

ORAL IVERMECTIN VS TOPICAL PERMETHRIN 5% CREAM IN THE TREATMENT OF SCABIES: A RANDOMIZED CLINICAL TRIAL

DILDAR FATTAH AL-DOSKY, MBChB, HDD*
ZEYAD SAMIM AL-DABBAGH, MBChB, FCABMS, FJMC**

Submitted 16 May 2015; accepted 31 June 2015

ABSTRACT

Background and Objective: Scabies is a common health problem in Duhok; with a considerable burden on patients, families, communities and the health system. Currently, different types of treatments are available, oral and topical. The study aims to compare the efficacy of oral ivermectin versus topical permethrin 5% cream in treating scabies.

Patients and Methods: A randomized control clinical trial was conducted in the dermatology outpatient clinic at Azadi General Teaching hospital in Duhok city, between April 2014 and August 2014. A total of 100 patients clinically diagnosed with scabies were divided randomly into two groups. The first group received topical 5% permethrin cream while the second group received 200 micrograms/kg oral ivermectin. The two groups were followed up for one week and those who did not achieve cure were given a second dose of either treatment and their clinical status was evaluated after two weeks.

Results: A total of 16 patients were excluded (8 from each group) during the course of the study because they did not show up during the follow up or received another treatment for scabies. The mean age of patients was 29.4 years. Treatment of patients with oral ivermectin resulted in curing 50% of patients, while only 42.9% of patients were cured by using topical permethrin after one week following a single dose of either treatment. The overall cure rate increased after a second dose for uncured cases to 95% with oral ivermectin and 88.1% with topical permethrin; after another two weeks of follow up. However, those differences were statistically not significant.

Conclusion: The study concluded that oral ivermectin was as effective as topical permethrin cream in the treatment of scabies.

Duhok Med J 2015; 9 (1): 83-90.

Keywords: Scabies, Ivermectin, 5% permethrin.

Scabies is a highly contagious skin disease which is commonly encountered in tropical countries, where scabies is endemic.¹ The disease is also common in during unfavorable events such as migrations and wars.² In Iraq, a prevalence of 3.3%, 1.2%, 1.9% and 2.7% were reported in Basrah, Tikrit, Samara and Kirkuk respectively.³⁻⁶ In recent years, scabies appear to have become endemic in Iraq.⁷

Scabies is also a common dermatological problem in Duhok as it is commonly seen in dermatology clinics and primary health care centres.⁸

In recent years the prevalence has even increased due to the mass migration to the province where the number of migrants has increased to constitute above 40% of the original population of Duhok governorate.^{9,10} Topical treatment is currently the only method used for its

*Specialist dermatologist, Duhok General Directorate of Health, Kurdistan Region, Iraq

**Lecturer, Dermatology Section, College of Medicine, University of Duhok, Kurdistan Region, Iraq

Corresponding author: Dr Zeyad Samim Al-Dabbagh Email: ziad_samim@yahoo.com. Mobile: +9647507513373

management in Kurdistan Region. A 5% permethrin cream is considered to be the most effective treatment and is usually the most commonly used treatment. This cream is safe and effective which can be used for all ages and also for pregnant and lactating patients. Nevertheless several difficulties of this method are encountered. All household members, including asymptomatic members should be treated. Additionally, clothing, linen and towels should also be washed by water and soap or bagged for 10 days, resulting in a poor compliance.^{11,12} Moreover those measures are now particularly more difficult to be achieved in the migration camps in Duhok. In addition a decreased sensitivity to permethrin, as well as to other topical scabidical agents, has been recently documented.¹¹ On the other hand, oral ivermectin is a safe and easy treatment. It has recently been licenced in several countries, including France. The drug has also been effective with a single or two doses of treatment.¹³

The study aimed to compare the effectiveness of oral ivermectin versus topical permethrin 5% cream in treating scabies in Duhok, Kurdistan Region

PATIENTS AND METHODS:

The study was done in the Dermatology Outpatient Clinic in Azadi General Teaching Hospital in Duhok city between the period April 2014 to August 2014. This is a tertiary care hospital where all dermatology patients are referred to from all over Duhok governorate.

Approval of the Scientific Research Committee at the University of Duhok and

Research Ethics Committee at Duhok Directorate General of Health was obtained prior to conducting the study. The aim of the study was explained to each patient and an oral consent was taken.

