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ORIGINAL ARTICLE

Comparative efficacy of topical applications of ivermectin 1% and permethrin 5% for the treatment of scabies.

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ABSTRACT… Objective: To determine the efficacy of 1% Ivermectin and 5% Permethrine in clinically positive cases of scabies after overnight topical applications of each drug. **Study Design:** Randomized Comparative study. **Setting:** OPD of the Department of Dermatology, THQ Hospital Kabirwala, Punjab, Pakistan. **Period:** 1st January to 31st March 2020. **Material & Method:** A total of 276 patients of either sex with typical signs of scabies (papules, nodules, vesicles, classical burrows and nocturnal pruritus) were selected and were randomly divided into two groups A and B, with 138 patients in each group. Patients of Group A were supplied Ivermectin 1% lotion and patients of group B were supplied Permethrin 5% lotion for topical application at night all over the body except face and this treatment was repeated after 7 days. After the 4-week post-treatment follow-up period, data for 185 patients (Group A=89, Group B=96) were analyzed statistically for comparative efficacy of each drug by applying Chi-square test statistics. **Results:** Demographic information showed that higher ($P<0.05$) occurrence of the disease (44.9%) was observed in patients between 21-30 years of age. Difference between patients belonging to the urban/rural area (105/80), lower/middle class (104/81), gender (Male/Female) 87/98, marital status (married/un-married) 129/56 was significant ($P<0.05$). Moreover, among the patients of various occupations, highest frequency (34.6%) was observed in house wives and the lowest (10.8%) was in laborers ($P<0.05$). Highest number of patients (33%) reported 15-30 days after they first noted signs of disease, while lowest number (9.7%) reported the problem >30 days after appearance of the disease ($P<0.05$). Difference between patients sh owing moderate/severe signs of scabies (88/97), history of close-contact/no-contact (65/120), showing high night-itch/no-itch (180/5), have signs of burrows with jet trail/no burrows (130/55) were significant ($P<0.05$), and 62.7% patients had less than 10 lesions. Cure rate reco.rded at 8th day, was 66.3 and 70.8% for Ivermectin and Permethrin, respectively, difference was non-significant. At day 14, 21 and at day 28, cure rate in patients treated with Ivermectin 1% was 85.4, 94.4 and 94.9%, respectively, and for patients treated with Permethrine 5% was 86.5, 99.0 and 99.3%, respectively, differences were non-significant. However, both of the treatments resulted in significantly ($P<0.01$) increased cure rate after day-8 to day-28th, being 66.3 to 94.4% and 70.8 to 99.3%, respectively. Both therapies resulted ($P<0.05$) recovery within 8 to 21 days after treatment from severity of signs, having contact history, presence of night itch, number of burrows/jet with trail and number of lesions, while difference between the therapies was non-significant. **Conclusion:** Topical application of Ivermectin (1%) and Permethrine (5%) lotion was equally effective by curing the patients having moderate to severe signs of scabies when applied twice at 7 days interval, and results in significant ($P<0.01$) increase in cure rate at 4th week.

Key words: In Vivo Efficacy, Ivermectin 1%, Permethrin 5%, Scabies.

INTRODUCTION

Scabies is an intensive pruritic and itching skin disease, caused by ectopic infestation of mite, affecting millions of people of all ages, races and socio-economic groups all over the world.[1,2] The disease has been documented since more than 1100 years BC.[3] This disease is commonly reported from developing countries, where it results in serious health issues through causing distress and disturbing the quality of human life.[1,4,5] and is blamed as associated with poverty.[6] The lesions caused by the scabies mite are prone to bacterial infection and may lead to immune-mediated diseases.[7] During the year 2017, World Health Organization included this disease in the list of neglected tropical diseases

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and recommended that a global control program along with safe treatment protocol of the disease may be developed.[7]

