Head Lice Infestation: Single Drug Versus Combination Therapy With One Percent Permethrin and Trimethoprim/Sulfamethoxazole

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ABSTRACT. Background. Head lice infestation (HLI) is a vexing problem for pediatricians and families because lice are becoming resistant to approved antipediculosis agents.

Objective. This study compared the efficacy of 3 different treatments for HLI and determined whether combination therapy reduced treatment failures.

Design and Setting. A randomized, clinical trial performed in 3 private practices.

Participants. The population was children ranging in age from 2 to 13 years.

Methods. HLI was diagnosed by direct inspection of the hair and scalp. Children were assigned to 1 of 3 groups: 1) 1% permethrin creme rinse (1% PER; n = 39); 2) oral administration of trimethoprim/sulfamethoxazole (TMP/SMX; n = 36); and 3) a combination of 1% PER and TMP/SMX (n = 40). Follow-up visits were done 2 and 4 weeks later, and parents or caregivers of those who did not return were interviewed by telephone. If HLI was present at the 2-week follow-up, the child was retreated per their protocol. We defined successful treatment as the absence of adult lice and nymphal stage or eggs (nits). The presence of nits alone was not considered a treatment failure.

Results. At the 2-week follow-up visit, successful treatment for groups 1, 2, and 3 was 79.5%, 83%, and 95%, respectively. At the 4-week follow-up, successful treatment was 72%, 78%, and 92.5% for groups 1, 2, and 3, respectively. The absolute risk reduction for recurrence comparing group 1 versus group 2 was 6%, group 2 versus group 3 was 14%, and group 1 versus group 3 was 20%. No major adverse complications were seen in any treatment group.

Conclusion. Our findings indicate that a combination of 1% PER and TMP/SMX is an effective alternative therapy for HLI. We recommend that the dual therapy with 1% PER and oral TMP/SMX be used and reserved in cases of multiple treatment failures or suspected cases of lice-related resistance to therapy. Pediatrics 2001;107(3). URL: http://www.pediatrics.org/cgi/content/full/107/3/e30; lice, Pediculus humanus var capitis, trimethoprim/sulfamethoxazole, resistance, permethrin.

ABBREVIATIONS. HLI, head lice infestation; PPB, pyrethrins with piperonyl butoxide; 1% PER, 1% permethrin creme rinse; TMP/SMX, trimethoprim/sulfamethoxazole.

Head lice infestation (HLI) caused by Pediculus humanus var capitis is a worldwide public health concern that affects mostly school-aged children. In the United States, ~6 to 12 million persons are infested with head lice, with an estimated $100 million being spent annually on treatment. HLI does not produce an illness, but it is physically unpleasant and bears a significant negative social stigma. Historically, permethrin creme rinse has been the drug of choice in treating pediculosis because of its long-lasting residual effect, which may be useful in killing nymphs. However, resistance to permethrin as well as other antipediculosis agents, including pyrethrins with piperonyl butoxide (PPB) and lindane, has recently been reported. Pediatricians and other pediatric health care workers are now faced with finding new strategies to combat drug resistance associated with HLI. In other countries, clinicians have found rotational therapy with different agents a useful approach. The rotation of therapeutic agents may slow the emergence of resistance, although this has yet to be proven.

Other methods to treat HLI include applying a heavy layer of petroleum jelly, olive oil, or mayonnaise to the scalp and covering the scalp overnight with a shower cap. This method reportedly kills lice through asphyxiation, immobilization, and/or an inability to feed. Head shaving is also used to treat HLI. This treatment is effective for male children but is not socially acceptable for the female population in which the majority of HLI occurs. Of particular concern is that parents and caretakers may use unsafe and dangerous methods, such as kerosene, alcohol, insecticides, and other toxic chemicals to treat HLI.

Three agents are currently approved by the US Food and Drug Administration for the treatment of HLI: lindane (Kwell, Jersey City, NJ), PPB (RID, Pronto, A-200, and others), and 1% permethrin creme rinse (1% PER; Nix, Research Triangle Park, NC). Because treatment resistance has become a primary concern for clinicians, they are beginning to use experimental treatments, such as trimethoprim/sulfamethoxazole (TMP/SMX), 5% permethrin (5% PER; Elimite, Irvine, CA), malathion, ivermectin, and car-
baryl to control HLI.\textsuperscript{4,13–15} Of these agents, TMP/SMX is a more commonly used medication in the pediatric population. Parents are more familiar with TMP/SMX compared with 5\% PER, malathion, ivermectin, or carbaryl.

