IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Research Article
June 2023 Vol.:27, Issue:3

A Study on Pharmacoepidemiology, Clinical Features and Prescription Pattern Analysis of Scabies

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Submitted: 24 May 2023
Accepted: 31 May 2023
Published: 30 June 2023

Keywords: Scabies, Sarcoptes scabiei var hominis, 5% Permethrin, Chlorpheniramine maleate, GBHC Lotion, Ivermectin, Itching, Dark-colored lesions, Pharmacoepidemiology

ABSTRACT

Scabies is an itchy skin condition caused by a tiny burrowing mite called Sarcoptes scabiei var hominis. Scabies is contagious and can spread quickly through close physical contact in a family, child care group, school classes, nursing home, or prison. We have conducted an observational study aiming at the pharmacoepidemiology of scabies to characterize the use and effect of scabies drugs in a well-defined population. We aimed to analyse the prescription pattern of scabies to assess the prescribing, dispensing, and distribution to facilitate the rational use of scabies medicine. We have studied the clinical features of scabies to overcome the symptoms using rational drug use. A data collection form will be designed and patients will be selected based on inclusion and exclusion criteria from the study duration of November 2021 to April 2022. Only the patients visiting OPD-DVL who are diagnosed with scabies will be included as a sample. Patients who are having any other infection/infestation and also patients who are not willing to participate will be excluded.

INTRODUCTION:

Scabies was first described in the Old Testament and by Aristotle. The name Sarcoptesscabiei is derived from the Greek word “sarx” which means flesh and “koptein” which means to cut, and the Latin word “scabere” which means to scratch. Scabies is an ectoparasite infestation; the mite itself was extracted from human skin, recognized as the causative organism by Bonomo in 1687, and demonstrated using light microscopy in the same year and in vivo by Renucci in Paris in 1814[1,2]. Human scabies is caused by the mite **Sarcoptes scabiei var. hominis**, an obligate ectoparasite that lives in the human epidermis [3]. The scabies mite belongs to the family Sarcoptidae that has 3 subfamilies. Sarcoptes belong to the Sarcoptinae subfamily. The female mite is 0.3–0.4 mm in size, and the male mite is half the size of the female and are not visible to the human eye [4,5]. The disease is transmitted by direct skin-to-skin contact, which is why transmission among family members is so common. It has been estimated that a patient with conventional scabies needs between 15 and 20 minutes of close contact to transfer the mites from one person to another [2]. Both sexes are affected equally. Ethnic differences in scabies epidemiology are most likely to be related to differences in overcrowding, housing, socioeconomic, and behavioral factors, rather than racial origin. The most common predisposing factors are immigration, poor hygiene, poor nutritional status, homelessness, dementia, and sexual contact. Seasonality trends of scabies have been documented. Some studies have suggested higher incidence during the winter months, and the likely explanation is mites survive longer away from the body in cooler weather and colder weather encourages overcrowding in human beings. Mites also might be sensitive to antimicrobial peptides contained in human sweat, leading to reduced infestation in summer [3]. The common clinical features are that patients typically present with severe itch, linear burrows and vesicles around the finger webs, wrists, upper and lower limbs and belt area. Infants and small children may have a more widespread rash, including involvement of the palms, soles of the feet, ankles and sometimes the scalp. Inflammatory scabies nodules may be seen, particularly on the penis and scrotum of adult males and around the breasts of females. Immunosuppressed individuals, including people living with HIV/AIDS, may develop an uncommon manifestation called crusted (Norwegian) scabies. Crusted scabies is a hyper- infestation with thousands to millions of mites, producing widespread scale and crust, often without significant itching. This condition has a high mortality if untreated due to secondary sepsis. Individuals with crusted scabies present with thick, exfoliating crusts that may be more widespread, including the face [6]. Scabies frequently imitates other skin diseases

