A CONTROLLED TRIAL OF LAMBDA-CYHALOTHIRN-IMPREGNATED BED NETS AND/OR DAPSONE/PYRIMETHAMINE FOR MALARIA CONTROL IN SIERRA LEONE

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Abstract. A randomized controlled trial investigated the impact of community-wide use of mosquito nets impregnated with lambda-cyhalothrin alone or with dapsone/pyrimethamine (d/p) prophylaxis on clinical malaria due to perennially transmitted Plasmodium falciparum in children in the Bo district of Sierra Leone. The 17 study communities were pair-matched and randomly allocated to receive treated mosquito nets or no nets and the children (age range = 3 months–6 years) in each community were randomly allocated to receive d/p or placebo individually every two weeks. This resulted in each of the approximately 2,000 children recruited being in one of four study groups (impregnated mosquito nets and d/p prophylaxis, impregnated mosquito nets, d/p prophylaxis, and controls). The intervention phase of the study lasted 12 months. A total of 1,800 children attended more than 25% of the 48 total weekly morbidity surveillance surveys and were included in the analysis. The effects of the exclusive use of either treated mosquito nets or d/p prophylaxis on protection against clinical malaria due to P. falciparum was significantly similar (49% and 42%, respectively), while in combination this protective efficacy was significantly increased to 72% (95% confidence interval = 67–76%). Children in the control group had an average of 1.3 clinical malaria episodes per child annually compared with 0.65 episodes or 0.78 episodes for those using treated mosquito nets and d/p, respectively. Children using both treated mosquito nets and d/p prophylaxis had an average of 0.37 episodes per child. The interventions significantly reduced spleen rates and increased hematocrit values, and reduced the duration of episodes of clinical malaria.

For many years, the World Health Organization has consistently advised communities in sub-Saharan Africa to adopt and implement a malaria control strategy based on early diagnosis and prompt therapy with antimalarial drugs (mainly chloroquine). However, the emergence and spread of Plasmodium falciparum resistant to chloroquine in almost all of sub-Saharan Africa has created an urgent need for additional, effective as well as sustainable control strategies.

The rediscovery of impregnating mosquito nets with insecticides opened up the possibility of exploring a malaria control strategy with potential for community-based implementation. Other advantages of using a treated mosquito net as a malaria control tool include its ability for maintaining the effectiveness of the protection provided by a damaged or badly used mosquito net by killing mosquitoes that try to bite through insecticide-impregnated mosquito nets and repelling others from human dwelling. In addition, the use of insecticide-impregnated mosquito nets may be easier to implement and sustain than available alternative vector control measures such as environmental sanitation because of their immediately perceptible benefit to the user in personally protecting them from other nuisance insects as well as malaria vectors.

Malaria control by mosquito nets treated with insecticide has not previously been assessed in the rain forest of west Africa under conditions of perennial transmission of P. falciparum. This investigation was therefore designed both to evaluate the protective efficacy of this potential control strategy and also to compare its impact with that of an effective and safe control measure, dapsone/pyrimethamine (d/p) prophylaxis.

SUBJECTS AND METHODS

The study area has previously been described. The 17 study villages were pair-matched for similarities in size, altitude, climate and temperature, presence of a health center, and number of children, and randomly allocated by a lottery between the chiefs of each matched-pair community for the distribution of treated mosquito nets or no nets for the intervention phase of the study. Inhabitants of the study communities between the ages of three months and six years were individually randomly allocated to receive d/p prophylaxis or placebo every two weeks after the informed consent of their parents or guardians was obtained. The Scientific Review and Ethical Committee of the Ministry of Health of Sierra Leone reviewed and granted ethical approval for this study. Dapsone/pyrimethamine was given in the fixed proportion of 100 mg of dapsone and 12.5 mg of pyrimethamine (adult dose). The dose was administered every two weeks, and children 3–11 months of age received 1/4 of a dose, those 1–4 years of age received 1/2 a dose, and those greater than five years of age received 3/4 of the adult dose. Each child recruited into the study was therefore considered as being randomly allocated into one of four groups: 1) treated nets and d/p prophylaxis, 2) d/p prophylaxis, 3) treated nets, and 4) a control group. Nets were provided to the remaining communities at the end of the trial.