Although TMP/SMX is unpopular in treating HLI because of its potential side effects, it is an emerging practice among clinicians to treat HLI with a combination of 1\% PER and oral TMP/SMX. To the best of our knowledge, no one has reported the therapeutic efficacy of combining the 2 medications in the treatment of HLI, especially when patients have experienced recent treatment failures or when lice-related resistance is suspected. The purpose of this study was to compare the efficacy of using single therapy (1\% PER or oral TMP/SMX alone) versus combination therapy with 1\% PER and oral TMP/SMX in treating \textit{P. humanis var capitatis} infestation. This approach might represent a better and safer alternative for treating HLI when treatment failure has occurred or lice-related resistance is suspected.

**METHODS**

**Population, Enrollment, and Assignment**

The study was conducted between July 1996 and December 1999 in San Joaquin County, California. The study sites were 3 private pediatric and family practices. The sample population was comprised of children ranging from 2 to 13 years old who were diagnosed with HLI in the physicians’ offices. The diagnosis of HLI was confirmed by clinical inspection of scalp and hair for the presence of adult lice, nymphal stage, or eggs (nits). Inclusion criteria for the study included a positive diagnosis of HLI by visual inspection and informed consent from the parents or caregivers that they understood the study design and were willing to participate. Exclusion criteria for the study included a hypersensitivity to TMP/SMX, a hypersensitivity to 1\% PER, and/or a history of parental noncompliance or neglect.

Demographic data including age, race, sex, and childcare attendance were obtained for all participants. A history of previous HLI was obtained from medical records and parental anecdotes. All children who met the inclusive criteria and whose caregivers gave informed consent were enrolled in the study. Children were randomly assigned to 1 of 3 groups. Participants assigned to group 1 received 1\% PER for 10 minutes over hair and scalp (per manufacturer’s instruction), with a repeat application after 1 week if necessary. Participants assigned to group 2 were prescribed oral TMP/SMX suspension 10 mg/kg/day based on TMP in 2 divided doses for 10 days. Participants assigned to group 3 were treated with a combination of 1\% PER and TMP/SMX as described for groups 1 and 2.

During the visual inspection of lice, parents were educated on how to recognize different stages of lice (adult lice, nymphal stage, or eggs/nits). Photographs of different stages of lice were also shown. Parents of all participants were given information on recognition of HLI and methods to prevent reinfection (cleaning of the home, bedding, and personal hygiene items; treatment of other family members; and other precautions to prevent reinfection).

**Drug Administration and Compliance**

**Group 1**

Participants were given 1\% PER as described by manufacturer’s insert package. In brief, the parents were instructed to wash their child’s hair with regular shampoo and then rinse clean, shake the bottle of 1\% PER, and apply the creme rinse to the scalp and hair for 10 minutes. Thereafter, the hair was rinsed with water and was towel dried. Nits were removed using the comb provided with the 1\% PER. Parents or caretakers were asked to comb participant’s hair as many strokes as they can after using the medication. The procedure was repeated after 1 week if HLI was still evident.

**Group 2**

Participants were given oral TMP/SMX (suspension or tablet) at a dosage of 10 mg/kg/day based on TMP for 10 days in 2 divided doses. Children who were able to swallow tablets were prescribed 1 tablet twice daily or 1 double strength tablet twice daily for 10 days depending on their weight. Parents or caretakers were instructed to use a regular shampoo. Nits were removed using a lice meister, and if not available, we recommended using a very fine toothed comb. Parents or caretakers were asked to comb the participant’s hair as many strokes as they could during the course of the treatment.

**Group 3**

Participants were prescribed both 1\% PER and TMP/SMX as same protocol outlined above. Nits were removed using a comb provided by 1\% PER. Parents or caretakers were asked to comb the participant’s hair as many strokes as they could during the course of the treatment.

**Follow-up Observations and Subsequent Treatment**

Children were reexamined at 2 and 4 weeks after treatment for HLI. A pediatrician or family practice physician performed examinations of scalp and hair. We defined treatment failures as the presence of adult lice, nymphal stage, or eggs (nits) and not just the presence of nits alone. On follow-up visits, we used a magnifying glass to identify a true viable egg with an empty egg casing to confirm HLI. If the child at 2 weeks still had HLI, the participants were retreated. The protocol for retreatment was as follows: group 1: reapplication of 1\% PER; group 2: another course of oral TMP/SMX suspension; and group 3: another course of 1\% PER and oral TMP/SMX suspension. The participants were then evaluated 4 weeks after the initial diagnosis. If the participants did not return for their follow-up visit, telephone interviews with the parents or caregivers were used for deciding outcome.

