

CLINICAL EFFICACY AND SAFETY IN HEAD LICE INFECTION BY *PEDICULUS HUMANIS CAPITIS* DE GEER (ANOPLURA: PEDICULIDAE) OF A CAPILLARY SPRAY CONTAINING A SILICON-OIL COMPLEX¹

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Summary:

Head lice are endemic worldwide. Resistance to permethrin and doubts about the safety of pesticides promoted the use of physical therapies (wet-combing, dry-on suffocation). The aim of our study was to test the pediculicidal and ovicidal effects of one application of a silicon-oil complex composed of dimethiconol and castor oil. The study was a prospective cohort of 108 infested patients (11 males, 97 females; 58 children, 50 adults), in Sri-Lanka. Pediculicidal efficacy was evaluated as the percentage of patients free of live lice one hour after the application of the treatment and at day 1 (wet combing). Ovicidal efficacy was calculated as the proportion of subjects without larval stages at days 1 and 7 among subjects followed up all over the study. In normal conditions of use, in this open cohort, a pediculicidal effect of a dimethiconol-castor-oil lotion was shown one hour after application in 99/108 (91.7 %) treated subjects and at day 1 in 86/99 (87 %) subjects and an ovicidal effect at day 7 in 79/108 (73.2 %) treated subjects. A second application of the same product was necessary to increase the cure rate to 79.6 % (86/108) at day 8. In our study, the second application of the same product was performed seven days later, but the best time for additional applications should be defined in further studies. However, the efficacy of this safe physical treatment was similar to that of chemical pediculicides (malathion, permethrin).

KEY WORDS: head lice, pediculicide, physical therapy, dimethicon, castor oil, clinical trial, Sri Lanka.

Résumé : EFFICACITÉ ET INNOCUITÉ D'UN COMPLEXE HUILE-SILICONE DANS LA PÉDICULOSE À *PEDICULUS HUMANIS CAPITIS* DE GEER (ANOPLURA : PEDICULIDAE)

La pédiculose à *Pediculus humanis capitis* est une ectoparasitose pandémique. Le traitement habituel par application externe d'insecticides chimiques est de plus en plus remis en question en raison de la chimiorésistance des poux et des risques de toxicité pour les patients. Les nouveaux produits à action mécanique doivent encore faire la preuve de leur efficacité. Nous rapportons les résultats d'une étude visant à évaluer l'efficacité d'un complexe huileux à base de diméthicone et d'huile de ricin. Il s'agit d'une étude prospective réalisée au Sri-Lanka sur une cohorte de 108 sujets des deux sexes, principalement des femmes (11 hommes et 97 femmes ; 58 enfants et 50 adultes), infestés par *P. capitis*. Les patients sont traités par une seule application de la lotion. Le produit est rincé au bout d'une heure. L'efficacité est évaluée par le pourcentage de sujets ne présentant plus de poux vivants au coiffage au peigne fin une heure après application et le lendemain du traitement. L'efficacité ovicide est évaluée par le taux de sujets ne présentant plus de larves de poux le lendemain et au septième jour après l'application. Les résultats confirment l'efficacité pédiculicide du complexe huileux diméthicone-huile de ricin dans le traitement de la pédiculose du cuir chevelu. Le produit est pédiculicide chez 91,7 % des sujets traités par une seule application suivie de rinçage à une heure (99/108). Il est ovicide chez 73,2 % des sujets évalués le septième jour après le traitement (79/108). Une deuxième application du même produit, effectuée au septième jour, permet d'atteindre 79,6 % d'efficacité ovicide (86/108) au 8^e jour. Cette deuxième application apparaît donc indispensable pour compléter l'efficacité initiale du traitement et pourrait augmenter considérablement le taux de guérison, mais l'intervalle, voire le nombre d'applications complémentaires restent à déterminer par une étude clinique plus poussée. Néanmoins, ces résultats prouvent que l'utilisation d'un produit réputé non toxique et agissant mécaniquement peut être aussi efficace contre les poux que les insecticides jusque-là utilisés.

MOTS CLÉS : pédiculose, traitement, diméthicone, huile de ricin, cohorte, Sri Lanka.

INTRODUCTION

Head lice pediculosis is a contagious but benign ectoparasitic disease. It is endemic worldwide and affects individuals at all ages and with various socioeconomic backgrounds. It seems particularly frequent in children 5 to 11 years old (Roberts, 2002; Sladden *et al.*, 2005). Although associated with a minor morbidity (pruritus and skin infections), head

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lice infection has a significant negative psychosocial impact due to the image of poor hygiene it conveys and in the United States, to unnecessary days lost from schools applying no-nits policies (Frankowski, 2004). The economic consequences are also considerable, with annual associated costs estimated to 367 million \$ in USA including treatment and school system costs (West, 2004; Hansen & O'Haver, 2004), and more than 38.5 million € in France (Chosidow, 2004).

