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Primary care

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

Recently, most Western countries have encouraged physical methods to treat head louse infestation, either alone or as a component of conventional insecticidal treatments.^{1 2} The commonest method used in the United Kingdom is wet combing with conditioner, known as "bug busting" (Community Hygiene Concern, London). Existing evidence suggests that this method is of low effectiveness,³⁻⁵ which, combined with treatment failure attributed to insecticide resistance, has resulted in an increased prevalence of lice in most communities since 1995.⁶⁻⁸

Dimeticone lotion is a new product, with no conventional insecticide activity. It contains 4% long chain linear silicone (dimeticone) in a volatile silicone base (cyclomethicone). Both compounds are used extensively in cosmetics and toiletries, and a shorter chain dimeticone is used as an anti-flatulent for infant colic. Dimeticone is a clear, odourless fluid, which is applied in the same way as other lotions for head lice infestation, by coating the scalp and full length of the hair. The product dries by evaporation of the cyclomethicone solvent. We selected application for

eight hours or overnight on the basis of a phase II clinical study that compared two 20 minute treatments a week apart with two treatments for eight hours or overnight. In 40 randomised participants (35 children), the 20 minute regimen cured 12 of 20 (60%) and the eight hours or overnight treatment cured 18 of 20 (90%), giving a difference of -30% (95% confidence interval -55% to -5%).

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 families who telephoned the study coordinator received an information booklet by post. 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. A signed, witnessed consent and assent procedure was followed. Other household members were offered examination and invited to join if eligible. Treatments and assessments were carried out in the participant's home. Ineligible household members were advised on treatment.

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 previous use of pediculicides. We chose the lower age limit of four years as children of this age understand explanations and can assent to procedures; we had no upper age limit.

We excluded participants who were pregnant, breast feeding, sensitive to phenothrin or chrysanthemums, or had a chronic scalp disorder,⁹ 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 using a computer generated list in balanced blocks of 10. Treatment allocation was by

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numbered sealed envelopes issued in batches of 10. A duplicate set was made in the event individual code breaking was required. At enrolment, participants were allocated treatment by the next available number held by the investigator. As randomisation was by individual, household members could receive different treatments.

Dimeticone 4% lotion was supplied in 100 ml glass bottles (Hedrin; Thornton and Ross, Huddersfield) and phenothrin 0.5% liquid in 200 ml bottles (Full Marks Liquid; SSL International, Oldham). Both products were applied to dry hair, using enough to thoroughly moisten the hair and scalp. Investigators applied the products a few drops at a time, spreading the liquid over the hair with their fingers, and working systematically around the head. They then combed the hair with a normal grooming comb to spread treatment evenly and to ensure coverage. Treatments were applied to the full hair length, as lice were observed to run down the hair shafts to escape the fluid, particularly when the silicone lotion was used. The lotion was left to dry naturally. 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 and not to divulge the treatment to assessors. Compliance with the protocol was assessed by retrospective questionnaire at each assessment.

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 with clear tape. The lice were later examined to determine their developmental stage and, if mature, their sex. Participants with lice 14 days after enrolment were supplied with 0.5% malathion lotion (Prioderm; SSL International).

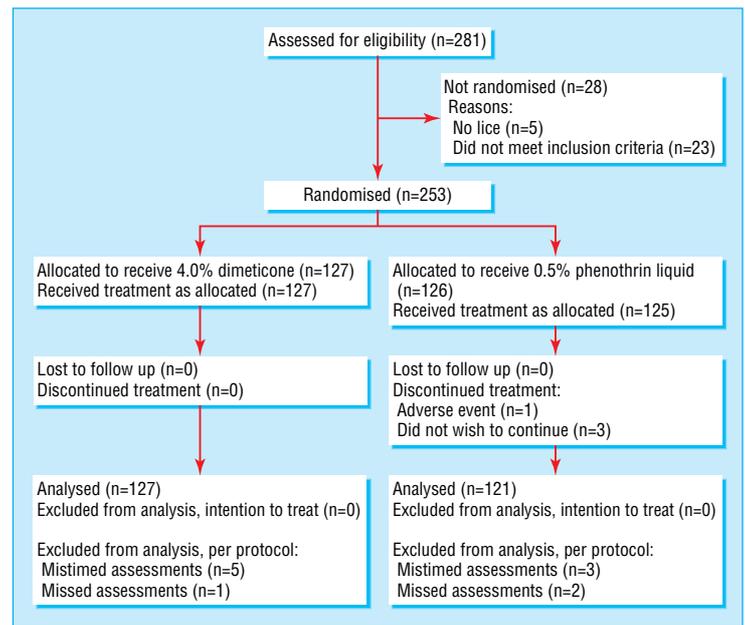
Statistical analysis

Our study was structured 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,^{3, 10} but the design was sufficiently robust that if the true success rates proved lower, the power would be reduced but still remain high—for example, over 80% power for 70% true success rates. For 90% power the sample size required for each group was determined as 114; the sample size allowed for protocol violations.

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. We recognised a relatively high risk of reinfestation after cure. 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.