A retrospective review of charts on all the participants who had their follow-up by telephone interviews in both first and second follow-up was performed at least 6 months after the enrollment. The review involved recording any repeat office visit(s) attributable to HLI.

**Statistics**

The sample size was estimated based on the recommendations of Cohen.\textsuperscript{16} Using an \( \alpha \) of 0.05, a power of 0.80, and an effect size of 0.50, a minimum of 39 participants were necessary for each group.

Statistical analysis of results was performed using the Fisher’s exact test and Student’s \( t \) test as was appropriate.\textsuperscript{17} Absolute risk reduction was calculated to compare the efficacy of treatment between groups.

**RESULTS**

**Population Characteristics**

Over a 3-year period from July 1996 to December 1999, 115 children were entered into the study. There were a total of 125 participants recruited with HLI, but 10 participants were excluded. Seven participants with HLI were not entered into the study because of previous hypersensitivity to TMP/SMX (\( n = 2 \)), hypersensitivity to 1\% PER (\( n = 2 \)), and a parental history of noncompliance/neglect (\( n = 3 \)). Three participants were removed from the study because of rash caused by TMP/SMX. The attrition rate was 2\%.

Demographic characteristics of the participants are shown in Table 1. Analysis of the demographic data among the 3 treatment groups revealed no differences. In all groups, \( \sim 53\% \) of the children were be-
tween the ages of 6 and 10 years. The predominant gender was female (female 70% and male 30%). The predominant ethnicity was Hispanic (48.7%).

Treatment Groups
At 2 weeks after therapy began, HLI was still present in 16 participants (Fig 1). The success rate of treatment for groups 1, 2, and 3 was 79.5%, 83%, and 95%, respectively. After 4 weeks of therapy, failures were present in 22 participants (Fig 1). The success rate for treatment at the 4-week follow-up for groups 1, 2, and 3 was 72%, 78%, and 92.5%, respectively.

Table 2 shows the calculation of the absolute risk reduction comparing the efficacy of treatment among groups. Treatment with 1% PER and TMP/SMX was more likely to prevent recurrence of HLI.

Follow-Up Observations and Subsequent Treatment
Table 3 shows the numbers of office visits versus telephone interviews that were required at the first and second follow-up visits. All treatment failures in groups 1, 2, and 3 showed up for their follow-up office visits.

Group 1
At first follow-up, 8 participants were retreated with 1% PER. At the second follow-up, there were 11 treatment failures. Of 8 treatment failures in the first follow-up, 4 participants needed another course of treatment, while 4 participants were free of lice both adult and nymphal stage or eggs (nits). Seven par-

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**TABLE 1. Demographic Characteristics of the Study Population With Head Lice Infestation**

<table>
<thead>
<tr>
<th>Treatment Groups</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1% PER</td>
<td>TMP/SMX</td>
<td>1% PER +</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(n = 39)</td>
<td>(n = 36)</td>
<td>TMP/SMX</td>
<td>(n = 40)</td>
</tr>
<tr>
<td><strong>n (%)</strong></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Age (y)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2–5</td>
<td>10 (26)</td>
<td>9 (25)</td>
<td>10 (25)</td>
<td>29 (25)</td>
</tr>
<tr>
<td>6–10</td>
<td>20 (51)</td>
<td>21 (58)</td>
<td>22 (55)</td>
<td>63 (55)</td>
</tr>
<tr>
<td>11–13</td>
<td>9 (23)</td>
<td>6 (17)</td>
<td>8 (20)</td>
<td>23 (20)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>10 (26)</td>
<td>10 (28)</td>
<td>9 (22.5)</td>
<td>29 (25)</td>
</tr>
<tr>
<td>Black</td>
<td>5 (13)</td>
<td>4 (11)</td>
<td>5 (12.5)</td>
<td>14 (12)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>15 (38)</td>
<td>20 (55.5)</td>
<td>21 (52.5)</td>
<td>56 (49)</td>
</tr>
<tr>
<td>Asian</td>
<td>9 (23)</td>
<td>2 (5.5)</td>
<td>5 (12.5)</td>
<td>16 (14)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13 (33)</td>
<td>11 (31)</td>
<td>10 (25)</td>
<td>34 (30)</td>
</tr>
<tr>
<td>Female</td>
<td>26 (67)</td>
<td>25 (69)</td>
<td>30 (75)</td>
<td>81 (70)</td>
</tr>
<tr>
<td>Previous history of HLI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15 (33)</td>
<td>12 (33)</td>
<td>14 (35)</td>
<td>41 (36)</td>
</tr>
<tr>
<td>No</td>
<td>24 (61.5)</td>
<td>24 (67)</td>
<td>26 (65)</td>
<td>74 (64)</td>
</tr>
</tbody>
</table>

