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Primary care

Single blind, randomised, comparative study of the Bug Buster kit and over the counter pediculicide treatments against head lice in the United Kingdom

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Abstract

Objective To compare the effectiveness of the Bug Buster kit with a single treatment of over the counter pediculicides for eliminating head lice.

Design Single blind, multicentre, randomised, comparative clinical study.

Setting Four counties in England and one county in Scotland.

Participants 133 young people aged 2-15 years with head louse infestation: 56 were allocated to the Bug Buster kit and 70 to pediculicide treatment.

Interventions Home use of proprietary pediculicides (organophosphate or pyrethroid) or the Bug Buster kit.

Main outcome measure Presence of head lice 2-4 days after end of treatment: day 5 for the pediculicides and day 15 for the Bug Buster kit.

Results The cure rate using the Bug Buster kit was significantly greater than that for the pediculicides (57% *v* 13%; relative risk 4.4, 95% confidence interval 2.3 to 8.5). Number needed to treat for the Bug Buster kit compared with the pediculicides was 2.26.

Conclusion The Bug Buster kit was the most effective over the counter treatment for head louse infestation in the community when compared with pediculicides.

Introduction

Infestation with head lice, *Pediculus capitis*, is a widespread, persistent, and recurring problem and although it poses no direct threat to health, it may lead to secondary infections if untreated.¹ The mere presence of head lice may cause distress to children and their families.^{2,3} Previous studies of insecticides have reported treatment failure in laboratory bioassays⁴⁻⁹ and field trials.^{4,5,9,10} Systematic reviews have identified several flaws in earlier study designs,^{11,12} and a clinical review of best practice compared the merits of each class of pesticide currently available.¹³ Several possible mechanisms for resistance in head lice have been reported.^{4,5,9,14} Treatment failure is likely to be an important factor in the reported rise in the incidence of head lice infestation, but of concern is the increased risk of toxicity this may pose to children. Although current insecticides registered for use against head lice are generally considered safe for occasional use,¹⁵ they may pose a greater risk of direct or cumulative toxicity if used frequently.

Wet combing with conditioner was first developed as a method of detecting head lice and was subsequently advocated as a means of treatment ("Bug Busting") by the UK charity Com-

munity Hygiene Concern.¹⁶ The method involves using a fine toothed comb on thoroughly wet hair. Over several years the charity has developed and trialled a Bug Buster kit comprising instructions and materials to undertake four sequential combings on wet, conditioned hair, leaving three days between each.² A recent Cochrane review highlighted the need for a clinical evaluation of the kit.¹¹ The only randomised controlled trial to date was carried out in two Welsh counties, an area with head lice showing intermediate resistance to treatment.¹⁰ The cure rate for the kit was only 38% compared with 78% for two doses of 0.5% malathion lotion six days apart.¹⁰ This early study used a prototype kit (1996 version), which has since undergone major developments in the design of the comb for removing small nymphs. We compared the effectiveness of the current (1998) Bug Buster kit with over the counter pediculicides containing malathion or permethrin among representative populations from four counties in England and one county in Scotland. We aimed to measure the effectiveness of the treatments under realistic conditions, as used by people in practice following the recommendations of the manufacturers.

Methods

Participants were recruited through general practices in Bedfordshire, Cornwall, Cumbria, Dumfries and Galloway, and Surrey. The general practitioners were contacted by the study coordinator or local study nurse and given full details of the study with an invitation to take part. To widen participation to reflect the broader community, school nurses placed posters in local pharmacies and primary schools and the study nurses in Surrey and Cumbria handed out information sheets at parents' meetings. We aimed to recruit from families who would normally go to their general practitioner for advice on head louse treatment or would buy treatment from pharmacies. We had no upper age limit for the study, but participants were aged up to 15 years. A lower age limit of 2 years was chosen for safety reasons.

The general practitioner or community nurse recruited infested young people into the trial if they had a live head louse, they had had no treatment for head lice in the previous three weeks, they or their guardian agreed not to use other head louse treatments during the trial, they or their guardian had provided written informed consent, and the guardian agreed that the immediate family would be examined for lice and, if necessary, given the same treatment as allocated to the family member with confirmed head louse infestation.

Design

For ethical reasons, we did not use a conventional double blind, randomised, placebo controlled trial. We therefore carried out a randomised, comparative study of the Bug Buster kit against the currently recommended insecticide products in any given area. The specimen louse from the confirmed index case was removed by the general practitioner or community nurse and stuck on a record card for later confirmation by the local study nurse. Only this one participant from each family who fulfilled the inclusion criteria was included in later analysis after being randomly assigned to one of two treatment arms: the Bug Buster kit (Community Hygiene Concern: London) or a proprietary bottle of insecticide treatment containing either 0.5% aqueous malathion (Derbac-M; Seton-Scholl Healthcare, Oldham) or aqueous permethrin (1% Lyclear, crème rinse; Warner Lambert UK, Eastleigh). We chose two different insecticides on pragmatic grounds, as accessibility to treatment varies nationwide according to local policy. We selected aqueous solutions of insecticides as opposed to those with an alcohol base because they are widely used formulations and are suitable for people with asthma.

