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Synergized Pyrethrin Mousse, A New Approach to Head Lice Eradication: Efficacy in Field and Laboratory Studies

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ABSTRACT

The purpose of this study was to evaluate the pediculicidal and ovicidal efficacy of a new, single-application formulation of synergized natural pyrethrins (presented in an aerosol mousse form) compared with an established, effective formulation based on permethrin (in a creme rinse form). The trial was a single-blind, comparative, randomized, parallel-group study. Children between the ages 7 and 15 years and adults with active head lice infections, identified by the presence of live lice, were enrolled from a school and a children's home in Dhaka, Bangladesh. Prevalence of infection ranged from 75% to 100% in the two study centers.

The field study confirmed laboratory findings showing pyrethrin mousse to be effective at killing both lice and their eggs with a single 10-minute application. Of 52 patients identified with lice, 42 were treated with pyrethrin mousse and 10 with permethrin creme rinse. In each case, a sample of viable

louse eggs was taken from the patients' hair before and after treatment. The eggs were then incubated to assess ovicidal activity. After treatment, the patients were examined for lice on alternate days until day 8 and then again on day 14. None of the patients in either group was found to have lice up to 2 days after treatment. One patient was found to have two moribund hatchlings on day 4. By day 6, when any eggs still present on the scalp would be expected to hatch, 19 pyrethrin mousse-treated patients were available for assessment. Two patients had been reinfected from contacts. No lice were found at 14 days on the four pyrethrin mousse-treated patients available for assessment. No lice were found on creme rinse-treated subjects.

A significantly lower hatch rate was found in eggs sampled after pyrethrin mousse treatment than after treatment with permethrin creme rinse ($P < 0.01$).

Synergized pyrethrin mousse is effective as a pediculicide and ovicide in one application.

INTRODUCTION

Head lice, *Pediculus humanus capitis*, persist in developed countries despite the availability of modern chemical insecticide treatments, public health education, and community-based programs to eradicate lice. Aside from logistical problems experienced by some lice control programs, the lack of efficacy of certain lotion treatments^{1,2} and the continued popularity of inefficient shampoo formulations^{3,4} for lice treatment have promulgated the survival of head lice to date.

Natural pyrethrins are used as pediculicides worldwide and demonstrate an enviable safety record. Although pyrethrins are the most common ingredient in anti-lice products, most of these formulations are shampoos with minimal activity against louse eggs due to the presentation.⁵ Consequently, pyrethrins are widely regarded as nonovicidal.

This report describes field and laboratory studies of the efficacy of pyrethrin mousse,* a novel formulation containing 0.165% pyrethrins and 1.65% piperonyl butoxide in a breakable foam base requiring a single application, compared with permethrin creme rinse,[†] an established formulation containing 1% permethrin.

PATIENTS AND METHODS

Laboratory Study

Tests against laboratory colony lice and their eggs were performed as described previously.^{1,2,6} Young adult and third instar nymphal lice and eggs

up to 48 hours old, from the Cambridge reference strain culture colony of clothing lice, *Pediculus humanus humanus*, were laid on nylon gauze. Because the intended mode of use is different for each of the two products, the laboratory test protocols were designed to mimic use by patients. Lice and eggs were treated with pyrethrin mousse by dipping them into the expressed foam, spreading it over the substrate with a fingertip, and washing the mousse off after 10 minutes using a 1:15 mixture of balanced pH shampoo (Timotei, Chesebrough Pond's Inc., Greenwich, Connecticut) and water. Those treated with permethrin creme rinse were washed with a Ph-balanced shampoo before the product was applied and then subsequently rinsed off with water.⁶ Control groups of lice and eggs were prepared concurrently and exposed to a 1:15 pH-balanced shampoo only. Pediculicidal effects were assessed after 18 hours. Ovicidal activity was assessed after 14 days of incubation, at 30° ± 2° C and 50% relative humidity, by which time the control batches of eggs had completed hatching.

Field Study

The field evaluation of pyrethrin mousse was performed as part of a wider project during January to March 1993, in Dhaka, Bangladesh. Permission to import the materials was obtained from the Bangladesh Drug Regulatory Authority. Ethical approval and clinical supervision were arranged via the Metropolitan Medical Center, Mohakali, Dhaka.

The trial was conducted at two centers. Forty-four children between the ages 7 and 15 years and eight adults with active head lice infections, identified by

*Trademark: Banlice Mousse (Pfizer Pty. Limited, West Ryde, New South Wales, Australia).

