Treatment of head louse infestation with 4% dimeticone lotion: randomised controlled equivalence trial

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Abstract

Objective To evaluate the efficacy and safety of 4% dimeticone lotion for treatment of head louse infestation.
Design Randomised controlled equivalence trial.
Setting Community, with home visits.
Participants 214 young people aged 4 to 18 years and 39 adults with active head louse infestation.
Interventions Two applications seven days apart of either 4.0% dimeticone lotion, applied for eight hours or overnight, or 0.5% phenothrin liquid, applied for 12 hours or overnight.
Outcome measures Cure of infestation (no evidence of head lice after second treatment) or reinfestation after cure.
Results Cure or reinfestation after cure occurred in 89 of 127 (70%) participants treated with dimeticone and 94 of 125 (75%) treated with phenothrin (difference −5%, 95% confidence interval −16% to 6%). Per protocol analysis showed that 84 of 121 (69%) participants were cured with dimeticone and 90 of 116 (78%) were cured with phenothrin. Irritant reactions occurred significantly less with dimeticone (3/127, 2%) than with phenothrin (11/125, 9%; difference −6%, −12% to −1%). Per protocol this was 3 of 121 (3%) participants treated with dimeticone and 10 of 116 (9%) treated with phenothrin (difference −6%, −12% to −0.3%).
Conclusion Dimeticone lotion cures head louse infestation. Dimeticone seems less irritant than existing treatments and has a physical action on lice that should not be affected by resistance to neurotoxic insecticides.

Introduction

The commonest mechanical method for treating head louse infestation in the United Kingdom is wet combing with conditioner, or "bug busting." Evidence suggests that this method is of low effectiveness,[1–3] which, combined with insecticide resistance, has resulted in an increased prevalence of lice in most communities since 1995.[4–6]

Dimeticone lotion is a new product, with no conventional insecticide activity. It is a clear, odourless fluid, applied in the same way as other head lice lotions.

We compared the efficacy of two applications seven days apart of either 4.0% dimeticone lotion or 0.5% *d*-phenothrin liquid. Phenothrin is currently the most widely used pediculicide in the United Kingdom, and we selected the liquid because its physical form and dosage is most similar to that of dimeticone lotion (it is applied for 12 hours or overnight), and it is safe for people with asthma.

Participants and methods

We recruited participants by advertising through local newspapers and radio. Those who wished to enrol telephoned the study coordinator to arrange a home visit. Trained investigators visited, usually within 24 hours, and followed a standard protocol to examine participants for head lice by using a plastic detection comb. If lice were found and the participant was eligible, he or she was invited to join the study. Household members were offered examination and invited to join if eligible. Treatments and assessments were carried out in the participant's home.

Design

Our study was single blinded because the products looked sufficiently different to preclude double blinding.

Participants provided baseline data on age, sex, characteristics of their hair, and use of pediculicides. We chose the lower age limit of four years as such children understand explanations and can assent to procedures.

We excluded participants who were pregnant, breast feeding, sensitive to phenothrin or chrysanthemums, or had a chronic scalp disorder,[7] as well as those who had used a pediculicide within the previous two weeks or had recently used bleaches, dyes, or permanent wave products. We also excluded anyone taking trimethoprim or cotrimoxazole at evaluation or during the previous four weeks or who had participated in another clinical trial within one month.

Participants were randomised to treatment allocation using numbered sealed envelopes in batches of 10. At enrolment, participants were allocated treatment by the next available number held by the investigator.

Dimeticone 4% lotion was supplied in 100 ml glass bottles and phenothrin 0.5% liquid in 200 ml bottles.

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Investigators applied the products to dry hair a few drops at a time, spreading the liquid with their fingers, and working around the head. They then used a normal grooming comb to spread treatment evenly. Treatments were applied to the full hair length and left to dry. The regimen was repeated seven days later.