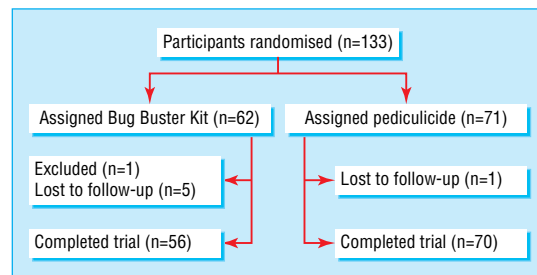
The Bug Buster kit is dispensed over the counter or through mail order. A survey of 92 pharmacies in our study areas (NH, unpublished data) found just 8% of outlets that offered the additional information of double dosing when a pediculicide was purchased. For this reason we provided no additional information on how to use the products other than that supplied with the products. Participants allocated to the Bug Buster kit used their own conditioner. The general practitioners stressed the importance of checking for lice in family members and reporting any finds. Each participating general practitioner was assigned an individual randomisation list at the start of the trial, generated using Minitab 11.0 for Windows, and provided with supplies of the treatments.

Participants were visited at home by the study coordinator or local study nurse or were asked to return to their surgery for follow-up five days after application of the pediculicides or 15 days after the start of the Bug Buster regimen. We decided to use different end points as the duration of treatments varied. We chose day 5 for pediculicides and day 15 for the Bug Buster kit to allow sufficient time for treatments to be completed and to provide a similar opportunity for reinfestation to occur (2-4 days after completion of treatment in each case). We did not evaluate ovicidal activity.

The study nurses attended a one day workshop on louse detection using the wet combing with conditioner method (combing wet and conditioned hair from root to tip across the whole scalp with a fine toothed comb, then repeated in rinsed hair). The nurses, unaware of treatment allocation, used this method at each follow-up. They recorded the presence, number, and stage of lice. From this we determined cure (no live lice) or failure (one or more live lice). Lice were stored at -20°C for detection of molecular or biochemical resistance mechanisms, specifically *kdr*-type mutations from genomic DNA.¹⁴ Participants or their guardians in both groups completed a simple questionnaire to determine compliance and satisfaction with the treatment and to obtain basic epidemiological information, including age, sex, number of siblings, history of head louse infestation and treatment, and recent use of antibiotics.

Statistical analysis

We calculated that we would need a sample size of 98 (49 in each arm) to detect a 30% difference between the two groups (80% for one treatment, 50% for the other), with a power of 80% and 5%



Flow of participants through trial

significance (Stata 8.1). We analysed the data from those participants who completed the study and provided outcome data. We carried out a univariate analysis using Yates corrected χ^2 test in Epi Info (version 6) to test the effect of treatment type (the relative risk) on cure rate. To estimate the effect of missing data for participants who were allocated treatment but did not complete the study, we used extreme case analysis. The number needed to treat was calculated.

Results

A total of 133 young people aged 2-15 years were recruited and received treatment: 66 from Bedfordshire, 15 from Cornwall, 34 from Cumbria, 4 from Dumfries and Galloway, and 14 from Surrey (figure). One participant from Surrey allocated the Bug Buster kit was excluded for also using an insecticide, and six participants were lost to follow-up (three each from Cumbria and Surrey; five received the Bug Buster kit and one malathion). We analysed the data on the remaining 126 participants who completed the study: 56 were allocated to the Bug Buster kit, 40 to permethrin, and 30 to malathion. The characteristics of the two groups were well matched at baseline (table 1).

The cure rates for malathion and permethrin were 17% (5/30) and 10% (4/40). The cure rate for the Bug Buster kit was significantly greater than that for the pediculicides (57% versus 13%; relative risk 4.4, 95% confidence interval 2.3 to 8.5; table 2). The significant difference remained after extreme case analysis, which included missing outcome data and assumed that all six missing or excluded participants allocated the Bug Buster kit were not cured but that the missing individual allocated insecticide was—that is, cure rates of 52% (32/62) and 14% (10/71), respectively (relative risk 3.7, 2.0 to 6.8). We determined that for every two or three people using the Bug Buster kit rather than pediculicides an extra person would be cured (number needed to treat 2.26).