**TABLE 2. ARR* Shows the Efficacy of Treatment Among the Groups**

<table>
<thead>
<tr>
<th>Groups</th>
<th>ARR (%)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 vs 2</td>
<td>6</td>
<td>.74</td>
</tr>
<tr>
<td>Group 2 vs 3</td>
<td>14</td>
<td>.14</td>
</tr>
<tr>
<td>Group 1 vs 3</td>
<td>20</td>
<td>.03†</td>
</tr>
</tbody>
</table>

ARR indicates absolute risk reduction.  
* Fisher’s exact test = P value.  
† Statistically significant.

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**TABLE 3. Numbers of Enrolled Participants Who Kept Appointed Follow-Up Visits at Two or Four Weeks After Treatment Began or Required Telephone Follow-Up Interviews to Determine Outcome**

<table>
<thead>
<tr>
<th></th>
<th>First Follow-Up</th>
<th>Second Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Office Visits</td>
<td>Telephone Interviews</td>
</tr>
<tr>
<td>Group 1 (n = 39)</td>
<td>23 (58%)</td>
<td>16 (42%)</td>
</tr>
<tr>
<td>Group 2 (n = 36)</td>
<td>25 (69%)</td>
<td>11 (31%)</td>
</tr>
<tr>
<td>Group 3 (n = 40)</td>
<td>16 (40%)</td>
<td>24 (60%)</td>
</tr>
</tbody>
</table>

Fig 1. Relationship between the number of enrolled patients and the number of treatment failures at the first (2-week) and second (4-week) follow-up appointments. Group 1 = 1% PER; group 2 = oral administration of TMP/SMX (10 mg/kg/day divided into twice-daily dosing); and group 3 = combined 1% PER and TMP/SMX.
participants on second follow-up were new treatment failures and needed to be retreated again.

**Group 2**

At the first follow-up, 6 participants were retreated with TMP/SMX. At the second follow-up, there were 8 treatment failures. Of 6 participants retreated in the first follow-up, 3 participants needed another course of treatment, while 3 participants were free of lice both adult and nymphal stage or eggs (nits). Five participants on second follow-up were treatment failures and needed to be retreated again. Group 2 had a better posttreatment follow-up than group 1 (Table 3), and we attributed this to the fact that group 2 protocol is new to the parents or caretakers.

**Group 3**

At the first follow-up, 2 participants were retreated with 1% PER and TMP/SMX. At the second follow-up, all of the participants retreated at first follow-up were free of lice both adult and nymphal stage or eggs (nits), while 3 participants were new treatment failures and needed to be retreated again. Group 3 had more telephone interviews that were used for follow-up (Table 3), and we attributed this to the fact that combination therapy had a greater success rate for treatment.

A retrospective review of charts on all the participants who underwent telephone interviews for decisioning outcomes in group 1, 2, and 3 during first and second follow-up revealed that there were no office visits attributable to HLI in a span of at least >6 months. This signifies that HLI was treated adequately.

**Adverse Reactions**

Of 115 participants, 8 had minor adverse reactions to the treatment. Three participants had mild scalp irritation after a 10-minute application of 1% PER. Five participants had nausea, vomiting, and/or minor rash from oral TMP/SMX. One quarter of participants (n = 9) in group 2 developed intense pruritus after 3 to 4 days of treatment, but the treatment was continued because the pruritus disappeared within 1 to 3 hours. Two participants in group 2 and 1 participant in group 3 were removed from the study because of an allergic-appearing rash caused by TMP/SMX. Participants who developed nausea and vomiting (n = 3) on TMP/SMX were not excluded from the study because the symptoms were transient. Participants who developed mild scalp irritation related to 1% PER were also not excluded from the study. No major side effects of TMP/SMX—such as Stevens-Johnson syndrome; erythema multiforme; and clinical signs and symptoms of megaloblastic anemia, hemolytic anemia, neutropenia, and renal impairment—were observed.

