

Original papers

Comparison of permethrin 2.5 % cream vs. Tenutex emulsion for the treatment of scabies

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ABSTRACT. Scabies is a common parasitic infestation that is an important public-health problem in many resource-poor regions. It is commonly treated with the insecticides but the treatment of choice is still controversial. This study aimed at comparing the efficacy of permethrin 2.5% cream vs. Tenutex emulsion for the treatment of scabies. In total, 440 patients with scabies were enrolled, and randomized into two groups. The first group received permethrin 2.5% cream twice with one week interval and the second group received Tenutex emulsion and were told to apply this once whole-body application. Treatment was evaluated at intervals of 2 and 4 weeks, and if there was treatment failure at the 2-week follow-up, treatment was repeated. Two applications of permethrin 2.5% cream provided a cure rate of 63.6% at the 2-week follow-up, which increased to 86.3% at the 4-week follow-up after repeating the treatment. Treatment with single applications of Tenutex emulsion was effective in 45.4% of patients at the 2-week follow-up, which increased to 59.1% at the 4-week follow-up after this treatment was repeated. Two applications of permethrin 2.5% cream was as effective as single applications of Tenutex emulsion at the 2-week follow-up. After repeating the treatment, permethrin 2.5% cream was superior to Tenutex emulsion at the 4-week follow up.

Key words: scabies, Permethrin 2.5% cream, Tenutex emulsion

Introduction

Scabies is a condition of very itchy skin caused by tiny mites that burrow into the skin. It can affect people of all ages and from all incomes and social levels. Even people who keep themselves very clean can get scabies [1,2]. It is estimated that there may be 300×10^6 cases of scabies worldwide each year. In some areas, scabies has a much higher prevalence than diarrhea or upper respiratory disease [3,4]. It is particularly a problem in situations of overcrowding, and in less developed countries and communities. Noncompliance or a lack of adequate treatment can result in scabies as a public health problem [5,6]. It can be a „marker” disease for immunocompromised patients, and the crusted form of scabies is not only difficult to treat, but is also highly contagious and presents a risk to health care workers. In rare cases, crusted (Norwegian) scabies,

a severe form of scabies, develops [7,8]. Usually, this type of scabies is most common in people who have weakened immune systems, such as those with HIV. People with crusted scabies may have extreme infestations with tens of thousands of mite [9,10]. In otherwise healthy people, an infestation is usually limited to about 10 or 15 mites. If a person has never had scabies before, symptoms may take as long as 4–6 weeks to begin. It is important to remember that an infested person can spread scabies during this time, even if he/she does not have symptoms yet [11,12]. In a person who has had scabies before, symptoms usually appear much sooner (1–4 days) after exposure. The intense itching of scabies leads to prolonged and often intense scratching of the skin. When the skin is broken or injured due to scratching, secondary bacterial infections of the skin can develop from bacteria normally present on the skin, such as *Staphylococcus aureus* or beta-

hemolytic streptococci [13,14]. All household members, sexual partners, and other close contacts should be treated at the same time regardless of whether or not they have symptoms. Anyone who has had skin-to-skin contact within the past month should be treated [15,16]. Scabicide lotion or cream should be applied to all areas of the body from the neck down to the feet and toes. In addition, when treating infants and young children, scabicide lotion or cream also should be applied to their entire head and neck because scabies can affect their face, scalp, and neck, as well as the rest of their body [17,18]. Permethrin 2.5% cream is applied to the skin from the neck down at bedtime and washed off the next morning. Dermatologists recommend that the cream be applied to cool, dry skin over the entire body and left on for 8 to 14 hours [19,20]. A second treatment one week later may be recommended. Side effect of 2.5% percent permethrin cream includes mild temporary burning and stinging. Lesions heal within four weeks after the treatment. If a patient continues to have trouble, reinfestation may be a problem requiring further evaluation by the dermatologist [21,22]. Tenutex is a prescription drug that is active against scabies, head lice and crab lice. Tenutex (50–60 g) is used thoroughly on to the entire body – except the head. Only on infants the head needs to be treated, it should be avoided getting Tenutex in the eyes [23,24].

The aim of this study was to compare the efficacy of permethrin 2.5% cream vs. Tenutex emulsion in the treatment of scabies.

Materials and Methods

This study was approved by the local ethics committee. Informed consent was obtained from the patients or their parents.

Patient recruitment. This was a single-blind, randomized controlled trial. Between August 2009 and August 2012, any patients with scabies who were older than 2 years of age and attending the dermatology outpatient clinic in Tabriz were assessed for enrolment in the study. Exclusion criteria were age younger than 2 years; pregnancy or lactation; history of seizures, severe systemic disorders, immunosuppressive disorders and presence of Norwegian scabies; and use of any topical or systemic acaricide treatment for 1 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 permethrin 2.5% cream, and group B were to receive Tenutex emulsion.

