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"A Prospective Study to Evaluate Safety, Efficacy in Use Of 5% Topical Permethrin and Oral Ivermectin In Patients With Scabies In Tertiary Care Hospital"

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Abstract
BACKGROUND AND OBJECTIVES: *The conventionally used topical antiscabietic drug permethrin has poor compliance. Ivermectin, an oral antiparasitic drug has been shown to be an effective scabicide and could be a usefel substitute.The main objective of the study is to know the safety, efficacy and cost effectiveness of oral Ivermectin in comparison to commonly used topical 5%Permethrin lotion.****METHODS:****A total of 290 patients clinically diagnosed as scabies attending the department of Dermatology, Venereologyand Leprology in Government General Hospital, Anantapuramu constitute source of the study. Study was carried out for a period of 6 months from Feb 2019 to July 2019 Out of 290 patients, 10 were dropouts. Patients were randomly allocated for each of two regimens by simple random sampling procedure. Regimen 1: oral Ivermectin (200 microgms/kg), 2; topical 5% Permethrin lotion was given to patients in each group.****RESULTS:****Male:Female ratio is 3:2 Majority of patients belong to middle and low income group. Commonly students (about 68% of total patients) were affected. Curative rate at the end of second week was 90% and 85% and at the end of fourth week 92.8% and 94.2% with topical Permethrin and oral Ivermectin respectively. Oral Ivermectin and topical Premethrin are found to be equally effective at end of 4th week.* ***INTERPRETATION AND CONCLUSION:*** *Oral Ivermectin is found to be as effective and safe as 5% Permethrin topical application. Oral ivermectin has the following additional advantages over 5% permethrin.More conventient for usage,Cost comfortable,Convenient for use during institutional outbreaks,No skip lesions,Easy manageability of excoriated lesions.*

Key Words *–Scabies, Permerthrin ,Ivermectin*

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I. Introduction

Scabies is a contagious skin infestation affecting humans .sarcopetius scabie is a tiny usually niot directly visible obligate parasite .an arthropod which burrows under the post skin,causing intense allergic itching. Scabies currently affects 300 million people annually [1] .Ivermectin is asemisynthetic anti helminthic agent for oral use .Ivermectin is derived from avcrmcclins [2,3] . A class of highly active broad spectrum anti-parasitic agent isolated from fermentation products of streptomyces avermitilis . Permethrinis a common synthetic chemical widely used as an insecticide .It belongs to a family of pyrethroids and functions as a neurotoxin affecting neuron membranes by prolonging sodium channel activation [4] .This study was aimed at comparing the therapeutic efficacy of oral ivermectin vs topical 5% permethrin cream in treatment of scabies

METHODOLOGY -Source of Data: The study was conducted on patients who attended out patients department of DVL, Government General Hospital, Anantapuramu. The study was approved by the institutional ethical committee and written informed consent was obtained from each subjects.

Methods of collection of data:

All the subjects were adequately educated about the aims and objectives of the study. Eligible Patients, fulfilling the inclusion and exclusion criteria were included in the study.

Study design:

This study was conducted as a randomized,comparative and interventional study. The study was started after the approval from institutional ethics committee. Informed consent from each of the eligible subjects was obtained in the written format. The study was conducted from Feb 2019 to July 2019 for 6 months period. The patients were randomized in 1:1 ratio into two treatment groups.A detailed history was taken

regarding the education, occupation, socioeconomic status, habits and the course of the disease and treatment. Previous and present history of illness and history of contact (in the family or in the institution where the patient worked) were obtained.

In each case the complaint and its duration etc were recorded. A through clinical examination was done to detect any systemic illness, the whole skin was examined for distribution and morphologyof the lesions. The following inclusion and exclusion criteria were followed.

