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Original Research

A comparative analysis of the effectiveness of ivermectin and permethrin 5% in treating patients with scabies

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ABSTRACT:
Aim: A comparative analysis of the effectiveness of ivermectin and permethrin 5% in treating patients with scabies. **Materials and methods:** Before entry into the study, patients were given a physical examination and their history of infestations, antibiotic treatment and other pertinent information was recorded. 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, 220 patients were initially enrolled. Of these, 20 patients were not able to return after the first follow-up examination, and were therefore excluded from the study. **Results:** 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 75 (75%) patients in the ivermectin group and 85patients (85%) in the permethrin 5% group, with no significant difference between the groups (P=0.23). Thus, the overall cure rate was 85/100 patients (85%) in the ivermectin group and 90 of 100 (90%) in the permethrin 5%group (P=0.21). None of the 200 participants experienced allergic reactions. The main adverse event (AE) was irritation, reported by 20 patients (13 in the ivermectin group and 7 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. **Conclusions:** While ivermectin was shown to be equally efficacious to permethrin, it had some benefits over the topical use of permethrin. Both medications are economically efficient, but ivermectin has the benefit of being able to be administered to a large number of patients with improved adherence, with or without monitoring.
Keywords: Ivermectin, Permethrin 5%, 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.[1] 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.[2] 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.[3] 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.[4] 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.[5] For many years, lindane was the preferred therapy until concern was voiced about its efficacy and safety. Permethrin, malathion

have become treatments of choice.[6] Currently, 5% topical permethrin cream is considered by many as the drug of choice in the treatment of scabies.[7] 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.[8] 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.[9] 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.[10] It is not yet approved by the US Food and Drug Administration for the treatment of human scabies.[11] 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.[12] 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 were recruitment in the study after obtaining approval from ethical committee and taking written informed consent from the patients. 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, 220 patients were initially enrolled. Of these, 20 patients were not able to return after the first follow-up examination, and were therefore excluded from the study.

The remaining 200 patients (110 male, 90 female; mean ± SD age 45.87 ± 7.89 years, range 6–68) 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 75 (75%) patients in the ivermectin group and 85patients (85%) in the permethrin 5% group, with no significant difference between the groups (P=0.23). The treatment was repeated for the 40 patients (25 in the ivermectin group and 15 in the permethrin 5% group) who still had infestation. At the second follow-up, at 4 weeks, only 10 of the 25 patients in the ivermectin group still had severe itching and skin lesions, compared with 7 of the 15 patients in the permethrin 5% group. Thus, the overall cure rate was 85/100 patients (85%) in the ivermectin group and 90 of 100 (90%) in the permethrin 5%group

(P=0.21). The remaining 40 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 200 participants experienced allergic reactions. The main adverse event (AE) was irritation, reported by 20 patients (13 in the ivermectin group and 7 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

	Permethrin 5% =100	Ivermectin =100)	Total	Percentage
	Number	Number	Number	Percentage
Gender				
Male	60	50	110	55
Female	40	50	90	45
Age	44.77±7.74	46.87±6.46	45.87 ± 7.89	

Table 2: Severity of infestation

	Permethrin 5% =100	Ivermectin =100)	Number	Percentage
Mild	15	25	40	20
Moderate	30	30	60	30
Severe	55	45	100	50

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 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

While ivermectin was shown to be equally efficacious to permethrin, it had some benefits over the topical use of permethrin. Both medications are economically efficient, but ivermectin has the benefit of being able to be administered to a large number of patients with improved adherence, with or without monitoring.

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