

ST PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE



**THE PRESCRIBING PATTERNS OF TOPICAL STEROIDS IN
PATIENTS VISITING THE DERMATOLOGIC CLINIC OF St
PAUL'S HOSPITAL, ADDIS ABABA, ETHIOPIA: 6 MONTH
RETROSPECTIVE REVIEW**

RESEARCH PROPOSAL

**TO BE SUBMITTED TO St PAUL'S HOSPITAL MILLENNIUM MEDICAL
COLLEGE, DEPARTMENT OF PUBLIC HEALTH AS A PARTIAL
FULFILLMENT FOR THE DEGREE IN DOCTOR OF MEDICINE**

BY: DR INAS BASHA (INTERM)

ADDIS ABABA, ETHIOPIA

MARCH, 2018

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REVIEW: 6 MONTHS RETROSPECTIVE REVIEW**

BY: DR INAS BASHA (INTERN)

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List of Abbreviations and acronyms

WHO- World health organization

SPH- Saint Paul's Hospital

SPHMMC- Saint Paul's Hospital Millennium Medical College

OPD- Out Patient Department

SPSS- Statistical Packages for Social Sciences

Summary

Background

Skin problems are generally among the most common diseases seen in primary care settings in tropical areas. It's also among the leading causes of hospital visits in Ethiopia. Although skin disease might not be fatal, it is truly bothersome. Topical steroids comprise the mainstay treatment of skin diseases. However, irrational prescription of topical steroids is a common occurrence all over the world, there is no enough study done in our country regarding this issue.

Objectives

The main aim of this study is to find out the common skin diseases for which topical steroids were prescribed in patients visiting the dermatologic clinic of St Paul's Hospital in the past 6 months.

Methods

The study will be conducted in the dermatologic clinic of St Paul's Hospital, Addis Ababa, Ethiopia. The study period will be from March 12, 2018 to April 12, 2018 which is a total of 30 days. The study will employ a retrospective chart review or medical record review from a total of 355 patient using quantitative methods between the months September 2017 to February, 2018 at St Paul's Hospital. Results will be analyzed using the SPSS and results will be expressed in terms of percentages and presented using tables and figures. A total of 4,362.00 Ethiopian birr is estimated to do the research, which will be partially funded by the research committee.

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1. Introduction

1.1 Background

The skin is the largest organ of the human body, a major interface between a person and the environment and the most diverse organ. It provides important functions, including protection from external insults and microorganisms, temperature modulations and synthesis of vitamin D. the importance of healthy intact skin is decisive in the optimal functioning of the human body. A healthy and attractive skin also plays an important role in most persons' self-confidence as it is a key component of the image they present to the outside world. However the skin is susceptible to a spectrum of insults including disorders caused by chemical and microbial agents, thermal and electromagnetic radiation, and mechanical trauma (1).

The importance of skin diseases is often overlooked. They are usually not life-threatening and tend to be "shrugged away". Skin diseases are, however, a significant problem all over the world. In 1996 11.3 % of the new attendances presenting at all OPD's in Masvingo Province, Zimbabwe concerned skin diseases. These figures are similar elsewhere (4). Skin diseases have been known for a long as "you hardly ever die from a skin disease, but it can be truly bothersome" showing that skin diseases are an important cause of health loss on a global level (2). Skin problems are generally among the most common diseases seen in primary care settings in tropical areas.

Topical corticosteroids have been used for over 60 years and their introduction was a milestone in dermatology. They are used to treat inflammatory skin conditions by suppressing the inflammatory reaction and relieving symptoms. However, they are not curative and attempts to increase potency have often been associated with more adverse effects (10).

1.2 Statement of the problem

Prevalence of skin diseases in developing countries ranges from 20 to 80 percent. The World Health Organization's 2001 report (WHO 2005) on the global burden of disease indicated that skin diseases were associated with mortality rates of 20,000 in Sub-Saharan Africa in 2001. This burden was comparable to mortality rates attributed to meningitis, hepatitis B, obstructed labor, and rheumatic heart disease in the same region(2). In a study done in western Ethiopia, between 47 and 53 percent of the members of two rural communities claimed to have a skin disease but when they were examined, 67 percent of those who denied having skin problems were found to have treatable skin conditions, most of which were infections(2). This shows how skin diseases are a big issue to the community but still is accompanied with poor awareness.