†Trademark: Nix Creme Rinse (Wellcome Australia Limited, Cabarita, New South Wales, Australia).

the presence of live lice, were enrolled. A prevalence of 75% lice infection was identified at a school and 100% at a child's home. Active infections were identified by combing through potential patients' hair with a polycarbonate detection comb. (The smallest, newly hatched nymphal stages of lice are able to be removed with these combs.) Those patients with both live lice and eggs present in the hair were admitted to the trial. In addition to informed consent granted by the head teacher and home superintendent, in loco parentis, all patients were given written and verbal explanations of the study purpose in their own language, and informed consent was obtained from a responsible person as designated or appropriate.

After each patient was admitted to the trial, an attempt was made to remove five eggs still attached to hairs from the scalp. It was not possible, however, to find five eggs on every patient. A maximum of 50 eggs were seen but the majority were already hatched so only a few viable eggs could be obtained from each patient. In some cases, fewer than six viable eggs were found, probably due to the regular grooming and nit removal procedures performed by most families in Bangladesh.

Treatments were distributed randomly and applied by one of the investigators in accordance with the manufacturers' instructions. (A 10-minute treatment time was required for both products.) The pyrethrin mousse was applied to dry hair by distributing the foam along partings or inserting the applicator nozzle under the hair and expressing a quantity of foam that was then massaged into the hair and over the scalp with the fingers. After the 10-minute treatment period, the pyrethrin mousse was washed off by another

investigator using a pH-balanced shampoo. Those treated with permethrin creme rinse were shampooed with a pH-balanced shampoo and towel-dried before treatment, then administered the formulation, which was massaged into the hair and spread evenly with a grooming comb. At the end of the 10-minute treatment time the permethrin creme rinse was washed off using plain tap water.

After removal of the pediculicide, each patient was re-examined to ensure that no live lice were present. An additional batch of five eggs was removed at this time if possible. The pre- and post-treatment eggs for each patient were enclosed in individual marked containers and incubated until the nymphs had completed hatching. Hatching was evaluated microscopically by an investigator unaware of which treatment had been used.

Following treatment, all patients were examined on at least two occasions on alternate days, up to 8 days post-treatment; some were examined on day 14. These examinations were performed by visual inspection and by drawing a polycarbonate detection comb through the hair several times over each sector of the scalp.

Eradication of lice infections in the field study was evaluated using the binomial test⁷ to compare treatments at each assessment point. The same analysis was used to compare the results of incubation of eggs from pre- and post-treatment specimens.

Evaluation of laboratory tests was made by Poisson approximation.

RESULTS

Laboratory Study

Both formulations produced toxic signs in lice within a few minutes of drying after the final wash. When assessed

16 hours later, all lice in both groups had been killed (Table I), although 35% of the permethrin-treated lice and 78% of the pyrethrin-treated lice still exhibited limb tremors.

When tested against louse eggs, however, pyrethrin mousse performed significantly better in preventing the emergence of nymphs from their egg shells ($Z = 8.38, P < 0.001$) and at stopping their development before they were able to lift the egg shell cap prior to emergence, recorded as half-hatched in Table II ($Z = 7.67, P < 0.001$). Neither of the nymphs from pyrethrin mousse-treated eggs that completed its emergence was alive when discovered. Most of the nymphs that emerged from permethrin-treated eggs continued to move for some time; however, these lice were intoxicated with insecticide and mostly unable to feed.

Field Study

Head louse eggs take 6 to 7 days to hatch; therefore, any eggs that survived treatment on day 0 would be expected to have hatched by day 6. Nymphal lice emerging during this period could, at most, reach the second instar development stage. Any lice found in the third nymphal instar or as adults could only be new, fresh lice from infected contacts.

By day 6, 19 pyrethrin mousse-treated patients were available for assessment; other patients were unavailable for assessment. Two girls treated with pyrethrin mousse were identified on day 6 as having been reinfected from contacts. Two adult female lice were removed from one patient; the other patient was found to have three third instar nymphs. Such reinfections were anticipated because no residual insecticide activity exists for pyrethrin mousse (Table III).

Only one patient in the pyrethrin group was found to have any newly emerged nymphs (identified on day 4). Both lice were moribund and had apparently been intoxicated with insecticide as they emerged from the egg shell.

None of those patients examined after permethrin treatment were found to have lice.

