Research Paper

Comparison of Topical Ivermectin and Oral Ivermectin in the Treatment of Human Scabies: A Randomized Controlled Trial

Swetabh Verma, Marya Ahsan[1]

Department of Pharmacology, Darbhanga Medical College, Darbhanga, Bihar, India, [1]Department of Pharmacology, College of Medicine, Imam Mohammad Ibn Saud Islamic University, Riyadh, Kingdom of Saudi Arabia

Abstract

Objective: To compare the topical and oral ivermectin (IVM) in the management of scabies. **Materials and Methods:** An open-labeled parallel randomized trial was conducted among patients of scabies. Group A (n = 51) received two applications of 0.5% topical IVM cream 1 week apart, while Groups B (n = 50) received single dose of oral IVM (200 μg/kg body weight. The scabies severity and pruritus severity on the Visual Analog Scale (VAS) were compared at baseline and at the end of the 1st, 2nd, and 4th weeks. Mann–Whitney U-test and Wilcoxon Signed-Rank test were used for statistical analysis. **Results:** Significant improvement in scabies severity was seen at the 1st and 2nd follow-up in both groups ($P < 0.001$). The cure rate was 2%, 96.1%, and 100% in Group A, while 68%, 98%, and 100% in Group B at each follow-up, respectively. Group B had significantly better improvement than Group A at the 1st follow-up ($P < 0.001$). Highly significant improvement in pruritus was seen at each visit in both groups ($P < 0.001$) with no difference between the groups ($P > 0.05$). Adverse events were reported nine and 12 times in Groups A and B, respectively. **Conclusion:** Two applications of 0.5% topical IVM cream and single dose of oral IVM are equally efficacious and safe for the treatment of scabies at the end of the 2nd and 4th weeks.

Keywords: Ivermectin, scabies, Visual Analog Scale

Introduction

Scabies is a contagious skin infection caused by a tiny mite *Sarcoptes scabei*.[1] The mite burrows under the host's skin causing skin lesions which present as tiny erythematous papules. Vesicles and pustules can also be present in severe cases. Classical linear burrows where the mite lays eggs are evident in the finger web spaces, flexor surfaces of the wrists, antecubital fossae, axilla, male genitalia, gluteal crease, female breasts, and waist. The rash is almost always accompanied by pruritus which is severe and typically worsens at night.[2]

Scabies is a major public health problem in many resource-poor regions where the disease is endemic.[3,4] The prevalence is about 100% in certain Indian villages.[5] In rural and urban areas of India, the incidence ranges from 13% to 59%.[6] In the developed world also, scabies can attain epidemic proportions in institutional environments such as prisons, nursing homes, and old-age homes.[4] Despite wide prevalence, the World Health Organization (WHO) included scabies under "neglected tropical disease."[7]

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Topical acaricides applied from neck to toe are considered as standard therapy but there is no international consensus on the management of scabies. In most cases, multiple topical applications over days or weeks, allowing a contact period of at least 8 h are required for eradicating the mite. Improper adherence to instructions often results in treatment failure.[8-10] In addition, management of scabies not only includes prescribing the drugs to the patients but also the concomitant treatment of family members.[3]

With the introduction of ivermectin (IVM) the management of scabies became easier as IVM is an effective oral alternative.[11] Oral IVM has been found to be equal to 5%

Address for correspondence: Marya Ahsan, Department of Pharmacology, College of Medicine, Imam Mohammad Ibn Saud Islamic University, Riyadh, Kingdom of Saudi Arabia.
E-mail: marya.ahsan@gmail.com

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permethrin cream.[3,12] It is also better than other topical agents such as lindane, crotamiton, benzyl benzoate, sulfur, and gamma benzene hexachloride in the management of scabies.[3,13-16] In 2012, topical IVM lotion was introduced as a safer alternative to oral IVM for eradicating head lice. In 2014, the Food and Drug Administration (FDA) gave approval for using topical IVM for other cutaneous ectoparasitic infestations.[17] However, topical IVM has been little explored in the management of scabies. We conducted this study to compare the efficacy and tolerability profile of topical and oral IVM in the management of scabies.

