



# INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare &amp; Pharmascope Foundation

Journal Home Page: [www.ijrps.com](http://www.ijrps.com)

## A comparative study to assess the efficacy of permethrin (topical) and ivermectin (oral) in scabies patients seeking care at a tertiary care teaching hospital of northern India

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### Article History:

Received on: 08.07.2019

Revised on: 14.10.2019

Accepted on: 22.10.2019

### Keywords:

Therapeutic intervention, improvement, scabies clinical grade, scabies itching grade

### ABSTRACT

The evidence for the superiority of Ivermectin (Oral) over topical preparations in the treatment of scabies conclusively lacks at present. Randomized controlled trials comparing ivermectin with topical permethrin have provided us the inconclusive results. To comparatively assess the efficacy of permethrin (topical) and ivermectin (oral) in scabies patients. After enrolling 178 study subjects, they were equally distributed to two study groups (I & II) and were given the desired respective therapeutic medication or interventions. Subjects in Group I was given permethrin 5% cream, and subjects in Group B were given a single dose of tablet ivermectin orally (200 mcg/kg). Efficacy of two groups of drugs was compared in terms of improvement in clinical grading of disease (%) & development in clinical grading of pruritus (%) during follow up visits at the end of 1, 2, 4 & 6 weeks. The mean age ( $\pm$  SD) for study subjects in Group I was  $18.18 \pm 11.33$  years, whereas, in the Group II, it was  $25.185 \pm 10.67$  years. The clinically observed cure rate among two groups i.e., Permethrin and Ivermectin at the end of the first and second weeks were 72% and 40%, and 96% and 58%, respectively. Rapid improvement in itching was noted down among subjects receiving topical permethrin as compared to those who received oral ivermectin. Comparatively, during different visits, permethrin provided better and fast improvement in itching grade than ivermectin. The improvement in scabies clinical grade and itching grade for permethrin (topical) was found to be more efficacious in comparison to ivermectin (oral).



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ISSN: 0975-7538

DOI: <https://doi.org/10.26452/ijrps.v11i1.1950>

Production and Hosted by

IJRPS | [www.ijrps.com](http://www.ijrps.com)

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### INTRODUCTION

"Scabies" is a parasitic infection which is very frequently observed and is caused by an obligate human parasitic mite, i.e., "Sarcoptes scabiei var. hominis". Global incidence per year for the scabies cases is more than three hundred million (Abedin *et al.*, 2007). Poor hygiene, overcrowding, under-nutrition are well-established risk factors for scabies (Campbell, 1993). Especially in developing nations, scabies, and related impetigo are significant associated risk factors for the development of chronic renal disorders (Chosidow, 2006). Several attempts have been made to find anti-scabies drugs

that are more efficient.

Ivermectin is an effective anti-parasitic drug that acts on most of the ectoparasites and endoparasites (Chosidow, 2000). The role of oral ivermectin as medication for the scabies treatment is being shown in the previous reports (Currie, 2015; Dhana *et al.*, 2018). Medication with permethrin has shown very minimal toxicity to achieve effective outcomes against mites. Its mechanism of action is paralyzing and killing lice and their eggs (nits). Body metabolism of permethrin is easy and rapid via skin esterases and excretion in the urine. Topical Permethrin (5% w/w) is applied overnight to the whole-body, including the head portion in the case of infants with a frequency of once a week for the two weeks with an optimal contact period of eight hours. So, the medication with permethrin against scabies is of the novel in nature and is highly effective (Feldmeier, 2009; Golant and Levitt, 2012).

The evidence for the superiority of Ivermectin (Oral) over topical preparations in the community treatment of common scabies conclusively lack at present, and this is recently reported in the meta-analysis too (Jackson *et al.*, 2007). Randomized controlled trials comparing ivermectin with topical permethrin have provided us the inconclusive results. Therefore, we planned this comparative study to assess the efficacy of permethrin (topical) and ivermectin (oral) in scabies patients seeking care at a tertiary care teaching hospital of northern India.

## MATERIALS AND METHODS

The present comparative study was conducted under the department of Pharmacology, FH Medical College and Hospital, Tundla from February 2016 to 2018. This investigation included those patients who came to the out-patient department (OPD) of skin and venereal diseases during the study period for taking treatment of scabies. Only those patients were included in the study who were confirmed as having scabies.

Patients with a confirmed diagnosis of scabies, aged more than 5 years and those willing for follow-up up to six weeks were included in this study. The study excluded subjects with a history of non-communicable diseases (NCD's) such as diabetes mellitus, hypertension, or cardiovascular disease, neurological diseases, chronic infectious disorders, deranged liver and renal parameters, thyroid disorder, psychiatric disorders, eligible couples, and pregnant women or lactating mothers. Also, the subjects having substance abuse of any kind, including chewing or smoking tobacco, alcohol, and consuming therapeutic drugs for other ongoing ill-

nesses, were not included in the present study. Study subjects with present secondary infection were first given treatment as per clinical decision from the senior dermatologist team with the oral Azithromycin once per day for 3 days (Dosage 500mg) or oral Ampicillin four times per day for 5 days (Dosage 500 mg). After getting cured, they were further enrolled in the study.

