

EUROPEAN JOURNAL OF

ped

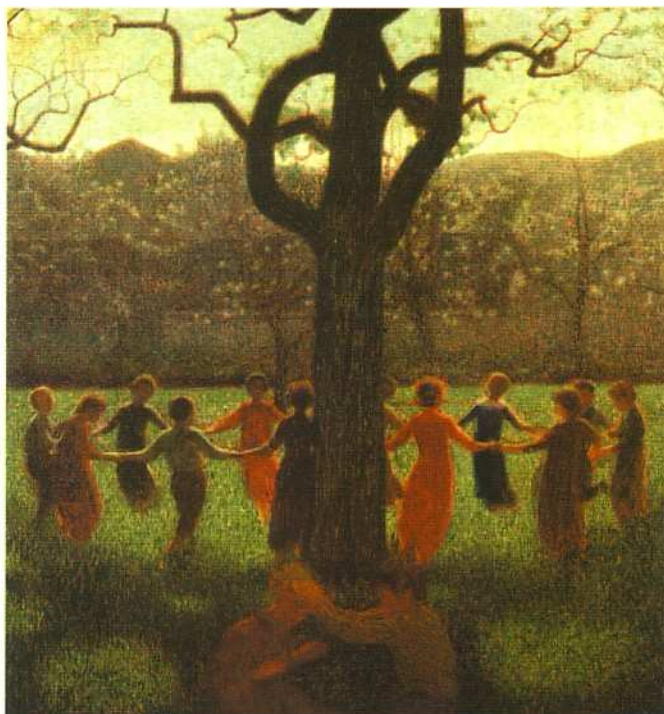
PEDIATRIC DERMATOLOGY

*Differential Diagnosis
in Pediatric Dermato-
logy: Angiofibroma/
Trichoepithelioma.* 230

*Solitary angiokeratoma
of the tongue.* 233

*LEOPARD syndrome.
First case in Saudi
Arabia.* 237

*Internet (Google) and
Pediatric Dermatology.
5 new functions that
have to be known.* 243



*Childhood acne rosa-
cea.* 246

*Dacryocystocele (mu-
cocele of the lacrimal
sac).* 247

*Efficacy and safety of a
new non-pesticide lice
removal product com-
pared to malathion.* 249

*Practical Pediatric
Dermatology:
Genital disease in chil-
dren. I.* 272

POST-GRADUATE JOURNAL OF
THE EUROPEAN SOCIETY FOR
PEDIATRIC DERMATOLOGY
ISSN 1122 - 7672



vol. 15, **4** 2005

Efficacy and safety of a new non-pesticide lice removal product.

Scanni G.*, Bonifazi E.**

*Dermatologist, school physician, "ASL Ba 4, Distretto n. 1", Bari (Italy)

**Pediatric Dermatology Unit, University of Bari, Bari (Italy)

Summary

This report is aimed at verifying in an open "in vivo" study efficacy and safety of a new lice removal product (Paranix®, Chefaro Pharma Italy). The latter is a non-pesticide spray consisting of active natural agents, particularly coconut oil extract, anise essential oil and Ylang ylang oil. The efficacy and safety of Paranix® was compared to those ones of malathion (Aftir® gel, Biochimici PSN Italy) in 24 subjects, whose age ranged between 4 and 15 years. The latter were randomly treated with one of the two products. No subject showed clinically evident side effects attributable to the used product. 11/12 subjects of both groups did not show live lice or nits when combed four days after the first treatment. Two subjects in the group treated with Aftir and one subject in the group treated with Paranix complained about the odor of the product. In conclusion Paranix proved as effective as the strong lice removal product of the control group and devoid of side effects.

Key words

Paranix, pediculosis capitis, non-pesticide lice removal product.

Pediculosis capitis probably exists from the appearance of humans on the earth, as shown by the recovery of dry lice and nits on the hair of Egyptian mummies (9). Although most civilizations and cultures considered pediculosis inappropriate, lice survived to all attempts of eradication, probably due to their capability of developing resistance against the various lice removal products. As the latter are not devoid of potential toxic effects, being more frequently pesticides, a need does exist for new lice removal products, possibly devoid of toxic effects.

Among the non-pesticide products a new all-natural product, consisting of coconut oil extract, anise essential oil, Ylang ylang oil and isopropyl alcohol, established itself on the market due to its efficacy and to the lack of toxic effects, as being a non-pesticide product. The product, which is on the market from 1995 in Israel with the name of Chick-Chack, from 1996 in the States with the name of Hair Clean 1-2-3 and from 2004 in the European Union,

included Italy, where it is on sale with the name of Paranix (Chefaro Pharma, Italy), proved (5) effective and safe, so that it is sold as medical device over the counter.