Materials and Methods

An open-labeled, parallel, prospective, randomized interventional study was carried out over a period of 1 year (January 2017–December 2017) at Rohilkhand Medical College and Hospital, Bareilly. Institutional Ethical Committee clearance was taken before commencing the trial (IEC/24/2015) and it was registered with the Clinical Trial Registry of India (REF/2017/01/013142). Patients of either gender, between the age group of 18 and 65 years, who were clinically diagnosed with scabies were selected for the study from the Skin outpatient department following convenient sampling method. Patients presenting with Norwegian crusted scabies, pregnant and lactating women, and those with a history of seizures, immunosuppressive disorders, congestive heart failure, renal and hepatic insufficiency were excluded from the study. Those who had a history of use of any topical or systemic acaricide in the previous 1 month were also not included in the study.

The selected patients were randomized into two Groups A and B of equal size (allocation ratio 1:1), following the odd-even technique of randomization. The 1st patient in our study was assigned to Group B after a lottery allotment and the subsequent patients were allotted to alternate groups. Patients in Group A were prescribed topical IVM (0.5% cream), two doses 1 week apart, while patients in Group B were prescribed oral IVM (200 μg/kg body weight), single-dose by the dermatologist. Written informed consent was taken from all the participants in the vernacular language. The patients were asked to report for follow-up at the end of 1st, 2nd, and 4th weeks or if any complaints arose. All the patients were given an instruction leaflet regarding the correct application of the drug and other general measures. The family members were also simultaneously treated with topical 5% permethrin, single application but were not included in the study.

Data collection

Clinical scabies severity grade and pruritus severity grade were used for assessment of efficacy in our study. At each visit, the number of scabeitic lesions was counted and clinical severity grading was done as below:[18]

- No scabies: 0 lesions
- Mild scabies: <10 lesions
- Moderate scabies: 11–49 lesions
- Severe scabies: More than 50 lesions.

The 10 cm line on the Visual Analogue Scale (VAS) was used for grading the severity of pruritus as below:[3]

- Point 0: No pruritus
- Point 1–3: Mild pruritus
- Point 4–6: Moderate pruritus
- Point 7–10: Severe pruritus.

The primary endpoint in our study was the complete cure of scabietic lesions and the secondary end point was relief of pruritus. Antihistaminics were not prescribed at baseline to any patient. Only patients who still reported pruritus at the end of the 2nd week were prescribed oral antihistaminics. Adverse drug reactions reported during the study were also recorded and were assessed using the WHO-UMC causality assessment scale.[19] Modified Hartwig and Seigel scale was used for assessment of the severity of adverse reactions.[20]

Statistical analysis

Keeping α error 0.05 and the power of the study at 80%, the total sample size was calculated as 106 using G * power 3.1.9.2. Statistical Package for Social Sciences Version 23.0 (SPSS/PC; SPSS-23.0, Chicago, USA) was used for computing data and calculating the mean. The Wilcoxon Signed-rank test and Mann–Whitney U test were used for statistical analysis. Independent *t*-test and Chi-square test were also used.

Results

Out of the 106 patients, 101 patients returned for regular follow-up of which $n = 51$ were in Group A (topical IVM), while $n = 50$ were in group B (oral IVM) [Figure 1]. There were 47 males and 54 females in our study with mean age 29.64 ± 10.58 years. At baseline, more than 70% of patients in our study had moderate-to-severe scabies and moderate-to-severe pruritus. Both the groups were comparable at baseline on the application of Mann–Whitney U test with respect to scabies severity ($P = 0.613$) and pruritus severity ($P = 0.704$). The topical IVM group had cure rate of 2%, 96.1%, and 100% at each follow-up, respectively [Figure 2]. On the application of Wilcoxon Signed-Rank test, the improvement in scabies severity was highly significant at the end of the 1st and 2nd week ($P < 0.001$). There was no change in severity between the 2nd and 4th week ($P = 0.157$). The oral IVM group had a cure rate of 68%, 98%, and 100% at the end of 1st, 2nd, and 4th weeks, respectively [Figure 3]. Improvement was significant in the oral IVM group at the 1st and 2nd weeks. However, clinical improvement in scabies severity was significantly better in the oral IVM group at the end of 1st week ($P < 0.001$). Scabies severity between the groups at 2nd week ($P = 0.984$) and 4th week ($P = 1.000$) were similar.

Majority of the patients reported improvement in pruritus severity at the end of 1st week in both Group A ($P < 0.001$) and group B ($P < 0.001$). Pruritus severity further decreased in both the groups at the end of the 2nd week ($P < 0.001$). 2%, 74.5% of patients were pruritus free in the topical IVM group ($n = 51$) while 24% and 68% patients were pruritus free in the oral IVM group ($n = 50$) at the 1st and 2nd follow-up [Figures 4 and 5].

