

Comparative Efficacy of Three Control Protocols of Head Lice (*Pediculus Humanus Capitis*) Infesting Schoolchildren in Mashhad City, Iran

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Abstract

Background: Head lice infestation constitutes a serious health problem in marginalized areas where schoolchildren and their families are mostly affected. This study aimed to compare 3 lice control protocols approved by Ministry of Health and Medical Education, based on 1% permethrin shampoo, 4% dimethicone lotion and (1:1) vinegar wet combing for the treatment of outpatients of Imam Reza Hospital of Mashhad city (Iran).

Materials and Methods: The quasi-experimental before-and-after design was applied to evaluate the effectiveness of protocols, using SPSS software version 16.0. The study involved 154 infested individuals from both sexes during 2015 and 2016. The patients were clustered into 4-age categories; < 5 to >13-year-old and their demographics were recorded. The results were recorded on weekly basis by a hospital-based dermatologist and an entomologist. Application times of permethrin, dimethicone and vinegar were 8-10 min, 8 h and 20-30 min respectively.

Results: Age, gender, family size and hair length were the most significant demographic variants involved in treatments outcomes at $P \leq 0.05$. The protocols showed different efficacies a week after intervention keeping the same trend to the end. The dimethicone treated group indicated the highest control levels (86% and 74%). The recovery rates at first endpoint were 86, 64.2 and 60.8%, and at the second endpoint were 74, 45.3 and 45.1% for dimethicone, permethrin and vinegar respectively. Dimethicone was 4.3 times more potent than either of vinegar or permethrin ($P < 0.05$).

Conclusion: Pediculosis infected school age children of both sexes. Permethrin was as effective as vinegar wet combing, but significantly weaker than dimethicone. Given its efficacy on both adult and nit stages, dimethicone can be the drug of choice for pediculosis control.

Key Words: Children, Head lice, 4% dimethicone lotion, Pediculosis, Permethrin 1% lotion.

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1- INTRODUCTION

Human head louse *Pediculus humanus capitis* has been a major public health concern worldwide affecting individuals of different socioeconomic backgrounds at all ages particularly schoolchildren (1). As an obligate holometabolous ectoparasite, head louse spends its 3-stage life cycle in hairs of human hosts where it resides and cements its nits near the scalp. The head louse pierces the skin several times daily for blood meals and therefore exposes hosts to diseases or at least to pruritus, excoriation, conjunctivitis, and secondary bacterial inflammation at feeding sites (2). Head lice have been reported to carry *Rickettsia prowazekii* (typhus agent) in Africa, South America, and Asia (3). Also, evidences have been shown from Ethiopia that *Bartonella quintana* (trench fever agent) and *Borrelia recurrentis* (relapsing fever agent) were present in 7% and in 23% of head lice respectively (4, 5). In addition, lice infestation may cause psychological distress, social stigma and absence from school and work for both schoolchildren and their parents and disrupt learning performance of the formers (6).

Although, gender, age group, race, type of hair and socioeconomic status are factors that influence the prevalence rate of pediculosis, increased seasonal infestations in many geographical regions have been reported to be due to insecticide resistance (7- 9). There are two basic ways to treat head lice; use of Pediculicide drug products and wet combing. Various form of Pediculicide drug products are marketed as over the counter drugs (OTC) in the form of lotion, shampoo, powder, washable creams, gels and so on. Lindane, Malathion, Carbaryl and Permethrin are examples of such products. Nowadays, in Iran, 1% permethrin shampoo is the first line treatment, whereas other organochlorine, organophosphorus and carbamate neurotoxic pediculicides are no

longer in use due to their side effects including emergence of resistant head lice populations (10). Plant essential oils such as tea tree oil and neem have also been used as bio-insecticides to control head lice but with conflicting results due to poor data and lack of standardization (11-13). However, wet combing method with a nit detection comb using wetting solutions such as water and vinegar is still an effective traditional practice to remove lice and nits (14). Many studies tackled head lice biology, epidemiology and control, but research on efficacy of pharmaceutical treatments is still required given its increasing resistance to a limited number of lousicide (15, 16). In this study, we intended to compare the efficacy of three lice control protocols namely 1% permethrin shampoo, 4% dimethicone lotion and vinegar wet combing method for the treatment of pediculosis in outpatients of Imam Reza Hospital of Mashhad city (North East of Iran).