A. Inclusion Criteria :

1. New patients of scabies either male or female as diagnosed by dermatologist (severity score 1, 2 and 3) where severity of scabies will be assessed by counting the number of lesions and assigning a score from 0-4 arranged as follows:

° 0 = free of lesion (no scabies)
° 1 = 10 or fewer lesions (mild)
° 2 = 11-49 lesions (moderate)
° 3 = 50 or more lesions (servere)
° 4 = crusty (very severe)

2. Patients between age group 15-40 years
3. Patient`s guardian given written informed consent. (Annexure I)
4. Patients with weight more than 15 kg

B. Exclusion Criteria:

1. Participants with abnormal hepatic and renal functions, know thyroid disease, cardiac disorders, nervous system disorders, and psychiatric illnesses
2. Participants with history of diabetes mellitus, hypertension.
3. Known/suspected immunocompromised individuals like HIV or parents diagnosed as HIV, having scabies with atypical presentation like crusted scabies or scabies Incognito.
4. Participants who had taekn any antiscabetic treatment in the preceding 4 weeks;
5. Noncompliants participants/guardians
6. H/o topitcal steroid in the previous 4 weeks
7. Known hypersensitivity to oral or topical preparations
8. Patients who are underweight to that age.
9. Any chronic infectious diseases.

Microscopic examination of the mite after exploring the burrow to identify the parasite was done in many patients. Examination of the skin scrapings mounted with mineral oil or Hoyer`s medium for demonstration or organisms. Biopsy of the skin lesions from the involved sites was done in few patients.Patients were randomly allocated for each of two regimens of following simple random sampling procedure using computer.

Regimen 1 : Oral Ivermectin tablets
Regimen 2 : Topical Permethrin 5% lotion

First group was given oral Ivermectin 6mg/12mg depending on weight of patient on day one to confirmed scabies patients attending out patient department of Dermatology, Venerology and leprology. Instructed same patients to come for follow up after 2 weeks.2^{nd} dose Invermectin was given to patients as 1^{st} follow up for complete elimination of mites and patients were followed up after 2 weeks.

Second group was given topical Permethrin lotion and advised to applylotion below neck up to toe after taking bath at night. Leave Permethrin lotion on bodyfor 8-12 hrs and take bath in morning. Instructed was patients to come for follow up after 2 weeks. 2^{nd} dose Permethrin was given to patients as 1^{st} follow up for complete elimination of mites and patients were followed up after 2 weeks.

PRIMARY OUT COME MEASURE:

Reduction in the number of lesions is considered as primary outcome measure in the study.
Severity of the disease is graded based on the number of lesions found.
It can be graded as:

Mild : < 10 lesions
Moderate : 11 – 49 leions
Severe : > 50 lesions

The individuals are considered as cured if the reduction in number of lesions is atleast 50% at the end of 2 weeks.

Secondary outcome measures:

Safety and tolerability and cost effectiveness are the secondary outcome measures. Adverse events were monitored and documented regularly.Anticipated adverse effects for Ivermectin are nausea, rash, dizziness, itching, eosinophilia, abdominal pain, fever and tachycardia.Adverse effects for Permethrin are pruritus and burning sensation.For purpose of evaluation of cost effectiveness among the two study durgs, commonly used and easily available brands were included in the study.Oral Ivermectin (6mg/12mg) is available with brand name IVERMECTOL. Cost of two tables of Ivermectol is rs.59.50 ps./- and each tablet Rs.29.75 ps/-.Topical 5% Permethrin is available with brand name PERIN. cost of one bottle lotion is Rs.60.30 ps/

II. Results

Method of Statistical Analysis:

All the data was entered carefully in the data recording sheet. Statistical analysis was done for the primary outcome variable. Significance is assessed at 5% level of significiance. Chi square test was used to assess significant difference with respect to efficacy between two drugs.

Statistical software:

The Statistical software Microsoft word and Excel were used for the analysis of the data, calculation of the statistical values and to generate graphs, tables etc.

