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ORIGINAL ARTICLE

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The authors declare that the data presented are original material and have not been previously published, accepted or considered for publication elsewhere; that the manuscript has been approved by all the authors, who have met the requirements for authorship.

## RANDOMIZED CONTROLLED TRIAL ON THE EFFECT OF COCONUT OIL, VINEGAR PLUS COOKING COCONUT OIL VERSUS 1% PERMETHRIN SHAMPOO IN THE TREATMENT OF PEDICULOSIS

### ABSTRACT

**Objective:** To determine the efficacy of cooking coconut oil and vinegar as compared to 1% Permethrin shampoo in the treatment of *Pediculus humanus capitis* in children 3 - 12 years old.

**Study design:** Single-blinded randomized controlled community trial

**Methodology:** The study was conducted in Barangay 704, Zone 77 in Malate among children 3 - 12 years old. Two hundred forty-five subjects were screened and the computed sample size was 150. Subjects were randomized to three treatment groups: coconut oil (CO) group; vinegar plus coconut oil (CV) group; and 1% permethrin shampoo (PS) group. Treatments were given on the 1<sup>st</sup> and 8<sup>th</sup> day. The final level of infestation was determined on the 14<sup>th</sup> day. Cure rates, failure rates, and expenses were also determined.

**Results:** Permethrin achieved superiority over plain coconut oil ( $X^2=18.77$  p-value = 0.00). There was no sufficient evidence to prove the superiority of permethrin over coconut-vinegar solution ( $X^2=1.04$  p-value = 0.30). Twenty-two percent (11) of the participants from the PS group developed itching and irritation. No adverse effect was reported from the CO and CV groups. Permethrin was 14 times and five times more expensive than coconut oil and vinegar plus coconut oil, respectively.

**Conclusion:** Permethrin shampoo had a cure rate of 98%. Plain coconut oil and vinegar plus coconut oil had cure rates of 68% and 94%, respectively. Plain coconut oil had the highest failure rate at 36%, vinegar plus coconut oil at 6%, and permethrin shampoo with 2%. Adverse effects were exclusive to the PS group. Plain coconut oil was the most economical but coconut oil with vinegar with its significant cure rate can be an alternative therapy to permethrin shampoo in the treatment of head lice in children.

### KEYWORDS:

*head lice, coconut oil, vinegar, permethrin, pediculosis*

## INTRODUCTION

Pediculosis is an ectoparasitic disease caused by an infestation of *Pediculus humanis capitis*. This ectoparasite inhabits the human scalp spending their entire life there being the only host. These parasites feed exclusively on blood every four to six hours a day<sup>1,2,3</sup>. Pediculosis is the third highest medical problem among school-aged children in the Philippines<sup>4</sup> following dental carries and impacted cerumen worldwide<sup>4,5</sup>. The infestation is both a social and public health problem among those aged 3 to 12 years.<sup>6</sup> The true prevalence of infestation is probably lower than the public and professional perception<sup>3</sup>. A local study done in Iloilo reported that the overall prevalence of pediculosis among schoolchildren was 85%; females were twice infected compared to males (66% vs 33%)<sup>7</sup>.

The hallmark of infestation is pruritus caused by sensitization taking place approximately after two to six weeks as an immune response to the antigen present in lice saliva. However, some individuals remain asymptomatic and never itch hence the infestation sometimes goes unnoticed and never gets appropriate treatment<sup>4</sup>. Head lice infestation does not constitute a serious public health problem although prolonged infestation may be related to iron deficiency and subsequent anemia<sup>4,5</sup>. Head lice infestation generates considerable anxiety and distress among parents and within schools, which is often due to myths and unjustified stigma. Health professionals have an important role in reducing the anxiety surrounding head lice infestation and in changing false perceptions about it<sup>6</sup>.

Several studies have proposed the use of over-the-counter treatments available in the market due to increasing incidence of Permethrin resistance that has been documented worldwide. Permethrin is widely available and is advertised as an effective treatment for head lice infestation. It has been

proven to have a cure rate of 80%– 90% but is reported to cause adverse reactions such as eye irritation and scalp itching<sup>8</sup>. Permethrin is quite expensive hence some parents opt to use a cheaper solution or not give treatment at all.

