

Efficacy of a single application of a new natural lice removal product. Preliminary data.

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Summary

In a previous report most subjects treated with lice removal products and daily using combs able to remove nits recovered within four days from the first application of pediculicides. In this preliminary open study we applied only once in 5 children a natural pediculicide spray consisting of coconut oil extract, anise essential oil and Ylang ylang oil (Paranix®, Chefaro Pharma, Italy). Viable elements were not shown in any case after 7 days, thus making further applications of the product unnecessary.

Key words

Paranix®, pediculosis capitis, single application of pediculicide.

The term pediculosis capitis or head lice infestation refers to infestation of the human hair with "Pediculus capitis humanus".

In contrast with body pediculosis, pediculosis capitis likes better healthy hosts with clean hair, thus being widespread in all the civilized countries.

Its larger incidence in underdeveloped countries is only due to the minor importance in these areas of pediculosis capitis as compared with perinatal mortality, AIDS and struggle for survival.

In a previous report (17) most subjects (11/12) treated with lice removal products and daily using combs able to remove nits recovered within four days from the first application of pediculicides.

Therefore, in this preliminary open study we decided to establish whether or not one of the two previously tested products (Paranix®, Chefaro Pharma, Italy), sprayed on the whole hair only once was able to heal pediculosis capitis.

Material and methods

5 subjects (5 females), whose age ranged between 6 and 9 years, with an actual infestation due to *Pediculus humanus capitis*, thus with adult lice, nymphs or viable nits on their hair entered the study. The subjects underwent a control visit after 7 days or the visit was substituted by telephone interviews, when the examining physician considered them sufficient.

The parents kept a daily diary, in which they reported the presence of lice and nits after every day combing with the special provided metal nit-picking comb, already included in the packaging.

One of the parents or responsible relative of the minor, after having paid careful attention to the modalities and aim of the study, signed the form of informed consent.

Exclusion criteria from the study were as follows:

1- subjects affected by scalp disorders of various type (psoriasis, ringworm, severe, febrile pyoderma, etc.);

2- subjects with actual febrile disorders requiring antibiotics;

3- subjects who in the week prior to the study took antibiotics or applied lice removal products;

4- subjects affected by disorders able to influence the response to lice removal products according to the responsible physicians;

5- subjects with confirmed hypersensitivity to malathion or to the essential oils of Paranix;

6- subjects who during the period of application of Paranix used other lice removal products.

During the study other drugs could be used, provided that they could not affect the results of the study according to the responsible physicians.

With regard to the use of the product the *instructions* as follows were given: spray on the dry hair a quantity variable according to their length but anyway sufficient to wet completely all the hair. 20 minutes later wash the hair with a non medicated shampoo and then comb the hair with the given nit picking comb, namely a comb with non-deformable teeth spaced out less than 0.3 mm away from each other. In the following days, once a day, comb the hair with the appropriate comb, writing down on the diary the possible presence of viable or dead lice and nits and their number.

Recovery. The subject was considered cured on the day during which the examination of his/her parents and the particular daily combing did not put in evidence adult lice or nymphs or nits.

Control visit. 7 days after the first application of the lice removal product, the treated subjects, in order to confirm their recovery, were carefully examined by the responsible physician. The subjects also gave the physician their daily diary.

The visit was substituted by telephone interviews according to the decision of the examining physician. When the visit was substituted by telephone interviews, the latter were repeated at least once two or three weeks after recovering.

Persisting infestation. In case of viable elements on the seventh day from the first application, a second treatment was indicated.

Results

Nobody of the 5 treated subjects, after combing with the particular comb included in the packaging of Paranix®, presented viable elements 7 days after the first application. Therefore, no patient repeated a second treatment.

Discussion

Pediculosis capitis, which is well documented in the most ancient books handed on to us, does not look as if it gets less frequent, in spite of the numerous treatments carried out by the human. The most ancient of these treatment is really scratching, which was probably voluntary at the beginning and then got a reflex. The most widespread type of treatment consists of paralyzing and kill the louse with neurotoxic drugs, as pesticides, which are able to block the synapses. This method survives in pediatric medicine, in spite of the success of the ecological struggle in strongly limiting the usage of pesticides in agriculture. Another method based on the use of antibiotics such as sulfamethoxazole-trimethoprim (5, 19) proved useful. Antibiotics act on the intestinal symbiont bacteria of the louse, which are essential in warranting the absorption of its monothematic meal consisting of the host blood. A more recent treatment was based on the usage of natural oils, which are inhaled through the 14 tracheae of the louse and induce its death by choking. The latter method is effective, devoid of toxic side effects and prevents the phenomenon of resistance.