Topical corticosteroids have greatly contributed to the dermatologist's ability to effectively treat several difficult skin conditions. The available range of formulations and potency gives flexibility to treat every group of patients, different phases of disease and different anatomic sites. However, the rapid rise in incidence of improper use of these drugs by dermatologists, general physicians, and patients threatens to bring disgrace to the entire group of these remarkable drugs. The cost of such irrational drug use is enormous in developing countries in terms of both scarce resources and the adverse clinical consequences of therapies that may have real risks, other than the side effects these classes of drugs cause(1).

1.3 Significance of the study

Skin diseases are one of the most prevalent disease conditions among the general population, representing a major public health problem (9). There are even some suggestions that skin disease prevention and treatment should be included in future global health strategies as a matter of urgency due to its high disease burden(7).

Regarding the common skin diseases in SPH, there is no recent study done but even in a study done in Addis Ababa, at 2 different hospitals, it was remote but showed a significant figure of different skin conditions(1)(8). In addition to this, there is scarcity on studies done on topical steroids for different skin conditions, and it is not known how often it is being prescribed. Therefore, this study will definitely be addressing these gaps and present with recent data that would be helpful to tackle problem either in the community or clinical setting.

Having information about the common skin diseases for which topical steroids were prescribed will enable us to have modifications on prescribing pattern to increase the therapeutic benefits and reduce adverse effects. And by having the knowledge to what magnitude these drugs are being used, an intervention program could be designed.

The purpose of this study is to find out common skin diseases for which topical steroids were prescribed in SPH. This is important to understand the common skin conditions presenting and act if possible at a community level to create awareness and decrease the occurrence of the diseases. It will also help us to know how common drugs are prescribed.

2. Literature review

2.1 Pattern of skin disease

The skin conditions expert group of the Global Burden of Disease 2010 study estimated the global burden of skin conditions worldwide. Health loss due to 15 skin diseases between 1990 and 2010 for 187 countries was quantified. All skin conditions combined were the fourth leading cause of non-fatal disease burden at the global level. The burden of skin conditions was high in both high- and low income countries (7).

An annual observational study done on the Pattern of skin diseases among patients attending a tertiary care hospital in Lahore, Pakistan in 2016, a total of 95,983 patients presented. Out of this sample, 24,302 patients repeatedly came to the hospital for a follow up visit related to their diseases, while 71,681 were enrolled as new cases. Out of 71,681, eczema was diagnosed in 31.07%, infections including bacterial, viral, fungal, sexually transmitted infections in 28.16% , acne 11.03%, drug reactions 6.74%, urticaria 4.06%, and pigmentary disorders such as lichen planus, melasma and vitiligo were reported in 3.82% cases. In addition, psoriasis was reported in 3.80%, bullous disorders in 1.66% and connective tissue disorders in 0.90%. (3)

Based on a study done on Pattern of Skin Diseases in a Tertiary Institution in Kolkata, India, it was found that skin OPD patients (new) were 4.16% of total new OPD patients, and male female ratio was 1.1:1. Among all patients (12910), infection was commonest (39.54%), followed by allergic skin disorder (29.20%). 25.05% patients were housewives, followed by students (23.21%). Study showed that 33.28% patients had per capita income of ` 361-720/month and 22.35% patients were educated and/or studied up to fifth grade (15).

Regarding a 12 month prospective study done on the Pattern of skin diseases at university of Benin teaching hospital, South-South Nigeria, a total number of 4786 patients were seen during the study period and these comprised 2647 HIV/AIDS patients and 2112 pure Dermatological patients. Out of 4786 patients, 755 (15.8%) were new patients. The new patients comprised 96 (12.7%) children patients (< 15 years) and 659 (83.7%) adult patients (>15years). The ages of the patients ranged from 2 weeks to 80 years and more than two-third were <40 years. There were 354 males (46.9%) and 401 females (53.1%). This represents female: male ratio of 1.1: 1.