Morbidity surveillance consisted of weekly active case detection where each child recruited into the study was visited by a field worker employed by the project. The child’s health status was assessed using a precoded questionnaire, and the axillary temperature was recorded with an electronic thermometer. A fingerprick blood film was made for those children fulfilling a set of criteria listed below and they were then referred to their Community Health Officer (CHO) for treatment or to the project nurse where a CHO was unavailable. The treatment policy of the Ministry of Health of Sierra Leone of administering chloroquine as a 10 mg/kg (single dose) as a presumptive treatment for malaria was followed based on the judgment of the CHO or the project nurse. The treatment afforded to each child was checked against the laboratory results to confirm that children meeting the case definition (given below) of clinical malaria were adequately
treated with chloroquine by giving an additional 15 mg/kg over a two-day period. The persistence of clinical malaria in consecutive weeks was considered as the prolongation of the initial episode (for reasons elaborated later) and treated with chloroquine. Despite evidence of chloroquine resistance at the RI/RII level (Marbiah NT, unpublished data), all cases treated with chloroquine eventually resolved and it was not necessary to resort to treatment with any second-line antimalarial drugs.

**Criteria for taking a blood sample.** Parents or guardians were asked if a particular child being seen at a weekly morbidity surveillance survey had any of the following conditions: 1) fever today?, 2) fever anytime during the last seven days?, 3) any occurrence of chills, rigors, or headache during the last seven days?, and 4) any occurrence of vomiting or diarrhea during the last seven days? The fifth criterion consisted of objective evidence of a recorded temperature greater than or equal to 37.5°C. The presence of any one or more of the above criteria led to the collection of a blood smear for a microscopic search for malaria parasites.

Parasite enumeration was done by examining Giemsa-stained thick blood films. One hundred high-power microscopic fields (HPFs) were examined systematically from edge to edge to ensure that each film was covered. The number of HPFs containing one or more parasites per HPF were counted. If all 100 HPFs examined contained at least one parasite, the number of parasites per HPF was then counted in 10–100 HPFs, depending on the number of parasites counted per HPF: 50 HPFs for 10–19 parasites/HPF; 25 HPFs for 20–39 parasites/HPF; and only 10 HPFs if the parasites counts were higher. The estimated parasite density per slide was calculated by multiplying the average number of parasites per HPF by 500 when all HPFs contained parasites. Otherwise, the estimated parasite density was determined by multiplying the number of HPFs containing parasites by 5. This calculation is based on evidence that the volume of blood in a well-prepared thick film is approximately 0.002 µl.\(^{10}\)

The results of the weekly morbidity surveys were used to calculate the incidence rates of clinical episodes of malaria. Age-specific illness thresholds were used to derive alternative definitions of clinical episodes. 1) Children less than 24 months of age were said to have an occurrence of critical parasitemia when smears collected because they fulfilled the sampling criteria were found by microscopy to contain 2,000 or more asexual *P. falciparum* parasites per microliter of blood on a thick smear. An episode of clinical malaria began with the occurrence of critical parasitemia and continued until the child had recovered, that is, was free of clinical manifestations. 2) A similar definition was used for children more than 24 months of age, but at a critical parasitemia of 5,000 asexual *P. falciparum* parasites or more per microliter of blood. A child fulfilling one or more of the criteria for taking a blood sample and having a critical parasitemia was regarded as having an attack of clinical malaria.

The incidence rates were calculated per 1,000 child-weeks at risk and from these a relative rate was derived by comparing children in each arm of the study with the control group. Because of the possibility that the impact of the treated nets on malarial transmission and clinical cases in children in the matched-paired communities may not be independent, the Wilcoxon signed rank test was used to compare the rates in the paired communities weighted for differences in sizes in calculating the overall effects in treated mosquito nets versus no nets villages. The confidence intervals for the protective efficacies were calculated from the mean and standard error of the log rate ratios of each pair.

Children participating in less than 25% of the weekly morbidity surveys conducted for a year have been excluded from the analyses. The smear results for those who did not fulfill the sampling criteria but for whom slides were inadvertently collected were also excluded from the analyses.

**RESULTS**

**Impacts of the interventions on traditional malarialmetric indices.** The frequency and distribution of *P. falciparum* densities observed in the study groups during the weekly morbidity surveys are shown in Table 1. The results presented in this table clearly indicate that after one year of follow-up the various study groups were still very similar in terms of the number of children per group (despite the fact that children were continually recruited during the course of the study), number of visits per child in each group, the contribution of the children in each group to the total number of slides collected, the average number of slides per child, and the proportion of contacts in each group during which smears were collected. The number of children in each study group excluded from this analysis because they completed less than 25% of the 48 possible weekly morbidity surveillance were as follows: 55 each in both the treated nets plus d/p prophylaxis group and d/p prophylaxis only group, and 81 each in the treated nets only group and in the control group. It was also noted that the number of presumptive treatments with chloroquine per child in each group were also very similar based on the number of referrals. Thus, the potential source of errors and bias that would have occurred if very different numbers of smears had been collected from the study groups or differing number of presumptive chloroquine treatment given was avoided.

