided that the advantages of this technology and its possible drawbacks are optimized.

The study also had systematic enrolment data that tried to comprehensively document the drug use habits and the right information about the patients. The following were the major items in the data collection process:

General Patient Information: This entailed the collection of simple demographic information which was; the name of a patient, first initials of the patient, sex of the patient, age of the patient and the weight of the patient. The study population will require the characterization of these parameters which shall serve to know how the patients are distributed along these parameters.

Symptomatology/Diagnosis: Explicit data concerning the symptoms and clinical diagnoses both conclusive and hypothetical of the patients were obtained. This aided to group the patients based on their individual skin types and be able to draw patterns of the diseases within the study population.

Drug Details: Details regarding the drugs that are to be used on the patients were recorded in details. This entailed the route of the administration, time of treatment, whether the drug was ordered in its generic or brand name, dose, frequency of administration and the availability of the drug on the hospital shelf. It was important to record this data to be used to assess pattern of prescribing, and compliance with formulary guidelines.

All that was carefully recorded in a case record form (CRF) specifically designed to capture it during the study.

2. DATA ANALYSIS

Parameters that were examined in the study included 11 different factors which provided knowledge about the circulation of drugs within the sample population. Such parameters were:

1. Demographic Parameters (Age and Sex): The demographic examination of the patients was done in terms of their dispersal in age and sex. This gave the distribution of the patients and allowed getting an idea of the situations in the use of drugs across various sections of the population.

2. Frequently Diagnosed Skin (Immunological): The researcher sought to establish the top-ranked skin conditions that have been diagnosed among the participants. Such information will be critical in determining prevalence of certain dermatology disorders within the study environment.

3. Type of IMDs Generally Prescribed: The research group identified potential categories of the various immunomodulator drugs (IMDs) most prescribed by physicians to patients. This discussion was used to come up with the preferences and practices of the treatment of the dermatology department.

4. Percentage of IMDs Prescribed by Generic and Brand Name: Comparing the percentage of IMDs prescribed by their generic names in comparison with their brand names was studied. The analysis helped to gain some insight into prescribing behaviour and the possibilities of saving money.

5. Recommended Doses against Each IMD: The amount of doses that was prescribed to the patients was compared with the recommendations of individual IMDs as postulated by the dermatological works of authorities like Wolverton in Comprehensive Dermatological Drug Therapy and Valia in Textbook of Dermatology.

6. Investigated Prescribed Route of IMDs: Analysis of the routes of administration of the IMDs being prescribed was done. This incorporated topical, oral and other administration, which assisted in the cognizance of the preference of various

routes in the treatment of various conditions.

7. Total Number of Drugs/IMDs/Corticosteroids (CS) Prescribed per Patient: This parameter calculated the average number of drugs, such as those IMDs and corticosteroids, prescribed to a patient. In this analysis, the prevalence of polypharmacy in patient group was described.

8. Type of common Prescribed Corticosteroids (CS): The types of the prescribed corticosteroids which are most common were revealed in the study. As corticosteroids have anti-inflammatory effects, they are also widely prescribed in dermatology, which is why the given analysis is also relevant to treat tendencies.

9. Route of Each Steroid: Akin to the analysis of IMD routes, in this parameter the emphasis is explicitly placed on the routes of administration of corticosteroids with the idea of determining whether they were introduced in a topical or systemic manner.

10. Strength of Topical Steroid: Topical corticosteroids were also checked to assess their potency, which were given to the patients. This is a critical parameter because the strength of topical steroids might largely affect the results and adverse effects of a treatment session.

11. Percentage of IMDs provided out of the Hospital Drug Formulary (HDF): The research has taken into consideration the number of the prescribed IMDs that are listed on the Hospital Drug Formulary. The current analysis helped to understand formulary compliance and access to the necessary medications.

