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Original Article

Efficacy and Safety of Oral Ivermectin and Topical Permethrin in the Treatment of Scabies

Mohsena Akhter,[1] Ishrat Bhuiyan,[2] Zulfiqer Hossain Khan,[3] Mahfuza Akhter,[4] Gulam Kazem Ali Ahmad,[5] Fahima Mumtaz[6]

Abstract

Background: Scabies is one of the most common skin diseases in our country. It is caused by the mite *Sarcoptes scabiei var hominis,* which is an ecto-parasite infesting the epidermis. Scabies is highly contagious. Prevalence is high in congested or densely populated areas. Individuals with close contact with an affected person should be treated with scabicidal which is available in both oral and topical formulations. The only oral but highly effective scabicidal known to date is Ivermectin. Amongst topical preparations, Permethrin 5 % cream is the treatment of choice.

Objective: To evaluate the efficacy & safety of oral Ivermectin compared to topical Permethrin in the treatment of scabies.

Methodology: This prospective, non-randomized study was conducted at the out-patient department of Dermatology and Venereology of Shaheed Suhrawardy Medical College & Hospital over a period of 6 months, from August 2016 to January 2017. The study population consisted of one hundred patients having scabies, enrolled according to inclusion criteria. They were divided into two groups. group A was subjected to oral Ivermectin and the group B to Permethrin 5% cream. Patients were followed up on day 7 and 14 for assessment of efficacy and safety.

Result: The mean scoring with SD in group A (Ivermectin) and group B (Permethrin) were 8.26 ± 2.22 and 7.59 ± 2.01 respectively at the time of observation. The difference between the mean score of the two group is not significant (p=0.117) The mean scoring with SD in group A and group B were 4.54 ± 2.05 and 1.64 ± 1.84 respectively at 7th days. The difference between the mean score of the two group is significant (p<0.001). The mean scoring with SD in group A and group B were 2.68± 2.35 and .36± 1.10 respectively at 14th day difference between the mean score of the group is significant (p<0.001).

Conclusion: Topical application of permethrin 5% cream is more effective and safer than oral Ivermectin in the treatment of scabies.

Key words: Ivermectin, permethrin, scabies

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Introduction

Human infestation by *Sarcoptes scabiei var hominis*, an obligate human ecto-parasite causes scabies. Scabies affects all races and social classes worldwide, but accurate figures of its prevalence are difficult to obtain. Incidence of scabies is quite

[1] HMO, Dermatology and Venereology, Shaheed Suhrawardy Medical College Hospital, Dhaka
[2] Associate Professor, Department of Dermatology and Venereology, Shaheed Suhrawardy Medical College,Dhaka
[3] Professor, Department of Dermatology and Venereology, Mughda Medical College,Dhaka
[4] Associate Professor, Department of Dermatology and Venereology, Shaheed Suhrawardy Medical College, Dhaka
[5] Assistant Professor, Department of Dermatology and Venereology, Shah Mokhdum Medical College, Rajshahi.
[6] Post-graduate trainee, Department of Dermatology and Venereology, Shaheed Suhrawardy Medical College Hospital, Dhaka.

high in India, Bangladesh and Pakistan. In Bangladesh, out of total population having skin diseases, eighty percent are suffering from scabies.[1] In a community based cross-sectional study, scabies was found in second position among infectious skin diseases in a rural area of Bangladesh.[2]

Scabies is usually transmitted by close physical contact, such as prolonged hand-holding or sharing of bed.[3] Itching is usually the most obvious manifestation of scabies. It is generally worst at night and when the patient is warm. The onset occurs 3–4 weeks after the infection is acquired and coincides with a widespread eruption of inflammatory papules. The pathognomonic lesions of scabies are burrows. Burrows occur on the wrists, borders of hands, sides of fingers and the finger web spaces, feet (particularly the instep) and in males, on the genitalia. They are often present on the palms and soles of young children and the elderly.[4]

There have been many suggested remedies for scabies including topical sulphar, 5% permethrin, benzyl benzoate, malathion, lindane, crotamiton, Monosulfiram and topical and systemic Ivermectin. The choice of therapy is determined not only by efficacy and potential toxicity, but also by considerations such as cost, ease of application, presence of secondary eczematization and age of the patient.[5]

Permethrin 5% cream is an effective scabicide. At present, it is the topical treatment of choice.[5] Permethrin is a synthetic derivative of the insecticide pyrethrum and function as a neurotoxin to mites and has low toxicity to human.

The only oral but highly effective scabicidal known to date is Ivermectin.[6] A single dose of 200 μg/kg body weight will be effective in many cases of ordinary scabies. Higher cure rates are obtained with two doses separated by an interval of one week.[5] It is effective, inexpensive and easy to administer.[5]

Materials and Methods

The study was conducted on 100 patients having scabies at the out-patient department of Dermatology and Venereology at Shaheed Suhrawardy Medical College Hospital, Dhaka over a period of 6 months, from August 2016 to January 2017, out of which 50 patients were treated with topical Permethrin and 50 patients with oral Ivermectin.