Head louse infestation occurred for the first time in 22% of the young people examined. In families of young people with previous head lice infestations, 55% usually went to their general practice for a pediculicide prescription and the remainder purchased treatment from a pharmacist or sought advice from friends. We had no reports of recent antibiotic use and no

Table 1 Baseline descriptive characteristics of participants with outcome data who were allocated to Bug Buster kit or pediculicide for eliminating head lice

Characteristic	Bug Buster kit (n=56)	Pediculicide (n=70)
Mean (SD) age (years)	7.66 (2.62)	6.91 (2.42)
% (No) female	77 (43)	81 (57)
Mean (SD) No of children per family	2.18 (0.94)	2.06 (0.92)
% (No) who had past infestation	79 (44)	77 (54)

Table 2 Outcome measures at follow-up for participants allocated Bug Buster kit or pediculicide for eliminating head lice

Analysis	Bug Buster kit (15 days)		Pediculicide (5 days)		P value	Relative risk (95% CI)
	Total	% (No) cured	Total	Cured		
Participants with complete outcome data	56	57 (32)	70	13 (9)	<0.0001	4.4 (2.3 to 8.5)
Assuming treatment failure for participants with missing data	62	52 (32)	71	13 (9)	<0.0001	4.1 (2.1 to 7.8)
Assuming treatment failure for participants with missing data in Bug Buster group but success in insecticide group*	62	52 (32)	71	14 (10)	<0.0001	3.7 (2.0 to 6.8)

*Extreme case analysis.

reports of lice among the family members of recruits during the trial.

Discussion

The Bug Buster kit was four times more effective than current over the counter pediculicides for eliminating head lice. This finding is contrary to a previous study in Wales in which malathion treatment was twice as effective as the Bug Buster regimen.¹⁰ It seems likely that the higher cure rate with the Bug Buster kit in our study is a result of improvements to the fine toothed comb, as this was the only major change. If so, it suggests that the success of fine toothed combing depends on the choice of comb. The effectiveness of the pediculicides was much lower in our trial than in the Welsh trial, and much more in line with the results from a previous trial in Bristol, which reported cure rates of 13% for permethrin and 36% for malathion.⁴

This discrepancy may be accounted for in several ways. Firstly, we used the manufacturer's recommended single dose of insecticide rather than two doses six days apart, which is now considered an unlicensed use.¹⁵ Owing to the limited residual effect, a double dose is likely to have greater success in killing nymphs that emerge from eggs not destroyed by the first dose. Secondly, our follow-up time was five days rather than seven days after insecticide treatment, as in the Welsh trial, but this is unlikely to have led to an underestimate of the cure rate given the lack of a significant residual effect. A longer period before measurement of outcomes increases the chance of nymphs emerging and being detected, and also increases the risk of reinfestation. Thirdly, we used an aqueous formulation rather than an alcohol one so that we could include people with allergies. The Welsh trial used either formulation, according to whether participants had allergies, but did not report any difference in effectiveness between the two. Fourthly, we recruited only people whose lice infestation had been reported by their families, rather than using school nurses to find cases by screening with fine toothed combs as in the Welsh trial. Our study population was reasonably representative of the population who normally seek treatment for head lice, as the ratio of those who had previously sought treatment from pharmacies or their doctors was similar to that reported in the national population.¹⁷ For several reasons we therefore believe our trial better reflects how over the counter products are used in the community.

Finally, the discrepancy may also be due to differences in resistance to insecticide, as our trial was carried out after the Welsh trial and included a range of urban settings. The particularly poor effectiveness of permethrin is likely to be due to widespread *kdr*-type resistance; all but one of the lice from treatment failures collected in this study were found to have the T929I and L932F resistant genotype mutations of the paratype sodium channel gene (MSW, unpublished data). On the basis of these and earlier similar findings we believe that the status of licensed

insecticide treatments needs to be assessed as they potentially expose users to repeat applications without any important reduction in infestations.

The updated Bug Buster kit seems to provide a viable alternative to over the counter insecticide treatments. An observational study in Ghent, Belgium reported promising findings on satisfaction with wet combing as a treatment.¹⁸ In this study, families of head lice infested schoolchildren were given impartial advice on treatment options and then allowed to choose the treatment; most chose wet combing with conditioner (29%) over pediculicides (19%) or a combination of the two (15%), which suggests the Bug Buster regimen may be readily taken up by the community.

Some may consider that the cure rate of only 57% we detected with the Bug Buster kit is still unacceptable and may not provide an efficient treatment against head lice. At present there are no readily available products that provide fully effective control of head lice, and there is an urgent need to identify safe, novel insecticides of proved efficacy.

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Contributors: NH initiated the research, secured funding, and led the design of the study; he is guarantor. MMC led the analysis of data and writing the report. GM coordinated the trial and with AB and SP participated in the fieldwork and contributed to writing the report. MSW and CB carried out the analysis of *kdr*-type resistance mutations.

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What is already known on this topic

Head lice have varying degrees of resistance to over the counter pediculicides

Fine tooth combing of wet hair is an effective method of detecting head lice but unproved as a treatment

What this study adds

Effectiveness of popular over the counter pediculicides for eliminating head lice is poor

The *kdr*-type resistance mechanism to pyrethroids is widespread in head lice in the United Kingdom

The Bug Buster kit is significantly more effective than common over the counter pediculicides for normal unsupervised use

Competing interests: NH has received funding over the past 10 years to screen pediculicides but not products or companies involved in this study.

Ethical approval: London School of Hygiene and Tropical Medicine research ethics committee, London multicentre research ethics committee, and individual local research ethics committees of the health authorities in each study area.

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