TABLE:1 Incidence Of Scabies Among Male And Females

SEX	NO OF PATIENTS	PERCENTAGE (%)
MALE	168	60
FEMALE	112	40
TOTAL	280	100

Males constituted the majority of patients.Male : female ratio 3:2

Graph 1 : Incidence of scabies among male and females

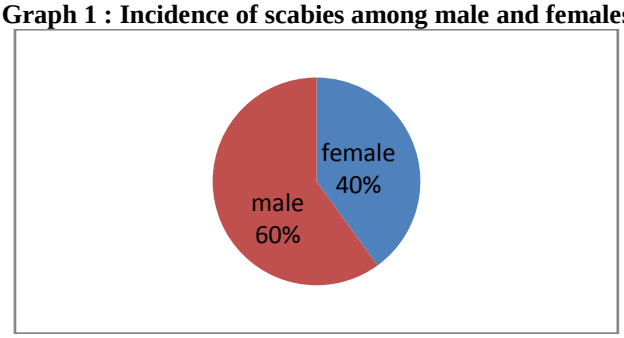


Table no.2: Incidence of scabies among various socioeconomic groups

CATEGERY	NUMBER OF PATIENTS	PERCENTAGE (%)
LOW INCOME	95	34
MIDDLE INCOME	165	59
HIGH INCOME	20	7
TOTAL	280	100

Graph 2: Incidence of scabies among various socioeconomic groups

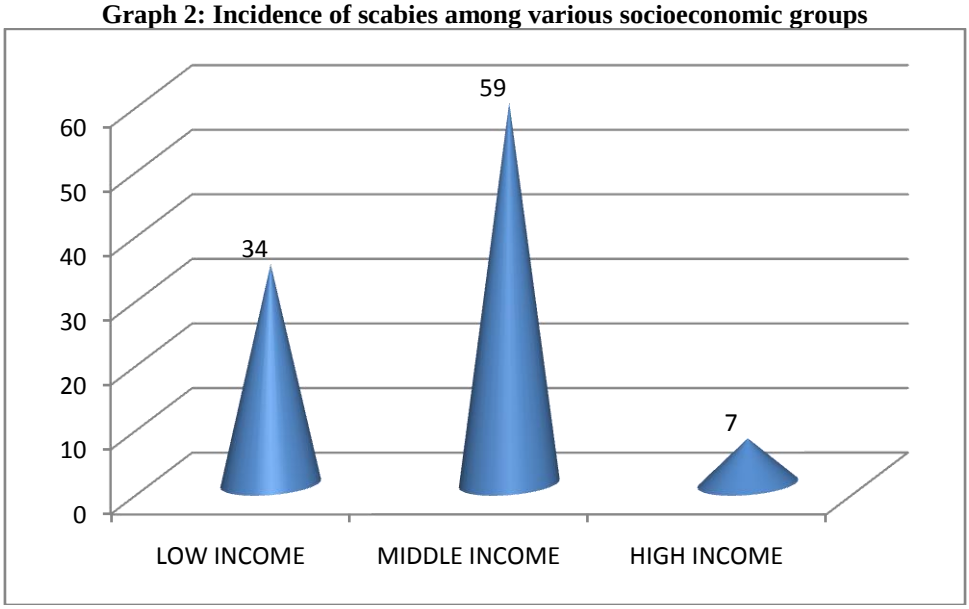


Table 3: Incidence of scabies among various occupational groups

OCCUPATION	NUMBER OF PATIENTS	PERCENTAGE(%)
STUDENT	182	65
FRAMERS	25	9
HOME MAKER	28	10
COOLIE	14	5
TEACHER	3	1
HOTEL WORKERS	3	1
OTHERS	25	9
TOTAL	280	100