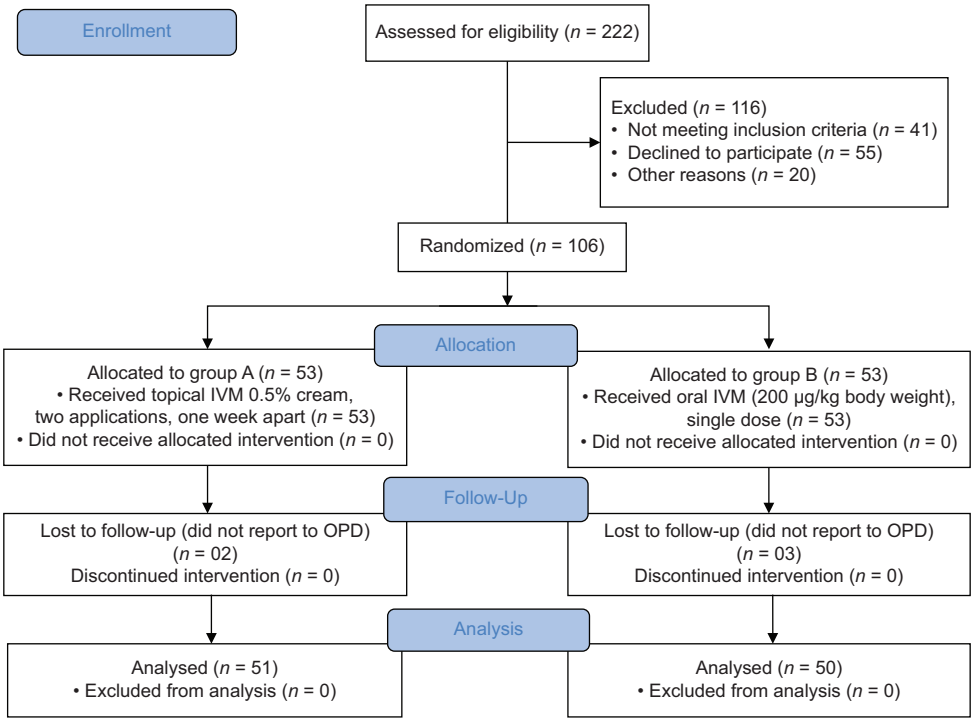

Figure 1: Consolidated standards of reporting trials (CONSORT) flow diagram of our study

Patients who still had complaints of pruritus at the end of the 2nd week were prescribed antihistaminic, following which 100% of patients were pruritus free at the end of the 4th week ($P < 0.001$). There was no difference in the improvement in pruritus between the groups at the end of 1st week ($P = 0.235$), 2nd week ($P = 0.439$), and 4th week ($P = 1.000$).

In total, 21 adverse events were reported of which 9 were in Group A and 12 were in Group B. The most common adverse event was burning sensation ($n = 5$) and itching ($n = 4$) in Group A. Nausea, headache, and abdominal pain were reported in Group B [Table 1].

Discussion

Scabies is a commonly encountered parasitic infection plaguing human beings since ages which affects everyone regardless of age, gender, race, social class, or personal-hygiene habits.[21] The treatment of scabies has undergone major developments with the evolution of newer anti-ectoparasitic drugs and new treatment strategies.[4,5,22] Management of scabies not only includes prescribing the drugs to the patients but also the concomitant treatment of family members. Educating the patients regarding the proper application of topical agents, besides other general measures plays a pivotal role in the management of scabies.[22]

The advent of IVM revolutionized the treatment of human scabies as it was not only equally efficacious to the gold standard treatment but also safe and superior in terms of administration.[4,5] IVM directly kills *Sarcoptes scabiei* by binding selectively to glutamate-chloride ion channels, found in nerve terminals. It also stimulates the inhibitory neurotransmitter GABA from pre-synaptic nerve terminals and encourages its binding to post-synaptic receptors. Thus, paralyzing the parasite and killing it. IVM is well tolerated in humans because the glutamate-gated ion channels or GABA-gated chloride channels are localized only in the central nervous system, and IVM cannot cross the blood-brain barrier.[23,24]

Recently, topical preparations of IVM are also being marketed. Topical IVM has shown great promise for eradicating the menace of head lice and has been approved by the FDA for the same. Topical preparation of IVM is also being used off-label as 2nd line drug to other topical agents for the treatment of scabies.[17,25]