Topical chemical pediculicides are currently the therapeutic option recommended by the most recent guidelines for management of head lice infection (West, 2004; Ministère de la santé, 2004). In a former Cochrane review (Dodd, 2001), only four studies of the 71 evaluating the effects of different pediculicides met the criteria for quality. This meta-analysis showed an efficacy of more than 95 % for malathion- similar to that of two recent studies (Taplin *et al.*, 1982; Meinking *et al.*, 2007) and pyrethroid-based treatments (Taplin *et al.*, 1986), including synergised pyrethrins (Burgess *et al.*, 1994). However, in real life setting, these chemical treatments recommended by all guidelines do not always lead to such optimistic results and repeated therapeutic failures are frequently observed (Chosidow, 2000). Besides poor observance and inappropriate conditions of use and re-infestations, an increasingly reported resistance of lice to pediculicides is one of the most critical factors predicting therapeutic failure. In particular, resistance to pyrethroids has been demonstrated in countries where these drugs are much more widely used compared to malathion (Chosidow *et al.*, 1994; Burgess *et al.*, 1995; Rupes *et al.*, 1995; Meinking *et al.*, 2004) and it has been confirmed by the presence of knock-down resistance-type genetic mutations in resistant lice (Yoon *et al.*, 2003; Kristensen *et al.*, 2005; Durand *et al.*, 2007).

To face this issue and according to the recently raised hypothesis that household exposure to pesticides might predispose children to leukaemia (Menegaux *et al.*, 2006), alternative physical therapeutic options have been proposed, such as the wet-combing or "Bug Buster" approach, consisting in combing the hair with conditioner using a fine-toothed comb (Roberts *et al.*, 2000; vander Stichele *et al.*, 2002; Hill *et al.*, 2005; Ibarra *et al.*, 2007) or the dry-on suffocation based pediculicides (Pearlman, 2004) or the use of hot air (Goates *et al.*, 2007). However, their efficacy, assessed in studies with design and methodology of questionable quality (Dawes, 2005; Roberts *et al.*, 2005; Chosidow, 2006), remains to be established.

Nevertheless, Burgess in recent studies evaluated the efficacy of a new dimethicone-based product without conventional insecticide activity compared with phenothrin (Burgess *et al.*, 2005, 2007). Its mode of action was based on the coating and irreversible immobilisation of lice, leading to their drowning (Burgess, 2009).

This latter study demonstrated an equivalent efficacy (less than 20 % difference) of dimethicone and phenothrin lotions, with cure rates of 70 % and 75 % respectively. Another randomized observer blinded controlled trial showed a high efficacy of a pediculicide based on dimeticone (Heukelbach *et al.*, 2008).

The product evaluated in our study contains 51 % of silicon-dimethiconol-castor oil complex (decamethylcyclopentasiloxane-isopropanol (96 %), castor oil (1 %) and dimethiconol (0.1 %)). A preliminary *in vitro* study demonstrated the killing effect of this complex on live lice (unpublished data). The aim of our study was to confirm these preliminary results *in vivo* by evaluating the pediculicidal and ovicidal efficacy in subjects infected with head-lice.

SUBJECTS AND METHODS

INCLUSION CRITERIA

Male or female children (aged 3 years or more) and adults, showing pediculosis of the scalp diagnosed by the presence of live lice, were recruited by French and Sri-Lankan physicians. Before enrolment, adult participants and the two parents or legal representatives of the children had to sign a written informed consent form. The study protocol was approved by the Sri Lankan sanitary authorities (05-April-06).

EXCLUSION CRITERIA

Subjects having used pediculicidal or ovicidal treatments within 14 days before inclusion or having participated in a clinical study within three months before study entry, pregnant or breastfeeding women or women not using any contraceptive method, were not included in the study. Women of childbearing age were included only if they had a negative test for pregnancy and if contraception was initiated or already taken. Subjects with a marked sensitivity to a component of the study product, or with any severe medical or psychiatric disease considered as dangerous for the subject or susceptible to interfere with the study were also excluded.