2- MATERIALS AND METHODS

2-1. Study Design

The study was based on quasi-experimental before and after design and included parallel trials (TCTR20180317003). The study was funded by Tarbiat Modares University (Tehran, Iran). The protocols for head lice control were based on Medical guidance provided by the Iranian Ministry of Health and Medical Education to the national health centers in the country (17). According to the protocol, 1% permethrin was applied to the clean-washed wet hair and scalp for 8-10 min, followed by thorough rinsing with water and repeated combing. On the other hand, 4% dimethicone was applied to dry hair and scalp and kept for 8 h (overnight) before shampooing followed by steps of rinsing and combing. The vinegar wet combing, however, was performed by rubbing the solution on entire hair followed by

washing with ample water and combing. The study was conducted in compliance with ethical considerations highlighted in the Declaration of Helsinki (2013 version). The study aimed to compare two head lice control methods; vinegar wet combing and dimethicone lotion (4 %) with the standard permethrin shampoo (1%). The patients' clinical examinations, demographic information collection via filling in questionnaires, instruction and follow up were performed under the supervision of a hospital-based dermatologist and an entomologist. Written informed consents were obtained from participants or their parents after full explanation of the objectives of study and before providing the necessary lousicide materials and instructions. The study was carried out from September 2015 to March 2016 at Imam Reza Hospital of Mashhad city. However, the effects of nonparametric demographic variables of patients assigned to various group of pediculosis control protocols were also studied with particular reference to gender, hairstyle and hair thickness as presented in the result section.

2-2. Study Patients

Eligible patients were individuals referred to Imam Reza Hospital in Mashhad city with lice infestation who agreed not to cut hair or use any louse control chemicals except of those recommended during this study. Each patient, from among 154 lice infested individuals, was randomly assigned to one of 3 treatment groups regardless of age or sex categories. However, 93 percent of them aged between 5 to 13 years and 80 percent of them were female. The infestation was confirmed upon finding live nits on scalp and hair particularly behind ears and at the nape of the neck by close examination using magnifier lens and hair clips. Active lice were less spotted on the scalp of infested people due probably to their small size, quick movement, negative phototaxis and dark colour which acted as a

camouflage against black and dark brown hairs of most participants. Patients were classified on the bases of infestation severity into three groups; mild infestation (1-2 adult/nymph or fresh/ hatched nits), moderate infestation (2-4 adult/nymph or fresh nits at the nape of the neck), and severe infestation (>4 adult/nymph or fresh nits everywhere on scalp and hair). All participants were fiddle to the follow-up process with no drop-out until the end of study.

2-3. Study Treatments

On day 1, each enrolled participant received (free of charge) a single 60 ml bottle containing 1% permethrin shampoo (Gilaranco, Iran), or 4% dimethicone lotion (Dilice®, Selmidaroo, Iran), or freshly made vinegary shampoo for wet combing, to be applied at home by the patient or her/his caregiver once per week for the first 2 weeks as per written instruction given during clinical visit. Patients who were to apply 1% permethrin were instructed to wash the hair with normal shampoo once and dry it before applying permethrin shampoo for 8-10 minutes followed by rinsing with water. The second patient group applied 4% dimethicone lotion to their dry hair and scalp and left it overnight (8 hours.) before rinsing the hair with water. The third group, however, applied the traditional vinegary shampoo (pH 5.5) containing white vinegar (5 % acetic acid) in water mixed with hair conditioner and olive oil (1:1 v/v) associated with 20 min gentle combing before rinsing the hair with water. The examination visits of the patients were to occur on day 7, 14 and 30 post-application. Each patient underwent 15 minutes examination at each visit to assess the efficacy of treatment upon detection of live lice or nits.

