

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 regimen 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

Wet combing with conditioner was developed for detecting head lice and was subsequently advocated as a means of treatment ("Bug Busting").¹ Over several years the charity Community Hygiene Concern has developed and trialled a Bug Buster kit comprising four sequential combings on wet, conditioned hair, three days apart.² The only randomised controlled trial of this kit to date was carried out in two Welsh counties, an area with head lice showing intermediate resistance to treatment.³ The cure rate for the kit was only 38% compared with 78% for two doses of 0.5% malathion lotion six days apart. Since this early study the kit has undergone major developments in the design of the comb. We compared the effectiveness of the current 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 as used by people 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 invited to take part in the study. School nurses placed posters in local pharmacies and primary schools or 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. 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 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

We 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 index case was stuck on a record card for later confirmation. Only this one participant from each family who fulfilled the inclusion criteria was included in later analysis. Participants were randomly assigned to either the Bug Buster kit or a proprietary bottle of insecticide treatment containing 0.5% aqueous malathion (Derbac-M; Seton-Scholl Healthcare, Oldham) or aqueous permethrin (1% Lyclear, crème rinse; Warner Lambert UK, Eastleigh). We selected aqueous rather than alcohol based solutions of insecticides because they are widely used and are suitable for people with asthma.



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The Bug Buster kit is dispensed over the counter or through mail order. On the basis of a survey, we provided no additional information on how to use the products other than that supplied with them. At the start of the trial each participating general practitioner was assigned an individual randomisation list and given supplies of the treatments.

Participants were visited at home 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. These end points were chosen to allow sufficient time for treatments to be completed and to provide a similar opportunity for reinfestation to occur.

The study nurses were trained in the wet combing with conditioner method. 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.⁴ Participants or their guardians in both groups completed a simple questionnaire to determine compliance and satisfaction with the treatment and to obtain basic information.

Statistical analysis

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 (see bmj.com). One participant allocated the Bug Buster kit was excluded for also using an insecticide, and six participants were lost to follow-up. 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 (see bmj.com).

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). 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).

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.³ 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.⁵

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.⁶ 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 by school nurses mass screening using 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.⁷ For several reasons we therefore believe our trial better reflects how over the counter products are used in the community.

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.

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

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.

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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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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A memorable patient

A late diagnosis

An 82 year old man was taken to casualty after being in a car crash. He had a fractured sternum but had no neck pain, and his cervical spine was cleared clinically. Over the next few days, however, he developed neck discomfort, mild weakness of his right hand, and intermittent paraesthesiae of his fingers. He mentioned these symptoms several weeks later in a follow-up clinic for the sternal fracture. Examination revealed kyphosis of the lower cervical spine, no tenderness, and a moderate range of movement. There was mild weakness of the right C6 and C7 myotomes, but normal sensation and no sign of myelopathy. He denied any previous neck problems.

Radiographs showed a 50% spondylolisthesis at C6-7; the right facet joint had dislocated and the left was subluxed. Magnetic resonance imaging showed mild deviation and indentation of the spinal cord from canal stenosis but no cord oedema. Computed tomography revealed a fractured posterior arch of C6, which seemed old, and a reduced anteroposterior diameter of the canal. The C6-7 disc space was degenerate with cystic changes in the vertebral bodies, confirming that the injury occurred some time ago.

We asked the patient if he could remember any possible injury to his neck. The only event to which he could ascribe the injury

was during the second world war, when he was an engineer in a Lancaster bomber. In 1943 his plane was shot down by night fighters, and he and four other surviving crew bailed out over enemy territory. He remembers only that the parachute gave him a severe jolt when it deployed. He was captured and, for the first two weeks, was held prisoner in northern Germany in a small cell with only a straw mattress bed. He recalls having a stiff neck for several days but received no medical attention. Apart from daily interrogation, he lay on the mattress for nearly 24 hours a day.

He could not recall having any trouble with his neck since then, but his son mentioned that he had always noticed his father's rather sway posture and his daughter reminded him that he often used to mention having a stiff neck and was always rubbing it.

Cervical fractures and dislocations are occasionally missed after inadequate clinical or radiological evaluation. However, it is rare for patients to survive such a serious injury without developing partial or complete paralysis. It is rarer still for them to be unaware of the injury.

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