TREATMENT

The study product was a physical treatment provided by Pierre Fabre Laboratories (Itax[®] lotion). It consisted of a lotion in spray containing a 51 % w/w silicone-dimethiconol-castor oil complex (isopropanol amount sufficient for obtaining 100 % w/w of product). The study lotion was applied (20 to 110 g of lotion depending on the length of hair, measured by weighing the bottle before and after application) once at D0 and, when

needed, repeated seven days later (D7). The application was performed at the investigation centre only by a nurse and the product was kept by the investigator. Another permethrin pediculicide (Pyrine®) was provided for the treatment of other members of the subject's family not participating in the study (e.g. pregnant women or children under 3 years of age) and of the subjects not responding to the tested product (rescue treatment).

One hour after application of the therapeutic lotion, a gentle shampoo was applied by a nurse in the study centre to wash the active product. The same gentle shampoo was provided to the subjects for use at home during study duration to avoid risk of use of any other active treatment. No other treatment product was allowed. Especially, participants were instructed not to use head lice combs between visits, not to use any other capillary product, shampoos other than the one provided or pharmacological pediculicidal treatment and to avoid hairdresser services (in particular to have hair coloured or make a permanent wave). They were also informed not to apply any product on the days of the visits (D0, D1, D7 and D14). For security reasons independent from the study, the final visit foreseen at D14 occurred in fact at D8.

Three hundred persons were examined by one physician from our team (MSG). The subjects were selected or rejected according to inclusion and exclusion criteria.

STUDY DESIGN

This observational open-label clinical study was conducted from April to May 2006 in the St Anthony's Youth Front Catholic Social Service Centre of Colombo in Sri Lanka. It was carried out according to the ethical principles stated in the Declaration of Helsinki, in accordance with local legal requirements of Sri Lanka and was permitted by the authorities of the country.

STUDY PROTOCOL

At inclusion visit (D0), subjects were examined and the number of live lice was determined using a fine-toothed comb. To define the severity of the infestation, we decided to adjust the combing time to length of hair: 1-3 minutes for short hair, 4-5 minutes for mid-length hair and 6-7 minutes for long hair. The severity of the infestation was stratified as severe if combing found 30 live lice or more per head and moderate or mild if combing found less than 30 live lice per head.

Product was applied by the nurse on the scalp and dry hair in sufficient amount to wet the whole scalp and thoroughly spread by massage with the fingers. The amount of applied product to their hair took into account hair length (from 20 g for the shortest hair to 110 g for the longest hair). The lotion was allowed to

act for one hour, and then the product was removed by washing the hair with a gentle shampoo. Thereafter, the investigator assessed main efficacy criterion and local tolerance.

EVALUATION CRITERIA

- Main efficacy criterion

A physician checked clinical efficacy by hair combing with a fine-toothed comb over a white smooth surface. Therapeutic failure was proclaimed when the physician noted one or more live lice. The pediculicidal efficacy of the product was evaluated by determining the number of subjects showing no live lice one hour after the first application of the tested product. For this purpose, the investigator determined and recorded the number of live lice and removed dead lice by combing, using the same method as for inclusion visit. When the presence of live lice was detected, the subject was considered as a therapeutic failure, and a rescue treatment (Permethrin 1 %) was proposed to him (her). The number of therapeutic failures was recorded.

- Secondary efficacy criteria

The ovicidal efficacy of the study product was evaluated at D1, D7 and D8: at each visit after product application, the investigator determined the number of subjects without live immature stages.

If the subject presented no adult louse but live immature stages at D1, he was followed up to D7 and if he still showed nymphs at this time, he was submitted to a second application of the product in the same conditions as at D0 and then followed up to D8.

The detection of adult live lice at D1 or D7 was considered as a treatment failure and led to prescription of a rescue treatment with a 1 % Permethrin lotion. If no live adult louse was observed, the subject was followed up to D7 or D8.

LOCAL TOLERANCE

The investigator evaluated local tolerance after product application at D0 and D1 with a 4-point scale, from very good to poor tolerance (functional and/or objective signs leading to treatment discontinuation). All adverse events occurring during the study were recorded in a diary and evaluated by a 3-point scale.

RESULTS

The trial flowchart is shown in Fig. 1. A total of 108 subjects were included in the study. All subjects received at least one application of the study product. As no major protocol violation was observed, no subject was excluded from the efficacy analysis.