2-4. Study End Points

The primary endpoint of the study was the patient cure from lice infestation (lack of

live nits) after a single treatment assessed at day 7 post application. The secondary endpoint was determined to be the patient cure and satisfaction at day 30 post-application.

2-5. Statistical Analysis

As there was no comparative study in Mashhad city on the applied lice control protocols of this study, the sample size was calculated as per the following formula (18):

$$N = \frac{10K}{P}$$

Where, n= sample size, K= number of controlled variables =7 and P = cure rate = 0.5. The Kolmogorov–Smirnov test was used to compare the distribution of samples with the theoretical reference distribution and to determine the nonparametric nature of the datasets. Accordingly, nonparametric tests such as Chi-square and Fisher tests were applied using SPSS software version 16.0. The statistics were used to test the equal distribution of frequencies of contingency table of louse control protocols in relation to demographic characteristics including gender, age and family size categories. However, logistic regression models were applied to calculate the regression coefficients and estimate the odd ratios as measures of association between control protocols and severity of pediculosis on the basis of cure outcomes at the final endpoint of treatment taking vinegar wet

combing and weak pediculosis as relative references.

3- RESULTS

The study aimed to compare the three recommended protocols for head lice control among children referred to Imam Reza Hospital in Mashhad city, Iran. From among 154 lice infested individuals, females and males consisted 121 (78.6 %), and 33 cases (21.4 %), respectively. The participants were assigned to 3 control methods so that 50 cases were treated with dimethicone lotion, 53 cases with permethrin and 51 cases with vinegary wet combing. Therapeutic interventions were evaluated on day 7, 14 and 30 post-treatment. The results showed significant differences among the treated groups of patients at the end of first week and 30th day (p=0.008, p=0.014). Dimethicone group recorded the best cure rate of 86 and 74 percent at the end of first week and 30th day post application, respectively. As in **Table.1**, at the primary endpoint of day 7 post-treatment, 86% of dimethicone treated individuals were cured, whereas 14% of them remained infested and unchanged. On the other hand, 64.2 % of those treated with 1% permethrin shampoo got rid of head lice, while 35.8 % of them rest unchanged. However, using vinegary wet combing, 60.8 % of infested cases recovered and 35.3 % remained unchanged, but 3.9 % showed lice re-infestation.

Table-1: Cure rates of the tested louse control protocols at days 7, 14 and 30 post application

Groups	End points	Vinegar (n=51)	Permethrin (n=53)	Dimethicone (n=50)	Total (n=154)	Chi-square test
Cured	7th day	60.8	64.2	86	70.1	11.25 P= 0.008
Re-infested		3.9	0	0	1.3	
Unchanged		35.3	35.8	14	28.6	
Cured	14 th day	56.9	56.6	80	64.3	8.18 P= 0.084
Re-infested		13.7	11.3	6	10.4	
Unchanged		29.4	32.1	14	25.3	
Cured	30 th day	45.1	45.3	74	54.5	12.42 P= 0.014
Re-infested		23.5	22.6	16	20.8	
Unchanged		31.4	32.1	10	24.7	

At the secondary endpoint of day 30 post-treatment, the success rate of dimethicone was 74% with 10% of cases remained infested and 16 % were re-infested. Permethrin and vinegary protocols, however, both recorded similar success rate of approximately 45 %. The infested rates of permethrin and vinegary protocols were 32.1% and 31.4%, while their re-infested rates were 22.6% and 23.5%, respectively. The results of Pearson's Chi-squared test (χ^2) for homogeneity at both primary and secondary endpoints indicated significant p-value which prove

meaningful differences between the performances of louse control protocols. Dimethicone recorded the highest cure rates at both endpoints, while the difference between permethrin and vinegary wet combing was marginal at both occasions. As presented in **Table.2**, the participants allocated evenly to the treatment groups in terms of hairstyle and hair thickness characters as the statistical analyses showed no meaningful differences ($P>0.05$). However, hair length differed among the treatment groups with a significant p- value equal to 0.005.