The study was a randomized clinical trial. The inclusion criteria was all patients with scabies attending the clinic during the work time. The exclusion criteria were patients less than 5 years old, pregnant and lactating ladies and all those who received treatment for scabies in the last week

Scabies was diagnosed by specialist dermatologist who also verified the severity of the disease and of pruritus.

The study was designed to include all patient who will fulfill the selection criteria until 100 cases achieved. After that the 100 clinically diagnosed scabies patients were randomly allocated into two groups of 50 patients. The first group received 5% permethrin cream for 8 hours topically(P- thrin- ALKEM labortaries - India). While the second group received ivermectin orally with a dose of 200 microgram per kilogram body weight. (Ivermectol, Ranbaxy labortaries limited ,India).All patients were given an appointment to come 1 week after treatment to be re examined for cure by the specialist. All patients who did not cured were given a second dose of either treatment and were asked to return after another 2 weeks for cure assessment.

A structured questionnaire form was filled in for each patient for basic information, such as name, age, gender, family members and number of rooms, residency, educational level, type of scabies treatment given previously and its type .

Overcrowding index was estimated as the total number of co-residents per household, excluding the new born infant divided by the total number of rooms, excluding the kitchen and bathrooms and more than 2 persons per a room was considered overcrowded.¹⁴

Patients were classified on the basis of severity of pruritus into: mild (if the total score between 0 and 5), moderate (if the total score between 6 and < 11) and severe (if the total score between 11 and 19).¹⁵ Severity of disease based upon the number of lesions (burrows and papules) was divided into mild (less than 10 lesions), moderate (10 to 50 lesions) and severe (more than 50 lesions).¹⁶

Cure was observed by the clearance of lesions and disappearance of itching. Patients were given a second dose of treatment in the second week if they were not cured.

Data were analyzed using SPSS version 20 and summarized using mean (standard deviation) for continuous variables and count (percentage) for categorical variables. Test for statistical significance was done using Chi-square test or Fisher Exact test (if there was violation of assumption of Chi-square test). Level of significance was set at $p \leq 0.05$.

RESULTS

During the course of the study, 16 patients were excluded from the study, 8 patients from each group. In the first group, 5 patients were discontinued because they did not show up in the next follow ups and 3 patients were excluded from the study due to the usage of other topical treatments

for scabies. For the second group, 8 patients were excluded because they did not show up from the follow ups.

In the first group, the age ranged from 6 to 46 years (with a mean of 27.52 year), while for the second group, the age ranged from 5 to 76 years (with a mean of 30.19 year).

Table (1) shows that there were no significant differences between the socio-demographic characteristics of the two groups including: gender, residency, education levels and overcrowding in houses. Table (1) also reveals that more than 60% of the patients were male coming from Duhok urban area, with primary/intermediate education and living in overcrowded houses.

Table 1. Sociodemographic characteristics of the study population

Character	Permethrin Group (42)	Ivermectin Group (42)	Total (84)	P-value
Male	24 (57.1%)	29 (69%)	53 (63.1%)	0.258
Female	18 (42%)	13 (31%)	31 (36.9%)	
Urban	32 (76.2%)	29 (69.0%)	61 (72.6%)	0.463
Rural	10 (23.8%)	13 (31.0%)	23 (27.4%)	
Illiterate / Read & Write	8 (19.0%)	13 (31.0%)	21 (25.0%)	0.177
Primary/intermediate	26 (61.9%)	26 (61.9%)	52 (61.9%)	
School				
Secondary	8 (19.0%)	3 (7.1%)	11 (31.1%)	
School + Overcrowded	29 (69.0%)	32 (76.2%)	61 (72.6%)	0.463
Not overcrowded	13 (30.1%)	10 (23.8%)	23 (27.4%)	

Table (2) reveals no significant differences regarding clinical histories of both groups including: previous treatment taken by patients, severity of the disease and severity of pruritus. Table (2) also shows that about half of the patient have had previous scabies treatment with 69.0% and 73.8% of them were suffering from severe disease with severe pruritus respectively.