Graph 3: Incidence of scabies among various occupational groups

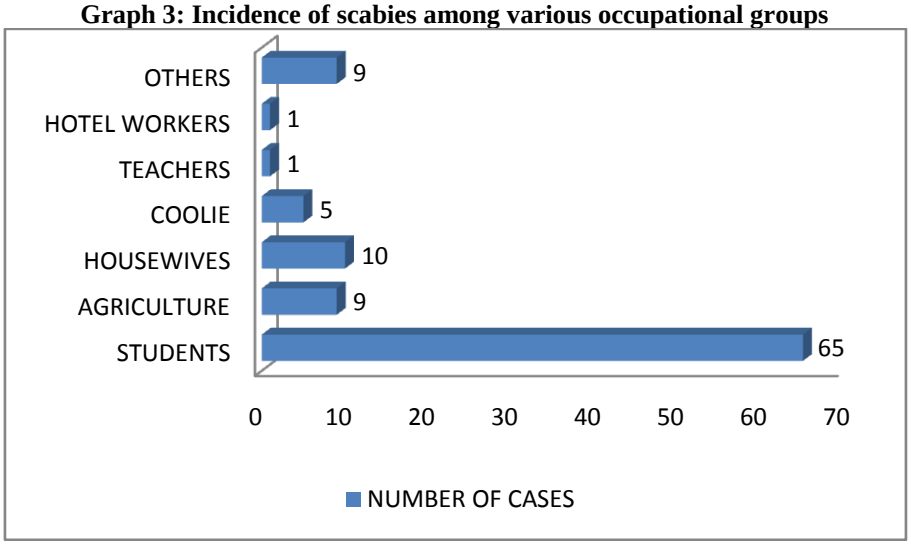


Table no.4:Percentage of patients cured by the study drugs at 2nd and 4th week

	Permethrin (%)	Ivermectin (%)	Chi square Charecteristic	P value
Curative rate at the end of 2nd week	90%	85%	0.205	0.05
Curative rate at the end of 4th week	92.8%	94.2	0.626	

Table value of chi square at 1 degree freedom and at 5% level of significance is 3.84 . calculated chi square value is less than table value, then we accept the null hypothesis (H_0), which means that there is no significant difference between the two study drugs with respect to their efficacy.

SAFETY AND TOLERABILITY:

Table no.5 : Percentage of patients in Permethrin group showing adverse effects

Adverse effects	Percentage of patients (%)
Pruritus	32%
Burning sensation	24%

Graph 4 : Percentage of patients in Permethrin group showing adverse effects

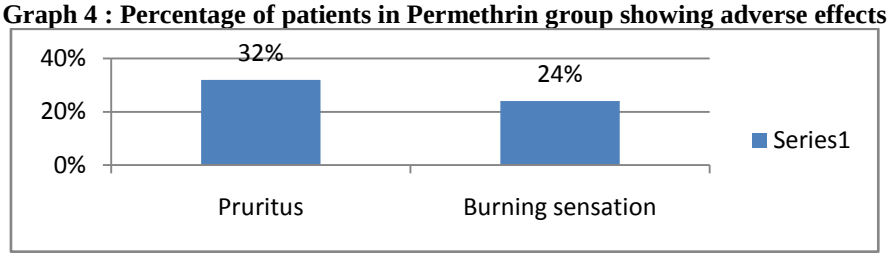
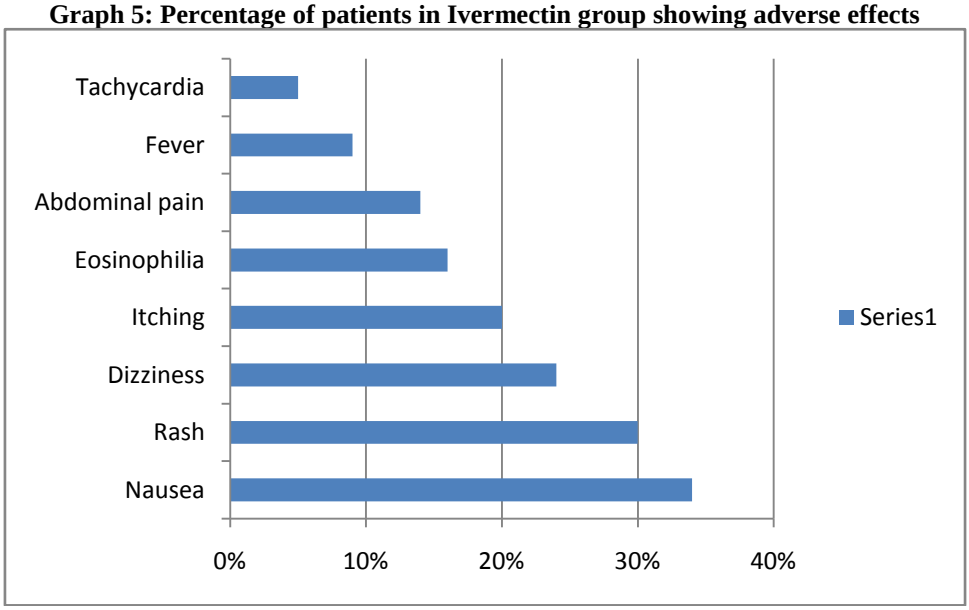