Table-2: Comparison of distribution frequencies of individuals to the treatment groups as per hair characters

Characters	Number of patients (%)	Dimethicone-treated (%)	Permethrin-treated (%)	Vinegar-treated (%)	Statistical analysis
Hair style					
Straight	131 (85.1)	39 (78)	46 (86.8)	46 (90.2)	$\chi^2 = 3.24, P \leq 0.518$
Curly	17 (11)	8 (16)	5 (9.4)	4 (7.8)	
Wavy	6 (3.9)	3 (6)	2 (3.8)	1 (2)	
Hair length					
Short	55 (35.7)	20 (40)	23 (43.4)	12 (23.5)	$\chi^2 = 3.20, P \leq 0.005$
Medium	68 (44.2)	14 (28)	23 (43.4)	31 (60.8)	
Long	31 (20.1)	16 (32)	7 (13.2)	8 (15.7)	
Hair thickness					
Thin	15 (11)	4 (8)	7 (13.2)	6 (11.8)	$\chi^2 = 1.48, P \leq 0.830$
Medium	101 (65.5)	33 (66)	39 (67.9)	32 (62.7)	
Thick	36 (23.4)	13 (26)	10 (18.9)	13 (25.5)	

χ^2 : Chi-square test.

Fisher's test was applied to the contingency table of variable control protocols and age categories of assigned individuals (**Figure.1**). The results indicated significant association between

the variables ($P<0.001$). This means that the cure rate may be interpreted in the light of age categories assigned to each protocol.

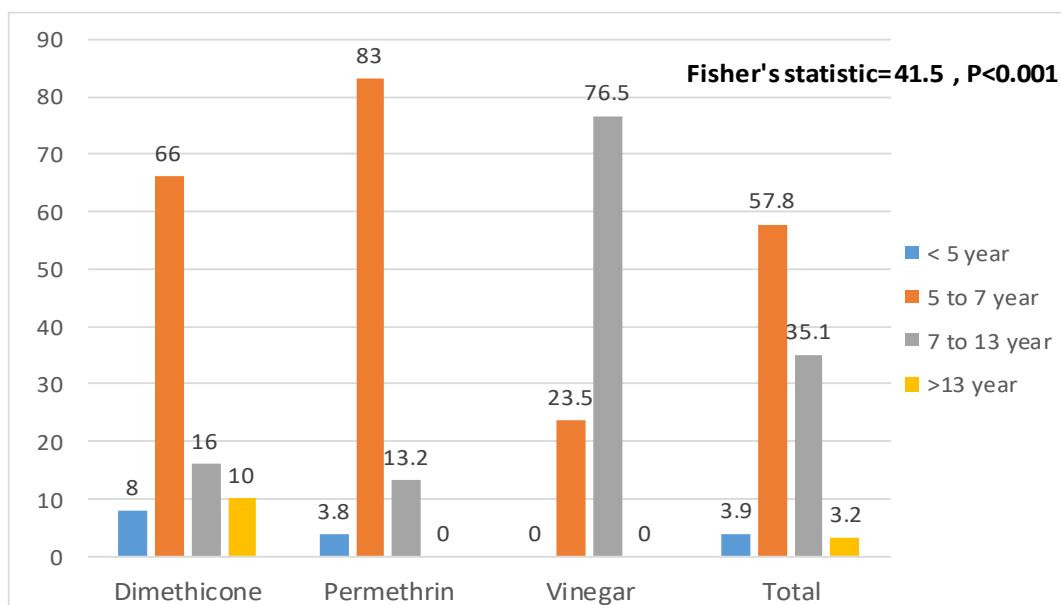


Fig.1: The association of age categories of assigned individuals and louse control protocols.

In addition, applying Fisher's test to contingency table of louse control protocols and sex categories of assigned

individuals revealed statistically meaningful dependence between the variables (**Figure.2**).