Flow of participants through trial

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 receive dimeticone and 126 to receive phenothrin. Overall, 248 (98%) participants (121 in the phenothrin group) completed the trial (figure). Five participants from the phenothrin group withdrew: one dropped out before any follow-up assessments, two dropped out after the first follow-up, one was given the wrong second treatment, and one washed the second application off early due to an adverse event. 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 (table).

The quantity of product applied depended on the length and thickness of hair. The amount of dimeticone lotion used (mean 54.8 ml) ranged from 13 ml for close cropped hair to 161 ml for thick hair longer than shoulder length. The amount of phenothrin liquid used ranged from 19 ml to 204 ml (mean 71.8 ml).

Adverse events occurred in 16 participants using dimeticone and 24 participants using phenothrin, total adverse events numbering 18 and 31, respectively. No difference was seen between groups in number of adverse events (seven participants had multiple events), severity of adverse events (15 participants had moderate or severe events), relation to study treatments (10 participants had events probably related to treatment), or action taken (only one participant had treatment interrupted for an adverse event). 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).

Personal characteristics of participants (intention to treat) at baseline. Values are numbers (percentages) unless stated otherwise

Characteristic	Dimethicone 4.0% lotion group (n=127)	Phenothrin 0.5% liquid group (n=126)
Mean (range) age (years):	13.3 (4-54)	12.9 (4-70)
Male	31 (24)	29 (23)
Female	96 (76)	97 (77)
Intensity of infestation at enrolment:		
Light*	52 (41)	58 (46)
Medium	57 (45)	53 (42)
Heavy†	18 (14)	15 (12)
Details of hair		
Length:		
Close cropped	11 (9)	10 (8)
Above ears	24 (19)	24 (19)
Ears to shoulders	29 (23)	25 (20)
Below shoulders	63 (50)	67 (53)
Thickness:		
Fine	25 (20)	27 (21)
Average	43 (34)	40 (32)
Thick	58 (46)	58 (46)
Wiry	1 (<1)	1 (<1)
Curl‡:		
Straight	93 (73)	90 (72)
Wavy	29 (23)	32 (26)
Curly	5 (4)	3 (2)
Oiliness:		
Dry	16 (13)	12 (10)
Normal	105 (83)	106 (84)
Greasy	6 (5)	8 (6)

*Many comb strokes needed to find one louse.

†Several lice found with first comb stroke.

‡Not recorded for one participant 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, 110 (44%) medium infestations, and 110 (44%) light infestations. A heavy infestation was defined as several lice found with the first comb stroke and a light infestation as many comb strokes needed 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.

Our study followed closely the methodological criteria set out in a recent Cochrane review.⁹ Carrying out our study in participants' homes ensured the highest level of follow-up and reduced the drop-out rate. The exception to Cochrane criteria was in accepting participants who had used an insecticide product within two weeks of the study rather than four weeks. A good precedent for this, however, comes from a study that found outcome was not affected by insecticide use two weeks previously.³ 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 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.⁵⁻¹¹ The posology and formulation excipients of phenothrin liquid, however, probably contribute towards activity to overcome low levels of resistance.¹² Overall, the efficacy for both products was comparable to that found for malathion lotions applied by parents in North Wales in 1999 and the investigator led study of permethrin in the United States, although the latter, as an efficacy study may not represent consumer use.^{3, 10}

Our method of finding head lice by dry combing with a plastic detection comb is similar to that used by another study.¹³ 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. The frequency of follow-up enabled us to identify differences between treatments, and removal of some, but not all, lice ensured diagnostic sensitivity without influencing outcome.

This is the first randomised controlled trial of an insecticide-free treatment that does not require physical methods to support its activity. Studies in vitro found dimeticone irreversibly immobilised lice within five minutes of application and indicate that it acts against head lice by coating the insects and thus disrupting their ability to manage water. The current treatment problems caused by resistance to neuroactive insecticides will not affect this product and it should be acceptable to people reluctant to use insecticides on safety grounds. Its efficacy, lack of odour, and relative ease of use make 4% dimeticone lotion a viable alternative to conventional treatments, especially for people who find combing laborious or impractical. Most participants had used combing extensively, often in combination with other products, but two thirds of participants had not succeeded, merely limiting the number of lice. Half had had head lice continuously for over a year, which is 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. We found that parents who used phenothrin liquid on family members excluded from the study were sometimes less successful than investigators treating other household members, indicating that failure to cure may not be

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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

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, especially in females with long thick hair, irrespective of which treatment was used. 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, a problem dealt with by the 100 ml bottle used for 4% dimeticone lotion. Better instructions for use and improved information at the primary care level could improve success.

Contributors: IFB conceived and designed the study, interpreted the data, wrote the paper, and contributed to the execution of the study. He will act as guarantor for the paper. CMB conceived, designed, and coordinated the study, was responsible for screening, treatments and assessments, interpreted the data, and helped write the paper. PNL was responsible for the randomisation process and statistical analyses, and helped interpret the findings and write the paper. Treatments and assessments were carried out by Anne Scarlett, Audrey Pepperman, Caroline Priestley, Nazma Burgess, and Matthew Southward. Kate King monitored and evaluated adverse events and acted as the medical contact throughout the study. Sam Shuster was the dermatological medical expert. Katharine Young and Yvonne

Cooper entered the data for statistical analysis and John Fry provided statistical assistance.

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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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