including atopic dermatitis, papular urticaria, folliculitis, dermatitis herpetiformis, prurigo nodularis, pityriasis rosea and insect bites. And it is important to make an early and accurate differential diagnosis [7,8]. There are several diagnostic methods for diagnosing scabies such as scrapings, skin biopsy, burrow ink test, adhesive tape test, video dermatoscopy, dermatoscopy, reflectance confocal microscopy, optical coherence tomography [9,10,11]. The ideal treatment for scabies should be effective against adult mites and eggs, easilyapplicable, nontoxic, nonirritant, safe for all ages, and economical. Topical treatments such as Permethrin 5%, Precipitated sulfur 2–10% in petrolatum, Lindane (gamma benzene hexachloride 1%), Benzyl benzoate 10–25%, Monosulfiram 5–25%, Crotamiton 10%, Malathion 0.5%, Esdepallethrin 0.63%, Ivermectin 1%. Oral treatment such as Ivermectin. Moxidectin is a new drug that is currently on study. Two pre-clinical trials revealed a single dose of moxidectin, a highly lipophilic macrocyclic lactone, or afoxolaner, a novel acaricide, to be more effective than two doses of ivermectin [12]. Prescribing pattern of scabies is analysed by using WHO core drug prescribing indicators by collecting the data of Average number of drugs per encounter, Percentage of drugs prescribed by generic name, Percentage of encounters with an antibiotics prescribed, Percentage encounter with injection prescribed, Percentage of drugs prescribed from essential drug list [13]. Pharmacoepidemiology is the study of the use and effects of drugs in large numbersof people [14].

This study was designed to analyse the common clinical features and drug prescribing patterns of scabies. In a pharmacoepidemiological study of scabies, we analysed the price list of generic drugs, the treatment period of the drugs, and clinical outcomes based on the clinical features.

METHODS AND MATERIALS:

Ethical Clearance:

This prospective study was approved by Institutional Human Ethics Committee, Number: IHEC/882/2022 and permitted by Member Secretary, Institutional Human Ethics Committee, Government Cuddalore Medical College & Hospital (RMMCH), Annamalai University. The registration number of IEC is EC/NEW/INST/2020/1249.

Study Site:

The study was conducted in Department of Dermatology, Venereology and Leprosy (DVL), Government Cuddalore Medical College & Hospital (RMMCH), Annamalai University,

Annamalai Nagar, Chidambaram, Cuddalore, Tamil Nadu, which is a multi-specialty tertiary care teaching hospital located in rural south India.

Study Period:

The study was carried out for a period of six months, starting from November 2021 – April 2022.

Study Design:

Prospective Observational Cross-sectional Study, where the patients visited DVL-OPD during the period of November 2021 – April 2022 was observed.

Study Population:

All the patients, who are affected with scabies visiting the OPD during the period of November 2021 – April 2022. The selection criteria were based on the inclusion and exclusion criteria.

Inclusion Criteria:

- Patient with scabies.
- Patients coming to DVL-OPD during the period of November 2021 – April 2022 only included.

Exclusion Criteria:

- Patients who are having any other skin infection/infestation will be excluded.
- Patients who are not willing to participate will be excluded.

Sample Size Determination:

Based on the observation, we took the sample size of 100 patients for the study.

Study Recruitment Procedure:

- The study procedure was completely explained to the patients (or caretakers) and a consent form has been collected from them.
- **Target Population:** Patient with scabies visiting OPD of DVL department, RMMCH.

- **Study Population:** Patients who fulfill both the inclusion and exclusion criteria.

Sources of Data:

- The data required for the study was collected from case sheets (outpatients) and personal interactions with patient's caretakers.
- Drug information obtained from physicians.
- Case history, physical examination form, Treatment chart and progress card.

Designing of Patient Data Collection Form:

The data collection form was designed to collect the required demographic and clinical data of the patients. The data collection form has the following patient details as per WHO recommendations: Name, Gender, Age, Contact details, Medical history, Laboratory investigations, Clinical Diagnosis and Treatment details such as Name of the drugs, prescribed dosage, Frequency and Route of administration.

Statistical Tools to Analyses Data:

- The data entry and data analysis were performed using **Microsoft Excel 2016.**
- The frequency tables and descriptive statistics were used to describe the variables of interest.