Human scabies is usually treated with topical insecticides; however, the protocol for the most effective treatment is still controversial.[8] Ivermectin and Permethrin are commonly used for the treatment of this disease in humans. Both these preparations have selectively high binding affinity with glutamate-gated chloride ion channels in invertebrate muscle and nerve cells, increase the permeability of the cell membrane to chloride ions and results in the hyperpolarization of the cells, which leads to paralysis and death of the causative parasites.[9,10] Moreover, Ivermectin act as an agonist of the neurotransmitter gamma-aminobutyric acid (GABA) and disrupts GABA-mediated neuro-synaptic transmission. It also impairs normal intra-uterine development of O. volvulus microfilariae and inhibits their release from gravid uterus.[10] However, there are contradictory reports regarding the efficacy of Ivermectin and Permethrin preparations for the treatment of scabies in human patients. Two topical applications of permethrin 5% cream at one week interval has been reported to cure 92.5 and 94.2% patients, while single oral dose of Ivermectin therapy resulted in a cure rate of 85.9% of patients after 2 weeks and using second dose of ivermectin the cure rate was increased to 100%.[8] Similarly, Ranjkesh et al. (2013) reported that topical use of permethrin 5% cream twice at one week interval cured 96.9% scabies patients, while, using single dose of oral Ivermectin, the cure rate was 62.4% and second dose at 2 week interval resulted in cure rate of 92.8% scabies patients.[11] It has also been shown that one topical application of 1% Ivermectin cream in patient suffering with scabies was as effective as using oral Ivermectin (200mcg/kg) along with topical application of Permethrin 5%. Moreover, topical application of 1% Ivermectin cream show relatively less chance of side effects.[1]

Therefore, the present study was planned to compare the efficacy of topical applications of Ivermectin 1% and Permethrin 5% for the treatment of scabies in human patients. Attempts were also made to investigate effects of different demographic factors on the prevalence of this disease.

MATERIAL & METHODS

This randomized comparative study was conducted at DHQ Kabirwala from 1ST January to 31st March 2020 approval from ethical committee was given (1171/HR//THQ). Patients of either sex, aged 18 years and above, showing clinical signs of scabies were included in the study. Selection of patients was undertaken by using the inclusive and exclusive criteria modified following Mushtaq et al. (2010) and Chhaiya et al. (2012), as summarized below:

Inclusion criteria of patients was based on i) presence of itching or nocturnal pruritus, ii) presence of nodules or vesicles at affected sites, iii) presence of burrows at affected sites and iv) microscopic demonstration of mites or their egg/larvae. Patients who could not be examined microscopically were only included if they satisfied at least two out of the first 4 inclusive criteria.

Cutaneous examination of a 27 years old patient showed scaly lesion and mite burrow in the inter-digital space of hand (Plate 1). Similarly, multiple excoriated papules with burrow observed in the 4th inter-digital space are presented in (Plate 2). There were multiple violaceous crusted excoriated papules in cubital fossa, spreading down to volar aspect of limb along with scratch marks in a young lady (Plate 3).

Plate 1: Inter-digital space of the hand of a patient showing scaly lesion and mite burrow.

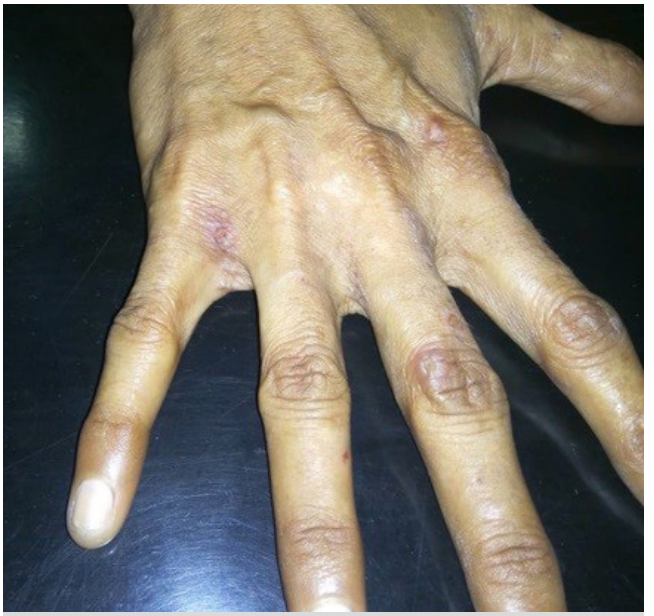

Plate 2: Hand of a patient showing multiple excoriated papules with burrow at the 4th inter-digital space.

Plate 3: Legs of a patient showing multiple violaceous crusted excoriated papules in cubital fossa spreading down to volar aspect of limb along with scratch marks.

Following criteria were followed to exclude patients: i) Patients less than 18 years of age, ii) pregnant women, iii) child feeding mothers, iv) patients showing sensitivity reaction, v) patients having any sort of systemic infection, vi) individuals recently treated for any of the systemic and skin disease and vii) patients suffering with HIV.

