Pyrethrins Combined With Piperonyl Butoxide (RID) vs 1% Permethrin (NIX) in the Treatment of Head Lice

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• In a randomized controlled trial, 58 subjects were treated for *Pediculus humanus* var *capitis* with either pyrethrins combined with piperonyl butoxide (RID, Pfizer Inc, New York) or 1% permethrin (NIX, Burroughs Wellcome Co, Research Triangle Park, NC); 31 subjects received RID and 27 subjects received NIX. Both products were applied according to manufacturer's directions so that NIX was applied only on the first visit and RID was applied on the first visit and again seven days later. After each treatment with a pediculicide, the comb supplied by the manufacturer was used to remove nits. Seven days after the initial visit, NIX was determined to be significantly better than RID for eradicating the lice infestation. Of the 27 subjects receiving NIX, 26 were lice free vs 14 of the 31 RID-treated subjects. At day 14, there was no statistically significant difference in the treatments (27 of 27 NIX-treated vs 29 of 31 RID-treated subjects were lice free). The RID comb was superior to the NIX comb for nit removal. Both treatments were effective and well tolerated, and no subject experienced adverse reactions.

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Pediculus humanus var *capitis* or head lice, although not a major health hazard or vector for disease,[1] can be the bane of existence for their victims as well as school nurses, teachers, and parents. It is estimated that several million schoolchildren in the United States are affected annually[2] and that at any given time as many as 10 million Americans may be infested with lice.[3]

The adult female louse lays encased eggs near the scalp, primarily at the base of the neck and above the ears. These egg cases (nits) are not removed with regular grooming and remain even after the eggs have hatched. Therefore, the duration of the infestation may be estimated by the distance of the nits from the scalp. Eggs will hatch in approximately seven days, and nits that are seen 10 mm or more from the scalp can be considered nonviable.[1] Head lice usually remain on the head and can only survive 48 hours away from the scalp; eggs can survive for ten days but will not hatch at room temperature.[1]

In the United States, three agents are approved for treatment of pediculosis capitis: pyrethrins combined with piperonyl butoxide, lindane, and, most recently available, permethrin. Both lindane and permethrin require a prescription and usually a visit to a physician. The pyrethrins and piperonyl butoxide combination is safe, effective, and available without a prescription.[4] Over-the-counter pediculicides are competitively priced compared with those requiring a prescription, and they remain the agents of choice for many clinicians.[5]

The 1% permethrin cream rinse has been favorably compared with 1% lindane shampoo for eradicating head lice.[6,7] The pyrethrins combined with piperonyl butoxide have not been compared with permethrin when both products were used according to the manufacturer's directions. Therefore, we conducted a direct comparison of the pyrethrins combined with piperonyl butoxide (RID liquid, Pfizer Inc, New York), two applications followed by nit combing one week apart, with 1% permethrin (NIX cream rinse, Burroughs Wellcome Co, Research Triangle Park, NC), a single application followed by nit combing.

PATIENTS AND METHODS

This study was conducted at Family Medicine Center, Medical University of South Carolina (MUSC), Charleston, between September 1986 and April 1987. The study was approved by the Human Research Board, and informed consent was obtained for all participants. Subjects received free treatment and monetary compensation for completing the protocol.

Subjects eligible for participation were 4 years of age or older and on inspection had an active infestation of pediculosis capitis with at least two live adult or nymphal lice and at least ten nits attached to the hair. Subjects were otherwise in good health. Subjects were excluded from the study if they had been treated for head lice within four weeks before the start of the study, had a sensitivity to any of the ingredients used in the study, were allergic to ragweed, had any dermatologic problem other than pediculosis capitis, or had any illness deemed by the investigator to render the patient unsuitable for the study. Pregnant or nursing women were not eligible.

This study protocol required no invasive procedures or deviation from normally recommended treatment of head lice. Eligible patients were randomized to one of two treatment groups, either RID or NIX, in combination with hair combing using the nit comb provided with the product by the manufacturer. The subject's medical history was obtained, and vital signs were recorded. On day 0, subjects in group 1 were treated with RID according to the manufacturer's recommended directions. RID was applied to the head in sufficient quantity to saturate the hair and left on the scalp for ten minutes. The hair was then thoroughly washed and towel dried, followed by combing with the nit comb provided in the manufacturer's package. The treatment was repeated one week later. Subjects in group 2 received NIX cream rinse treatment according to manufacturer's directions on day 0 after having their heads washed with regular shampoo (Johnson's Baby Shampoo, Johnson & Johnson, Skillman, NJ). NIX was left on the scalp for ten minutes and was rinsed off followed by combing with the manufacturer-provided comb. A placebo shampoo (Johnson's Baby Shampoo) was applied on day 7 to patients in group 2. Before and after each treatment on days 0 and 7 and again on day 14 when no treatment was given, another investigator inspected each subject's head and towel for hatched lice and nits. This investigator recorded on a case report form the presence of adult lice and nymphs and

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estimated the number of nits and their distance from the scalp. The numbers of nits were categorized as follows: grade 1, less than ten nits; grade 2, ten to 40 nits; and grade 3, more than 40 nits. Immediately after treatment and again in one hour, the subject's scalp was inspected for local reactions.