Traditional regimens are still used due to the belief that these are effective and more affordable<sup>2,9</sup>. One of the widely used home remedies for head lice treatment is coconut oil and vinegar. Coconut milk was found to have a cure rate of 90% in killing head lice<sup>5,8,10</sup>. Vinegar, on the other hand, was used as an adjunct and the main treatment solution for lice treatment in some studies and was reported to have a cure rate of 90%<sup>9,11</sup>. This study was conducted to provide trial based efficacy of coconut oil and vinegar plus coconut oil compared to 1% permethrin shampoo in the treatment of head lice among children aged 3 to 12 years.

## METHODOLOGY

### Study design

This was a single-blinded, randomized controlled community trial conducted among children aged 3 -12 years in July 2014.

### Study Population

Subjects were residents of Barangay 704, Zone 77 Malate Manila, an adopted community from the Bahay Bulilit Day Care Center. The participants and parents or guardians were interviewed. The subjects were selected based on the inclusion and exclusion criteria from the study conducted by Burgess IF, et al.

Included in the study were children and adolescents 3 to 12 years of age with head lice infestation based on the appearance of visible lice with the use of a nit comb and with a written signed informed consent. A participant is excluded in the study if he/she has any of the following: known sensitivity to coconut oil, vinegar or permethrin; recent use of hair bleach, permanent colorants or permanent waves; oral treatment with

trimethoprim or cotrimoxazole within the past 4 weeks; use of a pediculicide within the previous 2 weeks; presence of secondary scalp infection (e.g. impetigo); and those with chronic scalp conditions.

### **Sample Size Computation**

The sample size computed was 50 per group based on a 95% confidence level and 80% power to detect statistical significance at the assumed difference in magnitude of change in the level of infestation and cure rate. The assumption was based on the paper by Burgess IF, et al and Heukelback J, et al with an 82% cure rate in head lice infestation with coconut oil and 55% with permethrin.<sup>5</sup>

### **Study Procedure**

Baseline demographic data were obtained to describe the homogeneity of the participants. Eligible subjects eligible were randomized to three treatment groups by drawing lots. CO group was given coconut oil only. CV group was given vinegar and coconut oil. PS group was given permethrin shampoo. All the treatments were applied on days 1 and 8 of the study. Fifty subjects for each treatment were randomly allocated according to the treatment group to ensure equal distribution. The assistant investigator was in charge of the randomization and in keeping a record of the randomization list.

The chief investigator who was blinded to the group assignment evaluated the level of infestation on days 0, 1, 7 and 14 of the study and recorded adverse reactions as reported by the subjects, parents or guardians. Assessment of the level of infestation was done on days 0, 1, 8 and 14 using a nit comb. The subjects underwent final evaluation on day 14 of the study and were categorized as treatment success or failure.

The cure rate was determined for all treatment groups. The level of infestation was further determined in cases of treatment failure.

The secondary outcome measure is the presence of adverse effects. Parents, guardians and

the subjects were advised to look out for any possible side effects of the treatment such as eye irritation, scalp irritation, itching, and stinging sensation which were all contained in a checklist written both in Filipino and English. They were also instructed to immediately report any adverse reaction through SMS or phone call. The chief investigator likewise inquired for any adverse reactions.

The participants who were categorized as treatment failure in the CO and CV groups were given permethrin shampoo. The permethrin was administered twice at 7-9 days apart.

To prevent possible reinfection and cross infection among family members, those members who were more than 12 years old were given permethrin shampoo. The mothers and guardians were given instructions regarding household cleaning and hygiene.

### **Ethical consideration**

The research protocol was reviewed by the Research Officer and Consultants of the Department of Pediatrics of Ospital ng Maynila Medical Center. The protocol was presented and had been approved by the Hospital Research and Ethics Committee prior to its implementation.

The parents/guardians and subjects were given complete information on nature, purpose, procedures, possible risks, and benefits of the study. Written informed consent/assent was secured from all parents or guardians and subjects.

### **Treatments and Administration**

The three intervention drugs were packed in individual plastic containers for ease of administration per patient. Coconut oil and vinegar were packed in 10 ml plastic containers and permethrin shampoo was packed in a 10 ml sachet. A second container was used for patients with long, thick or curly hair to ensure full coverage of the hair. The coconut oil used in the study was manufactured by Novatech Agri-food Industries,

SM Corporation. The vinegar used was also from the same manufacturer. Permethrin shampoo was manufactured by GlaxoSmithKline.