In total, 253 patients, who qualified the inclusive criteria, were divided into two groups, A and B. Patients of group A (n=131) were subjected to topical application of 1% Ivermectin, while those of group B (n=122) were treated topically with Permethrin 5%. Before start of treatments, data regarding demographic factors including age, residential status, socio-economic status, gender, marital status, occupation, duration and severity of the disease, contact history, presence of night itch, presence of burrows/Jet with trail and number of lesions were recorded for each patient.

Preparation and Application of Drugs

Ivermectin 1% lotion was prepared by dissolving 10 gm of Ivermectin powder in 990 ml of distilled water and 60 ml of this lotion was supplied to each patient placed in group-A. Permethrin 5% (Scabfree Lotion 5%-ATCO) was supplied to each patient of group-B. Patients were advised to apply the provided lotion on the entire body except face at night before going to bed and repeat the application of lotion after 7 days. Patients were examined at the 8th, 14th, 21st and 28th day.

Attempts were made to follow all the patients for up to 4 weeks following treatment. However, 42 patients in group A and 26 of group B could not be followed. Thus, the data for 89 patients treated with topical ivermectin 1% and 96 patients subjected to topical Permethrin 5% were available for analysis. Flow chart for patients qualified the inclusive criteria for study is presented in Figure-1.

Statistical Analysis

The per cent prevalence of scabies in patients of different demographic characteristics was computed. Similarly, cure rate for each drug was calculated at 8, 14, 21 and 28 days of treatment. For statistical analysis, the data were subjected to Chi-square test, using IBM SPSS Statistics 23.

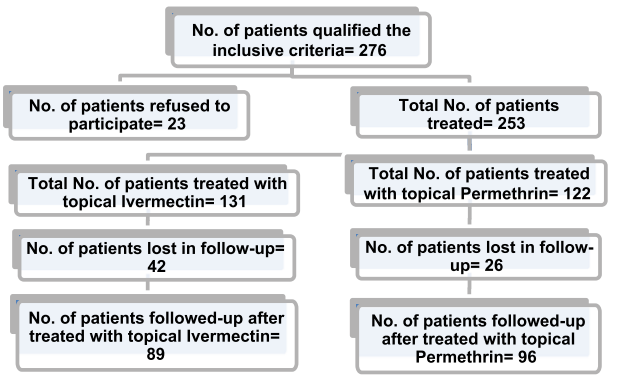

Figure-1. Flow-chart for number of patients qualified the inclusive criteria for study

RESULTS

Data regarding the effects of various demographic factors on occurrence of scabies are presented in Table-I. It shows that significantly higher occurrence of the disease (44.9%) was observed in patients between 21-30 years of age compared to those of other age groups (P<0.05). The number of patients belonging to the urban area was higher (P<0.05) compared to those from rural areas. Similarly, patients belonging to lower class showed higher infection rate than that of middle class. The gender (Male:Female) ratio for patients suffering with scabies was 47:53 (P<0.05), while higher infection rate was noted in married than in unmarried patients. Moreover, among the patients of various occupations, highest frequency (34.6%) was observed in house wives and the lowest (10.8%) was in laborers (P<0.05). Highest number of patients (33%) reported 15-30 days after they first noted signs of disease, while lowest number (9.7%) reported the problem >30 days after appearance of the disease (P<0.05). Moderate and severe signs of scabies were observed in 47.6 and 52.4% of the patients, respectively (P<0.05). The history of close contact was recorded in 35.1% patients, while 64.9% patients had no contact with diseased persons (P<0.05). Patients showing high night itch or no itch were 97.3% and 2.7%, respectively. Most of the patients (70.3%) showed signs of burrows with jet trail, and 62.7% patients had less than 10 lesions.

After first application of topical Ivermecti (1%) and Permethrin (5%), the cure rate recorded at 8th day, was 66.3 and 70.8%, respectively, difference was non-significant (Table-II). A gradual increase in cure rate was recorded at day 14, 21 and at day 28, being 85.4, 94.4 and 94.9%, respectively, in patients treated with topical application of Ivermectin 1%. Similarly, increase in cure rate was recorded in patients treated with topical application of Permethrine 5% at day 14, 21 and at day 28th, being 86.5, 99.0 and 99.3%, respectively. Non-significant differences were recorded between Ivermectin and Permethrine lotion in respect of their in vivo efficacy against scabies at day 8, 14, 21 and 28 (P= 0.506), (P= 0.835) and (P=0.079). However, both of the treatments resulted in significantly (P<0.01) increased cure rate after day-8 to day-28th, being 66.3 to 94.4% and 70.8 to 99.3%, respectively. Statistical analysis of data revealed that significant (P<0.05) improvement was recorded at 21st day of follow up after treatment in both male and female subjects, irrespective of their, age, rural/urban residence, marital status, occupation, duration of disease and presence or absence of contact history, night itch, number of lesions along with burrows/jet with trail (Table-III). No difference was recorded in the significance of recovery at 14, 21 and 28 day follow-up in respect of age, residence, social and marital status; occupation and presence of burrows/jet with trail.