Though majority of the patients in our study had moderate to severe scabies, both the topical IVM group and the oral IVM group were similar in terms of severity ($P = 0.613$). Highly significant improvement in the scabies severity was seen at the end of 1st week among patients on topical IVM and one patient had no evidence of any lesion ($P < 0.001$). Following the second application of topical IVM, a cure rate of 98.03% was achieved at the end of the 2nd week [Figure 2]. 0.8% lotion of IVM was used by Youssef *et al*. for scabies and they reported clinically and parasitologically cure within 48 h after single application.[26] However, itching persisted in the majority of patients which required a repeat application after 1 week. Victoria and Trujillo had used IVM 1% solution and reported that all the patients were cured with the two applications at weekly intervals.[27] Yeruham and Hadani had used 1.87% IVM cream at the weekly interval in 10 patients. They reported

marked improvement in the condition of the patients within 2 or 3 days of the first treatment and clinical cure occurred after 2 or 3 days of the second treatment.[28]

Among the patients prescribed oral IVM, 68% of patients had no evidence of any lesion at the end of the 1st week which increased to 98% at the end of 2nd week [Figure 3]. Khan and Yasmin showed the cured rate of 60% at the end of 1st week and 100% at the end of 2nd week with oral IVM.[2] Ranjkesh *et al*. found that 46.6% of patients in the oral IVM group demonstrated symptomatic improvement by the 1st week and by the 2nd week 73.3% of patients in the IVM group and by the 4th week 93.3% of patients on IVM had shown a symptomatic improvement.[29] Hafedh *et al*. reported that 88% of patients at

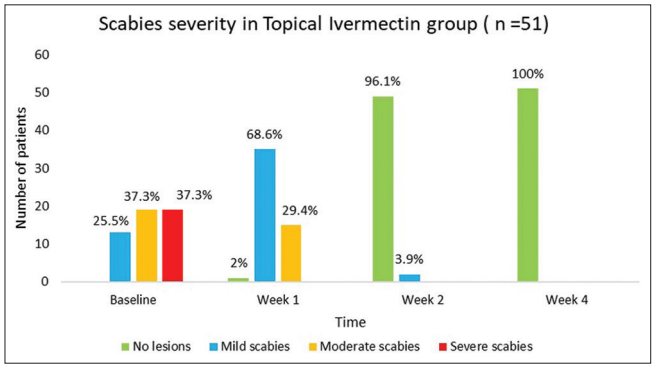

Figure 2: Patients with no lesions, mild (<10 lesions), moderate (11–49 lesions), and severe scabies (>50 lesions) at baseline and follow-up in the Group A, topical ivermectin group ($n = 51$). $P < 0.001$ at 1st and 2nd weeks

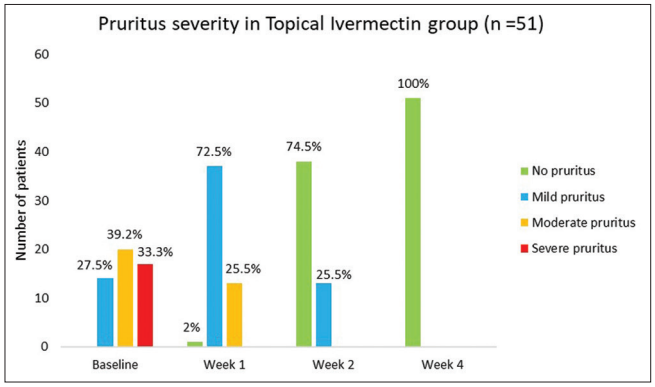

Figure 4: Patients with no pruritus, mild (1–3 cm), moderate (4–6 cm), and severe pruritus (7–10 cm) on Visual Analog Scale in Group A, topical ivermectin group ($n = 51$) at each visit. $P < 0.001$ at each follow-up