OBSERVATION AND RESULTS:

In this study, the total of 100 patients of data were collected and analyzed.

1. **Age wise distribution**:

According to clinical manifestations with respect to age, 32 patients (32%) belonging to the age group of 21-30 years were most commonly infected with scabies followed by 23 patients (23%) between the age group of 31-40 years while 16 patients (16%) were distributed between the age group of 41-50 years as shown in Figure 1.

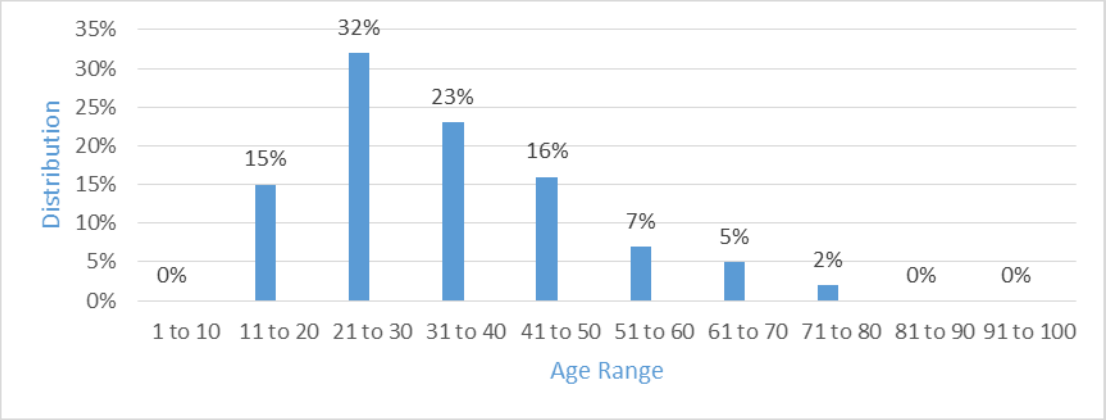

Figure 1: Demographic data of Age Wise Distribution

2. Affected Skin Areas:

From our observation, the commonly affected areas in patients with scabies were chest, abdomen, neck, thigh, upper limb, lower limb, ankles, scalp, finger web spaces, axillae, breast, scrotum and penis.

3. Complaint wise distribution:

From our observation, 57 patients had complaints of Nocturnal Itching, 55 patients had complaints of Itching all over the body, 22 patients had complaints of Dark-colored skin lesions and 12 patients had complaints of Generalized itching as shown in Figure 2.