Table no.6: Percentage of patients in Ivermectin group showing adverse effects

Adverse effects	Percentage of patients (%)
Nausea	34%
Rash	30%
Dizziness	24%
Itching	20%
Eosinophilia	16%
Abdominal pain	14%
Fever	9%
Tachycardia	5%

Graph 5: Percentage of patients in Ivermectin group showing adverse effects



III. Discussion

A total of 290 patients clinically diagnosed as scabies attending the department of Skin and STD in Government General Hospital, Anantapuramu constitute source of the study. The study was conducted for a period of 6 months from Feb 2016 to July 2016. Out of the total patients included, 10 patients were dropouts. Patients were randomly allocated for each of two regimens by simple random sampling procedure using computer software. Regimen 1: oral Ivermectin (200 mcg/kg). Regimen 2: topical 5% Permethrin cream was given to patients. Male:Female ratio is 3:2. Majority of patients belong to middle and low income group. Majority of the patients included in the study were students (nearly 68%).A comparative study was done to compare the efficacy of oral Ivermectin with that of topical agents.[6] This study was conducted on four groups including 60 patients in each group by simple random sampling. Treatment given in each group was: Group 1: Ivermectin (200 µg/kg body weight) oral in a single dose, Group 2: Topical Permethrin 5% cream single application, Group 3: Topical Gamma Benzene hexachloride (GBHC) lotion 1% single application and Group 4: Topical Benzyl Benzoate (BB) lotion 25% single application

Goldust M, etal ,[7] conducted a study to compare the efficacy of topical 5% Permethrin and oral Ivermectin. A total of 242 patients with scabies were divided into two groups. One group received 5% Permethrin cream and the other received oral Ivermectin,evaluation was made at 2 and 4 weeks.A single dose of Ivermectin provided a cure rate of 85.9% at a 2-week interval, which increased to 100% after crossing over to the Permethrin group at a 4-week interval. Twice application of Permethrin with a 1-week interval was effective in 92.5% of patients, which increased to 94.2% after crossing over to the Ivermectin group at a 4-week interval.Twice application of Permethrin with a 1-week interval is superior to a single dose of Ivermectin. A single-arm multi-center study[8]was performed in adults and children from 3 months of age with proven scabies to study the efficacy of 5% Permethrin cream.A total of 106 patients from 13 centers were enrolled in the study. On day 0, patients were treated once with Permethrin cream in the study center. Dermatoscopy examinations were performed on day 14±2 and on day 28±3. Patients who were not considered cured, received one further treatment with Permethrin cream on day 14±2. Itching and local tolerability of the cream were documented. Their mean age was 29.2 years (range, 141 days to 71.9 years); 34% of them were children or adolescents. The cure rate on day 28±3 was 95.1% (95% confidence interval, 91.0–99.3%). Pruritus declined markedly and continuously. In general, the cream was well tolerated and side effects were almost invariably mild. These results support the efficacy and safety of 5% Permethrin cream in adults, children and infants suffering from scabies. An open-label, randomized, comparative, parallel clinical trial[9]was done to compare the efficacy and safety of topical Permethrin, oral Ivermectin, and topical Ivermectin in the treatment of uncomplicated scabies. Narendra P Bachewar**,** et al[10] Mass treatment of scabies with Permethrin cream and oral Ivermectin in a closed urban pediatric population was evaluated in a study.[11] Saqib et al,[12] Ikramullah Khan and Rifat Yasmin conducteda clinical trail[13] Sunita B. Chhaiya et al[14,] The efficacy of topical Permethrin and oral Ivermectin was compared in the treatment of scabies in the patients suffering from diabetes mellitus.[15] Oral Ivermectin was evaluated as a therapeutic agent in the treatment of ordinary scabies.[16]

IV. Summary & Conclusion

This study was a randomized controlled study, conducted to compate efficacy, safety and tolerabilityand costeffectiveness of topical Permethrin and oral Ivermectin. Topical Permethrin was found to be effective than oral Ivermectin at the end of 2nd week but at the end of 4th week both drugs have almost same efficacy. There is no significant difference between the two study drugs.oral Ivermectin was cost effective drug compared to 5% topical Permethrin.

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