

# Comparative study of ivermectin and permethrin 5% in treatment of scabies patients

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## Abstract

Scabies is an ectoparasitic, highly contagious skin disease caused by a mite called *Sarcoptes scabiei*. The insecticides ivermectin and permethrin are commonly used for treatment of scabies. This study aimed at comparing the efficacy of oral ivermectin with topical permethrin in treating scabies. Patients were divided into two groups randomly. The first group and their family contacts received 5% permethrin cream and the other received oral ivermectin. Treatment was evaluated at intervals of 2 and 4 week. Ivermectin was found to be as effective as permethrin, it has a few advantages over topical permethrin. Both drugs are cost-effective, but ivermectin has the advantage that treatment can be given to large numbers of patients with better compliance and with or without supervision.

**Key Words:** scabies.

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## INTRODUCTION

Scabies is a common ectoparasitic infection caused by a mite, *Sarcoptes scabiei* var. *hominis*. It causes substantial morbidity from secondary infections and post-infective complications such as acute post-streptococcal glomerulonephritis.<sup>1</sup> Lesions consist of tiny gray specks, burrows, or both. Non-specific lesions consist of papules and itchy excoriations and crusts. The lesions are usually found in interdigital folds of the hands, the flexor aspects of the forearms, axillary folds, nipple areola and the periumbilical area.<sup>2</sup> Disease control requires treatment of the affected individual and all people they have been in contact with, but is often hampered by inappropriate or

delayed diagnosis, poor treatment compliance, and improper use of topical compounds such as benzyl benzoate.<sup>3</sup> In addition to concerns over the toxicity of such compounds, parasite resistance seems to be increasing. Treatment of scabies in poor countries needs to integrate drug treatment programs with efforts to improve the socioeconomic conditions and education programs to reduce stigma.<sup>4</sup> Treatment options that were formerly available included sulfur, crotamiton lotion and 25% benzyl benzoate. Sulfur in 5–10% petrolatum is relatively cheap, but must be applied on three successive nights to be effective. It is considered the safest treatment for pregnant women and very young children.<sup>5</sup> For many years, lindane was the preferred therapy until concern was voiced about its efficacy and safety. Permethrin, malathion have become treatments of choice.<sup>6</sup> Currently, 5% topical permethrin cream is considered by many as the drug of choice in the treatment of scabies.<sup>7</sup> Permethrin is a synthetic pyrethroid and was one of the first thermostable and photostable insecticides developed following the elucidation of the chemical structures of natural pyrethrins in 1947.<sup>8</sup> Permethrin demonstrates extremely low mammalian toxicity, combined with insecticidal activity even higher than natural pyrethrins. These properties, backed by extensive experience of

safety over 20 years in the veterinary and agricultural industry, made this compound an ideal candidate for use as a treatment for scabies.<sup>9</sup> Ivermectin is a novel antiparasitic agent effective against a variety of endoparasites and ectoparasites. With a single oral dose, ivermectin is effective against intestinal nematodes and appears to be a promising treatment for head lice infestations, which are common co-infections in developing countries.<sup>10</sup> It is not yet approved by the US Food and Drug Administration for the treatment of human scabies.<sup>11</sup> Initial reports have highlighted the utility of oral ivermectin in the treatment of scabies. Hence, it was considered worthwhile to generate more data regarding the human use of ivermectin in the treatment of scabies, comparing the result with the currently available firstline treatment of scabies, permethrin.<sup>12</sup> In the present study, we compared the efficacy and safety of oral ivermectin with topical permethrin in the treatment of scabies.

## MATERIALS AND METHODS

Patient recruitment in the study after obtaining approval from ethical committee and taking written informed consent from the patients. This was a single-blind, randomized controlled trial conducted between 2014 to 2015 patients with scabies who were older than 2 years of age and attending the Dermatology outpatient clinic. Exclusion criteria were age younger than 2 years; existing pregnancy or lactation; history of seizures, severe systemic disorders, immunosuppressive disorders and presence of Norwegian scabies; and use of any topical or systemic treatment for one month before the study. Before entry into the study, patients were given a physical examination and their history of infestations, antibiotic treatment and other pertinent information was recorded. Age, gender, height and weight were recorded for demographic comparison, and photographs were taken for later clinical comparison. None of the patients had been treated with pediculicides, scabicides or other topical agents in the month preceding the trial. The diagnosis of scabies was made primarily by the presence of the follow three criteria: presence of a burrow and/or typical scabietic lesions at the classic sites of infestation, report of nocturnal pruritus and history of similar symptoms in the patient's families and/or close contacts. Infestation was confirmed by demonstration of eggs, larvae, mites or fecal material under light microscopy. Patients who Satisfied the above criteria were randomly divided into two groups: group A were to receive ivermectin orally, and group B were to receive permethrin 5% cream. In total, 420 patients were initially enrolled. Of these, 40 patients were not able to return after the first follow-up examination, and were therefore excluded from the study.