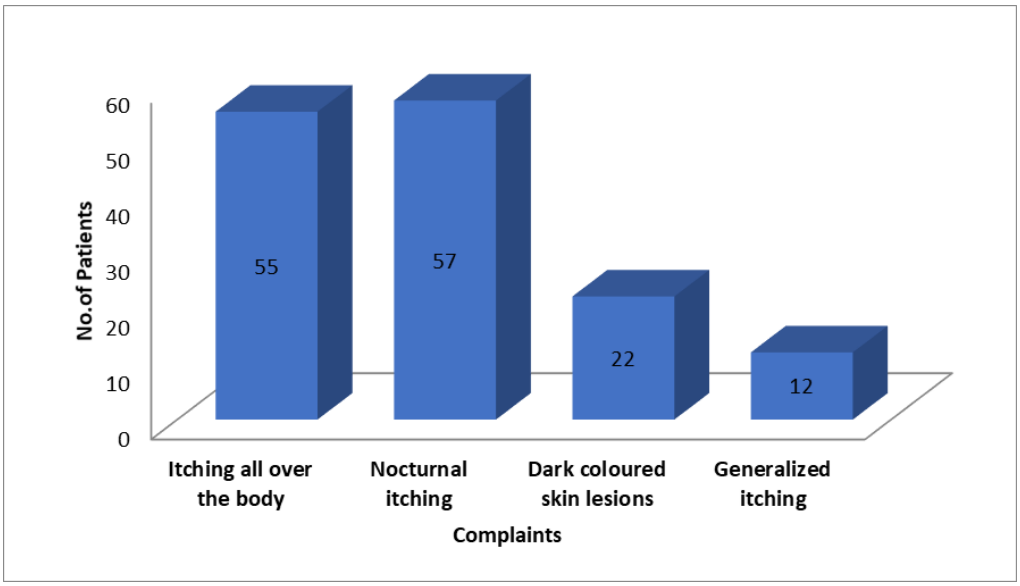

Figure 2: Demographic Data of Complaints Wise Distribution

4. Treatment pattern:

4.1 Drug wise distribution:

From our observation, 68 patients have prescribed Chlorpheniramine Maleate (CPM), 56 patients were prescribed Ivermectin, 49 patients were prescribed 5% Permethrin, 43 patients were prescribed Calamine Lotion, 36 patients were prescribed GBHC Lotion, 24 patients were prescribed Cetirizine and 14 patients prescribed with Albendazole.12 patients were prescribed Benzyl Benzoate Lotion while 9 patients were prescribed Fluconazole, 8 patients were prescribed Bandy plus (Albendazole + Ivermectin), 5 patients were prescribed Vaseline gel, 5 patients were prescribed Alograce, 4 patients were prescribed Liquid Paraffin, 3 patients were prescribed Vitamin B12, 2 patient was prescribed Ampicillin, 1 patient has prescribed Paracetamol and 1 patient have prescribed Ranitidine as shown in Figure 3.

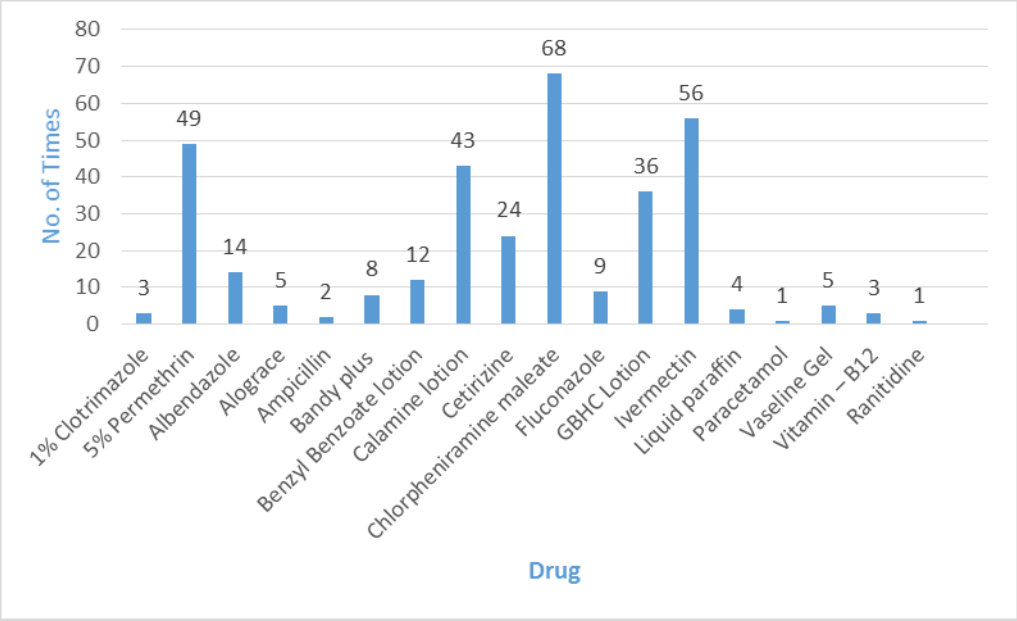

Figure 3: Demographic Data of Drug Wise Distribution

4.2 Route wise treatment distribution:

From this study, this was observed that 53% of drugs were prescribed with Oral Route followed by 46% of drugs were prescribed with Topical application while 1% of drugs were prescribed with IM Route as shown in Table 1.