Table 2. Clinical characteristics of the study population

Previous Treatment	Permethrin	Ivermectin	Total	P-value
Yes	18 (42.9%)	21 (50%)	39 (46.4%)	0.512
No	24 (57.1%)	21 (50%)	45 (53.6%)	
Severity of disease	Permethrin	Ivermectin	Total	1.000
Moderate	13 (31%)	13 (31%)	26 (31%)	
Severe	29 (69%)	29 (69%)	58 (69%)	
Total	42 (100%)	42 (100%)	84 (100%)	
Severity of pruritus	Permethrin	Ivermectin	Total	0.620
Mild/ Moderate	12 (28.4%)	10 (23.8%)	22 (26.2%)	
Severe	30 (71.6%)	32 (76.2%)	62 (73.8%)	
Total	42 (100%)	42 (100%)	84 (100%)	

Table (3) shows that eighteen patients (42.9%) from the first group and 21 patients (50%) from the second group were considered cured from scabies one week after the first dose; with no significant difference between the two groups(p value= 0.512).

Table 3. The cure rate after one week of the first dose

Cure rate	Permethrin	Ivermectin	Total
Yes	18 (42.9%)	21 (50 %)	39 (49.4%)
No	24 (57.1%)	21 (50%)	45 (53.6%)
Total	42 (100%)	42 (100%)	84 (100%)

Non-significant difference (p value 0.512)

Table (4) reveals that the overall cure rate increased considerably after weeks of giving the second dose for uncured cases with 37 patients (88.1%) from the first group and 40 patients (91.7%) from the second group considered to be cured from scabies; with no significant difference between the two groups(p value= = 0.433).

Table 4. The overall cure rate after two weeks of the second dose

Overall cure rate	Permethrin	Ivermectin	Total
Yes	37 (88.1%)	40 (95.2%)	77 (91.7%)
No	5 (11.9%)	2 (4.8%)	7 (8.3%)
Total	42 (100%)	42 (100%)	84 (100%)

Non-significant difference (p value 0.433)

DISCUSSION:

Azadi Teaching General Hospital is considered a pooling point for all referral dermatology cases from all over Duhok Governorate. This explains why most cases attend the clinic have moderate to severe form of scabies.

Due to the lack of safety evidence the study excluded patients less than 5 years old, pregnant and lactating ladies.^{11,12}

The follow up phase of the patients, after one and three weeks on initial treatment was difficult. Though patients were contacted by phone and reminded about their follow up, 13 patients failed to attend their follow up appointments and hence excluded from the study.

The majority of patients recruited in this study were males, reflecting the high rate of male's attendance to outpatient dermatology unit. Higher male prevalence was also reported in Tikrit, Iraq.⁷

Most of patients in this study were young with a mean age of 27, 52 years. Other study in Kurdistan Region and Iraq also concluded that more than 50% of patients with scabies fall within young age group⁷⁻⁹

The study found that 72.6% of selected patients were living in overcrowded conditions. This is consistent with other studies.¹¹

This study has also found that 72.6% of patients were from inside Duhok city. This might reflect the availability of treatment options in rural areas. The study found that 69% of patients had severe form of the disease and 73.8% had severe pruritus. This again might be a selection effect for severe cases to seek treatment at Azadi tertiary care hospital.

Oral ivermectin was as effective as topical permethrin, when single dose was used assessed one week after the first dose; where 50% and 42.9% of patients were cured respectively. This is similar to the findings of Mushtaq et al.¹⁶ who found that similar cure rates were 54.5% and 47.6% respectively. The cure rates were lower, however, than another study conducted by Goldust et al.¹⁷ This might be due to the longer follow up which gave more opportunity for signs and symptoms to disappear. A marked increase in cure rate was observed in both regimes after giving the second dose for those who were not cured by the first dose. The overall cure rate with oral ivermectin reached about 95% and with topical permethrin 88.1%. This is similar to the findings of other studies.¹⁶⁻¹⁸ Moreover in a study conducted in endemic area of India found that mass treatment with two doses of ivermectin was more efficacious than topical permethrin application in reducing the baseline prevalence, transmission and reinfection.¹⁹

The two weeks period given to patients after the second dose to achieve disappearance of signs and symptoms which usually took some time after cure from the parasite

REFERENCES

1. Wendel K, Rompalo A (2002) Scabies and Pediculosis pubis: an update of treatment regimens and general review. Clin Infect Dis 35 Suppl 2: S146-51.
2. Poddar A and Nasirian H (2007) Prevalence of Pediculosis and scabies in the prisoners of Bander Abbas,