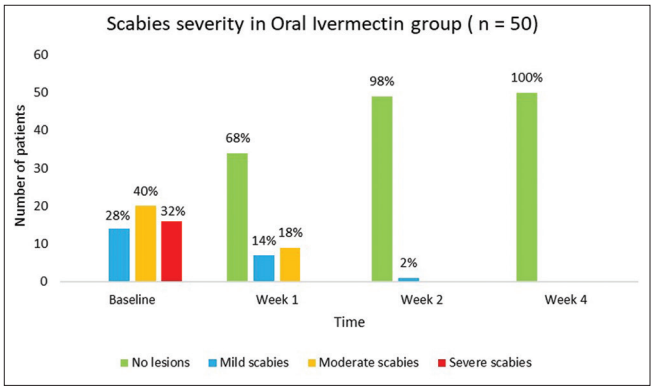

Figure 3: Patients with no lesions, mild (<10 lesions), moderate (11–49 lesions), and severe scabies (>50 lesions) at baseline and follow-up in the Group B, oral ivermectin group ($n = 50$). $P < 0.001$ at 1st and 2nd weeks

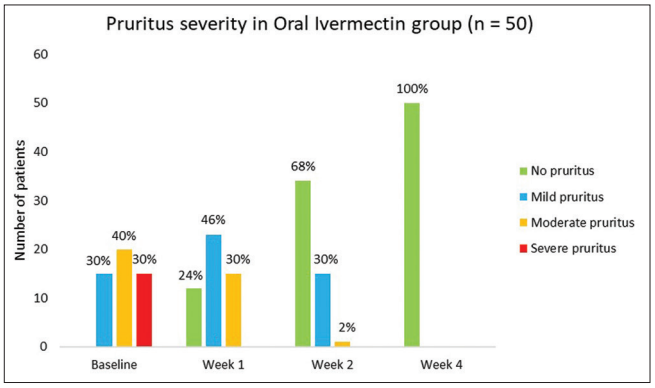

Figure 5: Patients with no pruritus, mild (1–3 cm), moderate (4–6 cm), and severe pruritus (7–10 cm) on Visual Analog Scale in Group B, oral ivermectin group ($n = 50$) at each visit. $P < 0.001$ at each follow-up

Table 1: Adverse drug reactions among patients of Group A, topical ivermectin group (n=51) and patients of Group B, oral ivermectin group (n=50).

Adverse drug reactions	Group A (n=51)	Causality assessment[19]	Severity assessment[20]	Group B (n=50)	Causality assessment[19]	Severity assessment[20]
Itching	4	Possible (4)	Mild (4)	0	-	-
Burning sensation	5	Certain (2) Probable (3)	Mild (5)	0	-	-
Headache	0	-	-	3	Probable (2) Possible (1)	Mild (2) Moderate (1)
Nausea	0	-	-	5	Probable (4) Possible (1)	Mild (5)
Abdominal pain	0	-	-	2	Probable (2)	Mild (2)
Arthralgia	0	-	-	1	Possible (2)	Mild (1)
Myalgia	0	-	-	1	Possible (2)	Mild (1)
Total	9	-	-	12	-	-

the end of 2 weeks had no lesions while 96% of patients were free from lesion by the 4th week.[30] The cure rate in our study at the end of 1 week with single-dose oral IVM is higher than in other studies. This could be because patients took oral IVM tablet under observation yielding 100% compliance and thus higher cure rates.

The cure rates were much higher at the end of 1st week in the oral IVM group in comparison to the topical IVM group ($P < 0.001$) in our study. This could be explained by the fact that the patients in the topical IVM group had received only one application of 0.5% topical IVM till then as opposed to a total of two applications. Chhaiya *et al*. used 1% topical IVM lotion and reported a cure rate of 69.3% in the topical IVM group after single application at the end of 1st week while a cure rate of 30% at the end of 1st week after single dose of oral IVM.[31] The higher cure rate observed by Chhaiya *et al*. could be because of the varying strength of topical IVM.

However, the cure rate at the end of the 2nd and 4th weeks was comparable in the topical and oral IVM group in our study. By the end of 2nd week, all the patients in the study had completed their treatment. The patients in the topical IVM group had received two applications of 0.5% topical IVM cream by the 2nd week. Furthermore, repeated directions on how to use the topical medication could have resulted in correct application of the 0.5% IVM cream.