Subjects assigned to treatment CO used coconut oil. The coconut oil was applied to dry hair with no prior washing. The oil was applied to the entire hair length ensuring full coverage. Each subject was given shower caps. Eight hours post application, the hair was rinsed with shampoo and water with no conditioner. Coconut oil was reapplied on day 8 of the study.

Subjects assigned to treatment CV used coconut oil and vinegar. Ample amount (10ml) of vinegar was initially applied to the entire hair length and allowed to dry for five minutes. Coconut oil was then applied thoroughly and was left for eight hours with shower caps on, then rinsed with shampoo and water. The application of vinegar plus coconut oil was repeated on day 8 of the study.

Subjects in the treatment group PS were given permethrin shampoo. The application was based on the manufacturer's recommendation. Permethrin was applied to the entire hair length, left for five minutes and rinsed thoroughly with water. The application was repeated on day 8 of the study. The hair was then rinsed with shampoo and water. Each subject was provided with an individual nit comb, shampoo, towels and shower caps.

### Method of Blinding

This is a single-blinded or assessor-blinded study. The assignment of intervention for each subject was unknown to the primary investigator who was in charge in the assessment of the level of infestation and determination of cure rates throughout the 14 days study duration. The nature of the treatment could not be blinded to the physical and chemical nature of the study drug.

### Definition of Terms

**a. Hair Length** was classified as:

- 

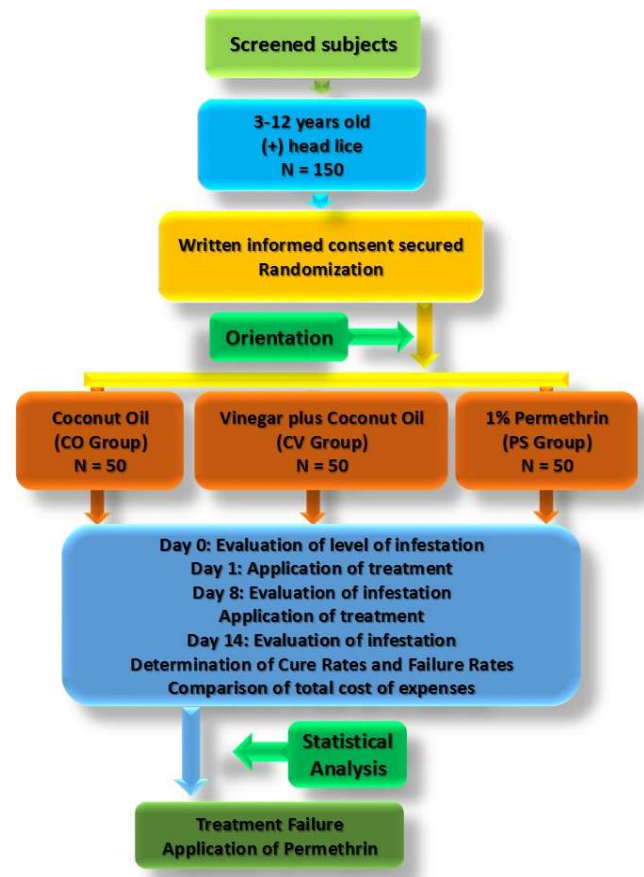


Figure 1: Diagram of the study procedure

- Close-cropped - hair is less than 5 cms from the crown
- Above the ears - hair is more than or equal to 5 cms from the crown and above the ears
- Above the shoulders - hair is measured from the crown and above the shoulders
- Below the shoulders - hair is measured from the crown up to or below the shoulders

**b. Hair Thickness** was classified based on the F.I.A. hair typing system (Third Classifier) determined by measuring the circumference of the hair after being tied in a ponytail.