No adverse reaction to either treatment was observed by the investigators or reported by the patients.

After discounting empty egg shells inadvertently removed, 127 eggs were obtained in both pre- and posttreatment groups from the 27 pyrethrin-treated patients who had at least 5 eggs. The permethrin group of 10 subjects provided 33 eggs before treatment and 37 after treatment.

Table I. Efficacy of treatments against clothing lice *in vitro*

Formulation	No. of Lice	Mortality (%)
Pyrethrin mousse	100	100
Permethrin creme rinse	100	100
Control	100	5

Table II. Efficacy of treatments against louse eggs *in vitro*

Formulation	No. of Eggs			Mortality (% ± SD)
	Total	Hatched	Half-Hatched	
Pyrethrin mousse	1887	2	3	99.9 ± 0.3
Permethrin creme rinse	1701	67	59	95.3 ± 5.8
Control	989	802	25	19.3 ± 6.5

This series of tests consisted of 21 replicates conducted in three groups over a period of 8 weeks.

*Percentage mortality adjusted using Abbott's correction for control mortality.

Table III. Efficacy of treatments measured as patients free of lice (number/total seen).

	Days After Treatment					
	0	2	4	6	8	14
Pyrethrin mousse	42/42	39/39	23/24*	17/19†	5/5	4/4
Permethrin creme rinse	10/10	8/8	8/8	3/3	2/2	NA

NA = not available.

*Two moribund newly hatched nymphs found on one patient.

†Two patients reinfected from contacts.

At the end of incubation, 52% of eggs removed prior to pyrethrin mousse treatment hatched successfully, which is statistically indistinguishable from the 48.5% found in the equivalent permethrin creme rinse group (figure). After treatment, however, the number of hatchlings in the pyrethrin mousse

group was reduced to 17.8%, compared with 40.5% for the permethrin creme rinse group. There was also a significant increase in dead embryos from 29.9% to 64.3% for the pyrethrin group ($P < 0.001$), whereas the increase in the permethrin group (from 45.5% to 48.6%) was insignificant. Overall, use

of pyrethrin mousse was more effective at preventing hatching of eggs than permethrin creme rinse ($P < 0.01$).

DISCUSSION

Natural pyrethrins have long been successful as insecticides because they rapidly incapacitate insects, an effect known as "knockdown." Provided that sufficient material is present, the knockdown effect persists to the eventual death of the insect. The lethal effect of pyrethrins is normally synergized by adding piperonyl butoxide to incapacitate the enzymes that would otherwise detoxify the pyrethrins. However, the rapid penetration and ac-

tion of pyrethrins on lice can be hindered if the insects are first exposed to moisture. Lice immersed in water grasp hairs reflexively (and close their spiracles) to avoid being washed away, which reduces insecticide penetration. As a result, treatment with pyrethrin shampoos may not kill lice consistently (L. Burgess, unpublished data, 1991).

Pyrethrin mousse **does** not have an aqueous base. Consequently, insecticide penetration is rapid, with a subsequent knockdown effect allowing lice to be washed from the head during the post-treatment shampooing process. During our field study, dozens of lice were washed from the hair of some subjects.