D0

Included and treated N = 108

- Main assessment efficacy 1 hour after treatment = **108**
- Premature withdrawal for failure (Permethrin rescue treatment) = **9**
- Followed = 99

D1

- Checked subjects = **99**
- Premature withdrawal for failure (Permethrin rescue treatment) = **13**
- Followed = **86**

D7

- Checked subjects = **86**
- Subjects received a 2nd application (same product as D0) = **7**

D8

- Checked subjects = **86**
- Cured subjects = **86**

Fig. 1. – Trial flowchart (Screened subjects: > 300)

Demographic characteristics	(N = 108)
Age (years)	
Mean ± SD	22 ± 15.2
Range	3-77
3-6 years: n (%)	2 (1.8)
6-10 years: n (%)	15 (13.9)
10-16 years: n (%)	41 (38)
> 16 years: n (%)	50 (46.3)
Sex	
Male n (%)	11 (10.2)
Female n (%)	97 (89.8)
Height (cm)	
Mean ± SD	143 ± 16
Range	95-188
Weight (kg)	
Mean ± SD	40.8 ± 17.6
Range	11-78
Thickness of hair	
Thin: n (%)	7 (6.5)
Medium: n (%)	49 (45)
Thick: n (%)	52 (48)
Length of hair	
Above ears: n (%)	11 (10)
Ears to shoulders: n (%)	11 (10)
Below shoulders: n (%)	86 (80)
Severity of infestation	
Mild/Moderate (< 30 live lice): n (%)	79 (73)
Severe (≥ 30 live lice): n (%)	29 (27)
Time spent to detect lice during fine-toothed combing	
< 3 minutes: n (%)	105 (97.2)
3-4 minutes: n (%)	2 (1.9)
4-7 minutes: n (%)	1 (0.9)

Table I. – Characteristics of the subjects at inclusion (D0).

DEMOGRAPHIC DATA AND BASELINE CHARACTERISTICS

Demographic data and pediculosis-related characteristics of subjects at inclusion are shown in Table I. The study population was mainly composed of female subjects (90 %) with long (80 %) and moderately thick (45 %) or very thick hair (48 %). Children less than 16 years old and adults were almost equally represented. Before treatment, 29 subjects (27 %) had severe louse infestation whereas 79 (73 %) had moderate or mild infestation.

The amount of product applied depended on the length and the thickness of the hair. The mean amount of product used was 79.7 g, ranging from 41.8 g for hair above the ears to 84.9 g for hair level longer than shoulders. Likewise, it ranged from 76.4 g for thin hair to 86.4 g for thick hair.

• Main efficacy criterion

The pediculicidal efficacy of the study product one hour after its application was 92 % corresponding to 99 subjects free of live lice compared with 100 % of subjects infested initially chi square ($X^2 = 183$; $p < 10^{-10}$). Among the nine subjects (8 %) still having live lice at D0, seven subjects presented only one louse, while the two others showed six and seven lice respectively.

For these nine subjects not responding to treatment, the amount of product applied was significantly lower than for the responders (67.8 ± 27.7 g *vs* 80.6 ± 21.4 g, $p = 0.05$).

• Secondary efficacy criteria

At D1, 24 hours after application of the product, the analysis of the efficacy was performed on the population continuing the study, the 99 subjects who did not show any live louse at D0. Results are shown on Table II: the pediculicidal and ovicidal efficacy was confirmed in 86 subjects. The 13 other subjects that were found infested with immature stages were considered as an ovicidal treatment failure: they received a rescue treatment (1 % permethrin lotion) and were withdrawn from the study. Then, only 86 subjects were still followed up.

At D7, 79 subjects were still free of lice, seven subjects were parasitized with live immature stages and/or adults and received a second application of the same treatment. At D8, all 86 subjects (79 + 7) were free of live lice.

The ovicidal efficacy of the product was calculated as the ratio of the subjects without live immatures at D7 (n = 79) over the number of subjects followed up all over the study (n = 108). Therefore, the ovicidal efficacy of the treatment was 73.2 %.

Eight days (D8) after the first application of the product, all subjects did not present anymore adult lice neither immatures, even those who had received a second application of the same product.

Observation	D0/H1	D1	D7	D8
Absence of live lice adults or larva	99/108	86/99	79/86	86/86
Presence of live lice	9/108	13/99	7/86	0/86
Subjects withdrawn from the study	9	13	0	0
Followed	99	86	86	End study

Table II. – Pediculicidal and ovicidal efficacy of the study product one hour (D0/H1), one day (D1) and seven days (D7) and eight days (D8) after the first application of the treatment.

TOLERANCE OF THE TREATMENT

The tolerance of the treatment was evaluated at D0 and D1 among the subjects who had received at least one application of the product. The product was very well tolerated by 89 % of the subjects and well tolerated by 10 %. Only one subject presented an adverse event possibly related to the treatment, with pruritus of mild intensity recovering without sequelae.