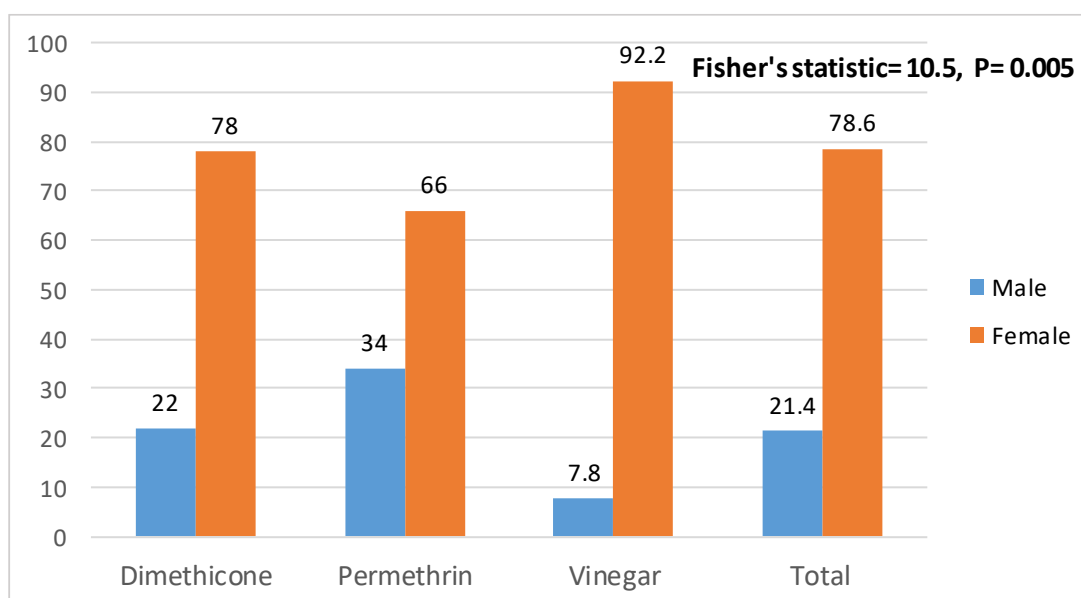


Fig.2: Association of sex categories of assigned individuals and louse control protocols.

Taking into account the importance of family size, which may reflect socioeconomic status of patients, Fisher's test was also applied to contingency table including louse control protocols and

family size categories (**Figure.3**). The results showed significant association between the variables which should be considered while interpreting the performance of control protocols.

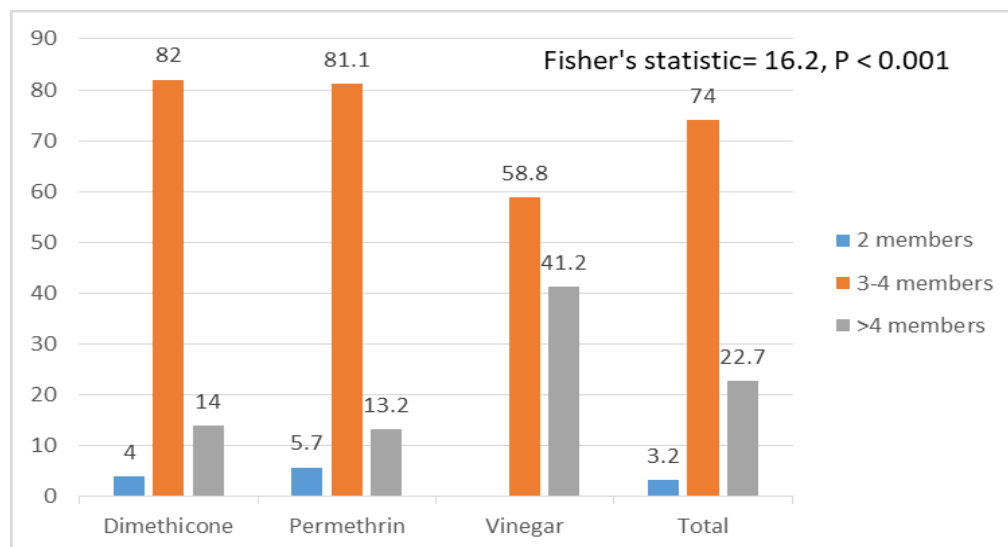


Fig.3: Association of family size categories of assigned individuals and louse control protocols.

