

# Clinical Response and Safety of Malathion Shampoo for Treatment of Head Lice in a Primary School†

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**Objective:** Help eradicate or at least alleviating head lice in a primary school with malathion shampoo and to study clinical response and safety of malathion shampoo.

**Material and Method:** All students were examined by using a fine-toothed lice comb to help detect live lice. Direct visual examination and the collection of nits for microscopic examination were performed to differentiate viable nits from empty nits. Diagnosis of head lice was made by the presence of lice. All students that had lice and/or nits were treated with malathion shampoo. Malathion shampoo was also provided for all family members. Pediculocidal efficacy was by the presence or absence of live lice. Blood for red blood cell cholinesterase activity was drawn in 32 volunteers before treatment and after the second treatment.

**Results:** At the first visit, 629 students were examined and 48 students had live head lice. The infestation rate was 13% in girls and 1.3% in boys. The cure rate was 93% after the first treatment. The reported side effects were nausea, a burning sensation, and irritation that was found in five (4%), 10 (7%) and three (2%) students respectively. The mean of RBC cholinesterase activity before and after two applications showed significant changes ( $p = 0.03$ ). It was  $-7.5 \pm 4.1\%$  reduction from the initial, but all were in the normal range. There was no report of clinical manifestation of malathion toxicity.

**Conclusion:** Malathion shampoo is safe and effective in the treatment of head lice. There is significant skin absorption so a scalp examination for head lice should be done before subsequent application to avoid unnecessary exposure.

**Keywords:** Malathion shampoo, Pediculosis, Head lice, RBC cholinesterase activity

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Pediculosis capitis is a common problem in school-age children worldwide<sup>(1-6)</sup>. Direct head-to-head contact is the primary mode of transmission. If a student has head lice, all household members and classmates should be screened. Infestation may cause itching or asymptomatic. More resistance to treatment has been reported<sup>(2-4)</sup>. Treatment failure may due to non-compliance, improper application of pediculicides or re-infestation<sup>(1,2)</sup>.

Malathion is an organophosphate (acetyl cholinesterase inhibitor) insecticide. Malathion lotion has been approved by the U.S. Food and Drug Administration for the treatment of pediculosis

capitis<sup>(1,2)</sup>. It is available only by prescription in the U.S., and is an over-the-counter agent in the United Kingdom. Malathion lotion is safe and effective but it has a potential toxicity<sup>(1,3,4,6)</sup>. The objective of the present study was to determine a clinical response and the safety of malathion shampoo for treatment of head lice in a primary school. Red blood cell cholinesterase activity is a marker for its effect and toxicity.

## Material and Method

The present study was conducted with helpful cooperation from a primary school in a suburban area of Bangkok. The present study was approved by the Ethics Committee of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand.

Prior to the field operation, the investigators sent each student a letter, an informed consent form and a questionnaire about head lice infestation in the

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family and the number of infested household members for whom medication should be provided. Students who were volunteers for red cell cholinesterase level were informed and had a separate information sheet and informed consent form. No student was treated within 4 weeks prior to the present study.

There were three school visits during the present study. The first and second visits were to examine and provide malathion shampoo to the students. The third visit was to examine the students in order to evaluate the treatment outcome. During these visits, all students were examined for head lice by combing with a fine-toothed lice comb<sup>(7)</sup>. Direct visual examination to collect 10 eggs nearest to the scalp for light microscopic examination to differentiate viable nits from empty eggs<sup>(8)</sup> was done. Scalp examination was conducted at each visit to detect lice, eggs and any adverse reaction.

Diagnosis of head lice was defined as the presence of the lice during the examination. Pediculocidal efficacy was evaluated in students who had live lice grouped by the presence or absence of live lice after treatment. Children who were free of lice after the first treatment, but had adult lice on the second visit were scored as re-infested. Children who had adult lice after two treatments were scored as a treatment failure. Those students who missed the protocol were welcome to be examined on all visits but were defined as missing or lost to follow-up.

All students that had lice and/or eggs were treated with 1% malathion shampoo (Hoe Pharmaceutical, Malaysia) by applying it to a dry scalp and hair for 10 minutes before washing it off. Malathion shampoo was also provided for all family members. Students who had no lice and eggs (mostly boys) but family members who requested the shampoo, were all provided with it. Students who had only eggs were divided into a viable group and a non-viable egg group.

To ensure the safety of the malathion shampoo, a questionnaire on the adverse effects and quality of life was distributed to all the children's parents.

Thirty-two students volunteered for red blood cell (RBC) cholinesterase activity determination. We drew 3 ml of blood before the initial treatment and after the second treatment. The RBC cholinesterase activity was measured by the electrometric (pH) method<sup>(9)</sup>.

Statistical analysis was carried out using SPSS version 11.5. The probabilities used the 2-tailed test and statistically significant level at p-value of 0.05.