DISCUSSION

This open cohort study demonstrated that a single treatment with the dimethiconol-oil lotion was able to kill head lice during the first hour after application in 92 % of subjects (99/108) with moderate to severe head lice infection. The pediculicidal and ovicidal efficacy was confirmed 24 hours after the product application in 79.6 % of subjects (86/108). This efficacy was confirmed in 73.2 % (79/108) seven days later in the absence of a second treatment and again raised to 79.6 % after the second treatment of seven subjects. These 79.6 % were considered as completely cured, according to the official guidelines (Roberts, 2002; Ministère de la santé, 2004; Frankowski, 2004).

The dimethiconol-oil lotion fulfils these requirements as it was also active in killing nits, showing an ovicidal efficacy at D7 of more than 73 %. This evaluation was performed seven days after the first application of the product, to let potential surviving eggs hatch and to ascertain that all nits were killed. Indeed, due to its mode of action, the dimethiconol-oil lotion does not directly kill the embryo but acts by coating the shell of the nit and obstructing the micropyles. Therefore, the oxygen supply is blocked and the development of the embryo is stopped. Nevertheless, if the nit is just about to hatch, the immature can survive 3 to 4 hours without oxygen. This may explain the 13 % of failures at D1.

This study confirms the results obtained in the two other studies (randomised controlled trials) evaluating a dimethicone-based non-conventional treatment, which reported 70 % of cure (no evidence of head lice) after two overnight applications of 4 % dimethicone lotion seven days apart (Burgess *et al.*, 2005, 2007). But, our results are less than those obtained by Heukelbach *et al.*

(2008) (curing rate of 94 % to 97 %) using a product with a high concentration of dimeticone (92 %). The efficacy of this physical treatment was comparable to that mentioned by other authors using chemical treatments such as malathion, permethrin or synergised pyrethrins (Taplin *et al.*, 1982, 1986; Burgess *et al.*, 1994), which are currently recommended by international guidelines (Roberts, 2002; Ministère de la santé, 2004; Frankowski, 2004). Contrasting with the numerous cases of resistance reported with insecticide treatments (Chosidow *et al.*, 1994; Burgess *et al.*, 1995; Rupes *et al.*, 1995; Meinking *et al.*, 2004), the dimethiconol lotion as an insecticide-free physical agent should not face any problem of resistance.

Wet combing is considered as the most efficient method for head lice diagnosis (Chosidow, 2000) and one study showed that it could also be used as a treatment in a mass-screening campaign (vander Stechele *et al.*, 2002). However, although a recent study reported greater rates of cure for this method compared to chemical treatments (57 % *vs* 13 %) (Hill *et al.*, 2005), its efficacy as a primary treatment against head lice infection remains to be established by rigorous randomised trials. Indeed, these results were controversial compared to a previous study, which showed a poor efficacy for wet-combing compared to malathion (38 % *vs* 78 %) (Roberts, 2000) and the quality of the study was questioned by other authors (Dawes, 2005; Chosidow, 2006). Furthermore, wet combing is time consuming and requires significant efforts to be effective (Roberts, 2000).

On the contrary, the dimethiconol-oil lotion needs only a single application for a rapid and efficient pediculicidal activity, with only 8.3 % of subjects showing live lice one hour after the application of the treatment in our study. The therapeutic failure observed in these subjects withdrawn at the end of the first visit (D0+1h) may be explained by the insufficient amount of product applied on their hair, which was long and thick in more than 66 % of the subjects. A post-hoc analysis of our data showed that the amount of product applied was significantly lower in therapeutic failures than in subjects continuing the study, whereas it should have been higher due to long and thick hair. This insufficient application may be related to the difficulty in applying the product. This difficulty has also been experienced in a study evaluating dimethicone and phenothrin, reporting

problems to ensure that hair and scalp had been well covered, in particular in girls or women with long and thick hair (Burgess *et al.*, 2005). Obviously, an insufficient amount of product applied is a common cause of therapeutic failure (Chosidow, 2000).

Treatment with dimethiconol-oil lotion was particularly well tolerated as only one subject presented pruritus of mild intensity and 99 % of subjects found the tolerance of the product as “good” or “very good”.

This preliminary study has several limits: uncontrolled design, absence of training of nurses prior to study, possibility of cure related to multiple use of fine-tooth comb. Although a randomised controlled trial is the gold standard for comparative assessment of head lice treatments, a cohort study of good quality can provide useful information, considering the rarity of spontaneous resolution and the purported absence of placebo effect.

Several conclusions can be drawn from this study. A single application of the product is not always sufficient for patients to get rid of lice. Therefore a second application, or even a third one, would be needed, after a time interval determined by the life cycle of the head lice.

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