Table 1: Route Wise Treatment Distribution

Route	%	Count
IM	1%	4
Oral	53%	182
Topical	46%	157

4.3 Dosage form wise distribution:

From our observation, 54% of drugs were prescribed in Tablet form, 26% of drugs were prescribed in Lotion form, 16% of drugs were prescribed in Cream form, 1% of drugs were prescribed in Injection, 1% of drugs were prescribed in Gel form and 1% of drugs were prescribed in Emulsion form as shown in Figure 4.

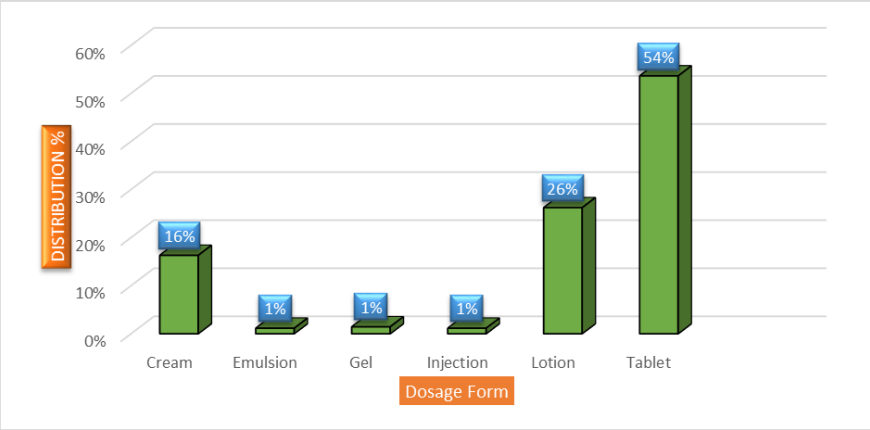

Figure 4: Demographic Data of Dosage Form Wise Distribution

5. Analysis of prescription:

From our observation, the Total number of prescriptions was 100. The total number of drugs prescribed was 343 with 3.43 as the average number of drugs per prescription. The total number of drugs from the Essential Drug List was 338 while 291 was the total number of drugs prescribed by generic name as shown in Table 2.

Table 2: Analysis of prescription

OBSERVATION	Counts (n)
Total. No. of prescription	100
Total. No. of Drugs prescribed	343
Average No. of Drugs per prescription	3.43
Total No. of Drugs from Essential Drug List	338
Total No. of Drugs prescribed by generic name	291

6. Pharmacoepidemiological study:

In pharmacoepidemiological study of scabies, we analysed the price list of generic drugs, treatment period of the drugs and clinical outcome based on the clinical features.

6.1 Treatment period and clinical outcome for Itching: (n = 67 patients)

For complaints of itching, 5% permethrin cream was prescribed to 43 patients 90% of patients were recovered followed by Calamine lotion was prescribed to 43 patients 88.3% patients were recovered. Chlorpheniramine maleate was prescribed to 40 patients 87.5% patients recovered followed by Cetirizine was prescribed to 24 patients 83.3% patients were recovered as shown in Table 3 & Figure 5.

Table 3: Treatment period and clinical outcome for itching.

DRUG USED TO TREAT	NO OF PATIENTS(n)	DURATION (IN DAYS)	OUTCOME (IN %)
5% Permethrin	43	12.5 ± 1.8	90
Calamine lotion	43	7.5 ± 1.5	88.3
CPM	40	4.7 ± 1.8	87.5
Cetirizine	24	9.6 ± 1.2	83.3