**Table 1.** Result of first examination

	Male	Female	Total
Student	369	347	716
Lice and egg	4	44	48
Egg only (viable/non viable)	4 (1/3)	156 (130/26)	160
No lice and no egg	294	127	421
Missing	67	20	87

Pair t-test was employed for comparison of the RBC cholinesterase activity.

## Results

There were 716 students (369 boys and 347 girls), age ranging from 7-14 years old in grades 1-6. On the first visit, 629 students were examined and 48 students had live head lice. The details of the examination are shown in Table 1. The infestation rate was 13% in girls and 1.3% in boys. Nits without lice were found in 21% (131 from 629 students). Viable nits were 82% (131 from 160 students) of collected nits.

### *After the first treatment*

Forty-three of the 48 students, who were diagnosed with head lice, were treated and five students refused to participate. The cure rate was 93% after the first treatment. Three children (7%) still had head lice. Household members of two the students did not comply with the use of malathion shampoo. The compliance of the family was 54%.

Of the 131 students who had only viable nits, one student had head lice and 27 children were lost to follow-up. The compliance of their families was 71%.

### *After the second treatment*

The three students who had head lice after the first treatment were cured. In addition, two students who had previously been cured after the first treatment had re-infestation and the authors found that their family members did not use the malathion shampoo that was provided for them.

In the group that had only viable nits, five from 106 children had re-infestation. Compliance of family members was 71% in the first treatment. The family members of these five students did not use malathion shampoo.

### *On the third visit*

None of the 146 students had lice. Compliance of family members was 77% in the second treatment.

The reinfestation rate was 4% (8 of the 208 intend to treat students), six of these eight families did not use the medication provided for them. Students who had lice and/or nits were provided with treatment.

For the quality of life, 28 of 48 parents (58%) completed the questionnaire. Seventy-one percent reported of better sleeping (mild, moderate and marked improvement in 21%, 21% and 29% respectively). Most (93%) reported a decrease in scalp itching (mild, moderate and marked improvement in 32%, 25% and 36% respectively). Most (70%) also reported an improvement in concentration (mild, moderate and marked improvement in 7%, 31% and 32% respectively).

Regarding its safety and adverse effects, 66% (137 from 208 intend to treat students) of the adverse effects questionnaire were received. The adverse effects were nausea, a burning sensation and irritation in five (4%), 10 (7%) and three (2%) of the students respectively. Sixty-seven students (49%) complained of a strong smell. However, there was no sign of inflammation except for the exacerbation of seborrheic dermatitis in one child detected by direct scalp examination.

RBC cholinesterase activity in all blood samples of both periods were in the normal range of 1.0-1.5 unit/ml as shown in Table 2. However, there were significant changes in RBC cholinesterase activity between the initial and after treatment period ( $p = 0.03$ ). Twenty-six students (81.3%) had a  $12.9 \pm 5.8\%$  decrease from the initial samples. Six students (18.7%) had an increase by  $16.0 \pm 8.0\%$  from the initial samples. The overall reduction was  $7.5 \pm 4.1\%$ . No clinical manifestation of organophosphorus (OP) poisoning was observed.

## Discussion

To have success in the treatment of head lice in a primary school, all students and household members who had head lice must be treated simultaneously to prevent reinfestation.

The authors considered treating not only students who had lice but also students who had nits only because if a child has only nits, it may represent past infection or misdiagnosis. In a previous study, 31% of children with nits had concomitant lice and 18% of those with nits alone converted to active infestation<sup>(10)</sup>. In the group of students who had only viable nits, five students turned out to have head lice after the two treatments. Family members of these four students did not use malathion shampoo. There are many possibilities for these conditions that might come from misdiagnosis at the first visit, or the lice being hatched, or being re-infested from family members or friends.

In the non-viable egg group, all but one student had no lice in the follow-up visit. The authors suggested that it was unnecessary to treat students who had only non-viable nits.

Treatment of head lice includes permethrin, lindane, ivermectin and trimethoprim-sulfamethoxazole<sup>(4,11-13)</sup>. Permethrin is safe and effective and the American Academy of Pediatrics recommends it as a first-line treatment for head lice<sup>(12)</sup> but it is not available in Thailand. Lindane is an organochloride compound that has several serious side effects including neurotoxicity. The US FDA approves the treatment of head lice only if it is unresponsive to other therapies<sup>(4,12)</sup>. Oral pediculocidal, ivermectin and trimethoprim-sulfamethoxazole are not recommended as a first-line therapy<sup>(4,5,12)</sup>.