Characteristics	Category	Number	Percentage
Age (Years)	≤ 20	38	20.5^{b}
	21 – 30	83	44.9^{a}
	31 – 40	42	22.7^{b}
	41-50	22	11.9^{c}
Residential status	Rural	80	43.2^{b}
	Urban	105	56.8^{a}
Socio-economic status	Lower Class	104	56.2^{a}
	Middle Class	81	43.8^{b}
Gender	Male	87	47.0^{b}
	Female	98	53.0^{a}
Marital status	Married	129	69.7^{a}
	Un-married	56	30.3^{b}
Occupation	Student	33	17.8^{b}
	House Wife	64	34.6^{a}
	Labourers	20	10.8^{c}
	Office Job	36	19.5^{b}
	Un-employed	32	17.3^{b}
Duration of disease	1-7 days	51	27.6^{c}
	8-15 days	55	29.7^{b}
	16-30 days	61	33.0^{a}
	≥ 30 days	18	9.7^{d}
Severity of disease	Moderate	88	47.6^{b}
	Severe	97	52.4^{a}
Contact history	No Contact	120	64.9^{a}
	Close Contact	65	35.1^{b}
Presence of night itch	No	5	2.7^{b}
	Yes	180	97.3^{a}
Presence of burrows/jet with trail	No	55	29.7^{b}
	Yes	130	70.3^{a}
No. of Lesions	No Lesion	20	10.8^{c}
	< 10	116	62.7^{a}
	10-50	44	23.8^{b}
	> 50	5	2.7^{d}

Table-I. Demographic information of patients suffering with scabies
Values with different subscripts differ significantly (P<0.05) from each other within each characteristic.

	Follow-up days			
Application Topical Lotion	**8**	**14**	**21**	**28**
Ivermectin 1%	66.3[c]	85.4[b]	94.4[a]	94.9[a]
Permethrin 5%	70.8[c]	86.5[b]	99.0[a]	99.3[a]
Significance	P= 0.506	P= 0.835	P=0.079	P=0.079

Table-II. Cure rate (%) in patients of scabies after treatment with topical lotion of Ivermectin 1% and Permethrine 5% at different follow-up days.
Values with different subscripts differ significantly (P<0.05) from each other within the row.

Characteristics	Days		
	14	**21**	**28**
Age	0.090	0.335	0.839
Residence	0.521	0.267	0.278
Status	0.871	0.324	0.176
Gender	0.002[b]	0.00[a]	0.650
Marital status	0.93	0.742	0.892
Occupation	0.780	0.897	0.790
Duration	0.182	0.026[a]	0.013[a]
Severity	0.013[a]	0.092[b]	0.551
Contact history	0.044[b]	0.031[a]	0.851
Presence of night itch	0.015[b]	0.001[a]	0.654
Presence of burrows/ jet with trail	0.638	0.274	0.091
No. of lesions	0.653	0.033[b]	0.012[a]

Table-III. Significance values for improvement/ recovery at follow-up.
Each subscript letter denotes significant (P<0.05) difference of improvement/Recovery during the follow-up periods.

DISCUSSION

The results of present study reveal that scabies affects the human of all ages and most of the people suffer with scabies during the age of 21-40 years, both rural and urban communities, male/females of all socio-economic status and occupation. These results are in close agreement with various researchers[12-19] who made similar observations. Nair et al. (2016) reported high prevalence of scabies in the students (41.17%), most probably due to their close association in the schools.[13] Lowest frequency of scabies was recorded in the laborers (10.8%) during the present study, which might be due to lower frequency of close contact (35.1%) compared to the high percentage (98.49% and 69.5%) of close contact through sharing of beds/cloths/towels in scabies patients reported in the literature[15,19] or unawareness of poor community about the disease[19,20] and/or poor access to medical facilities.[21-23] However, the discrepancies found in various reports might be due to differences in personal hygiene[24], socio-economic conditions, education and quality of life between various communities/countries.[23,25] Presence of peculiar signs of scabies (nocturnal itch and burrows with jet trail) and their severity shown by the patients did not differ in their occurrence as compared with the available literature.[19]