All the patients in our study complained of pruritus as the chief symptom and almost 70% of patients had moderate to severe pruritus. Pruritus has been reported as a cardinal symptom in most studies.[2,3,21,30-32] By the end of 1st week, patients in both groups reported highly significant improvement in pruritus severity and none of the patients complained of severe pruritus. Although only one patient (2%) in the topical IVM group was pruritus free in comparison to 12 patients (24%) in the oral IVM group, there was no difference in the improvement of pruritus between the groups ($P = 0.235$). Improvement in pruritus severity was significant at the end of the 2nd week also in both groups. Only 25.5% of patients in the topical IVM group and 30% of patients in the oral IVM group still complained of mild pruritus at the end of the 2nd week. These patients were prescribed oral antihistaminic and by the end of 4th week, all the patients in our study were free of pruritus. However, on comparing the efficacy of topical IVM and oral IVM, we found that both groups were comparable at each follow-up. Ahmad *et al*. have also reported no statistical difference in the improvement of pruritus among the topical IVM group and oral IVM group at the 1st week.[32] Though Chhaiya *et al*. have reported improvement in the severity of pruritus with single-dose IVM, none of the patients showed complete relief from pruritus by the 1st week.[31] This could be because 96% of patients in their study had severe pruritus at baseline. They also reported 100% cure from pruritus at the end of the 4th week in both the topical and oral IVM groups. Hafedh *et al*. reported that 88% and 94% of patients at the end of 2nd week and 4th week had no pruritus.[30]

In our study, 21 adverse drug reactions were reported [Table 1]. There were 9 adverse events reported in group A (Topical IVM) and 12 were observed in Group B (Oral IVM). Most of the adverse events in our study were mild in nature. Itching was reported in 7.84% of patients ($n = 4$), while burning sensation was reported in 9.8% of patients ($n = 5$) in the topical IVM group. As none of the adverse drug reactions reported in the topical IVM require any change in treatment or decrease in dose and subsided without any medication, they were classified as "mild" on the Hartwig Seigel scale. Itching, had a "possible" association on WHO-UMC causality assessment because it could also be explained by ongoing scabies and was reported only after 1st application and not after 2nd application.[19,20] Earlier studies have reported a transient aggravation of pruritus the 1st day after treatment and have cautioned against considering it as treatment failure.[33]

In the topical IVM group, 3.92% of patients ($n = 2$) reported that the burning sensation recurred at the repeat application. Since the re-challenge was positive, the causality association was classified as "certain" in 3.92% of cases.[19] However, three patients reported that the burning sensation subsided in the drug-free period after the first application (de-challenge positive), but did not reoccur after the second application (rechallenge negative). Hence, the burning sensation was classified as having a "probable" association in 5.88% of cases ($n = 3$). Very few studies have accounted for adverse events with topical IVM. Ahmad *et al*. reported that topical IVM was well-tolerated among all the patients and cutaneous adverse events like burning sensation and topical irritation were mild and rare.[32] However, Chhaiya *et al*. did not report any adverse events with topical IVM use.[31]

In the oral IVM group, there were three reports of headache, five cases of nausea, two cases of abdominal pain, and one report each of myalgia and arthralgia [Table 1]. Headache was the most common complaint in the oral IVM group in our study. The causality association of headache with oral IVM use was "probable" twice as de-challenge was positive. It was classified as having a "possible" association in one patient because of hot weather [Table 1]. As none of the patients were given a repeat dose of oral IVM, the adverse events could not be classified as "certain" in any case. One patient reported a moderate grade of headache and self-prescribed analgesic for relief from headache while two patients had mild headache which subsided on its own. As painkiller (Tab. Paracetamol 500 mg) was taken for relief of headache in one patient, it was classified as of "moderate" severity on the Modified Hartwig Seigel scale.[20] Nausea and abdominal pain reported in our study had a causality association of "probable" with oral IVM and was of "mild" grade while myalgia and arthralgia had a causality association of "possible" and was of "mild" grade. Sharma and Singal had also reported headache in four patients and two cases of nausea in patients given oral IVM. All the reports were mild in nature as the symptoms subsided on their own in their study.[18] Prabodh *et al*. have reported adverse drug reaction in only 2% of patients such as mild

headache and increase in pruritus which subsided without any intervention.[34] Chhaiya *et al*. reported headache and increase in pruritus in the oral IVM group.[31] All these adverse events subsided without any medication.

One of the limitations of our study was that we used 0.5% topical IVM as it was the only available topical IVM preparation in our set-up. Further studies with varying strengths of topical IVM can be conducted to evaluate its efficacy and tolerability in the management of scabies.

Conclusion

Both topical IVM and oral IVM are equally efficacious and safe in curing scabies. Single-dose IVM (200 mcg/kg body weight) is equivalent to two applications of 0.5% topical IVM at the 2nd and 4th weeks post-treatment both in terms of scabies severity and pruritus severity.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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