After enrolling 178 study subjects, they were equally distributed to two study groups (I & II) using a computer-generated random allocation number and were given the desired respective therapeutic interventions.

### Participants in Group I

The intervention permethrin dermal cream (5% w/w) was provided by the "Shalaks Pharmaceutical Ltd., New Delhi." Along with the intervention, the study subjects were also offered with subject information sheets printed in their local vernacular language. The instructions given to study subjects included that the overnight topical application of intervention from neck to toe, with optimum contact of minimum eight hours, and to take a bath with warm water after the required contact period is achieved.

### Participants in Group II

The intervention tablet ivermectin was provided by the "Shalaks Pharmaceutical Ltd., New Delhi." Along with the intervention i.e., a single dose of tablet ivermectin orally (200 mcg/kg), the study subjects were also provided with subject information sheet printed in their local vernacular language.

Data was collected in a structured sheet. The data included demographic details of study subjects like age, sex, educational status, working status, and marital status. The data collected from study subjects also included contact history with scabies patient, history of scabies disease among members of the family, and details regarding nocturnal itching problem. The body of study subjects was clinically thoroughly examined to look for the classical burrows and typical scabies lesions presence i.e., nodules, papules, or vesicles.

The dermatologist examined the study subjects on their respective follow-up visits. On each visit, the study subjects were given proper instructions regarding to avoid the use or mix of different drugs, which also included antihistaminic or antipruritic drugs. The subjects with complaints and symptoms of pruritis were treated by giving oral hydroxyzine twice daily (dosage 10 mg or 25 mg).

Prior to enrollment, informed consent was obtained from each subject. The study protocol was pre-

sented to the Institutional Ethical Committee (IEC) and was approved as the study was in accordance with the Declaration of Helsinki for human research. Analysis of data was done using Open Epi software. Efficacy of two groups of drugs was compared in terms of improvement in clinical grading of disease (%) & improvement in clinical classification of pruritus (%) during follow up visits at the end of 1, 2, 4 & 6 weeks. Results were expressed after applying appropriate statistical tests and drawing conclusions.

## RESULTS AND DISCUSSION

We processed and analyzed data of 178 subjects (89 each in Group I & Group II). Basal characteristics of the study subjects of the two treatment groups are tabulated below. Both the study groups were comparable. As the Table 1, shows the mean age ( $\pm$  SD) for study subjects in Group I was  $18.18 \pm 11.33$  years, whereas, in the Group II, it was  $25.185 \pm 10.67$  years. The mean weight ( $\pm$  SD) for study subjects in Group I was  $44.91 \pm 18.41$  Kg, whereas, in Group II, it was  $57.4 \pm 16.61$  Kg. In Table 1, as such, no statistically significant difference was observed between the study groups with respect to basal characteristics Table 1.

In Table 2, data shows that permethrin (topical) was found to be highly efficient than ivermectin (oral) in improving the clinical grade of scabies. Improvement in the clinical grade of scabies was assessed at the scheduled follow-up visits each time in both the treatment groups. In Table 2. The clinically observed cure rate among two groups i.e., Permethrin and Ivermectin at the end of first and second week were 72% & 40%; and 96% & 58% respectively; and these observations were statistically significant ( $P < 0.05$ ), but as such no statistically significant difference between was observed at the end of four and six weeks ( $P > 0.05$ ).

Table 3 shows that the efficacy of topical permethrin was better than oral ivermectin in improving the itching grade. Rapid improvement in itching was noted down among subjects receiving topical permethrin as compared to those who received oral ivermectin. Comparatively, during different visits, permethrin provided better and fast improvement in itching grade than ivermectin Table 3.

Due to the worldwide distribution of scabies, the World Health Organization (WHO) has defined it as a "neglected tropical disease." It's a contagious disease related to poverty and overcrowding. It affects people from every country, and its transmis-

sion occurs from person to person. When a non-infected person comes in the skin to skin contact with scabies patient for a more extended period of duration, he/she develops the scabies disease. Scabies is more prevalent in overcrowded communities with low socioeconomic conditions. Scabies generally occurs as an outbreak in institutions such as childcare facilities and group homes. The infection by scabies is a serious one as it can result in secondary bacterial infection, which can develop into skin sores resulting in further complications such as septicemia. There are enhanced chances of getting scabies among the children under 5 years of age and old age individuals belonging to low socioeconomic groups (Fatimata *et al.*, 2009).