In the present study, non-significant differences were observed between the effects of Ivermectin 1% and Permethrine 5% after two applications at day-0 and day-8. Similarly, Verma et al. (2019), Goldust et al. (2012), Mushtaq et al. (2010), Chandler and Fuller (2019) reported non-significant differences between the effects of Ivermectin 1% and Permethrin 5% after using two doses at day-0 and day-8.[1,8,26,27] Topical application of Ivermectin 1% and Permethrin 5% lotion resulted in gradual and significantly (P<0.01) increased relief from scabies signs from day-8 to day-28th. Moreover, slightly better effects of Permethrin 5% lotion compared to Ivermectin 1% (70.8% Vs 66.3%) recorded during the present trial are in agreement with those of Mushtaq et al. (2010) and Verma et al. (2019), who also reported non-significant difference between Permethrine 5% and Ivermectin 1% but marginally better efficacy of Permethrin than Ivermectin (88.1% Vs 79.5%) after four weeks.[1,26] Similarly, Verma et al. (2019) reported that one application of Ivermectin 1% cream was as effective as application of Permethrin 5% topical cream along with oral Ivermectin 200mcg/Kg.[1] They reported that use of topical Ivermectin (1%) reduced the number of follow-up visits required, thus reduced the cost of treatment and less chances of side

effects compared to Permethrin. Goldust et al. (2012) reported cure rate of 63.1 and 65.8% at 2 week follow-up in patients of scabies treated with Ivermectin 1% and Permethrin (2.5%), respectively.[8] They advised to apply Ivermectin 1% and Permethrin 2.5% topically at one week interval. They also reported that cure rate was increased to 89.5% after one more application of Ivermectin 1% and Permethrin 2.5% at 4-week follow-up. Moreover, Ivermectin 1% was as effective as Permethrin 2.5% cream at the 4 week follow-up. Literature also showed non-significant difference in cure rate of scabies by using oral Ivermectin at dose rate of 200mcg/kg versus topical Ivermectin 1% lotion after 4 weeks of single treatment, values being 97% vs 96%.[6] However, Ivermectin was reported superior than Permethrin in reducing prevalence of scabies (94% Vs 49%) based on one year published data.[6]

Topical application of Permethrin 5% cream or oral use of Ivermectin are now commonly used against scabies, as they have proved highly effective in many cases; however, it is usually recommended to repeat the treatment after one week to kill the larvae reaching to adulthood.[6,27] The understanding of life cycle of Sarcoptes scabiei mite is the key to effective treatment and control of scabies.[4] Effectiveness of similar treatments may vary between clinical trials.[15] Permethrin has been known to produce local reactions such as skin burning, pruritus and erythema in some patients.[8,26-28] Moreover, in vitro and in vivo permethrin resistance in scabies-mites has also been documented.[3,9,29,30] According to Thomas et al. (2015), it is difficult to treat the patients of scabies with secondary complications like eczema or ulceration.[3] Furthermore, treating large populations or communities may help to reduce the prevalence but may contribute to the development of resistance.[31]

The results of present study might be due to the reason that two doses of Ivermectin and Permethrine were applied on patients at an interval of 7 days. Both of these drugs have been reported as selectively high binding affinity with glutamate-gated chloride ion channels in invertebrate muscle and nerve cells and increase the permeability of the cell membrane to chloride ions and results in the hyperpolarization of the cells leading paralysis and death of the parasites.[9,10] Moreover, Ivermectin act as an agonist of the neurotransmitter gamma-aminobutyric acid (GABA) and disrupt GABA-mediated neuro-synaptic transmission. It also impairs normal intra-uterine development of O. volvulus microfilariae and inhibits their release from gravid uterus.[10] It is recommended that while treating patients of scabies, topical agents should be applied over the entire body from the neck down and kept overnight. Moreover, all family members or close contacts should also be treated to eliminate the mite.[31,32] Survival time of mite outside host is about three days[32] therefore, all items used within the last three to four days should be placed in plastic bags for at least three days. All wears and bed linens must be washed in hot water (above 60°C) and sun-dried.[31]

CONCLUSION

Topical application of Ivermectin (1%) and Permethrine (5%) lotion were equally effective by curing the patients having moderate to severe signs of scabies when applied twice at 7 days interval. There was significant ($P<0.01$) increase in the cure rate after 2nd week and follow up at 3rd and 4th week.

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