- Fine - hair circumference of less than 5 cms
- Average - hair circumference of more than or equal to 5 cms but less than 10 cms



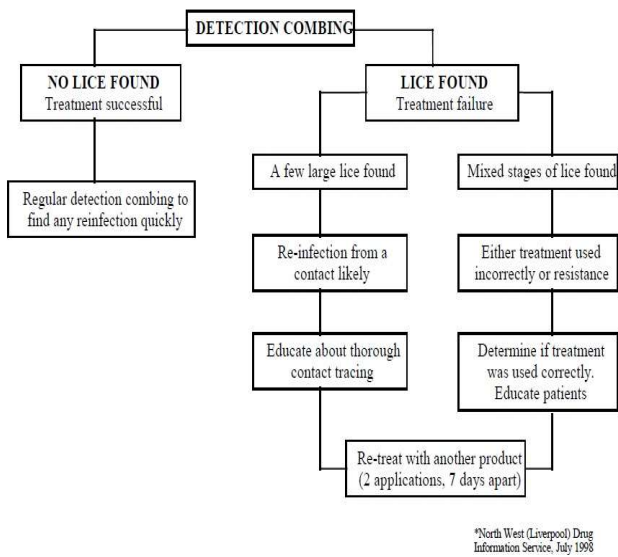


Fig. 2: Procedure for detection combing during screening and evaluation of the level of infestation

- Thick - hair circumference of more than or equal to 10 cms

**c. Dryness/Oiliness of Hair** is classified as:

Dry hair is described as dull and coarse  
 Normal hair is described as soft and shiny  
 Oily hair is described as clumped and oily to touch

**d. Nature of Hair** is classified using Andre Walker hair typing system.

- Straight hair (Type 1) - straight strand but may have 1 visible S wave when at the level of the neck or nape
- Wavy hair (Type 2) - strand of hair with loose, stretched out S-waves throughout the hair; it lies somewhere between straight and curly hair
- Curly hair (Type 3) - strand of hair with definite S shape or it may even resemble a Z on some occasions

**e. Level of Infestation** was classified based on the study of Burgess et al.

- Heavy Infestation - more than one louse in a single stroke of a nit comb

- Medium Infestation - one louse in a single stroke of a nit comb
- Light Infestation - one louse after four strokes of a nit comb
- No infestation/Cure - absence of louse after repeated strokes of a nit comb

**f. Cure Rate** – defined as the percentage of the reduction in the number of the nits after Day 14 of treatment. No louse found after day 14 of treatment.

**g. Failure rate** – defined as the percentage of the remaining number of nits after Day 14 of treatment. With louse found after day 14 of treatment.

**Statistical Analysis**

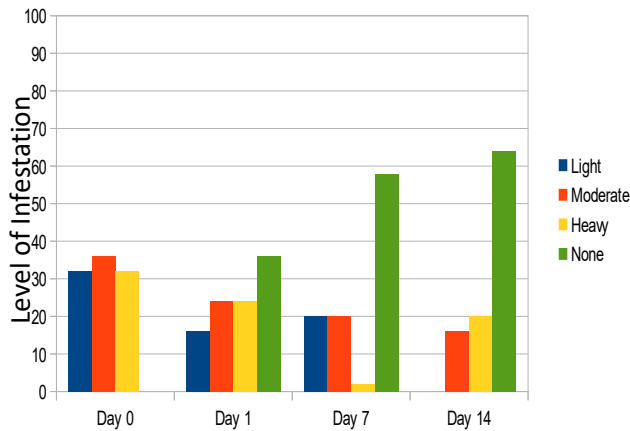
Epi Info Stat Calc was used to compute the sample size needed for assuming the difference in the magnitude of change in the level of infestation and cure rate. The confidence interval was set at 95% with the power to detect association set at 80% and the prevalence of the exposed at 62%. The minimum sample size computed was 49. EPI Info 7 Software was used to analyze the data. In order to detect differences in three means, the F-test was computed. Chi-square test of homogeneity was computed to check for the differences in proportions between the groups.

**RESULTS**

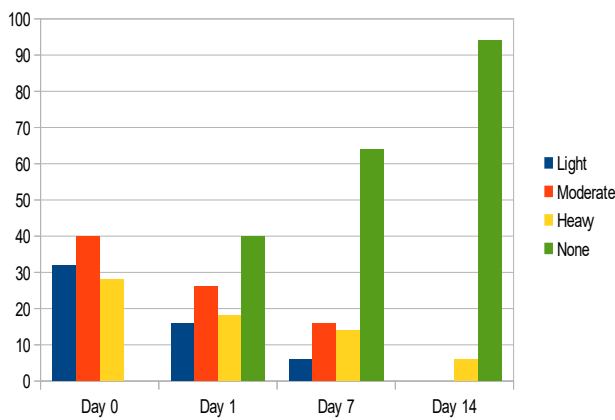
One hundred fifty participants were randomly allocated to 3 groups, CO (coconut oil), CV (coconut oil plus vinegar) and PS (permethrin solution). Table 1 shows the socio-demographic characteristics of the study population. It was found out that the age was not statistically different between groups. Hence, homogeneity or similarities in the age distribution were noted among the groups. The majority of the participants were females. With regards to hair length, there is no significant difference (p-value 0.9083) between the groups. It was also found out that hair thickness and oiliness and dryness are statistically significant.