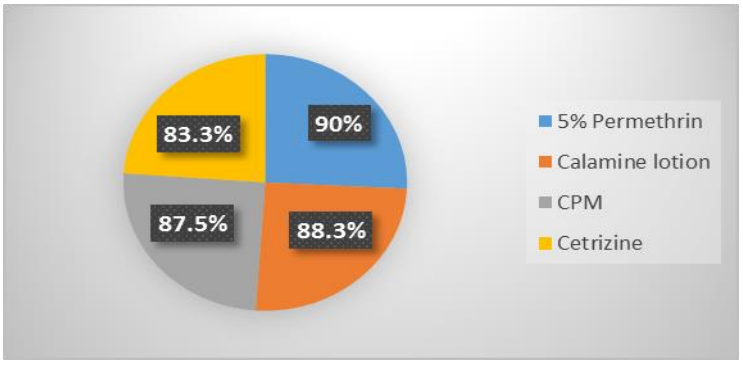

Figure 5: Demographic data of treatment period and clinical outcome for itching

6.2 Treatment period and clinical outcome for Nocturnal itching: (n=57)

For complaints of nocturnal itching, Ivermectin was prescribed to 36 patients 91.6% recovered followed by Chlorpheniramine maleate was prescribed to 28 patients 89.2% were recovered. GBHC Lotion was prescribed to 26 patients 88.40 % were recovered and Benzyl Benzoate Lotion was prescribed to 6 patients 83.30 % were recovered as shown in Table 4 & Figure 6.

Table 4: Treatment period and clinical outcome for nocturnal itching

DRUG USED TO TREAT	NO OF PATIENTS(n)	DURATION (IN DAYS)	OUTCOME IN %
GBHC Lotion	26	6.5 ± 1.1	88.4
Benzyl Benzoate Lotion	6	5.5 ± 1.9	83.3
Ivermectin	36	3.5 ± 1	91.6
CPM	28	5.4 ± 1.6	89.2

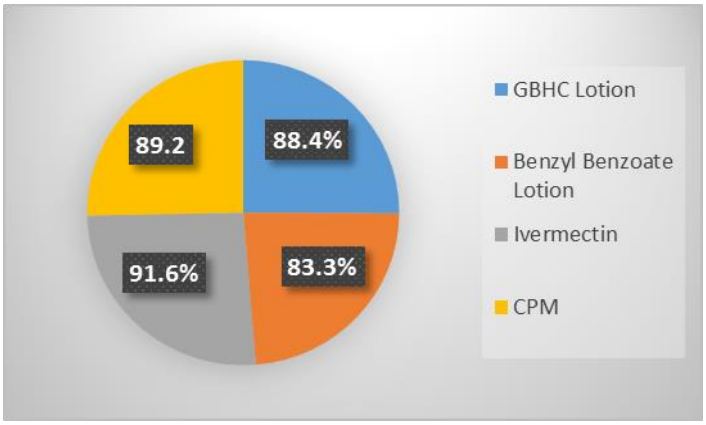

Figure 6: Demographic data of treatment period and clinical outcome for nocturnal itching

6.3 Treatment period and clinical outcome for Dark-colored Skin Lesions: (n=27 patients)

For complaints of dark-colored skin lesions, GBHC Lotion was prescribed to 10 patients 90% were recovered followed by Ivermectin was prescribed to 20 patients 84.60% were recovered. 5% permethrin was prescribed to 6 patients 83.3% were recovered and BenzylBenzoate Lotion was prescribed to 6 patients 83.30 % were recovered as shown in Table 5 & Figure 7.

Table 5: Treatment period and clinical outcome for nocturnal itching

DRUG USED TO TREAT	NO OF PATIENTS (n)	DURATION (IN DAYS)	OUTCOME IN %
GBHC Lotion	10	6.5 ± 1.2	90
Benzyl Benzoate Lotion	6	5 ± 2.5	83.3
5% permethrin	6	12.5 ± 1.9	83.3
Ivermectin	20	3.6 ± 1.1	84.6

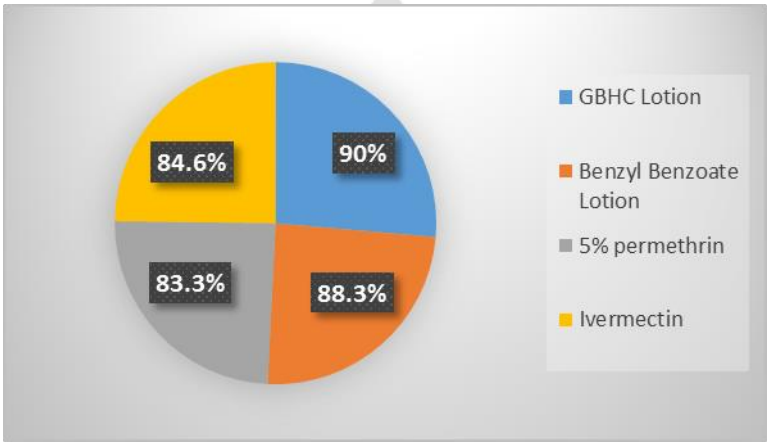

Figure 7: Demographic data for treatment period and clinical outcome for dark-colored skin lesions