A purposive sampling was carried out. All the patients were diagnosed clinically and allocated into two random groups, group A and group B. All the patients had given informed written consent.

Pregnant and lactating women, patients with immunodeficiency or severe systemic disease, heavily crusted or nodular lesions, secondary infection or eczematization, coexisting dermatological disease and known hypersensitivity to the trial drugs were excluded from the study. A total of 100 patients with scabies were enrolled in the study. They were randomized into two groups: group A Ivermectin (n=50) and group B Permethrin (n=50). All hundred patients completed 2 weeks study period and were reviewed on the 7^{th} and 14^{th} day. Outcome measures were assessed at baseline, 7^{th} day and the 14^{th} day.

Results

The mean scoring with SD in Group A and Group B were 8.26 ± 2.22 and 7.59 ± 2.01 respectively at the time of observation. The difference between the mean score of the two group is not significant (p=0.117) The mean scoring with SD in group A and group B were 4.54 ± 2.05 and 1.64 ± 1.84 respectively at 7^{th} days. The difference between the mean score of the two group is significant (p<0.001). The mean scoring with SD in group A and group B were 2.68± 2.35 and .36± 1.10 respectively at 14^{th} day difference between the mean score of the group is significant (p<0.001).

Table-1: Distribution of patients according to sex

Sex	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)	p value
Male	27 (54.0)	26 (52.0)	0.841[ns]
Female	23 (46.0)	24 (48.0)	
Total	**50 (100.0)**	**50 (100.0)**	

Chi-square test was done to measure the level of significance, ns= not significant

Table 1 shows the distribution of patients according to sex. In group A male was predominant than female which was 27 (56.7%) cases and 23 (43.3%) cases respectively. In group B male was predominant than female which was 26 (53.3%) cases and 24 (46.7%) cases respectively. The difference between these two group was not statistically significant (p=0.795).

Table-2: Distribution of patients according to age group

Age (in years)	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)	p value
13 – 22	06 (12.0)	12 (24.0)	
23 – 32	13 (26.0)	14 (28.0)	
33 – 42	15 (30.0)	11 (22.0)	
43 – 52	10 (20.0)	08 (16.0)	
>52	06 (12.0)	05 (10.0)	
Total	**50 (100.0)**	**50 (100.0)**	
Mean ± SD	37.86±12.81	34.28±12.74	0.156[ns]

T test was done to measure the level of significance
ns = not significant

Table 2 shows the distribution of patients according to age group A majority of the patients were in the age group of 33-42 years which as 15 (30.0%) cases followed by 23-32 years were 13 (26.0%) cases, 43-52 years were 10 (20.0%) cases, >52 years and 13-22 years were 6 (12.0%) cases respectively. In group B majority of the patients are in the age group 23-32 years 14 (28.0%) followed by 13-22 years 12 (24.0%), 33-42 years 11 (22.0%), 43-52 years 8 (16.0%) and >52 years 5 (10.0%) cases respectively.

The difference between the ages of the two groups was not significant (p=0.156)

Table-3: Distribution of patients according to site of involvement.

Site of involvement	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)	p value
Finger webs	45 (90.0)	47 (94.0)	0.714 ns
Wrist	48 (96.0)	46 (92.0)	0.677 ns
Periumbilical region	47 (94.0)	45 (90.0)	0.714 ns
Genitalias	48(96.0)	49 (98.0)	1.000 ns
Areola	23 (46.0)	24 (48.0)	
Axillae	35 (70.0)	33 (66.0)	

**Chi-square test was done to measure the level of significance*

Table 3 shows the distribution of patients according to site of involvement. In group A shows that the most common site was the wrist and genitalia 48 (96.0%) followed by periumbilical region 47 (94.0%), finger web 45 (90.0%) lower on axillae 35 (70.0%) and areola 23 (46.0%). In group B shows that the most common site was genitalia 49 (98.0%) followed by finger web 47 (94.0%), wrist 46 (92.0%), periumbilical region 45(90.0%), axillae 33 (66.0%) and areola 24 (48.0%).The differences among the site of involvement of two groups were not significant.

Table-4: Distribution of patients according to clinical findings of integumentary system.

Clinical findings of integumentary system	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)	p value
Erythematus papules	47 (94.0)	49 (98.0)	0.617ns
Excoriation	44 (88.0)	42 (84.0)	0.564 ns
Burrow	12 (24.0)	15 (30.0)	0.499 ns
Nocturnal pruritus	50 (100.0)	50 (100.0)	1.000 ns

**Chi-square test was done to measure the level of significance*
ns = not significant

Table 4 shows the distribution of patients according to clinical finding of integumentary system. In group A, erythematous papules were present in 47 cases, excoriation was present in 44 cases, burrow was present in 12, and nocturnal pruritus was present in 50 cases. In group B, erythematous papules were present in 49 cases, excoriation was present in 42 cases, burrow was present in 15 cases, and nocturnal pruritus was present in 50 cases.

Table-5: Efficacy of Ivermectin & Permethrin at 1st& 2nd week (n= 100) after treatment according to scoring.