**DISCUSSION**

Treatment of *P humanis var capitis* infestation has been a long-term problem for clinicians and parents. The management is complicated by increasing resistance to the presently approved antipediculosis agents. Drug resistance has also increased the risk of infestation among family members. HLI inflicts a negative social stigma on the children and their parents or caretakers. Because of parental and caretaker’s frustration with resistant head lice, dangerous methods of treating HLI (use of kerosene, insecticides, gasoline, and head shaving) may be used. In this trial, combination therapy had less recurrences of HLI compared with treatment with either 1% PER or TMP/SMX alone. This study suggests an alternative therapy in the management of HLI where treatment failure or suspected lice-related resistance exists.

The mechanism by which permethrin and TMP/SMX kills lice differs from each other. Permethrin is a synthetic compound derived from pyrethrin and acts on the nerve cell membranes of the parasites causing disruption of the sodium channel, delayed nerve repolarization, and paralysis of exoskeletal muscles. This inhibits respiration and the lice succumb. By comparison, TMP/SMX applies the principle of a symbiotic relationship. According to Burns, TMP/SMX kills lice by inhibiting their intestinal flora. When lice suck the blood of treated patients, they ingest TMP/SMX. The TMP/SMX kills the bacterial flora in the gut that synthesize B vitamins. Lice lose their ability to obtain B vitamins and die as a result. Other antibiotics can also be used in the treatment of HLI, but they are still under investigation by other researchers. So far, TMP/SMX is the only antibacterial agent being used as an experimental therapy for HLI.

Historically, TMP/SMX was accidentally discovered by Shashindran and colleagues as a therapy for lice in 1978. These physicians were giving TMP/SMX to a 12-year-old girl with a bacterial upper respiratory infection and HLI, and they noted a concurrent improvement in her HLI. In their study, they used 2 courses of TMP/SMX spaced 10 days apart (1 tablet twice daily for 3 days), and they found that this approach eradicated the infestation without requiring any external antipediculosis therapy. Morsy and colleagues also studied the efficacy of TMP/SMX in treating HLI. In their study, the lice demonstrated decreased movement and death by the fourth to seventh day of oral TMP/SMX. The complications seen in that study included severe pruritis, skin rash, nausea, and vomiting. For unknown reasons, patients in our study that combined 1% PER and TMP/SMX therapy did not experience severe pruritis, although intense pruritis was seen in some children treated with TMP/SMX alone.

We propose that using both 1% PER and oral TMP/SMX can provide a synergistic effect. Permethrin can kill lice immediately during the application and it may still have a residual effect on emerging nymphs. Paradoxically, the waning residual levels of permethrin may promote the emergence of resistant lice. If there is a development of resistance in some lice to permethrin, the ingestion of the TMP/SMX may lead to their ultimate eradication. Moreover, after a full course of TMP/SMX, we speculate that blood levels of the medication may still afford protection to newly emerging lice that ingest blood from the human scalp.
Aside from using TMP/SMX, primary health workers can choose other experimental drugs in the management of resistant head lice. These include 5% permethrin cream, carbaryl, malathion, and ivermectin.4,13–15 Five percent permethrin cream still was associated with reinfection and required retreatment.8 Malathion was reported recently by Dawes10 to have double resistance to lice. Carbaryl is carcinogenic, whereas ivermectin is neurotoxic.1 Hence using these alternative drugs in treating HLI would be less appealing to pediatric health professionals and is not commonly used in the United States.

Although TMP/SMX has serious side effects such as Stevens-Johnson syndrome, neutropenia, hemolysis, and even renal impairment,23 these are rare complications and were not seen in our trial. Compared with the above-mentioned medications, parents are often more familiar with TMP/SMX.

Dual therapy with 1% PER and TMP/SMX may reduce parental frustration with the recurrence of HLI. Although dual therapy with 1% PER and TMP/SMX is a more expensive therapy compared with a single drug regimen, the parents seemed more satisfied with its effectiveness in this trial. Cost savings may be realized by fewer clinic visits and less need for retreatments. We speculate that dual therapy with 1% PER and TMP/SMX may lower the emotional and economic costs of HLI in infants and children, but larger clinical trials with more outcome variables will be required to draw that conclusion.

CONCLUSION

Our findings suggest that using both 1% PER and oral TMP/SMX is a more effective therapy in the management of HLI. We recommend that dual therapy with 1% PER and TMP/SMX be used by pediatric health care professionals in cases of treatment failures or suspected cases of lice-related resistance to therapy. The dual therapy should be reserved only in cases of multiple treatment failures or suspected cases of lice-related resistance to therapy and not a first line of therapy. We also recommend that hair care and HLI education and awareness should be a part of anticipatory guidance during well-child visits, especially in school-aged female children.

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