**Table 2.** Red blood cell cholinesterase activity from the 32 volunteers before the initial treatment and after the second treatment

RBC cholinesterase activity	Before the initial treatment	After the 2 <sup>nd</sup> treatment
Mean $\pm$ SD iu/ml	1.29 $\pm$ 0.98	1.21 $\pm$ 0.07*
Range (normal 1.0-1.5 iu/ml)	1.03 to 1.42	1.05 to 1.35
Changes in the enzyme activity	n (%)	% of changes
Decrease	26 (81.3)	12.9 $\pm$ 5.8 (-5 to -26)
Increase	6 (18.7)	16.0 $\pm$ 8.0 (3 to 29)
Overall	32	-7.5 $\pm$ 16.8

\*  $p = 0.03$  by paired t-test

The efficacy of 0.5% malathion lotion *in vitro* study found that all lice were dead within 10 minutes and none of the eggs had hatched<sup>(11)</sup>. *In vivo* study, the cure rate of a 20-minute application of 0.5% malathion lotion and 0.5% malathion gel was 98%<sup>(11,14)</sup>. In the present study, a 10-minute application of 1% malathion shampoo yielded a 93% cure rate after the first treatment and all students were cured after the two treatments. The lower efficacy may have been due to the application time and/or the adequacy of the application.

Malathion is an organophosphorus (OP) insecticide that is highly active for various insects. The main mechanism of action is to inhibit acetylcholinesterase enzyme irreversibly. The enzyme is responsible for cleavage acetylcholine in the synapses<sup>(16,17)</sup>. Thus, OP causes acetylcholine excess in the body. The acute and sub-acute toxicity of OP are well known and of concern. As malathion are lipid soluble and penetrate well through the skin and gastrointestinal tract<sup>(18,19)</sup>, the toxicity of OP by dermal absorption is also well recognized. Therefore, safety of the topical OP preparation should be of concern. Cholinesterase, especially acetylcholinesterase (AChE), is used as a biomarker for OP exposure and toxicity. Reduction of the enzyme activity correlates with the severity of toxicity; a reduction to less than 50% of baseline suggests OP toxicity and to less than 10% suggests severe toxicity<sup>(20,21)</sup>. The present study showed that after two application of 1% malathion shampoo, the majority of the students had a minimal reduction in their AChE activity. It was only trivial and may correlate with a very low risk of developing OP toxicity.

The authors suggested that to eradicate head lice from school, every student must be examined and treated simultaneously as should their family members who have an infestation. Malathion shampoo is effective and safe for treating head lice. It may produce only local adverse effects but no systemic toxicity.

#### Potential conflicts of interest

None.

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## ประสิทธิภาพและความปลอดภัยของการใช้มาลาไธออน (malathion) แชมพูในการรักษาเหาในเด็กนักเรียนโรงเรียนประถม

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**วัตถุประสงค์:** เพื่อกำจัดหรือลดการเกิดเหาในโรงเรียนประถมโดยใช้แชมพูมาลาไธออน (Malathion shampoo) และศึกษาความปลอดภัยของแชมพู

**วัสดุและวิธีการ:** โดยการตรวจนักเรียนทุกคนโดยใช้วิธีที่ีตีสางเหา และตรวจไข่ด้วยกล้องจุลทรรศน์เพื่อแยกไข่เหาที่มีชีวิตกับไข่ที่ตายแล้ว การวินิจฉัยเหาต้องพบตัวเหา นักเรียนทุกคนที่มีเหา และ/หรือ ไข่เหา จะได้รับมาลาไธออนแชมพู และให้แชมพูกับคนในบ้านด้วย ประสิทธิภาพในการฆ่าเหาขึ้นกับการพบตัวเหาหรือไม่ การเจาะเลือดเพื่อตรวจ red blood cell cholinesterase activity ทำในอาสาสมัคร 32 ราย ก่อนเริ่มการรักษาและหลังให้แชมพูครั้งที่ 2

**ผลการศึกษา:** ผลการตรวจเด็กนักเรียน 629 ราย พบเหา 48 ราย พบเหาในเพศหญิงร้อยละ 13 ส่วนเพศชายร้อยละ 1.3 ผลการรักษา หลังการรักษาครั้งแรกได้ผลร้อยละ 93 ผลข้างเคียงที่พบได้แก่ คลื่นไส้ อาเจียน แสบ และระคายเคือง พบร้อยละ 4, 7 และ 2 ตามลำดับ ค่าเฉลี่ยของ RBC cholinesterase activity หลังการใช้แชมพูมาลาไธออน 2 ครั้งลดลงอย่างมีนัยสำคัญทางสถิติ คือลดลงร้อยละ  $7.5 \pm 4.1$  แต่ยังคงอยู่ในค่าปกติ

**สรุป:** แชมพูมาลาไธออน มีประสิทธิภาพและปลอดภัยในการรักษาเหา เนื่องจากมีการดูดซึมผ่านหนังศีรษะได้ จึงควรตรวจว่ายังมีเหาหรือไม่ก่อนจะให้แชมพูครั้งต่อไป เพื่อหลีกเลี่ยงการสัมผัสกับแชมพูมาลาไธออนโดยไม่จำเป็น