Figure 3 shows the magnitude of change in the level of infestation of head lice using the three treatment solutions.

Figure 4 shows the trend in the magnitude of lice infestation using the combination of vinegar plus coconut oil. Compared with the previous group, this group achieved a faster decrease in infestation as early as day1.



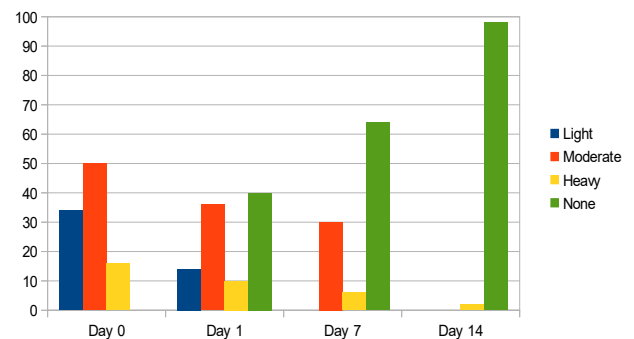
**Fig. 3.** Magnitude of Change in the Level of Infestation of Head Lice using Coconut oil



**Fig 4.** Magnitude of Change in the Level of Infestation of Head Lice using Coconut oil with Vinegar treatment

**Table 1.** Sociodemographic and Characteristics of the Study Population (p-value 0.05)

	CO	CV	PS	p-value
AGE (mean±SD)	9.2±2.32	8.2±2.84	8.54±2.86	0.18
SEX				
Male	9 (18%)	1 (2%)	1 (2%)	0.0019
Female	41 (82%)	49 (98%)	49 (98%)	
HAIR LENGTH				
Close	9 (18%)	12 (24%)	10 (20%)	0.9083
Cropped				
Above	11 (22%)	11 (22%)	12 (24%)	
Ears				
Above	18 (36%)	12 (24%)	14 (28%)	
Shoulder				
Below	12 (24%)	15 (30%)	14 (28%)	
Shoulder				
HAIR THICKNESS				
Fine	13 (26%)	15 (30%)	10(20%)	0.0016
Average	28(56%)	16 (32%)	35(70%)	
Thick	9(18%)	19(38%)	5(10%)	
DRYNESS and OILYNESS				
Dry	8(16%)	13(26%)	15(30%)	0.0404
Normal	32(64%)	19(38%)	18(36%)	
Oily	10(20%)	18(36%)	17(34%)	
NATURE OF HAIR				
Straight	17(34%)	16(32%)	17(34%)	0.861400
Wavy	19(38%)	20(40%)	23(46%)	
Curly	14(28%)	14(28%)	10(20%)	
HISTORY OF PERMETHRIN USE				
Present	1(2%)	0	0	0.3624
Absent	49(98%)	50(100%)	50(100%)	



**Fig 5.** Magnitude of Change in the Level of Infestation of Head Lice using Permethrin Shampoo treatment

Figure 5 also shows that as early as day 1 there was a decrease in head lice infestation. However, this group achieved about 98% decrease at the end of day 14.