6.4 Price list of Generic drugs:

In this study, we observed the generic price of the drugs that were commonly prescribed for the treatment of scabies to calculate the average cost per prescription as shown in Table 6.

Table 6: Price List of Generic Drugs

Class	Drug	Price (INR)
Anti-parasitic	5%Permethrin	24
Adsorbent and protective agent	Calamine lotion	28
Anti-parasitic	Ivermectin	21
Anti-parasitic	GBHC Lotion	55
Anti-histamine	Cetirizine	8
Anti-histamine	CPM	10
Anti-parasitic	Benzyl Benzoate Lotion	14

DISCUSSION:

Pharmacoepidemiology, Clinical features, and Prescription pattern analysis of scabies in the DVL department have been reviewed and discussed.

According to age, patients belonging to the age group of 21-30 years (32%) were most commonly infected with scabies followed by 31-40 years (23%). The majority of the affected patients were females between the age group of 21-30 years.

Clinical manifestations can be either objective when observed by a physician or subjective when perceived by the patient. The major symptoms of scabies that we observed from patients include; Itching all over the body, nocturnal itching, dark-colored skin lesions, and generalized itching. Based on our observation 80% of people suffered from generalized and nocturnal itching, and 20% suffered from dark-colored skin lesions. During cutaneous examination papulae (pimples or swelling of the skin), multiple papules, excoriated papules, erythematous papules, and hyper pigments commonly appeared on the neck, finger web spaces, upper and lower limbs, chest, breast, axillae, abdomen, and genitalia. Based on chief complaints (subjective) and cutaneous examination (objective), patients were diagnosed to have scabies.

Based on our prescription analysis the commonly prescribed Antiparasitic agent includes – 5% Permethrin (49%), GBHC (Gamma Benzene Hexachloride and Cetrimide) (36%), Benzyl Benzoate (12%), and Ivermectin (56%); Antihistaminic agents includes- Chlorpheniramine maleate (68%), Cetirizine (24%), and Ranitidine (1%); Adsorbent and protective agents

includes- Calamine lotion (43%); Anthelminitics includes- Albendazole (14%), Combination of Albendazole and Ivermectin (8%). The other class of drugs commonly prescribed along with the scabicides were Antifungals (Fluconazole-9%, 1% Clotrimazole-3%), Hematinics (Vitamin B12-3%), Laxatives (Liquid paraffin-4%), Aminopenicillins (Ampicillin-2%), Moisturizer (Vaseline gel-5%), Analgesics (Paracetamol-1%), and Emollient (Alograce-5%).

Based on the route of administration; Oral drugs - 182 (53%) were the most prescribedroute followed by Topical drugs - 157 (46%). Based on the dosage form-wise distribution; Tablet - 184 (54%) was the mostprescribed dosage form followed by Lotion - 90 (26%) and Cream-56 (16%).

Based on the analysis of prescriptions; the total number of drugs prescribed was 343. The average number of drugs per prescription was 3.43. The total number of drugs prescribed by the generic names was 291. Prescribing the drugs under generic names increases patient compliance, minimizes drug cost and the chances of duplication are avoided. Prescribing from the essential drug list means rational prescribing. The present study revealed that the number of drugs prescribed from the essential drug list was found to be 338.

In our pharmacoepidemiological study, we observed and analyse the use, effect, and outcome of commonly prescribed drugs in scabies treatment, and also explained the effectiveness of cost.