- Hormozgan province, Iran. Pakistan J Biol Sci 10: 3967-3969
3. Al Rubaiy KK (2001) Determinants and illness behavior of patients with skin diseases in Basrah Governorate. Ph.D. thesis, Basrah University College of Medicine. 1-253.
 4. Alaa NH (2002) Epidemiology of skin diseases in Tikrit and vicinity: a community based study. MSc thesis, Tikrit University College of Medicine 1-93.
 5. Al Samarai AM (1995) Incidence of skin diseases in Samara, Iraq. Sci J Tikrit University 1: 53-60.
 6. Murtada SH (2001) Epidemiology of skin diseases in Kirkuk. MSc thesis, Tikrit University College of Medicine 1-71.
 7. Al Samarai A M (2009). Frequency of Scabies in Iraq: Survey in a Dermatology Clinic. J Infect Dev Ctries; 3(10):783-9.
 8. Mehmood S (2011) Epidemiological profile of Scabies in Duhok. High Diploma thesis. Univesity of Duhok.
 9. Hassan H K (2014). The Prevalence of Human Scabies and its Association with Socioeconomic Factors in Duhok Province, Kurdistan Region/ Iraq. A master thesis, University of Zaxo, Zaxo.
 10. Duhok Directorate General of Health, Data from planning department, 2015.
 11. Burkhart C N, Burkhart CG, Morrel DS (2012). Infestations. In: Bologna JL, Jorizzo JL, Schaffer JV et al (Eds). Dermatology. 3rd ed. Philadelphia, Pa: Mosby Elsevier.
 12. Hengge U R, Currie B J, Jager G, Lupi O and Scwartz R A (2006). Scabies: A ubiquitous neglected skin disease. Lancet Infect Dis; 6:769-79.
 13. Currie BJ, Mc Carthy. Permethrin and Ivermectin for Scabies. N Engl J Med 2010;362:717-25.
 14. Melki I S, Beydoun H A , Khogali M, Tamim Hm Yunis KA; National Collaboration Perinatal Neonatal Network (NCPNN) (2003) Household crowding index: a correlate of socioeconomic status and inter-pregnancy spacing in an urban setting. J Epidemiol Community Health; 58:476-80.
 15. Al-Qarqaz FA, Al Aboosi M , Al-Shiyab D, Bataineh A (2012). sUsing Pruritus Grading System for Measurement of Pruritus in Patients with Diseases Associated with Itch. J Med;46 (1):39- 44.
 16. Mushtaq A, Khurshid K, Suhail Pal S (2010). Comparison of efficacy and safety of oral ivermectin with topical permethrin in treatment of scabies. Journal of Pakistan Association of Dermatologists; 20: 227-31.
 17. Goldust M, Rezaee E and Hemayat S Treatment of scabies: Comparison of permethrin 5% versus ivermectin. Journal of Dermatology 2012 ; 39: 545–7.
 18. Usha V, Gopalakrishnan Nair TV. A comparative study of oral ivermectin and topical permethrin cream in the treatment of scabies. J Am Acad Dermatol 2000;42(2 Pt 1):236-40.
 19. Abedin S , Narang M , Gandhi V, Narang S (2007). Efficacy of permethrin cream and oral ivermectin in the treatment of scabies. Indian J Pediatr; 74(10): 915- 6.

پوخته

حه بکین ئایفرمکتین به رامبه کریم پیرمترین ۵٪ بو چاره سه ریا گوریاتی قه کولینه کا کلینیکی یا به ره لایی

پیشه کی وئارمانج: گوریاتی ئیکه ژ ئاریشن ساخلمی بین مشه لهوکی، ئەق نه خوشیه بارگرانیه کی پیدانکهت ل سه ره نه خوشی و خیزانا وی و جفاکی ب گشتی و سیسته می ساخلمی. ژبو چاره سه رکنا فی نه خوشی ریکن جوداجودا یین چاره سه ری هه نه. ئارمانج ژفی قه کولینی به راوردکرنا چاره سه ری ب هه بکین ئایفرمکتین دگه ل کریم پیرمترین ۵٪ بو چاره سه ریا نه خوشیا گوریاتی.

ریکن قه کولینی: قه کولینه کا کلینیکی یا به ره لایی یا کونترولگری هاته نه جامدان ل راویژکاریا نه خوشی پستی ل نه خوشخانا ئازادی یا فیژکری ل دهوکی دناقبه را نیسانی هه تا ته باخی ۲۰۱۴. سه رجه می ۱۰۰ نه خوشی ده ستیشانگری ب گوریاتی به شداری کر و هاتنه دابه شکر ل سه ره دوو گروپا. گروپا ئیکی کریم پیرمترین ۵٪ وه ک چاره سه ری وه رگرت و گروپا دووی هه بکین ئایفرمکتین ۲۰۰ مایکروگرام بو هه ر کیلوگرامه کا سه نگا له شی. نویفچوونا هه ردوو گروپا هاته کرن پشتی هه فتیه کی و ئه وین چاره سه رنه بووین نوباره درمان وه رگرت و نویفچوونا پشتی دوو هه فتیه هاته کرن.