The remaining 380 patients (220 male, 160 female; mean  $\pm$  SD age  $46.57 \pm 13.67$  years, range 4–72) constituted the final study population. The first group received ivermectin orally. The dose employed was 200 microg/kg, repeated once the following week, while the second group received permethrin 5% cream and were told to apply this twice with a one-week interval. The treatment was given to both patients and their close family members, and they were asked not to use any antipruritic drug or any other topical medication. The clinical evaluation after treatment was made by experienced investigators who were blinded to the treatments received. Patients were assessed at 2 and 4 weeks after the first treatment. At each assessment, the investigators recorded the sites of lesions on body diagram sheets for each patient, and compared the lesions with those visible in the pretreatment photograph. New lesions were also scraped for microscopic evaluation. Patients were clinically examined and evaluated based on previously-defined criteria. "Cure" was defined as the absence of new lesions and healing of all old lesions, regardless of presence of postscabetic nodules. "Treatment failure" was defined as the presence of microscopically confirmed new lesions at the 2-week follow up. In such cases, the treatment was repeated at the end of week 2 and patients were evaluated again at week 4. "Re-infestation" was defined as a cure at 2 at one month. Any patients with signs of scabies whether as a result of treatment failure or reinfestation, would then be treated with 1% lindane lotion.

## Statistical Analysis

The  $\chi^2$  test or the Fisher exact test was used as appropriate to examine the difference between groups, and  $P < 0.05$  was considered significant.

## RESULTS

There were no significant differences in age or gender between the two groups (Table 1). On entry into the study, no significant difference was seen between the groups with regard to the number of patients graded as having mild, moderate or severe infestation (Table 2). At the 2-week follow-up, the treatment was found to be effective in 120 (63.1%) patients in the ivermectin group and 125 patients (65.8%) in the permethrin 5% group, with no significant difference between the groups ( $P=0.68$ ). The treatment was repeated for the 135 patients (70 male, 65 female; 70 in the ivermectin group and 65 in the permethrin 5% group) who still had infestation. At the second follow-up, at 4 weeks, only 30 of the 70 patients in the ivermectin group still had severe itching and skin lesions, compared with 20 of the 65 patients in the permethrin 5% group. Thus, the overall cure rate was 160/190 patients (84.2%) in the ivermectin group and 170

of 190 (89.5%) in the permethrin 5% group ( $P=0.43$ ). The remaining 50 patients who were considered treatment failures in the study were retreated with open-label lindane lotion 1%, which cured the infestation in 2–3 weeks.

### Adverse Events

The treatments were considered cosmetically acceptable by both patients and parents. None of the 400 participants experienced allergic reactions. The main adverse event (AE) was irritation, reported by 50 patients (30 in the ivermectin group and 20 in the permethrin 5% group), but this was not serious and did not affect compliance. None of the patients experienced worsening of the infestation during the study; even the treatment failures were improved compared with their pre-treatment status, and none had > 50 new lesions.

**Table 1: Demographic characteristics**

Age	Permethrin 5% (n=190)	Ivermectin (n=190)
	37.46±14.73	37.46±14.55
	Sex	
Male	100	120
Female	90	70

**Table 2: Severity of infestation**

Lesions	Permethrin 5% (n=190)	Ivermectin (n=190)	Total (n=380)
Mild	30	40	70
Moderate	50	50	100
Severe	110	100	210

## DISCUSSION

Permethrin, 5% dermal cream, is a welcome addition to the available therapies for scabies. It is cosmetically elegant and easy to use, has no objectionable odor and does not stain clothing. Skin irritation, including itching, swelling and redness, may occur with scabies and temporarily worsen after treatment with permethrin, presumably due to absorption of dead parasite proteins. Mild burning or stinging may also occur. Ivermectin is an effective and cost-comparable alternative orally agents in the treatment of scabies infection. It may be particularly useful in the treatment of severely crusted scabies lesions in immune compromised patients or when other topical therapy has failed. In this study, ivermectin was seen to be as effective as permethrin at 2 weeks follow up in treating scabies, and this is in accordance with previous studies that have reported excellent cure rates with permethrin. In our patients, we found orally ivermectin to be as effective as topical permethrin when used twice over a period of 4 weeks. The data from the 4th week showed that ivermectin continued to decrease both the lesions and the degree of pruritus as compared to permethrin but this difference was not significant

( $P>0.05$ ). Patients on ivermectin showed less rapid symptomatic response (itching) and signs (papules). This could be because of the permethrin acts on all stages of mites (ovum, larva and adult) and also stem from its action on the voltage sensitive sodium channel of the parasite; as this channel is necessary for the generation of action potentials in excitable cells, its disruption causes paralysis of the mite and leads to its death<sup>13,14</sup>. Since the prior dose of permethrin killed most of the mites, the improvement in pruritus can be due to decrease in the egg laying stages of the mite<sup>15,16</sup>. Ivermectin, though very effective on the adult stages of the mite, has not been proven to be ovicidal, and so a single application may be inadequate to eradicate all the stages of the parasite, and a second dose may be required within 1 to 2 weeks for a 100% cure<sup>17,18</sup>. Usha *et al.* report a higher number of patients showed clearance of lesions as compared to our results, and that both permethrin and ivermectin are effective in preventing recurrences of scabies over a period of 2 months<sup>[19]</sup>. In a study carried out by Mumcuoglu *et al.*<sup>20</sup>, a 100% cure was seen in both treatment groups, possibly because the study was carried on a smaller number of patients with a follow up of 2 weeks, or possibly that they were aged 12 years or above, when the activity of the sebaceous glands is greater. Permethrin is known to be significantly safer than ivermectin ( $P<0.05$ ). Ivermectin has been reported to cause rare serious side effects, which are seen when the drug is used in high doses, such as when it is accidentally ingested. However, in our study, we found it to be safe without significant adverse effects.

## CONCLUSIONS

Although ivermectin was found to be as effective as permethrin, it has a few advantages over topical permethrin. Both drugs are cost-effective, but ivermectin has the advantage that treatment can be given to large numbers of patients with better compliance and with or without supervision.

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