Evaluation of Efficacy and Safety of Lindane 1% Lotion in the Treatment of Scabies

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Abstract

Background: Scabies is one of the health care problems in our community and is an endemic problem at any time. Its current therapy in Iran is lindane 1% lotion, which is deleted from market in many countries because of multiple side effects and better alternatives. The aim of this study was to evaluate the efficacy and side effects of lindane in patients with scabies and to replace lindane with other safer and more effective scabicides in case of high treatment failure rates.

Method: 100 patients with clinical diagnosis of scabies were treated with two lindane 1% lotions with an interval of one week. The patients were examined two and four weeks after the initial treatment in order to evaluate clinical cure. Data was analyzed with SPSS-13.

Results: The mean age of the patients was 33.74 years. Of them, 52% were male and 48% were female, 60% were married and close contact was found in 100% of the patients as the route of transmission of the disease. Symptoms reduced in 75% of the patients after two times of applying lindane. Itching decreased 3 days after applying Lindane and disappeared completely on the seventh day. Fifty four percent were free of disease 28 days after treatment.

Conclusion: In this study, the failure rate of treatment with lindane was relatively high; therefore, it seems necessary to think of other alternative scabicides (such as permethrin 5% cream) for the treatment of scabies. Furthermore, with accurate usage, lindane is a safe topical modality and we found no adverse effects related to lindane. *(Iran J Dermatol 2010;13: 87-90)*

Key words: scabies, lindane, efficacy, adverse effects

Introduction

Scabies, an itchy skin disease, is caused by the mite sarcoptes scabies var hominis [1]. It is transmitted via close physical or sexual contacts and is more common in children and young adults with an equal sexual incidence. It has been a health-care and endemic problem in developing countries [2]. Its clinical manifestations include burrows, itchy papular lesions, and nodules [3-5]. Cutaneous vasculitis has been reported as an unusual presentation of scabies [6]. It has been suggested that scabies may induce true bullous pemphigoid [7]. Genital lesions in male patients are pathognomonic. The typical history of pruritus with nocturnal accentuation, burrows, papules and contact cases within family members are clues to the diagnosis and in atypical cases, PCR has been used with successful results [8]. Its current therapies include benzyl benzoate, lindane, permethrin, sulphur, crotamiton, monosulfiram and oral ivermectin. Its current therapies in Iran are lindane 1% lotion for adults (two applications with a one-week interval) and sulphur for pregnant women and children. Crotamiton is used as an adjuvant therapy [9].

Lindane, γ-benzene hexachloride, is an organochloride insecticide that causes neurotransmitter inhibition and respiratory and muscular paralysis in the insect. It is contraindicated in pregnant and lactating women and children less than 2 years of age, due to CNS toxicity. Resistance to Lindane is increasing throughout the world and in 2002, it became forbidden in California State due to environmental pollution. Because of its potent toxicity, low efficacy, increased resistance and environment contamination, lindane is inferior to permethrin or ivermectin in the treatment of scabies.