**Table 2. Differences in the Cure Rate among the three treatment groups**

Treatment Group	Cure Rate	p-value
CO	64.00%	0.02
CV	94.00%	0.00
PS	98.00%	0.00

P-value (0.05)

**Table 3. Differences in the Failure Rate among the three treatment groups**

Treatment Group	Failure Rate	p-value
CO	36.00%	0.02
CV	6.00%	0.00
PS	2.00%	0.00

P-value (0.05)

**Table 4. Adverse Effects among the three treatment groups**

Adverse Effects	CO	CV	PS
Scalp Irritation	0	0	0
Eye Irritation	0	0	8 (16%)
Itching	0	0	3 (6%)
Others	0	0	0
TOTAL	0	0	11 (22%)

Table 2 shows the differences in the cure rates among the three treatment groups. All groups have statistically significant cure rates with p values less than 0.05. Chi-square test was used to compute the differences in the efficacy of the three treatment groups. It was found that there were significant differences in the cure rate and failure

rate among the three groups ( $X^2=27.60$  pvalue=0.0000001). Furthermore, the CO and CV groups were then compared with the PS group wherein Permethrin was considered as the standard treatment for lice infestation. Between the Permethrin and coconut oil group, it was found that permethrin was still more superior to coconut oil ( $X^2=18.77$  pvalue=0.0001). However, between permethrin and vinegar followed by coconut oil group, there was no sufficient evidence to say that permethrin was more superior between the two ( $X^2=1.04$  p value=0.3078). Further studies must be done to ascertain the comparable efficacy of the combination of vinegar and coconut with permethrin solution.

Treatment options should include the safety index of the drugs. This study looked into the adverse effects which arose from the three treatment groups. It was found that 11 participants (22%) among the 50 participants in the PS group developed eye irritation and itching. No adverse effect was observed from the CO and CV groups.

In accounting for the expenses per treatment group during the treatment period, it was found out that PS is 14x more expensive than coconut oil alone and 5x more expensive than coconut-vinegar treatment.

**Table 5. Differences in the cost per treatment group**

Treatment Groups	Cost
CO	Php296
CV	Php740
PS	Php4000

## DISCUSSION

The present study showed that permethrin shampoo gave the highest cure rate of 98%. Vinegar plus coconut oil and plain coconut oil only had 94% and 68% cure rates respectively. The statistical analysis showed a significant difference in the cure rate among the three treatment groups,



p-value 0.00001. This showed that Permethrin shampoo is more effective in the treatment of head lice compared to coconut oil alone and the ones combined with vinegar. This may also suggest that vinegar had a synergistic effect with coconut oil in the treatment of head lice. However, only a few study has proven the efficacy of vinegar in the treatment of head lice.<sup>11</sup>

Further comparative analysis of cure rates based on hair thickness and oiliness or dryness of the three treatment groups showed statistical significance (p-value <0.05).

A successful suffocation can only be achieved by blocking 100% of the louse's spiracles, as well as the entirety of its cuticle.<sup>2</sup> In previous studies done in developed countries, permethrin resistance has been reported as a result of the recurrent use of the drug. This may have caused the lower cure rates in permethrin compared to the alternative treatments studied. In the present study, only one out of the one hundred eighty subjects had previous treatment with permethrin.

Well established treatment options for proven head lice infestations include topical insecticides such as 1% permethrin which is 100% ovicidal; however, increasing resistance to this treatment were reported. Though with little evidence, wet combing was mentioned as part of the primary treatment. Other treatments include household products such as coconut or olive oil, petroleum, alcohol, and vinegar with approximately 50% effectiveness<sup>4,6</sup>.

A randomized controlled community trial conducted by Ramiro, et. al in 2013 investigated the efficacy of virgin coconut oil, 70% isopropyl alcohol and virgin coconut oil against permethrin shampoo in a daycare center in Caloocan City.<sup>4</sup> A total of 180 children aged 2 – 19 years were included in the study. The final evaluation was done on day 14 after two applications of the medications with an interval of 9 days. Permethrin had a 57.1% cure rate while virgin coconut oil had

a 34.5% cure rate, and the 70% isopropyl alcohol plus virgin coconut oil had a 36% cure rate. Permethrin in this study proved its efficacy over the two medications using a p-value of 0.026. In the same study, the cure rate of virgin coconut oil and isopropyl alcohol followed by virgin coconut oil was not statistically significant (p-value = 0.854). The comparative cost analysis of the three treatment groups per individual showed that virgin coconut oil is more economical as compared to permethrin shampoo (p-value <0.0001).

A local study by Matos et al in 2012 in vitro assays determined the effective concentration of coconut-vinegar concoction (CVC). The effective dosage was 60 ml applied for 30 minutes twice a week.<sup>8</sup> Thirty-two participants, 3-14 years old with moderate to severe head lice infestation were randomly allocated to receive either Permethrin or CVC. Permethrin and CVC did not differ in their ability to kill the various stages of lice. On the second week, the cure rate of CVC was 99% and Permethrin was 100% (p-value=0.07). No adverse reaction was noted. There was a 72% decreased the cost of CVC use for two weeks compared to permethrin.

