Original Article

Comparison of Oral Ivermectin and Permethrin 1% Shampoo in the Treatment of Pediculosis Capitis

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[1,2,3,4,5,6] *Conception of study*
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Abstract

Objective: To compare the efficacy of Oral Ivermectin with Permethrin 1% Shampoo in the treatment of Pediculosis Capitis.

Materials and Methods: This Randomized controlled trial was conducted at the Department of Dermatology, Bolan Medical College Quetta from December 24, 2016, to June 23, 2017. All children of either gender having age 5 and above weight, more than 15 kg presented with head-lice infestation confirmed by combing the wet hair with a fine-toothed detection comb were enrolled. All patients were randomly allocated into two groups. Patients in group A received oral Ivermectin in a dose of 200mcg/kg while patients in group B received an application of 1% Permethrin Shampoo. They were called after one week and they received a second dose of oral Ivermectin in the same dose of 200mcg/kg and application of Permethrin 1% Shampoo and re-evaluated after one week. Treatment was considered effective by the absence of live lice by day 15 of treatment.

Results: The majority of the patients presented were females in both groups, i.e. 20 (66.7%) and 23 (76.7%) respectively. An insignificant difference was observed in the mean age in the between-group (p-value=0.482). Efficacy was found significantly higher in oral Ivermectin group 26 (86.7%) as compared to 1% Permethrin Shampoo (P-value <0.001).

Conclusion: The efficacy of the oral Ivermectin group was considerably higher as compared to 1% Permethrin Shampoo in our cohort.

Keywords: Pediculosis, Oral Ivermectin, 1% topical Permethrin.

Introduction

Head lice infestation (Pediculosis Capitis) is a condition caused by an infestation of the hair and scalp by Pediculus Humanus Capitis (the head louse).[1] It is an important public health problem mainly affecting school-going children of 8-11 years of age.[2] In Europe prevalence varied from 1-20%.[1] In developing countries, prevalence up to 40% has been observed.[3] Mostly seen in people with poor hygiene and low socioeconomic status.[1,4,5]

Pediculosis Capitis is a contagious infestation and an infected person can commonly spread it through direct head to head contact. The head louse sucks blood from the human scalp 4-5 times per day and injects saliva into the scalp which causes pruritis. The resulting repeated scratching leads to loss of hair integrity and secondary bacterial infections and reactive Cervical and Occipital Lymphadenopathy.[6]

Head louse infestation can be easily diagnosed by inspecting the hair and scalp or by dry/wet combing. However, the superior method is wet combing.[7] The nits can be seen in the occipital and post-auricular regions.[6]

Treatment options include manual removal (using wet comb and conditioner).[8] Topical medications include neurotoxic drugs including permethrin, malathion, phenothrin and carbaryl,[9] lindane,[10] benzyl alcohol 5%,[11] spinosad,[12] dimeticone[13,] and oral medication such as ivermectin.

Permethrin is a synthetic drug which acts as a neurotoxin. It belongs to the pyrethroids neurotoxin family which affects voltage-sensitive Na+ channels of the nervous system of the insect, causing depolarization of the nerve resulting in hyperexcitation followed by muscle paralysis and ultimately death of the parasite. In a study performed by Ian F Burgess et al the efficacy of 1% Permethrin was found out to be 14.9% when compared to Dimeticone.[13]

Antiparasitic drug Ivermectin binds to glutamate-gated chloride ion channels in invertebrates and interrupts neurotransmission can be used to treat conditions such as lymphatic filariasis, helminthiases, onchocerciasis, and ectoparasite infestations, mainly scabies.[14]

The dose of oral ivermectin in pediculosis capitis is 200mcg/kg, which is repeated after one week. Ivermectin is a safe drug however it can cross the blood-brain barrier and cause neurotoxicity in children with weight less than 15 kg and in pregnant and breastfeeding mothers.[15] A study conducted by Ameen et al on oral ivermectin for pediculosis capitis showed efficacy of 93%.[14]

The rationale behind my study was that to date only topical medications have been used in the local population, which are messy to use and resistance to topical medications has been reported.[16] Ivermectin is the only oral pediculicide drug available for pediculosis capitis. However, no local or national study on the efficacy of oral Ivermectin has been performed to date and therefore it is not used routinely in our department by health professionals. Rather the patients are treated with topical Permethrin for pediculosis capitis.

Materials and Methods

This Randomized controlled trial was conducted at the Department of Dermatology, Bolan Medical College/ Sandeman Provincial Hospital, Quetta. The study duration was 6 months. The sampling technique used was Consecutive (non-probability). The sample size calculated is 10, five in each group, keeping efficacy of Permethrin as 14.9%, the efficacy of Ivermectin as 93%, confidence level 95%, and power of the test 90%. Since the sample size is very small so it was increased to 30 in each group and the total sample size was 60 patients.