Participants were provided with 30 ml bottles of non-medicated, conditioner free shampoo. Carers were advised of the earliest time treatment should be removed—usually the next morning. They were asked not to use head louse combs or treatments during the study.

Investigators, blinded to the treatment, carried out examinations at follow-up using plastic head louse detection combs. Lice found on the hair or scalp were removed and fixed to the case record. They were later examined to determine their developmental stage and sex. Participants with lice 14 days after enrolment were supplied with 0.5% malathion lotion.

Statistical analysis

We designed our study to detect equivalence to within 20% between treatment groups on the basis of 95% confidence limits derived from the normal approximation to the binomial distribution. We assumed that success rates in the two groups would be 77.5%, based on current best evidence,[1 8] but the design was sufficiently robust that if the success rates proved lower, the power would be reduced but still remain high.

We compared groups using Fisher's exact test and the Mann-Whitney U test. Equivalence was tested on the per protocol population. The primary outcome measure was elimination of head lice using two applications of treatment. Cure was defined as no lice after the second application, on days 9 and 14. Reinfestation was defined as, on days 9 or 14, no more than two adult or third instar lice removed from participants who had been free from infestation after the first treatment.

Results

Our study was carried out between June and November 2003. Overall, 214 young people aged 4 to 18 years and 39 adults agreed to take part. Duration of infestation before the study varied widely. Nineteen (8%) participants had had infestations diagnosed fewer than seven days before treatment. In total, 168 of 253 infested people (66%) had had lice for more than three months, with 118 (47%) having lice continuously for more than one year, the longest being nine years.

Most participants had used insecticides, with 36 (14%) treated between two and four weeks previously. Fifty seven (23%) had not used insecticides for more than three months and 73 (29%) had never used an insecticide, with 69 (27%) having used only wet combing.

We randomly assigned 127 people to dimeticone and 126 to phenothrin. Overall, 248 (98%) participants completed the trial (see bmj.com). Five participants from the phenothrin group withdrew. For per protocol analysis we excluded eight participants (five in dimeticone group) who had complete datasets but one or more assessments outside the scheduled timing; and three (one in dimeticone group) who were unavailable for the day 9 assessment.

The groups were similar in age, sex, intensity of infestation, and hair length, thickness, degree of curl, and dryness or greasiness (see bmj.com).

Adverse events occurred in 16 participants using dimeticone and in 24 participants using phenothrin, total adverse events numbering 18 and 31, respectively. No difference was seen between groups in number of adverse events, severity of adverse events, relation to study treatments, or action taken. Treatment related events included mild eye irritations from dimeticone drips (n=2) and itching or irritation of the scalp or neck (three in dimeticone group and 11 in phenothrin group).

At follow-up examinations, cures were identified in 83 participants in the dimeticone group and 87 in the phenothrin group, with reinfestation after cure in six participants in the dimeticone group and seven in the phenothrin group. These represented positive outcomes of, respectively, 89 of 127 (70%) and 94 of 125 (75%), with a difference of −5% (95% confidence interval −16% to 6%). Positive outcomes in the per protocol population were 84 of 121 (69%) for dimeticone and 90 of 116 (78%) for phenothrin, with a difference of −8% (−19% to 3%). The products were equivalent to within 20%, on the basis of either the intention to treat or per protocol populations.

Before treatment, 33 (13%) participants had heavy louse infestations (several lice found with the first comb stroke), 110 (44%) medium infestations, and 110 (44%) light infestations (many comb strokes to find one louse). Cure, or reinfestation after cure, was influenced by intensity of infestation, occurring in 13 (39%) cases of heavy infestations, 78 (71%) of medium infestations, and 92 (84%) of light infestations. Twenty eight participants had more than 20 lice on either day 2 or day 6. Five of these had more than 20 lice removed on both days, with more newly hatched nymphs found on day 6 (mean 250 insects; range 81-823 insects) than on day 2 (74; 24-151). We found no difference in success between the treatments related to intensity of infestation at any level.