ئه انجام: شازده نه خوش هاتنه لادان ژقه کولینی ژبه ره نه ئاماده بوونا و ل نویفچوونی یان بکارئینانا هنده ک چاره سه ری یین دی یین گوریبوونی. تیکرایی ژبی وان ۲۹،۴ سال بوو. پشتی جاره کی بکارئینانا درمانی ۵۰٪ ژئه وین هه بکین ئایفرمکتین وه رگرتین چاره سه ربون وبتنی ۴۲،۹٪ ژئه وین کریم پیرمترین بکارئینای پشتی هه فتیه کی ژ نویفچوونی. ریژا گشتیا چاره سه ری زیده بوو بو ۹۵٪ دگه ل هه بکین ئایفرمکتین ۸۸،۱٪ دگه ل کریم پیرمترین پشتی جارا دووی ژکارئینانی بو ئه وین چاره سه رنه بووین، هه رچه نده ئەق جیاوازیه نه یا ب بها بوو ژلایی ئاماریقه.

دهرئه انجام: بکارئینانا هه بکین ئایفرمکتین هه مان ئه انجامی چاره سه ری یی هه ی وه کی بکارئینانا کریم پیرمترین بو چاره سه ریا گوریاتی.

الخلاصة

حبوب آيفرمكتين مقابل كريم بيرمثرين ٥% لمعالجة الجرب؛ دراسة سريرية عشوائية

الخلفية والأهداف: الجرب من المشاكل الصحية الشائعة في دهوك ويشكل عبئاً كبيراً على المريض وأسرته والمجتمع والنظام الصحي. هناك أنواع مختلفة من العلاج للمرض منها ما يُتناول عن طريق الفم ومنها العلاج الموضعي. تهدف الدراسة إلى مقارنة فعالية حبوب آيفرمكتين مع كريم بيرمثرين ٥% في علاج الجرب.

طريقة البحث: البحث عبارة عن دراسة سريرية عشوائية مع الشاهد أجريت في العيادة الخارجية للأمراض الجلدية في مستشفى آزادي التعليمي العام في مدينة دهوك في الفترة بين نيسان ٢٠١٤ وأب ٢٠١٤. شملت الدراسة (١٠٠) مريضٍ ممن شخصوا سريريّاً ببدء الجرب، تم تقسيمهم إلى مجموعتين عشوائياً، حيث تم علاج المجموعة الأولى باستخدام كريم بيرمثرين ٥% والمجموعة الثانية باستخدام حبوب آيفرمكتين ٢٠٠مايكروغرام لكل كغم من كتلة الجسم. تمت متابعة المرضى في المجموعتين بعد الاسبوع الأول من العلاج، وقد اعطيت جرعة ثانية من طريقي العلاج لمن لم يشفى من المرض و تمت متابعتهم بعد اسبوعين.

النتائج: تم استبعاد ١٦ مريضاً من الدراسة (٨ من كل مجموعة) بسبب تسربهم من المتابعة أو استلامهم لنوع آخر من العلاج أثناء البحث. كان معدل الأعمار للمرضى (٢٩.٤) سنة. كانت نسبة الشفاء ٥٠% لمن استخدموا حبوب آيفرمكتين مقارنة ب ٤٢.٩% فقط لمن استخدموا كريم ثيرمثرين أثناء المتابعة الأولى بعد اسبوع من استخدام جرعة واحدة من الدواء. ارتفعت النسبة الاجمالية إلى ٩٥% بالنسبة لآيفرمكتين و ٨٨.١% لثيرمثرين بعد اعطاء جرعة ثانية لمن لم يشفوا أثناء متابعتهم بعد اسبوعين، رغم أن هذا الفرق لم يكن ذا أهمية إحصائية.

الاستنتاجات: توصلت الدراسة الى أن حبوب آيفرمكتين لها فعالية مماثلة لاستخدام كريم ثيرمثرين الموضعي في علاج الجرب.