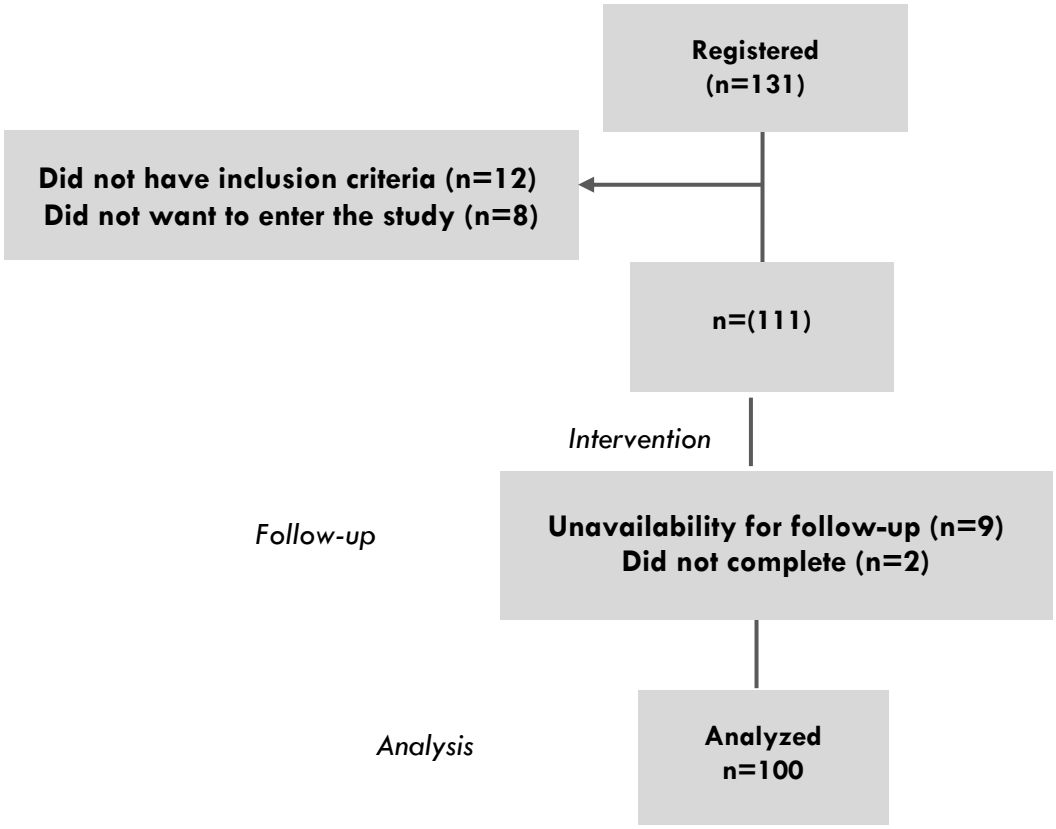

Figure 1. *Patient selection diagram*

Patients and Methods

In this clinical trial, 100 patients with clinical diagnosis of scabies were enrolled through simple random sampling (Figure 1). Patients younger than 5 years of age, pregnant and lactating women, patients with a past history of seizures, severe systemic disorders or immunosuppression and patients with Norwegian scabies were excluded. Patients had not received any topical or systemic acaricide therapy for 1 month prior to study. Informed consents were obtained from patients. Information about the infestation, its natural history, treatment modalities and preventative measures were given. Two bottles of lindane 1% solution were given to each patient to use it on the whole body (when dry) from neck to toes and wash it after 8-12 hours. Treatment had to be repeated after 1 week. All members of the family and close physical contacts were also treated. Disinfestation of clothing and bedding, other than by ordinary laundering, was not necessary. The patients were evaluated 2 and 4 weeks after the initial visit for clinical cure (decrease of lesion counts) and decrease of pruritus and the information was documented on a questionnaire. Data was analyzed using SPSS 13 (Chi-square and Exact Fischer tests). P-Values less than 0.05 were considered as significant.

Results

In our study, the mean age of the patients was 33.74±20.14 years (range: 12 to 71 years) with a male to female ratio of 1.07 (52 men, 48 women). There was no difference in response to treatment between genders as 23 out of 52 male patients (53.8%) and 26 out of 48 female patients were cured 28 days after treatment (P=0.17). The ratio of married to single patients was 1.5 (60 married and 40 single patients). No difference was observed in the response rates between married and single patients (P=0.164) with a response rate of 48.3% (24 patients) for married and 62.5% (25 patients) for single patients. Close physical contact was the way of transmission in almost 100% of the patients. In married patients (60 patients), 34% of the spouses were affected. In the initial visit, burrows were seen only in 14% of the patients, 10% had lesions on palmar and plantar areas, the genital area was affected in 100% of the male

patients but no lesion was seen on the head and face. Areolar and nipple involvement was seen in 80% of the female patients. Papular lesions were the single most common type of lesions which were present in almost 100% of the patients.