3. STATISTICAL ANALYSIS

The statistics regarding baseline demographics and clinical profiles of the patients were in the form of frequency percentages. The reason behind this choice is explained by the fact that the skew of the data would support a less accurate representation of the data by the mean values, which is distorting the distribution of the population. The frequencies percentages were also used in the expression of the results of the parameters that defined drug use patterns hence the presentation of the results were clearly and concisely.

4. RESULTS

Age Distribution:

The research noted that, the ages of the patients varied between 6 to 68 years with the median age of 35 years. Fifty percent of the cases were in the age range of 21 to 40, whereas 27.5 were in the 41 to 50 range. Of the cohort, patients between the age of 1 to 20 represented 16.88% with patients above the age of 60 representing 5.62%. And, to note, there were no patients of the 51 to 60 age range.

Sex Distribution:

The total number of study patients was 160 impeding that 96 of them were women (60 percent), and 64 were men (40 percent) creating the equivalent of 1:1.5 between men and women.

Some of the most Commonly Diagnosed Skin conditions:

The study also had an objective to arrive at the most common immunological skin conditions amongst the patients, so as to present a better premise on the dermatological issues that occur in the study environment.

To sum up, it is possible to say that the close study of IMD use in one of the dermatology outpatient departments can be very helpful in gaining specific knowledge about prescribing behavior, the tendency towards stratification, and the compliance with the set recommendations on treatment. The research can promote patient care improvement and the better management of skin conditions as it defines the areas of improvement, including adhering to the formulary and rational drug use.

The study listed some relevant yet not so frequent conditions in the category entitled Other. In particular, 4 were represented with mixed connective tissue disorder, 3 with systemic lupus erythematosus (SLE), 2 with dermatomyositis, 2 with pityriasis rubra pilaris (P. erythromatoses), and 1 with Behcurts disease. These cases reflect a few diverse autoimmune and connective tissue disorders, which brings forth the heterogeneity of the autoimmune and connective tissue conditions served with immunomodulator drugs (IMDs) in the study.

Overview of Drug Prescription

Drugs: 607 drugs were prescribed on the target population of 160 patients who participated in the study. Out of which 317 were IMDs which meant that more than half (52.2%) of the drugs given were concerned with immune system modulation to cure the dermatological and autoimmune skin diseases referred by the patients. This tremendous percentage highlights just how crucial IMDs are to the therapy of such intricate conditions inside the dermatology outpatient facility.

3b) Some other classes of different IMDs prescribed were as follows.

The Patterns of Prescription and Dosing Analysis of the Immunomodulator Drugs (IMDs)

The given research study examined the pattern of immunomodulator drugs (IMDs) prescribing and revealed the following main specifics:

Generic vs. Brand Name Prescriptions: Of the 317 IMDs prescribed, 120 (38%) were prescribed using their generic names with the other 197 (62%) prescribed using their brand names. Here it is notable that there is a tendency toward brand-name prescription among the research subjects, which might affect the prices and availability of the medications [12-13].

Dosage Adherence: In 93 percent of the cases involving the patient, the IMDs were given at the recommended doses. This degree of close observation to instructions pointing to dosages indicates that the prescriptions were within the accepted clinical therapies practices, hence patients were provided with effective dosage.

Route of Administration: Two main routes of administration were used in the case of the IMDs; i.e. the local and systemic route. In particular, 157 (49.52%) of the IMDs were administered along the route of local administration that consists of topical and intralesional administration. Conversely, 160 (50.47 percent) of the IMDs were used systemically either as the taken orally or as through intramuscular (IM) injections. This close equivalence of local and systemic administration is an indication of the variety of therapeutic approaches that is used in the treatment of the dermatological condition based on the severity of the condition and the nature of the condition [14].

Drugs Per Patients: Another outcome measurement in the study included the drugs per patient, making an assessment of polypharmacy trends of the population of the study. The statistics showed that:

The total number of drugs that were prescribed was 607 in 160 patients, which makes the average of 3.79 drugs per patient. In particular, there were 317 IMDs prescribed the average number of IMDs was 1.98 IMDs per patient.