The results of the preintervention cross-sectional survey (March 1992) and another survey conducted a year later, nine months after the trial started, are summarized in Table 2. During the preintervention survey, the children allocated to the study groups for the intervention phase were similar both in terms of the spleen rate and mean packed cell volume \((P = 0.962\) and \(P = 0.839,\) respectively). A comparison of the groups on these same indices from the March 1993 cross-sectional survey after nine months of intervention revealed significant differences in the mean packed cell volume \((P < 0.0001)\) and the spleen rate \((P < 0.001)\) among the groups. It is of particular interest that the reduction observed in the spleen rate is closely associated with a simultaneous increase in the mean packed cell volume and this is most evident in children using nets exclusively.

**Impacts of the interventions on clinical malaria.** The protective efficacies of the interventions on the incidence rate of clinical malaria observed during the weekly morbidity surveys are shown in Table 3. The effects of the exclusive use of treated mosquito nets or d/p prophylaxis on protection against clinical malaria are similar (49% and 42%, respectively).
Table 1

Frequency and distribution of *Plasmodium falciparum* densities observed in the study groups during the weekly morbidity surveys

<table>
<thead>
<tr>
<th>Parasite density/μl</th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1,928 (58.8%)</td>
<td>2,225 (65.5%)</td>
<td>2,111 (66.2%)</td>
<td>2,610 (79.3%)</td>
</tr>
<tr>
<td>1–1,999</td>
<td>961 (28.1%)</td>
<td>766 (22.6%)</td>
<td>638 (20.0%)</td>
<td>471 (14.3%)</td>
</tr>
<tr>
<td>2,000–4,999</td>
<td>146 (3.96%)</td>
<td>74 (2.18%)</td>
<td>68 (2.13%)</td>
<td>41 (1.24%)</td>
</tr>
<tr>
<td>5,000–9,999</td>
<td>207 (5.6%)</td>
<td>96 (2.9%)</td>
<td>106 (3.3%)</td>
<td>65 (1.9%)</td>
</tr>
<tr>
<td>10,000–24,999</td>
<td>226 (6.1%)</td>
<td>113 (3.3%)</td>
<td>129 (4.04%)</td>
<td>58 (1.8%)</td>
</tr>
<tr>
<td>25,000–49,999</td>
<td>124 (3.4%)</td>
<td>72 (2.1%)</td>
<td>77 (2.4%)</td>
<td>32 (0.97%)</td>
</tr>
<tr>
<td>50,000–99,999</td>
<td>60 (1.6%)</td>
<td>55 (1.03%)</td>
<td>34 (1.06%)</td>
<td>12 (0.36%)</td>
</tr>
<tr>
<td>≥100,000</td>
<td>30 (0.81%)</td>
<td>15 (0.44%)</td>
<td>26 (0.81%)</td>
<td>4 (0.12%)</td>
</tr>
</tbody>
</table>

% positive slides

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>47.6%</td>
<td>34.5%</td>
<td>33.8%</td>
<td>20.7%</td>
</tr>
</tbody>
</table>

% contacts when slides were collected

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24.1%</td>
<td>21%</td>
<td>20.9%</td>
<td>20.3%</td>
</tr>
</tbody>
</table>

Contribution to total no. of slides collected/group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27.1%</td>
<td>25%</td>
<td>23%</td>
<td>24%</td>
</tr>
</tbody>
</table>

Average no. of contacts/child/group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>33.9</td>
<td>34.3</td>
<td>34.9</td>
<td>34.8</td>
</tr>
</tbody>
</table>

Average no. of smears/child

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.2</td>
<td>7.2</td>
<td>7.3</td>
<td>7.1</td>
</tr>
</tbody>
</table>

Total no. of children per group

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Nets</th>
<th>Dapsone/pyrimethamine</th>
<th>Dapsone/pyrimethamine and nets</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>450</td>
<td>470</td>
<td>436</td>
<td>467</td>
</tr>
</tbody>
</table>

Table 2

Changes in the mean packed cell volume and the average spleen rate in the study group observed during cross-sectional surveys