On day 0, all subjects and parents or guardians were instructed on home techniques for head lice removal and asked to follow the instructions as soon as they got home.

The results were tallied according to the presence or absence of live lice before retreatment at day 7 and at day 14. We also evaluated for a change in nit count grade before and after combing on day 0. The χ^2 statistical test was used to analyze the data.

RESULTS

Seventy-one subjects participated in the study, and 58 completed the protocol, with 13 patients unavailable for follow-up. Of those completing the study, 31 subjects were treated with RID and 27 subjects were treated with NIX. The study participants ranged in age from 4 to 39 years, with a median age of 9 years. The treatment groups were comparable in all demographic aspects except that the NIX group contained more female patients (21 of 27 vs 17 of 31 treated with RID) and had a longer duration of symptoms before treatment (24 days vs 13 days in the RID-treated group). All other aspects, including length and texture of hair, degree of infestation, and presence of lice in the school or in other family members, were similar in both groups.

Twenty-six (96.3%) of the 27 patients treated with NIX did not have lice present at day 7. The mother of one severely infested child reported that she observed live lice two days before the second visit. None was found on inspection by the investigator, but because the child did have nits close to the scalp, we recorded this as an active infestation. In the RID treatment group, 14 (45.2%) of the 31 participants were lice free before retreatment at day 7. At day 14, all 27 (100%) of the patients in the NIX treatment group were lice free, as were 29 (93.5%) of the 31 in the RID-treated group. One of the day 14 "treatment failures" in the RID treatment group had been lice free at day 7 and probably was reinfested.

On day 0, patients in both treatment groups had their hair combed with the fine-tooth comb provided by the manufacturer. Information obtained at this visit was analyzed to see if there was a difference in the ability of the combs to remove nits. Information obtained at day 7 was not used because only one group of patients underwent combing at this visit. The NIX comb was able to reduce the nit count grade in seven (25.9%) of 27 patients, while the RID comb reduced the nit count grade in 16 (51.6%) of 31 patients.

COMMENT

We found no statistically significant difference in RID vs NIX for the treatment of head lice when the products were used according to manufacturer's recommendations, ie, one treatment with NIX and two treatments with RID, separated by one week. Seven days after the initial treatment, 1% NIX cream rinse was superior to RID liquid for eradicating adult and nymphal lice ($P<.005$). At the end of 14 days, however, the effects of both treatments were similar ($P>.1$). Neither product produced adverse reactions in any of the study participants. The RID comb was more effective in removing nits from the hair shaft than the NIX comb ($P<.05$). It was observed, however, that in patients treated with RID, we had difficulty combing the hair. We found that the use of a cream rinse after shampoo alleviated this problem without affecting the ability of the RID comb to remove nits from the hair. Nit removal is important aesthetically and because the presence of nits is often the only criterion for making a diagnosis, especially in the community. Several previously treated children were removed from class and referred to us by the school nurse when the only evidence of head lice was the presence of nonviable nits (ie, >10 mm from the scalp).

Any study designed to evaluate treatment of head lice is flawed, unless the environment to which the patient is returning is adequately treated as well. In this study, we were able to treat all infested family members at the same time and to provide specific instructions for treatment of bedding, clothing, toys, etc. As an added attempt to control the environment, we offered to provide a pediculicidal environmental spray and encouraged the subjects to alert any contacts who had head lice to our program. We also had difficulty "blinding" the study because each treatment medication had a distinctly different smell and effect on the ability to comb the hair. Another hindrance to the study was a surprising, but not totally unexpected, hesitancy in the community to participate in a head lice study. Many schools were known to be experiencing an outbreak during the study period, but parents were reluctant to admit openly that their child had head lice or that they or other children in the family might carry the parasite.

Safe and effective treatment is available for the removal of head lice with or without physician assistance. Efforts to control pediculosis capitis epidemics will be blunted unless the social stigma associated with a head lice infestation is removed and patient education is discussed openly. If parents and the community could have more accurate information regarding the transmission, reproductive cycle, and eradication measures associated with head lice, there is no reason that children or their parents should have to miss time from class or work due to *P humanus* var *capitis*.

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