The product of this study is based on the latter mechanism and its effectiveness in pediculosis capitis has been already shown (11, 17). In a previous study (17) this product had been applied three times, with an interval of 5 days between each treatment. The treatment had been repeated because of the previous experience with the other pediculicides. For the latter a second treatment is necessary 7-10 days after the first one, both for the scarce activity of most products on the nits and for the phenomenon of the resistance, which has been proven for almost

all pediculicides. Permethrin itself, when first appeared on sale, was effective as a single treatment without the need of removing nits in 99% of cases (10). However, less than 10 years later the resistance to permethrin became evident (3, 14). The latter was more evident where permethrin had been first introduced (15). Lee et Al (6) showed that the resistance to permethrin was due to the appearance of a strain of "*Pediculus capitis humanus*", which carried a specific mutation of its chromosome complement.

Our study, although carried out on a limited number of cases shows that a single treatment with a new pediculicide based on natural oils, associated to careful daily combing of the hair with a nit-picking comb, is able to heal pediculosis capitis. The role played by the pediculicide and by the regular daily combing with a nit-picking comb should be however established. The single mechanical measures, such as scratching and daily combing with a nit-picking comb are not really able to heal a florid pediculosis. At least when the external temperature is lower than that one of the body, the louse remains as close as possible to the scalp and thus is barely visible and cannot be easily flushed out. Moreover, every adult female is able to lay 10 eggs a day (7). Every egg hatches in about 10 days and a nymph goes out. 10 days later, the latter gets an adult louse able to start again the life cycle. When there are numerous viable elements able to move rapidly -the louse can cover 23 centimeters in a minute (13)- even the most methodic combing made with a nit-picking comb can be ineffective, due to the recolonization of already combed locks by lice coming from near areas not yet combed.

The same applies to improbable effectiveness of a pediculicide, especially when used as single treatment, without combing with a nit-picking comb. We already mentioned the phenomenon of resistance. The latter is evident not only for permethrin, but for all the pediculicide products of the past, for instance lindane (1, 2, 8). Even in this case the resistance is greater in the areas where the product was used for a longer time, leading to hypothesize the presence of genetically mutated strains, which are resistant to the drug. Even for malathion the phenomenon of

resistance was shown in England (4). Some studies showed that the percentage of nits able to experience the toxic activity of lindane corresponds to about a third of that one of adult lice (9, 12).

In this issue of EJPD we underlined that the ovicide activity of a pediculide product can be shown also morphologically with the phenomena of natimortality and abortion. Natimortality means the incapacity of the louse to go out completely from the nit, after having uncorked its operculum. This phenomenon can also be independent of the activity of a pediculicide product, when the environmental humidity goes down 70% (9). The phenomenon of abortion (18), namely the death of the embryo inside the nit, is characterized by the appearance of longitudinal or roundish depression on the external surface of the nit, by fragmentation of the embryo material and by the presence of void spaces filled in with air inside the nit. It is possible that the pediculicide damages the embryo entering the nit through the doughnut-shaped holes of the operculum, which under normal conditions allow air and water vapor to enter the nit.

Anyway, at the moment, waiting for further studies showing in an incontestable way that the new pediculicide product based on natural oils has real ovicide activity and does not cause resistance, we think that it can be used in a single treatment in association with daily combing with a nit-picking comb. The single pediculicide treatment should kill all the viable elements and the mature nits, whereas the daily combing should remove nits at an early stage of development, which were not killed by the pediculicide treatment. Further studies in a larger series of cases will tell us whether a single treatment is really enough and the daily combing with a nit-picking comb is necessary.

In conclusion, in this open study 5 subjects with pediculosis capitis received a single treatment with a natural pediculicide product based on coconut oil extract, anise essential oil and Ylang ylang oil (Paranix®, Chefaro Pharma, Italy). Viable elements were not shown in any case after 7 days, thus making further application of the product unnecessary.

Acknowledgments. We thank the nurse Marcella Pastore, who significantly contributed to OPS project.

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