Sample Selection:

Inclusion Criteria:

1. Both genders.
2. Age 5 and above.
3. Weight more than 15 kg. Since the safety of this drug in patients weighing below 15 kg has yet not been established.
4. Head-lice infestation (defined as the presence of live lice) is confirmed by combing the wet hair with a fine-toothed detection comb.

Exclusion Criteria:

1. Pregnancy or breastfeeding. Since Ivermectin is a category c drug and can be excreted in breast milk.
2. Use of any pediculicidal treatment or any potentially interacting drug within the 2 weeks before treatment.
3. A hairstyle (e.g.; tight plaiting) that may cause difficulty in combing.

The above mentioned are confounders and not included in the study to reduce bias.

Data Collection Procedure:

The study was conducted after getting approval from the hospital's ethical and research committee. All patients meeting the inclusion criteria with active head

louse infestation were included in the study throughout the patient department. The purpose and benefits of the study were explained to the patient and they were assured that the study is done purely for data publication and research purpose and written informed consent was obtained. All patients were subjected to detailed history and physical examination and they were diagnosed with active louse infestation by visual inspection of hair and wet hair combing. Ethical issues were addressed and confidentiality was maintained and during an examination, patient comfort was taken care of. All patients were randomly allocated into two groups. Patients in group A received oral Ivermectin in a dose of 200 mcg/kg while patients in group B received an application of 1% Permethrin Shampoo. They were called after one week and they received a second dose of oral Ivermectin in the same dose of 200 mcg/kg and application of 1% Permethrin Shampoo and re-evaluated after one week. Treatment was considered effective by the absence of live lice by day 15 of treatment. All the observations and assessment of treatment were conducted by me under the supervision of a single expert dermatologist with having a minimum of five years' experience. All of the above information including name, age, and gender were recorded in a predesigned proforma.

Data Analysis:

Data were analyzed in SPSS version 17. The mean age of the patient in the sample was calculated. The male to female ratio was determined in the sample. In both, groups, the frequency of patients having no live louse in the head on the 15th day was calculated. The frequency in both groups was compared by applying the chi-square test keeping a p-value≤ 0.05.

Results

The mean age of the patients was 9.25 ±1.27 years. The majority of the patients were presented with ≤10 years of age in both groups, i.e. 27 (90%) and 21 (70%) respectively.

An insignificant difference was observed in the mean age in the between-group (p-value 0.482). (Table 1)

There were 43 (71.7%) females and 17 (28.3%) males.

The majority of the patients were females in both groups, i.e. 20 (66.7%) and 23 (76.7%) respectively.

Overall, frequency of Pediculosis Capitis on the 15th day of treatment was found in 38 (63.3%) of the patients. (Figure 1)

In the oral Ivermectin group, the majority of the patients had no Pediculosis Capitison 15th day of treatment 26 (86.7%) while in 1% Permethrin Shampoo 18 (60%) of the patients had Pediculosis Capitison 15th day of treatment. (Figure 2)

Efficacy was found significantly higher in oral Ivermectin group 26 (86.7%) as compared to 1% Permethrin Shampoo (P-value <0.001). (Table 2)

Significant association of oral Ivermectin group and 1% Permethrin Shampoo was also observed in patients having ≤10 years of age (p-value <0.001), male gender (p-value=0.009), and female gender (p-value=0.005). (Table 3-4)

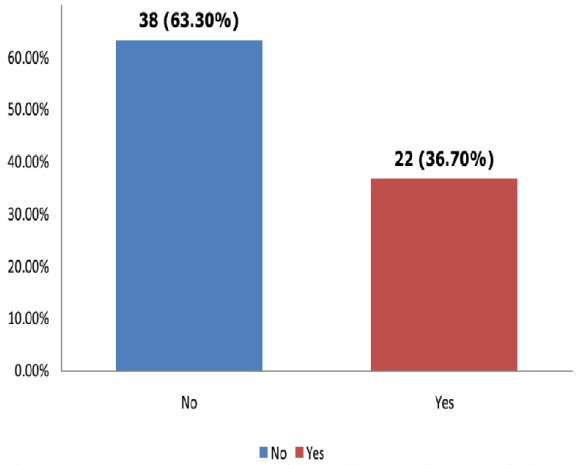

Figure 1: Frequency of Pediculosis Capitis on 15th day of treatment

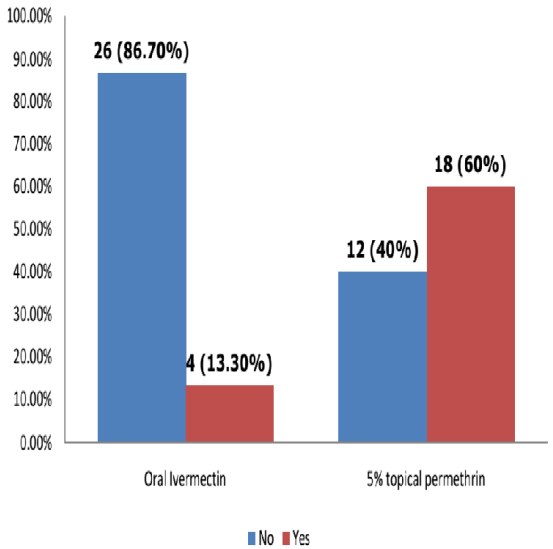

Figure 2: Comparison of Pediculosis Capitison 15th day of treatment with respect to group