<table>
<thead>
<tr>
<th>Parameters</th>
<th>March 1992</th>
<th>March 1993</th>
<th>Change*</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average spleen rate</td>
<td>45.45% (40, 50)</td>
<td>46.11% (40, 51)</td>
<td>+0.65% (−6.8, +8.1)</td>
<td>0.863</td>
</tr>
<tr>
<td>Mean hematocrit</td>
<td>36% (35, 37)</td>
<td>38% (37, 40)</td>
<td>+2.03% (+0.43, +3.6)</td>
<td>0.013</td>
</tr>
<tr>
<td></td>
<td>Dapsone/pyrimethamine prophylaxis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average spleen rate</td>
<td>44.13% (38, 49)</td>
<td>35.5% (30, 40)</td>
<td>−8.65% (−1.3, −16)</td>
<td>0.022</td>
</tr>
<tr>
<td>Mean hematocrit</td>
<td>37.09% (36, 37)</td>
<td>40% (38, 41)</td>
<td>+3.25 (+1.5, +5.02)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Treated nets</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average spleen rate</td>
<td>46.2% (40, 51)</td>
<td>32.9% (28, 37)</td>
<td>−13.3% (−5.8, −20.8)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean hematocrit</td>
<td>37.2% (36, 38)</td>
<td>43.4% (41, 45)</td>
<td>+6.2% (+4.4, +8)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>Treated nets and dapsone/pyrimethamine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average spleen rate</td>
<td>45.2% (39, 51)</td>
<td>34.2% (29, 39)</td>
<td>−11% (−3.2, −18.8)</td>
<td>0.006</td>
</tr>
<tr>
<td>Mean hematocrit</td>
<td>37.2% (36, 38)</td>
<td>42.2% (40, 43)</td>
<td>+5.02% (+3, +7)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

* Values in parentheses are 95% confidence intervals.

*+ means an increase in the parameter at the March 1993 survey, − indicates a decrease in the parameter at the March 1993 survey.
four episodes (only three children in this group had four episodes).

The number of episodes evident during a weekly visit and those persisting during consecutive visits have been summarized by intervention group and are shown in Table 6. The proportion of the number of episodes persisting for more than a week was very similar in the control, treated mosquito nets, or d/p prophylaxis groups but differs significantly in children using both nets and d/p prophylaxis (χ² = 12.67, df = 3, P < 0.01).

**DISCUSSION**

Numerous studies over the past 50 years have demonstrated that regular chemosuppression reduces malaria morbidity and spleen rates while improving the hematocrit level.11, 12 A large study conducted in The Gambia reported that the effects of treated mosquito nets on malaria morbidity could be augmented by chemoprophylaxis with d/p every two weeks in children.13 Earlier studies14, 15 from this same locality indicated that chemosuppression with d/p was effective in reducing malaria morbidity and mortality. During these trials, no side effects were seen and drug resistance did not develop in children using both nets and d/p prophylaxis (χ² = 12.67, df = 3, P < 0.01).

**Comparison of the protective efficacies of the interventions on episodes of clinical malaria observed during the weekly morbidity surveys**

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Number of episodes observed</th>
<th>Child weeks at risk (cwar)</th>
<th>Incidence rate/1,000 cwar</th>
<th>Rate ratio</th>
<th>95% confidence interval</th>
<th>Protective efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>576</td>
<td>15,269</td>
<td>37.7</td>
<td>1</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Nets†</td>
<td>309</td>
<td>16,126</td>
<td>19.2</td>
<td>0.51</td>
<td>0.44, 0.58</td>
<td>49%</td>
</tr>
<tr>
<td>Drug‡</td>
<td>338</td>
<td>15,205</td>
<td>22.2</td>
<td>0.58</td>
<td>0.51, 0.66</td>
<td>42%</td>
</tr>
<tr>
<td>Nets and drug</td>
<td>169</td>
<td>16,248</td>
<td>10.7</td>
<td>0.28</td>
<td>0.24, 0.33</td>
<td>72%</td>
</tr>
</tbody>
</table>

* – = not applicable.
† Lambdacyhalothrin-impregnated mosquito nets.
‡ Dapsone/pyrimethamine.

(3) Dapsone/pyrimethamine.

(7) Overall protective efficacies (Protective efficacies × combined population of village pair)/Total population.

(9) 95% confidence interval.

(10) Parasite density >25,000 parasites/μl.

(12) Slide positivity.

(13) The results presented in this paper demonstrate that the children receiving the various interventions did significantly better than those in the control group by all of the parameters assessed. In terms of the traditional malariometric indices, the combined use of treated mosquito nets and d/p prophylaxis every two weeks had a significant impact on overall P. falciparum prevalence, reducing slide positivity by more than 50% in children receiving the combined strategies compared with those in the control group. Children in the intervention groups also showed reductions in the higher parasite densities classes (Table 1), and a seven-fold difference when the intervention groups were compared with the control group. Changes in the mean packed cell volume (hematocrit) and the average spleen rates observed over two timepoints (Table 2) support the trend observed with parasite density and slide positivity.