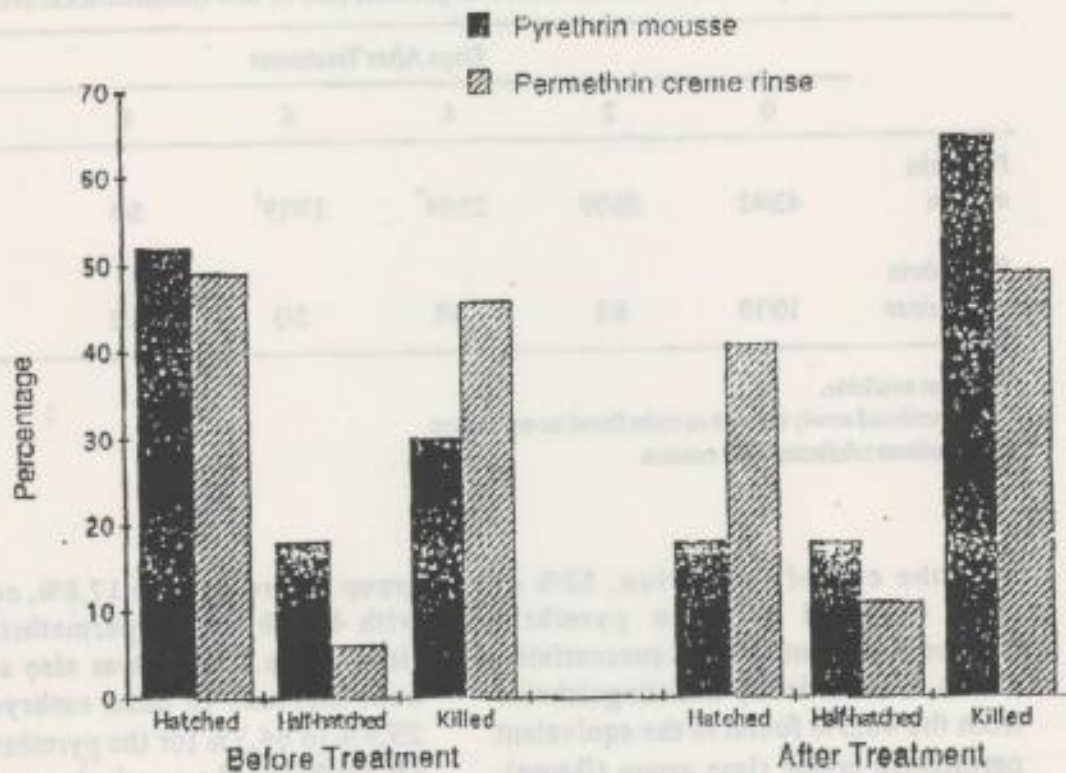


Figure. Comparison of hatching and mortality of eggs removed from patients before and after treatment. Columns represent percentage of eggs in each category.

Because permethrin creme rinse does not exert the same type of knockdown effect, a similar rapid action and physical elimination are not observed with this insecticide. In addition, because the creme rinse is applied after shampooing, many of the lice are not easily dislodged from grasping the hairs. Dead lice may only be found during subsequent washing or grooming.

In vitro work shows that pyrethrins in a suitable alcohol-based vehicle can penetrate the aeropyle breathing pores of the louse egg shell cap with a rate of deposition sufficient to generate ovicidal activity equal to the best pediculicide formulations available.^{1,2,6} Field results show that pyrethrin mousse is as effective against head lice as against laboratory clothing lice. The mousse exerts a high level of direct ovicidal activity, making it effective with a single application. In contrast, many of the eggs treated with permethrin creme rinse emerged, indicating that efficacy is largely by means of residual insecticide on the hair. A similar dependence on residual activity was noted by Taplin et al.⁴ in their original field studies. However, despite the convenience of residually active insecticides for some consumers, the effect may be inconsistent in development or reduced by environmental conditions resulting in treatment failures.⁹

The weaknesses of residual action are inadequately explained in product literature written for consumers, leading them to believe it will give total protection from reinfection or hatching of eggs. The product monograph for permethrin creme rinse⁷ notes the

emergence of nymphs but stipulates that they will subsequently die from exposure to residual insecticide.¹⁰ This information does not appear in the product insert in any country where the product is marketed. Therefore, most consumers automatically assume product failure and re-treat with insecticide if they find hatching lice a few days after treatment, resulting in a potential overuse of insecticides. Therefore, a thorough ovicidal activity, as delivered by pyrethrin mousse, should reduce the amount of pesticides to which infected persons are exposed.

Any residual activity will slowly wear off, and as it does, a point will be reached beyond which any lice invading the head could come into contact with the insecticide without being killed. It is believed that such conditions can lead to resistant strains of lice.⁵ Nonresidual insecticides are less likely to induce resistance; they also permit users the opportunity to trace the source of the infection,¹⁰ which ultimately gives a better chance of eradicating the infection.

CONCLUSIONS

This is the first trial of pediculicide use to report parallel in vitro and field studies. Consequently, there was a unique opportunity to evaluate the efficacy of pyrethrin mousse. The field study confirmed the high level of pediculicidal and ovicidal efficacy identified in vitro. Because the pyrethrin mousse is capable of eradicating an infection with a single treatment, without depending on residual insecticide activity, it offers the patient a lower level of exposure to pesticides and the opportunity to trace the source of the infection,

*Marketed in Great Britain as Lyclear® (The Wellcome Foundation Limited, London, United Kingdom).

the only certain means of avoiding re-infection. In this context, synergized pyrethrin mousse is a novel development in the treatment of head lice that should satisfy the convenience, safety, and efficacy requirements of consumers and professionals alike.

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