Treatments did not significantly differ at any time in the percentage of participants with lice or the total number of lice detected.

Discussion

Head louse infestation can be cured with two applications of 4% dimeticone lotion a week apart. This silicone compound is the first medical product with a formulation specifically designed for use against head lice. Participants treated with dimeticone reported a significantly lower incidence of irritant adverse events.

By carrying out our study in participants' homes, we ensured the highest level of follow-up and reduced the drop-out rate. We accepted participants who had used an insecticide within two weeks of the study rather than four weeks. A good precedent for this comes from a previous study.[1] Unlike that study, we were unable to undertake random sampling of the population by screening in schools, and some participants acknowledged difficulties in curing louse infestations. We found no evidence that recruitment by advertising selected a biased population who wanted to eliminate head lice by intensive insecticide treatment, as half the

What is already known on this topic

Head louse infestation is widespread in children, and its prevalence has increased since the early 1990s

Treatment with insecticides may be affected by resistance, and combing has become more common as a treatment option

Evidence from randomised controlled trials for any form of treatment is limited

What this study adds

Dimeticone 4.0% lotion is efficacious at treating head louse infestation

Phenothrin 0.5% liquid is effective when properly applied

A high proportion of children with lice may be infested for several months despite parents' attempts to treat by various means

participants had either never used insecticides or had not used one for over three months. This may explain why we encountered little evidence for insecticide resistance through treatment failure with phenothrin, unlike recent studies in which participants were referred by general practices.[3 9] The posology and formulation excipients of phenothrin liquid, however, probably contribute towards activity to overcome low levels of resistance.[10] Overall, the efficacy for both products was comparable to that found for malathion lotions and permethrin.[1 8]

Our method of finding head lice by dry combing with a plastic detection comb is similar to that used by another study.[11] Our team is experienced in the technique. Consequently, we believe all treatment failures were identified and any potential bias due to under-reporting was eliminated.

This is the first randomised controlled trial of an insecticide-free treatment that does not require physical methods. Studies in vitro found dimeticone irreversibly immobilised lice within five minutes of application. The current treatment problems caused by resistance to neuroactive insecticides will not affect this product. The efficacy, lack of odour, and relative ease of use of 4% dimeticone lotion make it a viable alternative to conventional treatments. Most participants had used combing extensively, often with other products, but two thirds of participants had merely limited the number of lice. Half had had head lice continuously for over a year, a clear indication that current policies are not working.

Products used in this study worked well to kill lice, even when a cure was not achieved. Unlike phenothrin, however, dimeticone is not absorbed transdermally and could be used more than twice to effect a cure. Failure to cure may not be due to resistance but to application method. In some cases we found it difficult to ensure that the hair and scalp had been thoroughly covered. The amount of product used for each application of phenothrin liquid was, mostly, greater than the current 50 ml single treatment pack. Consequently, under-dosing is probably widespread in the community. Better instructions for use and improved information at the primary care level could improve success.

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Competing interests: IFB has been a consultant to various makers of pharmaceutical products, alternative therapies, and combs for treating louse infestations. PNL has analysed similar studies for other pharmaceutical companies.

Ethical approval: Ethical approval for this study was granted by Cambridge research ethics committee, and issues related to the locality were approved by Peterborough and Fenland and Huntingdon local research ethics committees. This clinical trial was monitored and audited by Covance.

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Endpiece

An egotistical and dictatorial style

The author is aware that in some parts of his volume he has been betrayed into the adoption of an egotistic, in other parts of a dictatorial style. For this he craves the indulgence of the reader. Almost everything here recorded has passed under his immediate observation. Ardently and deeply interested in all that he has described, he so completely identified self with subject, that he found it impossible to separate them. Where he assumes a dictatorial language, it must be remembered that he is not insisting upon the efficacy of his individual practice, but upon that of Physicians who have long distinguished themselves by an eminent display of talent, and who now most deservedly enjoy the public confidence.

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