Eczematous dermatitis accounted for 20.9% of the skin diseases and was the most common of the skin diseases observed. Other skin diseases observed in order of frequencies included: Papulosquamous disorder (9.0%), Infectious skin diseases like fungal, viral, bacterial and parasitic infestation, at 7.9%, 7.7%, 2.3% and 2.1% respectively. Pigmentary disorders (5.0%), hair disorders (4.2%) and Benign neoplastic skin disease (6.5%). All the patients that had neurofibromatosis were females (1.9%). HIV-related skin diseases were observed to have increased remarkably (7.9%) with Kaposi's sarcoma, papular pruritic eruptions and drug eruptions being the commonest mode of presentation (16).

The prevalence of skin disease in two different rural communities in southwestern Ethiopia was determined using descriptive epidemiologic techniques showed that there were skin symptoms in 47% and 59% at the first and the second community respectively. But the true dermatological needs of these communities was far greater than the expressed values, as an examination by a dermatovenerologist of randomly selected households revealed that 67% of them not reporting skin diseases had significant skin disease(6).

Study was done on the pattern of skin disease among clients attending dermatologic outpatient clinic at Finote Selam Hospital, West Gojjam Zone, Amhara Region, North West Ethiopia, 2017. which was Hospital based cross-sectional study. Descriptive statistics was done and the results showed that the magnitude of noninfectious skin disease was 62% the majorities 29.5% were eczema. Fungal infections 11.5% were the most common infectious skin problem (14).

Prospective analysis done on Pattern of skin diseases at the University teaching hospital, Addis Ababa, Ethiopia, on 2000 showed that among A total of 1505 patients assessed, the most common skin diseases were allergic skin diseases (25.5%), infections (25.4%), the photodermatoses (22.9%), followed by papulosquamous diseases (11.4%) and pruritus of unknown origin (3.3%). Skin manifestations of collagen diseases were less common findings (0.7%) (8).

2.2 Overview of topical steroids

Steroids are used to suppress inflammation and come in many forms, including topical steroids, inhaled steroids, oral steroids, injectable steroids, and IV (intravenous) steroids. Oral steroids, also called systemic steroids, systemic corticosteroids, or glucocorticoids, are a class of steroids taken by mouth and used for many human diseases, including various skin conditions. They are synthetic forms of the natural hormone cortisol, which is produced by the adrenal gland (15).

Topical corticosteroids have been used for over 60 years and their introduction was a milestone in dermatology. They are used to treat inflammatory skin conditions by suppressing the inflammatory reaction and relieving symptoms. However, they are not curative and attempts to increase potency have often been associated with more adverse effects. The emphasis should be on limited, selective and careful use with clear explanation and instruction to patients (10).

Topical corticosteroids are grouped according to their potency: Very high potency: betamethasone dipropionate (Diprolene), clobetasol propionate (Clobex, Temovate, Olux), diflorasone diacetate, fluocinonide (Vanos), and halobetasol propionate (Ultravate). High potency: amcinonide (Cylocort), desoximetasone (Topicort, Topicort LP), halcinonide (Halog), and triamcinolone acetonide (Kenalog). Medium potency: betamethasone valerate (Luxiq), clocortolone pivalate (Cloderm), fluocinolone acetonide (Synalar), flurandrenolide (Cordran), fluocinonide (Lidex), fluticasone propionate (Cutivate), hydrocortisone butyrate (Locoid), hydrocortisone valerate (Westcort), mometasone furoate (Elocon), and prednicarbate (Dermatop). Low potency: alclometasone dipropionate (Aclovate), desonide (Desowen, Verdeso), and hydrocortisone (Hytone) (13).