The logistic regression models were applied to compare the success of two chemical louse control protocols namely application of 4% dimethicone and 1% permethrin with the traditional vinegary wet combing on one hand and the relapse of pediculosis in moderately and severely infested cases compared to mildly infested cases across all control protocols (**Table.3**). In this case, the data obtained at the secondary endpoints were used so that binary responses of cured and uncured (including relapsed and re-infested) cases were considered. The results showed a significant p-value ($P=0.002$) for dimethicone treatment with an odds ratio representing 4.3 times greater change of lice control compared to the odds of outcome occurring upon application of vinegary wet combing method. The

positive beta coefficient estimates increase in the odds of the success equal to 1.5 per unit increase in the value of dimethicone exposure. This indicates efficacy of dimethicone in controlling head lice. On the other hand, permethrin outcome was not significantly different from that of vinegary wet combing method. However, comparing the relapse of pediculosis in moderate and severe infestations with mild infestation showed that, in contrast to moderate infestation, severely infested cases were significantly ($P= 0.002$) more prone (odds ratio [OR]=1.8) to re-infestation than those with mild infestation. The negative beta coefficient of severely infested cases indicates that the increase in severity was associated with increased odds of re-infestation and aggravation of pediculosis.

Table-3: Results of logistic regression models applied to compare louse control efficacy as per protocols and infestation severities

Variables	Regression Beta Coefficient	P-value	Odds Ratio	95% confidence interval	
				Lower limit	Upper limit
Dimethicone*	1.46	0.002	4.30	1.26	10.42
Permethrin*	-0.239	0.561	0.787	0.352	1.63
Moderate**	-0.351	0.361	0.04	0.331	1.496
Severe**	-1.28	0.002	1.8	0.06	5.16

* Reference: vinegary treated group; ** Reference: mild infestation.

4- DISCUSSION

Despite the application of different chemical methods for the treatment of head lice infestation, the prevalence of pediculosis remains high in many countries due to the lack of efficacy of applied chemicals (18, 19). The reduced effectiveness of insecticides can be attributed to both louse resistance to active ingredients and/or inefficient dose delivery via applied formulation (20). Efficient formulations of pediculicides meant to produce effective control, retard resistance and enable easy application by households. Most of pediculicides are marketed in the form of lotions. Lotions have higher efficacy because of their longer contact time with scalp compared to shampoos, though the latter are preferred by many due to fast action and short exposure time. A number of studies have tackled evaluation of different formulations of lousicides, but with controversial results.

In this study, we meant to compare efficacy of three protocols recommended by local health centers to control pediculosis among schoolchildren in Mashhad city which witnessed increasing incidence of pediculosis since 2004 (21). We recorded cure rates for dimethicone equal to 86% and 74% at first and second endpoints respectively which is higher than 70 % obtained by Burgess et al for the same compound (22). As shown in Table.1, the cure rates of dimethicone were significantly higher than those of permethrin and vinegary wet combing both at the first and second endpoints. In this study, the treatments were set to be one week apart with two arbitrary endpoints of 14 days, which allowed plausible comparisons and reproducible results as appeared in some studies (23). Researchers found dimethicone to be more effective than permethrin in controlling head lice. Once, being effective in 97% of cases, permethrin lost efficacy down to 30% over two decades application from 1990 to

2010 (24). The loss of efficacy of Nix formulation (1% permethrin) from 1998 to 2013 was attributed to parallel increase of kdr-type mutations in head lice (25), although, some could not establish correlation between kdr-like gene and failure of permethrin (26). Burgess et al. compared pediculicidal activity of one application of 4% dimethicone gel with 2 applications of 1% permethrin cream and showed that dimethicone was 4.6 times more potent than permethrin both in controlled trials and household uses, suggesting permethrin withdrawal (27).