Randomization and treatment. In total, 480 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 440 patients (290 male, 150 female; mean±SD age 42.47±12.43 years, range 4–72) constituted the final study population. The first group received permethrin 2.5% cream twice with one week interval and the second group received Tenutex emulsion and were told to apply this once whole-body application. 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.

Evaluation. 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 the previously defined criteria (see: Patient recruitment). „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 weeks but development of new lesions with positive microscopic findings at 1 month. Any patients with signs of scabies (whether as a result of treatment failure or re-infestation) would then be treated with oral ivermectin.

Statistical analysis. The χ^2 test or the Fisher exact test was used, as appropriate to examine difference between groups, and $P < 0.05$ was considered significant. SPSS software (version 16; SPSS Inc., Chicago, IL, USA) was used for all analysis.

Results

There were no significant differences in age or gender between the two groups. On entry into the study, the number of patients in each treatment group who were graded as having mild, moderate or severe infestation was also not significantly different (Table 1).

At the 2-week follow-up, the treatment was effective in 140 (63.6%) patients in the permethrin 2.5% cream group and 100 patients (45.4%) in the Tenutex emulsion with no significant difference between the groups ($P = 0.72$). The treatment was repeated for the 200 patients (120 male, 80 female; 80 in the permethrin 2.5% cream and 120 in the Tenutex emulsion group) who still had infestation.

At the second follow-up, at 4 weeks, only 30 of the 80 patients in the permethrin 2.5% cream group still had severe itching and skin lesions, compared with 90 of the 120 patients in the Tenutex emulsion group. Thus, the overall cure rate was 190/220 patients (86.3%) in the permethrin 2.5% cream group and 130 of 200 (59.1%) in the Tenutex emulsion group ($P < 0.05$).

The remaining 120 patients who were considered treatment failures in the study were retreated with open-label oral ivermectin, which cured the infestation in 2–3 weeks.

Adverse events. The treatments were considered cosmetically acceptable by patients. None of the 440 participants experienced allergic reactions. The main adverse event (AE) was irritation, reported by 60 patients (20 in the permethrin 2.5% cream group and 40 in the Tenutex emulsion 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.

Discussion

Scabies treatment involves eliminating the infestation with medications. Several creams and lotions are available. Patients usually apply the medication over all body, from the neck down, and leave the medication on for at least eight hours. A second treatment is needed if new burrows and rash appear [25,26]. All people in the household who have had close skin-to-skin contact with a scabies-affected person during the past month must be treated. This usually includes everyone in the home, even if they don't have symptoms. (Symptoms can take 4 to 6 weeks to develop after a person is infested) [27,28]. The usual scabies treatment is with permethrin 5% dermal cream. Permethrin cream (5%) was introduced in 1989 for the treatment of scabies and seems to be a good substitute for previous medications. It is considered to be the drug of choice in many countries [29,30]. The 5% permethrin preparation kills the organisms and eggs, and has an extremely low rate of absorption, making the toxicity potential nonexistent. Weekly applications have been extremely successful in preventing reinfection. It is probably the most reliable topical scabicide. Resistance to permethrin in developed countries has been reported in 1999 [31,32]. 100 ml of Tenutex cutaneous emulsion contains: Disulfiram 2 g, benzyl benzoate 22.5 g, cocoa butter, stearic acid, trolamin,

Table 1. Severity of infestation pretreatment of all patients

| Lesions | Permethrin | Tenutex | Total subjects | <i>P</i> |
|------------------------|------------|---------|----------------|----------|
| | | | | 0.32 |
| Mild < 50 | 30 | 40 | 70 | |
| Moderate 50–100 | 80 | 50 | 130 | |
| Severe > 100 | 110 | 130 | 240 | |
| | n=220 | n=220 | 440 | |

cetostearyl alcohol, eucalyptus oil and water [33]. This study demonstrated that permethrin was as effective as Tenutex emulsion at two weeks follow up in treating scabies and this is in accordance with previous studies that have reported excellent cure rates with permethrin [34,35]. Permethrin treatment yielded higher healing rates than the topical Tenutex emulsion treatment 30 days after the initial treatment. Although the persistence of pruritus in scabies for several weeks after cure is not uncommon and is not necessarily predictive of treatment failure, since it is the primary symptom of scabies, a drug with a more rapid effect on relieving pruritus is much more acceptable to patients [36,37]. In the study carried out by Usha et al. [38] higher number of patients showed clearance of lesions as compared to our results. This could be explained due to the longer follow up. They showed that both permethrin and Tenutex are effective in preventing recurrences of scabies over a period of 2 months [38]. In the study carried out by Mytton et al. [39] 100% cure was seen in both treatment groups possibly because study was carried on smaller number of patients with follow up of 2 weeks and ages were 12 years or above, when the activity of sebaceous glands is more. There are some reports that complete clearance of lesions occurs earlier in permethrin-treated patients and we think the better response to permethrin in our study is partially related to its properties in reducing pruritus.

Conclusions

Permethrin is a cost-effective and as treatment can be given to masses with better compliance with or without supervision.

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