Also, 191 corticosteroids (CS) were given out with an average of 1.19 corticosteroids per patient.

This discussion shows that every patient was on average given around two IMD to undergo the treatment regime in addition to the use of other drugs like corticosteroids. The judiciousness of the topical and systemic routes of administration and its compliance with the recommended doses of drugs implies a cautious and wise policy of medication in this outpatient dermatology facility [15-16].

Analysis of Prescribing and Administration of Corticosteroids

The paper presented an elaborate distribution of the route of administration of the 191 corticosteroids (CS) served. It was found that in 121 (63.35 %) of these corticosteroids the local administration route was used, and 70 (36.65 %) was implemented systemically. The topically administered corticosteroids amounted to 114, and 7 were intralesional-administered. In the systemically administered corticosteroids, there were 67 oral (PO), and three intramuscular (IM) injections [17-18].

Oral Prednisolone:

Prednisolone became the most popular prescription of corticosteroids of oral (systemic) use. Of the 156 immunomodulator drugs (IMDs), administered orally, 44 (28.20%) consisted of prednisolone. Taking into account the entire number of corticosteroids (191), the share of prednisolone prescription made 44 (23%) of the total number. In addition, the most widely used systemic corticosteroid in pediatrics which was mentioned in the 67 oral systemic corticosteroids was the prednisolone, comprising 44 (65.67 %) of the total percentage [19].

Betamethasone (BM):

The commonest oral steroid was betamethasone as well as the topical one. Betamethasone was used in 45 (23.56%) of the 191 corticosteroids prescribed. Particularly, out of 70 prescriptions of the systemic corticosteroids, 23 (32.85%) was to betamethasone and 23 (34.32%) out of 67 administrations of the oral corticosteroids was betamethasone. In the same way, 22 (18.18%) of the 121 local corticosteroids and 22 (19.29) topical corticosteroids involved betamethasone [20].

Topical steroids Potency

In relation to potency of topical corticosteroid prescription, the study shows that, there were 80 topical steroids of superpotent and 34 topical steroids of mid-strength among the 114 topical steroids. Markedly, no corticosteroid, either strong, medium power, and less powerful were prescribed in this group. This reveals the supremacy of stronger topical corticosteroids used, which may be pointing at the severity of the conditions to which they are applied [21].

The use of Hospital Drug Formulary (HDF)

The use of the Hospital Drug Formulary (HDF) in the prescription of the immunomodulator drugs (IMDs) was also studied. Of 317 prescribed IMDs, 169 (51%) were sourced based on the hospital formulary and the rest 158 (49%) were prescribed outside the formulary. The ratio between these almost equal proportions points to the possibility of the formulary expansion, incorporating a higher number of IMDs so that patients could readily obtain the basic medications as a part of the hospital system [22].

This elaborate study depicts prescribing trend, the strength of drugs and their consumption through formularies with the utmost top importance of the corticosteroids and immunomodulators in the treatment of dermatological patients.

Table 1: Distribution of Dermatological Conditions among Study Patients

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

Table 2: Classification of Immunomodulator Drugs (IMDs) Prescribed and Their Corresponding Classes

IMD drug class	**Prescribed drug class**
Steroids	191
Methotrexate	43
Tacrolimus	30
Azathioprine	18
Levamisole	11
Cyclophosphmide	11
Imiquimod	7
Cyclosporin	5
Mycophenolate mofetil	1

Table 3: Distribution of Different Corticosteroids (CS) Prescribed:

Corticosteroids	**Number of CS prescribed**
Prednisolone	44 #
Clobetasol	25
Halobetasol	40

Betamethasone	45 $
Fluticasone	05
Mometasone	20
Flucinolone	02
Triamcinolone	10
TOTAL	191

5. DISCUSSION

The research was carried at dermatology outpatient-department of a tertiary care teaching hospital to determine immunomodulator drug (IMDs) prescription practices and gauge their application in dermatology practice. A total of 160 patients were selected over a 9-month duration, and their information was obtained to give an understanding of the nature of a demographic distribution, prevalence of disease, and prescribing of IMDs.