On the other hand, dimethicone is silicon oil that kills head lice by physical suffocation through blockage of the trachea outermost sections and stopping water excretion. This may result in gut rapture, permanent paralysis and death of head lice without eliciting resistance (28). The anti-resistance properties of dimethicone as well as its safety to human have enhanced its widespread use. Taking into consideration the non-toxicity, low cost price and unexpected resistant risk of dimethicone, Balçioğlu and Karakuş recommended its use as a successful lice protocol at public level (29).

Using 100 % dimethicone, Ihde et al. achieved 96.5 % lice free, and 80.7 % nit free subjects among treated school-age children after 14 days of treatment, suggesting dimethicone as a first-line treatment for head lice control (30). Despite the enthusiasm of using dimethicone for lice control, the excessive fluidity of lotion formulation and dripping off the active agent away from hair root remain an obvious setback, which may contribute to its reduced ovicidal activity reported by some researches (31, 32). Moreover, in this study, we recorded re-infestation rates equal to 6% and 16% at days 14 and 30 post application of 4% dimethicone (Table.1), given that 74% of subjects were less than 7 years old on their first infestation (Figure.1). Ferrara et al.

reported re-infestation rates equal to 5.3% at 7 days and 11.5% at 30 days using the same product (33). In fact, re-infestation remains an essential risk factor of pediculosis as revealed by many studies (34-36). Many studies found that children aged 10–11 years were mostly prone to pediculosis, as they have frequent head-to-head contacts (37, 38). Whereas, others reported that students ages 6 to 10 years old were the most infested of which 98.7 % were female (15). As shown in Figure.2, in total 78.6% of infested subjects of this study were females. In their meta-analysis of 40 studies carried out among about 200 thousand elementary schoolchildren in Iran, Moosazadeh et al. found that head lice infestation rate was 8.8%, and girls were 5.5 times more prone to pediculosis than boys are particularly among those of low socio-economic status (39).

In this study, permethrin and vinegary wet combing protocols has produced similar results including cured, re-infested and unchanged rates after 7, 14 and 30 days post application including. However, taking into consideration the results of Fisher tests for sexes and age categories (Figures 1-3), significant correlations with the variables was observed which indicate better performance of vinegary wet combing protocol over permethrin protocol. As shown, the majority of subjects undergoing vinegary wet combing protocol were girls of more than 7 years old living with families of more than 3 members which were more prone to sever infestation and re-infestation as compared with that undergoing permethrin protocol. Therefore, similar control results for these two protocols may be to some extent misleading if the relapse of pediculosis and its trend on recovery are not considered. In fact, many studies have proven the gender or sex specific prevalence of head lice in various communities (40, 41). One more thing, which needs to be considered, is the combing practice associated with all the

tested protocols that may play a significant role in the outcome of the treatment particularly in pediculosis relapse. Given the different physiochemical properties of tested lousicides, one may expected their different efficacy in nit removal which may reflect the inconsistency of results of both permethrin- and vinegar-treated group. Ortega-Insaurralde et al. found a significant egg removal activity using wet-combing compared with other lousicides (42). In our study, dimethicone showed a higher potency in controlling pediculosis over other tested lousicides producing stable results throughout all endpoints (Table.3). This was despite the significant difference in the frequencies of participants allocated to treatment group who differed in terms of gender and hair length (Table.2), although dimethicone group has more females of long hair than other two. Thus, we may recommend 4 % dimethicone as a successful lousicide.

5- CONCLUSION

Based on the results of this study, we recommend dimethicone (4%) as a safe and highly effective lousicide for pediatric head lice control. If applied correctly, dimethicone results in quick recovery from pediculosis and minimizes re-infestation.

6- CONFLICT OF INTEREST: None.

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