The life cycle of mite includes egg, larva, and adult. To lay down the eggs, burrows are prepared in human epidermis by pregnant female bug and eggs laid per day ranges between two to three. From the laid eggs, the larvae usually emerge after a period of 2-3 days, which again develops new burrows, and it reaches the adult stage in around ten to fourteen days. The adult's mate and there is a repetition of a similar cycle. This results in scabies infestation, and the most common symptoms are severe itchiness and a pimple-like rash (Paasch and Haustein, 2000). For effective transmission of itch mite, only fifteen to twenty minutes of direct dermal to dermal contact is sufficient. Usually, the average count of mite ranges between five to twelve on an individual, but there are plenty of mites are being shredded by the patient with crusted scabies (Roos *et al.*, 2001; Scheinfeld, 2004).

In our study it was noticed that clinically observed cure rate among two groups i.e., Permethrin and Ivermectin at the end of first and second week were 72% & 40%; and 96% & 58% respectively; and these observations were statistically significant ( $P < 0.05$ ), but as such no statistically significant difference between was observed at the end of four and six weeks ( $P > 0.05$ ).

Our findings confirm the results of previous studies that have reported reasonable cure rates with permethrin (cure rate of 91%) (Currie, 2015; Jackson *et al.*, 2007). Another review by (Thawani *et al.*, 2009; Speare and Durrheim, 2004) was in concordance with our observations. In that study, a cure rate of hundred percent was observed after the administration of two oral doses of ivermectin. Whereas in another randomized controlled trial from Senegal (Strong and Johnstone, 2007), it was observed that the clinical cure rate at the end of two weeks after administration of a single dose of ivermectin was only 25%, which appears to be very

**Table 1: Distribution of basal characteristics among study subjects in respective groups**

Variable	Group I	Group II
Age (mean $\pm$ SD) in years	18.18 $\pm$ 11.33	25.185 $\pm$ 10.67
Weight (mean $\pm$ SD) in Kgs	44.91 $\pm$ 18.41	57.4 $\pm$ 16.61
Family History (%)	91.01%	86.52%
Nocturnal pruritus (%)	100%	98.87%

Group I = Topical permethrin, Group II = Oral ivermectin

**Table 2: Descriptive analysis of clinical-grade improvement (%) during each follow-up visit in two treatment groups**

Variable	Group I				Group II			
	No lesions	Mild	Moderate	Severe	No lesions	Mild	Moderate	Severe
Baseline	4	42	38	16	6	40	36	18
After 1 <sup>st</sup> week	72	18	10	0	40	34	24	2
After 2 <sup>nd</sup> week	96	2	2	0	58	24	18	0
After 4 <sup>th</sup> week	100	0	0	0	90	8	2	0
After 6 <sup>th</sup> week	100	0	0	0	98	2	0	0

Group I = Topical permethrin, Group II = Oral ivermectin

**Table 3: Descriptive analysis of itch grade improvement (%) during each follow-up visit in two treatment groups**

Variable	Group I			Group II		
	Mild	Moderate	Severe	Mild	Moderate	Severe
Baseline	0	10	90	0	4	96
After 1 <sup>st</sup> week	30	64	6	2	62	36
After 2 <sup>nd</sup> week	44	8	0	42	54	2
After 4 <sup>th</sup> week	2	0	0	48	4	0
After 6 <sup>th</sup> week	0	0	0	0	0	0

Group I = Topical permethrin, Group II = Oral ivermectin

low. But most of the researches have revealed that the clinical cure rate at the end of four weeks after administration of two oral doses of ivermectin was more than 90% (Sule, 2007; Thawani *et al.*, 2009).

This study observed that the efficacy of topical permethrin was better than oral ivermectin in improving the itching grade. Rapid improvement in itching was noted down among subjects relieving topical permethrin as compared to those who received oral ivermectin. Comparatively, during different visits, permethrin provided better and fast improvement in itching grade than ivermectin. A similar finding was recorded by Bachewar NP *et al.* in his study and it was shown that effectiveness in reducing pruritus was lesser for ivermectin (oral) in comparison to permethrin (Speare and Durrheim, 2004). Abedin S *et al.* observed in his research that there was much higher reduction in the frequency of re-

infestation after medication with oral ivermectin in comparison to permethrin and which was statistically significant (Usha, 2000). With the above findings, it becomes clear for the topical permethrin being recommended as medication for masses by the World Health Organization and other international studies and organizations (Walker and Johnstone, 2000). But at present, the defined optimal medication for classical scabies is still the question of hour (Yeruham and Hadani, 1998).

## CONCLUSIONS

On the basis of empirical findings of the present study, it concludes that the improvement in scabies clinical grade and itching grade for permethrin (topical) was found to be more efficacious in comparison to ivermectin (oral). The clinically observed cure rate among two groups i.e., Permethrin and Iver-

mectin at the end of the first and second weeks were 72% and 40%, and 96% and 58%, respectively. Further controlled trials are warranted to support the findings of this study.

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