We have discovered that 60 percent of the patients at the immunology clinic are females and there is a feminine rate of 1.5: 1. The same outcome can be correlated with other research conducted by Sarkar et al. in Western Nepal, Yuwanate et al. in Wardha, and Rathod et al. in Ambajogai that have found their results to possess even greater prevalence of women as patients [23]. This disparity could be due to the prevalence of autoimmune diseases in females such as that of systemic lupus erythematosus (SLE) and scleroderma and increased risks of polyautoimmunity among women.

The age of the patients that formed the median was 35 years with a range of 6-68 years. Patients aged 21 to 40 years comprised half of all patients similar to the findings of Sarkar et al. in Nepal, Yuwanate et al. in Wardha and Javsen et al. in Mumbai. Having vitiligo vulgaris and psoriasis vulgaris were the most diagnosed conditions with a percentage of 21.25 and 16.90 respectively. Yet, other surveys like that of Yuwanate et al. in Wardha and Bijoy et al. in Pune showed variations in the trend, acne vulgaris and fungal infections being the topmost popular against diagnosis respectively [24].

Of the 160 patients, 317 IMDs were prescribed to them, whereby the most common class of IMDs prescribed was corticosteroids (CS) with 191 (60.25%) IMDs prescribed. This observation is in line with the finding of Sarkar et al. in Nepal, who found out that corticosteroid uses is also high. In our study, preference towards prescribing by brand name (62%) as opposed to generic name (38%) was noted in line with the findings of Uppal et al. and Narwane et al. who revealed the prevalence of 65 and 83.4 percent prescribing by brand name respectively. Most of them are prescribed by names even though the process can result in increased expenditure as well as confusion given that some products have close names.

The research revealed that 93 percent of the IMDs were prescribed at the recommended doses hence, the study by Sharma et al. laid emphasis on the need to give the right dose in order to maximize therapeutic effects and minimize side effects. Local and Systemic modes of administration of IMD were almost equal (49.52 and 50.47, respectfully) as reported by Sarkar et al., who gave a similar description of the proportional distribution of administration modes [25].

In terms of corticosteroids, the prevalent form of oral corticosteroid was prednisolone that constituted a proportion of 28.20 percent of orally dosed IMD and 65.67 percent of all systemic corticosteroids. The most popular corticosteroid that was prescribed with both oral and local routes was betamethasone (BM) which comprises 23.56 percent of corticosteroids prescribed. Such results are reflected in the literature of other authors who wrote about the presence and popularity of prednisolone and betamethasone (Divyashanthi et al., Javsen et al.).

A proportion of 70.17 percent of topical corticosteroids medicines recommended were in the category of super-potent and 29.83 percent of medicines recommended were of mid-strength. This pattern is consistent with the results of Bijoy et al. and Divyashanthi et al. who found an extreme proportion of super-potent corticosteroid use, too. Finally, 51 percent of the IMDs were prescribed using the formulary of the Hospital Drug Formulary (HDF), which is a higher indication, compared to the finding of Narwane et al., where only 30 percent of the drugs were disbursed through the formulary.

6. CONCLUSION

In this study, I have taken a closer look at immunomodulator drugs (IMDs), namely corticosteroids, in the treatment of immune-mediated dermatological disorders in a Tertiary Care Teaching Hospital. IMDs of all the prescribed medications were more than half, and there was a tendency to prescribe brand names. According to the study, the best compliance to recommended dosages was attained with a satisfactory proportion of both local and systemic application routes. Most frequently they were prescribed corticosteroids such as prednisolone and betamethasone in super-potent forms. Rather high usage of the Hospital Drug Formulary (HDF) is observed; however, accessibility should be improved. Altogether, the study points to the value of surveillance of IMD prescription that could optimize patients care, utilizing the drugs, and the outcomes of the dermatological treatment.

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