5% Permethrin, calamine lotion, Chlorpheniramine maleate, and Cetirizine were intended to cure the symptom of itching. On the above prescribed drugs 5% Permethrin, Chlorpheniramine maleate, and cetirizine were effective in treating itching. 5% Permethrin, Chlorpheniramine maleate, and cetirizine were administered for a course of 10 to 15 days, which gives more than 87% of positive outcomes. Patients who were treated with 5% Permethrin and Chlorpheniramine maleate relieve the symptom of itching within 2 weeks.

GBHC lotion, Benzyl Benzoate lotion, Ivermectin, and Chlorpheniramine maleate act in scabies patients by curing the symptom of nocturnal itching. On the above-prescribed drug GBHC lotion and Ivermectin have better efficacy in treating nocturnal itching. Both the drugs were intended for a period of 3 to 8 days, which produce a positive clinical outcome of more than 88%. Patients who were treated with GBHC lotion and Ivermectin relieved the symptom of nocturnal itching in a week.

GBHC lotion, Benzyl Benzoate lotion, 5% Permethrin, and Ivermectin were intended to cure

the symptom of itching. All the above-prescribed drugs have shown better efficacy in treating dark-colored skin lesions.

Overall findings based on observation and analysis of prescriptions show that 5% Permethrin, Ivermectin, GBHC lotion, Chlorpheniramine maleate, and Cetirizine have better efficacy in the treatment of scabies. Above mentioned drugs help in curing the major symptoms of scabies.

The generic price of the above drugs were listed below:

- 5% Permethrin – INR 24
- Ivermectin – INR 21
- GBHC lotion –INR 55
- Chlorpheniramine maleate – INR 10
- Cetirizine – INR 8

Based on the observation and analysis rational prescription containing the drugs 5% Permethrin, Ivermectin, GBHC lotion, Chlorpheniramine maleate and Cetirizine was effective in scabies treatment and cost effective. A prescription with above medication provided a beneficial outcome. The average cost of drugs in a prescription of scabies treatment will range between INR 53 to INR 86.

CONCLUSION:

We conducted the observational study of patients with scabies in a tertiary care hospital and we included patients infected only with the scabies. We analyzed the prescriptions of those patients and made follow-ups on those patients. Based on the subjective and cutaneous examination of scabies patients; Generalized itching, Nocturnal itching, and Dark-colored skin lesions were the major clinical manifestations. In our findings over the analysis of prescriptions, we concluded that 5% Permethrin, Ivermectin, GBHC (Gamma Benzene Hexachloride and Cetrimide), Chlorpheniramine maleate, and Cetirizine were the most commonly prescribed drugs in scabies treatment. We observed the use of the above-mentioned drugs in a study population and the effectiveness of the drug in treating scabies and the clinical outcomes of the treatment. We concluded that a rational prescription of scabies includes the following drugs; 5% Permethrin,Ivermectin, GBHC (Gamma Benzene

Hexachloride and Cetrimide), Chlorpheniramine maleate, and Cetirizine. The effective prescription contains all the above medications. Based on the cost (Generic) analysis of the prescribed drugs in scabies treatment, we stated that the prescription containing the above medication was cost-effective and beneficial.

ETHICAL CLEARANCE:

This prospective study was approved by Institutional Human Ethics Committee, Number: IHEC/882/2022 and permitted by Member Secretary, Institutional Human Ethics Committee, Government Cuddalore Medical College & Hospital (RMMCH), Annamalai University. The registration number of IEC is EC/NEW/INST/2020/1249. Patient Informed Consent form were obtained. Since, human participants were involved in this investigation.

ACKNOWLEDGEMENT:

The authors would wish to extend their gratitude to Department of Dermatology, Venereology and Leprosy (DVL).

FUNDING:

None of the authors received funding to conduct this study nor the submission of this manuscript.

AUTHOR CONTRIBUTION:

Conceptualization and methodology including data collection: ST, SI, TS; Writing – original draft preparation and literature search: ST, SI; Writing – Review and Supervision: TS. The final manuscript has been read and approved by all the authors.

CONFLICT OF INTEREST:

The authors affirm that the publishing of this paper is free of conflict of interest.

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