About 74% had severe pruritus (leading to sleep and daily work disturbance) and 21% had moderate pruritus (sleep awakening with no functional disturbance). Response rate was significantly different between these two groups ($P<0.001$) with a 46.8% cure rate in the first and a 81% cure rate in the second group. In the initial visit, 7% of the patients had fewer than 10 lesions, 33% had between 10-40 lesions and 60% had more than 50 lesions. There was a significant difference in the response rates of these 3 groups ($P=0.007$) with a cure rate of 100%, 63.6% and 43.3% in the first, second and the third group, respectively. Fifty four patients were free of scabies 28 days after treatment (54%). In 46 patients, the pruritic lesions persisted 28 days after the treatment which required re-treatment (46%). Most cases of treatment failure occurred in cases with severe pruritus and widespread lesions. No cutaneous or systemic drug-related adverse effects were seen in this study. In 75% of the patients, the symptoms and signs of the disease (pruritus and skin lesions) decreased after two times of administering lindane; pruritus started to alleviate on the 3rd day after treatment and disappeared completely on the seventh day .

Discussion

The mean age of our patients was 33.74±20.14, indicating that scabies was more common in children and young adults. No difference was found regarding the sexual incidence of scabies in our study. Close physical and sexual contact was the most common route of transmission of the disease (100% of the cases) and family history was positive in 94% of the cases. These findings are compatible with the available literature [2, 10, 11]. Concurrent involvement seen in 34% of the patients' spouses supports the fact that scabies is a sexually transmitted disease [11]. The pathognomonic skin lesions of scabies, burrows, were present in 14% of our patients which indicates its rarity. In this study, pruritus was the most obvious manifestation of the disease which was severe (resulting in functional disturbance) in 79% and moderate in 21% of the patients. Male genital involvement in 100% of our patients and areolar and nipple involvement in 80% of our female patients are compatible with the literature [10]. Papular skin lesions were the commonest lesion type seen in 100% of our patients. Nodules, vesicles and crusts were infrequent. No head and face involvement was observed in our patients; head and face lesions may occur in infants, the elderly, immunocompromised patients and those who have used corticosteroid for seborrhoeic dermatitis [12].

In spite of the fact that lindane is no longer the first choice for scabies therapy in many countries due to its potent toxicity, low efficacy, high resistance rates and environmental contamination, it is the most widespread medication used for scabies in Iran. Alleviation of the pruritus on the third day after treatment, with a peak on the seventh day in 75% of the patients is compatible with the literature that says pruritus decreases 24 hours after treatment is started. The high failure rate in our study (46%), which means the persistence of lesions and pruritus 28 days after lindane therapy, indicates a high resistance to lindane which is compatible with other studies [9].

In a study comparing lindane 1% lotion with 5% permethrin in 52 scabies patients, 21 out of 33 patients in the permethrin group and 15 out of 24 in the lindane group were microscopically cleared of lesions [13]. In a systematic review of all treatment modalities for scabies in cochrane database, permethrin was considered the best modality [14]. In a study on 476 patients treated with lindane for scabies, cure rate was 80% [14]. In a recent study in Ghuilan, Iran, cure rates of 48.9% for lindane-treated patients (47 patients) and 86.16% for permethrin-treated group (52 patients) were obtained after 28 days of therapy [15]. In a randomized double-blind study on 200 patients, ivermectin yielded better response rates than lindane 1% lotion [16]. High resistance to lindane and its more toxicity compared to permethrin cream 5% make lindane the second choice of scabies therapy in the USA. Also, this agent has been deleted from many countries [3]. There have been reports of neurologic toxicity (epileptic convulsion in a 3-year-old child), haematologic disturbances (anemia), toxic hepatitis and recently leydig cell dysfunction in mouse models due to lindane, although it has proved effective in millions of patients [9]. Overtreatment or prolonged therapy with lindane and its cutaneous and gastrointestinal absorption may lead to neurologic, hepatic and renal toxicity. In our study, no cutaneous or systemic adverse effects were seen. We found no difference in the response rate between male and female patients or between married and single patients but a significant relationship was observed between the

response rate and the number of the lesions and severity of pruritus and the best results were seen when there was a limited number of lesions in the absence of severe pruritus. However, no study has yet evaluated the effect of these variables on the response rate. It is suggested that if pruritus or cutaneous lesions persist after four weeks of therapy with lindane, microscopic evaluation of the lesions should be performed and if mite is seen, treatment failure or re-infection requiring re-treatment or alternative treatments should be considered [17].

However, it seems necessary to conduct more studies investigating other scabicides and the authors suggest that lindane should be replaced with permethrin 5% cream similar to many other countries.

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