Topical corticosteroid is one of the oldest and most useful treatments for dermatologic conditions. Successful treatment depends on an accurate diagnosis and consideration of the steroid's delivery vehicle, potency, frequency of application, duration of treatment, and side effects. Although use of topical steroids is common, evidence of effectiveness exists only for select conditions, such as psoriasis, vitiligo, eczema, atopic dermatitis, phimosis, acute radiation dermatitis, and lichen sclerosus (11).

Topical steroids, if the correct potency and base are selected, play an important role in management of skin diseases. They have a beneficial effect, particularly in inflammatory skin

diseases. They also have adverse effects, such as dermal atrophy, which may be used with benefit on occasion e.g. in intralesional treatment of keloids (12).

Study done on the prescribing pattern of topical corticosteroids in dermatology out patients department in a tertiary care hospital, India showed that the most common indication for prescription of topical steroids was eczema (22.33%). The most commonly prescribed topical steroid was clobetasol (68.66%) followed by mometasone (11%), betamethasone (9.33%) and halobetasol (3%). Cream was the most frequently prescribed formulation (85.66%). 28 patients (9.33%) out of 300 showed adverse drug reactions, of which, erythema was the most common (50%) (17).

Literature analysis and an empirical study on the treatment patterns of dermatological disorders in the private healthcare sector of Namibia on November 2013 done indicated that eczema was the dermatological disease with the highest incidence of 11.2%. The disease was mostly treated with medium strength corticosteroids over a period of 14 days (5).

A study performed to assess the utilization pattern of topical steroids in ALERT Hospital, Addis Ababa, between August and November, 2013 showed that Eczematous dermatitis 30.0% was the single most common skin diseases observed. However, infectious skin diseases were the most common skin dermatoses 33.8% when combined. The most commonly prescribed classes of drugs were topical steroids and its combination 28.4% followed by anti-fungal drugs 22.1% (1).

3. Objectives

General objectives

To identify the common skin diseases for which topical steroids were prescribed in patients visiting the dermatologic clinic of St Paul's Hospital in the past 6 months

Specific objectives

To identify the common skin diseases presenting to the dermatologic clinic in St Paul's Hospital.

To address how often topical steroids are prescribed in the dermatology clinic of St Paul's hospital.

To determine the types of topical steroids patients were prescribed in the dermatology clinic of St Paul's hospital.

4. Methods

4.1 Study setting

The study is to be conducted in St. Paul's Hospital Millennium Medical College which is located in Addis Ababa the capital city of Ethiopia, with altitude of 3,000 meters above sea level and a population of 2 million. It is the second largest hospital in Ethiopia. The Hospital was built by Emperor Haile Selassie I in 1969 with the help of the German Evangelical Church. It has a catchment population of more than 5 million. It has over 13 departments, one of which is the dermatology. The dermatologic clinic in St Paul's Hospital has 3 examination rooms and a procedure room. It works on weekdays and about 57 patients can be evaluated per day.

4.2 Study period

The study period will comprise 30 days from March 12, 2018 to April 12, 2018 GC.

4.3 Study design

Retrospective cross-sectional chart review or medical record review, using quantitative methods between September, 2017 and February, 2018 will be employed for the study.

4.4 Population

4.4.1 Source population

The source population includes, all those patients registered on registry book of the dermatologic clinic from September, 2017 to February, 2018.

4.4.2 Study population

The study population will include those patient charts registered on registry book of the dermatologic clinic and which have been chosen as a sample by the systematic sampling technique.

4.4.3 Inclusion criteria

All those patient charts registered on registry book of the dermatologic clinic and which have been chosen as a sample by the systematic sampling technique will be included in this study.

4.5 Sampling and Sample size determination

Records of patients with skin diseases that were treated in the OPD of the dermatology clinic during the period mentioned above will be taken as a study population and patient cards will be the sampling units. Sample size will be determined using the single proportion formula; individuals will be determined by systematic sampling technique.