Efficacy	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)	p value
Base line	8.26 ± 2.22	7.59 ± 2.01	0.117^{ns}
7th Days	4.54±2.05	1.64±1.84	<0.001^{s}
14th Days	2.68±2.35	0.36±1.10	<0.001^{s}

** t-test was done to measure the level of significance.*

Table 5 shows the distribution of patients according to scoring. The mean scoring with SD in group A and group B were 8.26 ± 2.22 and 7.59 ± 2.01 respectively at the time of observation. The difference between the mean score of the two group is not significant (p=0.117) The mean scoring with SD in group A and group B were 4.54 ± 2.05 and 1.64 ± 1.84 respectively at 7th days. The difference between the mean score of the two group is significant (p<0.001). The mean scoring with SD in group A and group B were 2.68± 2.35 and .36± 1.10 respectively at 14th day difference between the mean score of the group is significant (p<0.001).

Table 6: Adverse Effects of Ivermectin & Permethrin

Adverse effect	Group-A Ivermectin (n=50) No. (%)	Group-B Permethrin (n=50) No. (%)
Nausea	2 (4.0)	0
Vomiting	1 (2.0)	0
Headache	1 (2.0)	0
Pruritis	0	1 (2.0)
Burning	0	2 (4.0)
Total		

Discussion

Scabies is one of the most common infectious diseases in our country. In this study, we evaluated the efficacy & safety of oral Ivermectin and topical Permethrin in the treatment of scabies. Hundred patients clinically diagnosed with scabies were recruited as per inclusion criteria. They were divided by using random number table into group A and group B. Oral Ivermectin was given to group A patients in a single dose of 200 µg/kg body weight. Group B patients were subjected to single application of topical Permethrin 5% cream at night on whole body for 12 hours. Patients were followed up on day 7 and 14 and assessed for the efficacy and safety. In the present study, male patients were predominant than female in both groups A and B. In group A, number of males was 27 (56.7%) and female was 23 (43.3%). In group B, number of male was 26 (53.3%) and female was 24 (46.7%). The difference between these two groups was not statistically significant (p=0.795). Similar results were found in a study that males were more affected by scabies than females.[7] According to age, majority of the patients in both groups belonged to age group of 13-22 to 33-42 years. The difference between the age group was not statistically significant (p = 0.156). In general, prevalence of scabies is more in children & young adults but it can affect all ages.[1,7]

This study shows that the most common site was the wrist and genitalia -48 (96.0%) followed by periumbilical region-47 (94.0%), finger web-45 (90.0%), axillae- 35 (70.0%) and areola- 23 (46.0%). In group B, the most common site was genitalia- 49 (98.0%) followed by finger web- 47 (94.0%), wrist- 46 (92.0%), periumbilical region-45 (90.0%), axillae-33 (66.0%) and areola- 24 (48.0%). The differences according to the site of involvement of two groups were not significant. Almost similar results were found in a study, that the most common site was the genitalia (98%) followed by wrist (96%) then periumbilical region (94%), and web space (94%) lower on axilla (70%) and areola (48%).[8]

Nocturnal pruritus was the most common clinical findings of integumentary system followed by erythematous papules, excoriations and burrows. There is no significant difference between the two groups in clinical features.

The cure rate was more in case of single application of topical Permethrin than single oral Ivermectin at the end of 1st week, which was significant (p=<0.001). At the end of 2nd week, topical Permethrin had better cure rate than oral Ivermectin. This was also statistically significant (p=<0.001). According to Aisha Mushtaq et al. topical Permethrin is used nowadays for being safer and more effective than the previously used drugs.[9]

The scoring at follow up and observation shows that the outcome of patients with topical Permethrin was better than the oral Ivermectin. Some previous study documented that single oral Ivermectin provide a cure rate of 70% whereas topical Permethrin was associated with 98.0% cure rate at 2nd week of treatment. According to Reena Sharma and Archana Singal, both Permethrin and Ivermectin in single and two dose regimen are equally efficacious and well tolerated in scabies.[10] Usha and Nair have shown efficacy of Ivermectin 200µg/kg to be equivalent to topical 5% Permethrin.[11] According to Munazza S, Lamees MM and M Jahangir, there is no significant difference regarding efficacy of topical Permethrin and oral Ivermectin when used in treatment of scabies.[12] Ivermectin is known to have limited ovicidal activity. So a single oral dose is not appropriate for the treatment. On the other hand, Permethrin has ovicidal property, so a single application may be appropriate.[13]

Conclusion

The present study demonstrated that administration of single application of topical Permethrin was more effective and had better safety profile in the treatment of scabies. Treatment with Permethrin has the benefits of rapid resolution of skin lesions and itching compared to oral Ivermectin.

Recommendations:

Following recommendations are made based on the study findings:

- This study consists of small number of patients & shorter durations. Further evaluation is needed in larger number of patients with longer duration.
- More follow up should be done to evaluate the better outcome of the patients.

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All correspondence to
Dr. Ishrat Bhuiyan
Associate Professor
Department of Dermatology and VD
Shaheed Suhrawardy Medical College
E-mail: ishratskin@yahoo.com