There was a clear impact of the interventions on clinical malaria due to P. falciparum. We found that the effects of lambda-cyhalothrin–treated mosquito nets were comparable with d/p given every two weeks, with protective efficacies of 49% and 42%, respectively. The impact of combined lambda-cyhalothrin–treated mosquito nets and d/p prophylaxis on the incidence of clinical malaria showed an additive effect that corresponds to results reported from The Gambia.13 This study further demonstrated that lambda-cyhalothrin is an effective insecticide that retains its effect over a 12-month period.9

Chemosuppression and treated bed nets interfere with asexual parasites in the blood and the number of infective bites, respectively. It is therefore not surprising that their combined effect is additive. This is further illustrated by the reduction in the number of children with multiple episodes of malaria (Table 5). Our results are in agreement with those of other studies of treated nets, in which it was found that treated nets have a more marked effect on high parasitemias than on overall parasitemia.17, 20

The interventions reduced not only the number of episodes in some children, but also appeared to shorten their duration as well. Although this may partly be due to treatment failure, this observation suggests that some prolonged episodes may be manifestations of separate but overlapping infections. This reduction of the duration of a clinical malaria attacks by treated mosquito nets appears not to have been previously noted, and may have implications in the development of immunity and the outcome of cases. As far as the outcome of cases is concerned, our data suggest that the likelihood of a child developing anemia is higher following many overlapping continuous episodes than if the same number of episodes were interspersed by gaps during which the child recovered.

If acquisition of immunity depends on either multiple infections with a single strain or upon gradually acquiring the experience and through immunity to an increasing number of separate strains,21, 22 it follows that reducing exposure to...
the local repertoire of strains by using treated mosquito nets may affect the rate of the acquisition of immunity. This may result in individuals, especially children of a given age, being less immune, and thus may shift the burden of disease to older age groups without reducing the overall number of disease episodes over a lifetime as argued by Trape and Rogier. However, there is evidence of nonspecific age-related immunity: Schuffner noted an age-dependent immunity in people lacking a history of heavy exposure, and Christo-

gier.

Treated nets

Dapsone/pyrimethamine

Control

Number of episodes persisting/consecutive visits

<table>
<thead>
<tr>
<th>Intervention</th>
<th>1 week</th>
<th>2 weeks</th>
<th>3 weeks</th>
<th>4 weeks</th>
<th>5 weeks</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>501 (86.9%)</td>
<td>56 (9.7%)</td>
<td>12 (2.1%)</td>
<td>4 (0.7%)</td>
<td>3 (0.5%)</td>
<td>576</td>
</tr>
<tr>
<td>Treated nets</td>
<td>273 (88.3%)</td>
<td>32 (10.4%)</td>
<td>2 (0.6%)</td>
<td>2 (0.6%)</td>
<td>0</td>
<td>309</td>
</tr>
<tr>
<td>Dapsone/pyrimethamine</td>
<td>297 (88%)</td>
<td>34 (10.1%)</td>
<td>6 (1.8%)</td>
<td>1 (0.3%)</td>
<td>0</td>
<td>338</td>
</tr>
<tr>
<td>Treated nets and dapsone/pyrimethamine</td>
<td>163 (96.4%)</td>
<td>5 (2.8%)</td>
<td>1 (0.6%)</td>
<td>0</td>
<td>0</td>
<td>169</td>
</tr>
</tbody>
</table>

Table 5
Effects of the interventions on the frequency of attacks of clinical malaria

Table 6
Categorizing the duration of episodes by interventions

Acknowledgments: This study was only possible due to the continued support of the people of the 17 study villages north of Bo. The paramount chief in Bo, the District Medical Officer, and the Ministry of Health followed the progress of the project with great interest throughout. Gillian H. Maude (Department of Epidemiology and Population Sciences, London School of Hygiene and Tropical Medicine) and Adam Gottschau (Department of Biostatistics, Statens Serum Institut) are thanked for assistance with organizing the data management and initial randomization of the study population. We are grateful to Chris Curtis and Brian Greenwood (London School of Hygiene and Tropical Medicine) for fruitful comments during the implementation of this study and the data analysis. The staff of the project worked under considerable hardship collecting, processing, and analyzing the blood smears, blood samples, and data under sometimes very difficult conditions.
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