The sample size was determined using this formula:

$$n = \frac{(Z_{\alpha/2})^2 p (1-p)}{d^2} = \frac{(1.96)^2 0.284(1-0.284)}{0.05^2} = \frac{0.78116}{0.0025} = 312.46$$

Where: n = the required sample size

$$Z_{\alpha/2} = (Z \text{ critical value}) = 1.96$$

$$p = \text{Extent of steroid utilization} = 28.4\% \text{ (from ALERT hospital, 2013)}$$

$$d = \text{the margin of error (precision)} = 0.05$$

Then adding 10% contingency for incomplete records, the total sample size will be 343.71~344 patient records.

From the hospital registration book of records, it was found out that a total of 10,964 patients were treated at the OPD of the dermatology clinic in St Paul's Hospital in the past six months. Dividing the total number of patients by the required sample size (344) and using systematic random sampling, the sample to be used for the data collection will be chosen at regular intervals of 31 by drawing a random starting card until the total sample size was reached. When a selected patient record is missing, the next patient record will be selected and then moved from that at a regular interval of 31.

If p value for the common skin disease which is 30 % (from ALERT hospital) is taken the sample size will be 354.9~ 355 i.e. along with the 10% contingency. Therefore the larger sample size will be taken.

4.6 Study Variables

- Demographic characteristics of the patients
- Types of skin conditions
- Frequency of skin diseases
- Types and potency of topical steroids prescribed
- Frequency of steroid prescription
- Frequency of topical steroid prescription
- Duration of the drug prescribed
- Number and types of other drugs prescribed
- Comorbid illnesses

4.7 Operational Definition

Topical steroid refers to the preparation intended only for a dermatological condition but excludes topical steroids in the form of inhalers, drops and nasal sprays.

Topical steroid and topical corticosteroids are used interchangeably.

Skin diseases: a condition or a disease affecting the skin, infectious or non-infectious, systemic or local. In this study the diagnosis put by the evaluating physician will be taken as the skin disease that the patient has.

Dermatoses and skin disease are used interchangeably.

4.8 Plan for Data collection

The list of the charts of patients who have visited the dermatologic clinic in SPHMMC during the past 6 month will be obtained from the registry book .The data that is needed for this research will be collected by reviewing the charts using a modified checklist developed for this study. The data will be collected by the primary investigator from March 12 to April 12 Of 2018, by taking approximately 12 patient charts per day then replacing those with another twelve the other day by making sure that the charts are in place until data collection is done by 30 days. The sociodemographic data, the skin disease the patient has, type of drug prescribed, number of drug prescribed, for how long the drugs were prescribed and presence or absence of comorbid illness

will be retrieved from the charts. After data collection, until it is entered, it will be kept safe with the primary investigator.

4.9 Data quality control

10% was added on the sample size as a contingency for incomplete charts. Pretest will be done on 5% of the population and maximum number of sample size was taken to increase the accuracy of the study.

4.10 Plan for Data processing and analysis

The data collected will be entered into a computer and analyzed using SPSS (Statistical Packages for Social Sciences). For descriptive statistics results will be expressed in terms of percentages and presented using tables and figures.

4.11 Ethical considerations

As charts contain vital information regarding patients demographic factors and health status, proper chart handling will be given priority. Patients' identification will not be exposed and all charts taken from the chart store for the study will be returned timely and properly as they may be needed for other purpose.

Ethical approval will be obtained from the public health department of St Paul's hospital Millennium Medical College and the study will be conducted in St Paul's Hospital after obtaining the permission from the hospital.

4.12 Dissemination of results

After being finalized, this study will be submitted to the department of public health. It will also be submitted to the department of dermatology so that the results and the recommendations that are going to be forwarded by this study will be considered and get to practice. This paper will also be disseminated through the internet so that the findings can be viewed and used as reference by others.