The use of coconut oil for the treatment of *Pediculus humanus capitis* has been a practice in the Philippines. However, evidence of its effect in the treatment of head lice remains to be determined. According to local and international studies, coconut oil has the ability to suffocate the head lice by occluding the air channels located throughout their bodies. When louse is threatened with suffocation, they use spiracles to occlude air tunnels without suffocation and can survive for prolonged periods without air. In addition, lice have a pressure mechanism that allows them to open blocked spiracles.<sup>6</sup>

The use of shower caps as suffocation could have contributed to the outcome of this study. This was similar to the study done by Bogayong in 2010.

The study determined the percent reduction in the prevalence after treatment using a dry-on, suffocation-based pediculicide (Cetaphil). An overall prevalence of pediculosis was 85%, and significantly twice in females (66%) compared to males (33%) (p-value 0.010). A decrease in the prevalence of pediculosis was achieved after the first week (44%) and last week (0.03%). The overall cure rate was 97.2%. The study showed no topical or systemic adverse reactions to the treatment modality. This study concluded that the dry-on, suffocation based-pediculicide is effective in reducing the high prevalence rate of pediculosis in the study area. However, it was suggested that a control group be included<sup>7</sup>.

The result of the study also showed that despite treatment failure, there was a significant difference in the level of infestation from day 0 and day 14 in the three treatment groups (p-value <0.0001). An implication of this could be that coconut oil may have a pediculicide activity. However, the frequency of application or the number of the doses applied may be inadequate to render complete eradication of the head lice. Several studies mentioned that a pediculicide requires three treatment applications, on days 0, 7 and anytime between 13 to 15 days. The rationale is that on day 0, all lice would be killed, leaving only newly laid eggs and eggs just about to hatch. The treatment application on day 7 would kill those eggs that were hatched. What would remain are those eggs that are 7 days old but did not hatch. The therapy anytime between 13 and 15 days would kill the nymphs from those eggs, precluding development of the egg-laying adult. In using the average, rather than the extreme, values for egg hatch (8.5 days) and maturation time (9.7 days) lower the demand for treatment by a solely pediculicidal agent to days 0 and 7.<sup>10</sup>

In 2004, Takano-Lee et al examined six home remedies including vinegar, isopropyl alcohol, olive oil, mayonnaise, melted butter, petroleum jelly,

and water immersion in an attempt to drown lice.<sup>9</sup> This study investigated the effect of home remedy treatment on live lice and on egg viability and the likelihood of drowning lice by prolonged water submersion. The results showed that only the application of petroleum jelly caused significant louse mortality (p-value <0.05). None of the treatment tested prevented lice from laying eggs. The study concluded that the only good options for treating lice are pesticides and manual removal.

Eleven participants (22%) from the permethrin group reported adverse reactions such as eye irritation and scalp itching. Despite the high cure rate of permethrin shampoo at 98%, it is noteworthy that its use may pose several unwanted reactions. This may be the edge of the other groups over permethrin having no report of any adverse reactions.

The cost analysis of the three treatment groups within the two week period showed that the use of coconut oil (even with vinegar) is more economical as compared to permethrin shampoo.

## CONCLUSION

Permethrin shampoo gave the highest cure rate of 98%. Plain coconut oil and vinegar followed by coconut oil had cure rates of 68% and 94%, respectively. The statistical analysis showed a significant difference in the cure rate among the three treatment groups. Plain coconut oil showed the highest failure rate of 36%, virgin coconut oil at 6%, and permethrin shampoo at 2%. Adverse effects were noted exclusively among subjects in the permethrin group.

Coconut oil with vinegar with its significant cure rate can be an alternative therapy to permethrin shampoo to treat head lice in children.

## RECOMMENDATIONS

It is recommended to conduct further researches using a bigger sample size to validate

the result of the present study. Researchers are encouraged to come up with different study methods to determine the appropriate duration and frequency of treatment application with the highest cure rate. Furthermore, the conduct of efficacy studies on other alternative remedies for pediculosis is encouraged.

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