Table 1: Comparison of age of the patients with respect to groups (n= 60)

	Group	*Mean ± SD*	*P-value*	*95% CI*
Age of the patients (in years)	Oral Ivermectin	9.13 ± 0.93	0.482	-0.89 to 0.42
	1% topical permethrin	9.36 ± 1.54		

Table 2: Comparison of age of the patients with respect to groups (n= 60)

Group	*Efficacy*		*Total*	*P-value*
	Yes	**No**		
Oral Ivermectin	26 (86.7)	4 (13.3)	30 (100)	**<0.001**
1% topical permethrin	12 (40)	18 (60)	30 (100)	
Total	38 (63.3)	22 (36.7)	60 (100)	

Table 3: Efficacy between groups with respect to patient's age

Group	*Efficacy*		*Total*	*P-value*
	Yes	**No**		
Oral Ivermectin	*24 (88.9)*	*3 (11.1)*	*27 (100)*	*<0.001*
	2 (66.7)	**1 (33.3)**	**3 (100)**	
1% topical permethrin	*8 (38.1)*	*13 (61.9)*	*21 (100)*	**0.505**
	4 (44.4)	**5 (55.6)**	**9 (100)**	
Total	*32 (66.7)*	*16 (33.3)*	*48 (100)*	
	6 (50)	**6 (50)**	**12 (100)**	

Age ≤10 years n=48 (represented in italic letter)
Age ≥ 10 years n=12 (represented in Bold letter)

Table 4: Efficacy between groups with respect to male & female gender

Group	*Efficacy*		*Total*	*P-value*
	Yes	**No**		
Oral Ivermectin	**9 (90)**	**1 (10)**	**10 (100)**	*0.009*
	17 (85)	*3 (15)*	*20 (100)*	
1% topical permethrin	**2 (28.6)**	**5 (71.4)**	**7 (100)**	**0.005**
	10 (43.5)	*13 (56.5)*	*23 (100)*	
Total	**11 (64.7)**	**6 (35.3)**	**17 (100)**	
	27 (62.8)	*16 (37.2)*	*43 (100)*	

Male n= 17 (represented in bold letter)
Female n=43 (represented in italic letter)

Discussion

Head lice (pediculosis capitis) are a highly contagious infestation and an infected person can commonly spread it through direct head to head contact. The head louse sucks blood from the human scalp 4-5 times per day and injects saliva into the scalp which causes pruritis. The resulting repeated scratching leads to loss of hair integrity and secondary bacterial infections and reactive Cervical and Occipital Lymphadenopathy.[6]

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ultimately death of the parasite. In a study performed by Ian F Burgess et al the efficacy of 1%, Permethrin was found out to be 14.9% when compared to Dimeticone.[13]

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In this study, in the oral Ivermectin group, the majority of the patients presented with no Pediculosis Capitis on the 15th day of treatment 26 (86.7%) while in 1% topical Permethrin 18 (60%) of the patients presented with Pediculosis Capitis on 15th day of treatment. Moreover, efficacy was found significantly higher in oral Ivermectin group 26 (86.7%) as compared to 1% topical Permethrin (P-value< 0.001).

The mode of action of Permethrin (a pediculicide neurotoxin) is to derange the sodium channel current leading to delayed repolarization, and ultimately resulting in paralysis of the nerves of the muscle of the exoskeleton of lice which allows it to breath.

The residual activity of Permethrin may last over 2 weeks which is the only available pediculicide in this range. It is a pediculicidal as well as an ovicidal drug.

Therefore, one application is usually sufficient. However, another course, 7 to 10 days later, maybe used which ensures a pediculosis clearance rate of about 95%. Reports of resistance to 1% Permethrin is available but the prevalence of this resistance is uncertain.

Permethrin 5% topical solution is applied at night for scabies treatment. FDA initially approved Permethrin for the treatment of scabies but later also approved 1% Permethrin for the treatment of head lice. It is applied to the scalp and left on for several hours or overnight, and then it should be washed off.

No case-control studies have reported efficacy to date. One study suggested that lice resistant to 1% permethrin will not succumb to higher concentrations.

Conclusion

Our study result showed that the efficacy of the oral Ivermectin group was considerably higher as compared to 1% Permethrin Shampoo

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