5. Budget plan

Budget category				
1. Personel cost		Rate per day	No of days	Total cost (in birr)
Data collection		12*5birr	30	1,800.00
Data entry		12	30	-
Secretarial work		12*3	30	1,080.00
Sub-total				2,880.00
2. Supplies	Measurement	Unit cost	Quantity	Total cost (in birr)
Pen	Each	5.00	10	50.00
Printing paper and binding		2.00	80	160.00
Photocopy cost	Page	0.50	355	172.00
Printing the proposal	Page	2.00	25*2	100.00
Sub-total				482.00
3. Transportation, telephone and internet service cost				1,000.00
Grand total				4,362.00

6. Work plan

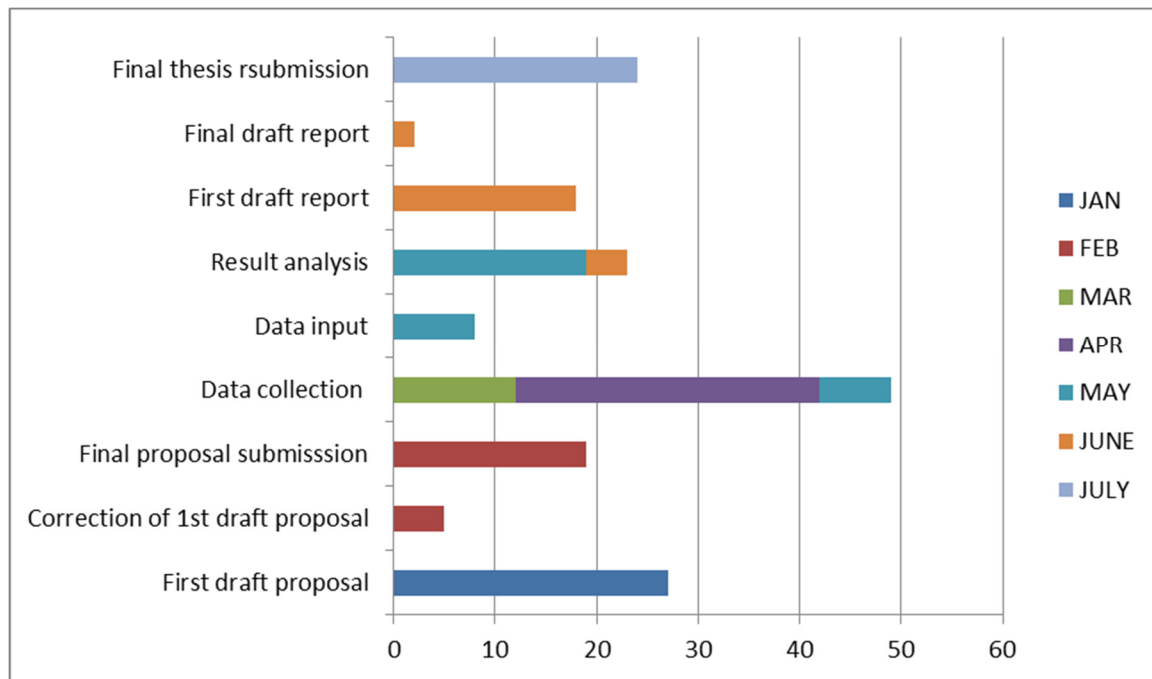


Figure 1: Gantt chart of work plan

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Annexes

Annex I: Data abstraction format: patient records review in St Paul's Hospital, 2018

1. Patient information

1.1.Card number _____

1.2.Age _____

1.3.Sex _____

1.4.Place of residence/address _____

1.5.Dermatological condition/Type of diagnosis _____

1.6 .Previous history of topical steroid ☐ Yes ☐ No

If yes, Prescribed ☐ OTC ☐ Not specified ☐

2. Treatment

2.1.Date of visit _____

2.2.Qualification of prescriber _____

2.3.Number of drugs prescribed _____

Drug 1	_____	Drug 2	_____	Drug
3	_____	Drug 4	_____	Drug
5	_____			

2.4.Topical steroid prescribed _____

2.5.Dosage form _____

2.6.Dosage schedule _____

2.7.Frequency of application _____

2.8.Duration of treatment _____

2.9.Site (area) of application _____

**Annex II: Ethical clearance from the public health department, St Paul's Hospital
Millennium Medical College.**