This study is aimed at testing even in Italy the safety and effectiveness of Paranix in comparison with one of the more popular product containing malathion (Aftir gel) for the treatment of pediculosis capitis.

Material and methods

24 subjects, whose age ranged between 4 and 15 years, with an actual infestation due to *Pediculus humanus capitis*, thus with adult lice, nymphs or viable nits on the hair entered the study. The subjects underwent a control visit after 12 days. The subjects or their parents kept a daily diary, in which they reported the presence of lice and nits after combing with the specially 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 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 or Aftir 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.

Subjects who entered the study were numbered according to the order of entry and received Paranix or Aftir according to the scheme as follows: 1, 4, 5, 7, 10, 11, 12, 15, 17, 19, 22, 24 received Paranix, whereas 2, 3, 6, 8, 9, 13, 14, 16, 18, 20, 21, 23 received Aftir. The subjects entering the study also received together with the lice removal product, a metal comb and a daily diary. They or their parents had to report on the diary the presence and number of viable or dead lice and nits every day during the period of study.

How to use products. With regard to the use of products the instructions as follows were given:

Aftir gel: apply 5 centimeters of gel or more than 5 according to the length of the hair all over the dry hair, making easier the contact of the product with the hair thanks to a normal comb. 10 minutes later wash the hair with a non medicated shampoo and then comb with the nit picking comb, given by the responsible physician because not present in the packaging. In the following days, once a day, comb daily with the

special comb, writing down on the diary the possible presence of viable or dead lice and nits and their number. Repeat the treatment after 7 days and go on with daily combing of the hair till the control visit.

Paranix: spray on the dry hair a quantity variable according to their length but anyway sufficient to wet completely all the hair. 15 minutes later wash the hair with a non medicated shampoo and then comb the hair with the given nit picking comb. In the following days, once a day, daily 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. Repeat the treatment a second time after 5 days and a third time after other 5 days, going on with the particular daily combing till the control visit.

Recovery. The subject was considered cured 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. Healing was in all cases confirmed on the control visit.

Control visit. 12 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.

Results

In the "paranix group" 11/12 subjects (92%) recovered within 3 days from the first treatment, whereas 1/12 subjects recovered within 12 days from the first treatment.

In the "aftir group" 11/12 subjects (92%) recovered within 4 days from the first treatment, whereas 1/12 subjects recovered within 8 days from the first treatment.

Particularly, in the "paranix group" 8/11 subjects recovered within 1 day, 2/11 within 2 days and 1/11 within 3 days from the first application of the product. In the "aftir group" 9/11 subjects recovered within 1 day, 1/11 within 2 days and 1/11 within 4 days from the first application of the product.

the products were really also the subjects who recovered in longer time, favoring the hypothesis of an insufficient usage of the product. This is why the patients and their parents should be instructed in the usage of an amount of product able to completely wet the hair. This is also why a single packaging of product may be insufficient in some subjects with very long hair.

Finally, we should talk about prevention of pediculosis capitis. When an infestation with lice occurs in a family or social group, which is an almost obligatory event during the school period in all the developed countries, parents always ask teachers, physicians and druggists how to prevent the infestation in their children. The products actually on sale for the so-called "prevention" of pediculosis capitis are not effective and potentially toxic. The lack of toxicity of Paranix could promote its usage in the prevention of pediculosis. However, we believe that also a product seemingly devoid of side effects should not be used with the aim of prevention and we confirm that the only solution of this problem is an early diagnosis. The latter can be done with the daily use of a nit picking comb during the periods of infestation. This type of "prevention" should be done by parents and/or by an expert such as a social worker or a school

physician, when parents do not cooperate properly.

In conclusion this study, although in a small number of subjects, showed that a product containing only natural oils (Paranix®) and thus probably devoid of side effects is as effective as one of the strongest lice removal product on sale (Aftir®), that inhibits cholinesterase. In the usage conditions none of the products of the study was responsible for clinically evident side effects.

Dr. Scanni was responsible for the clinical study, visited and controlled the patients. He also reviewed the report.

Dr. Bonifazi wrote the study protocol and the report.

Address to:

Ernesto Bonifazi, MD

Pediatric Dermatology Unit

University of Bari - Policlinico

Piazza G. Cesare, 11 - 70124 Bari (Italy)

e-mail: ejpd@dermatologiapediatrica.com

References

- 1) Blommers L., van Lennep M. - Head lice in the Netherlands: susceptibility for insecticides in field samples. *Entomol. Exp.* 23, 243-51, 1978.
- 2) Blommers L. - Insecticidal tests on immature head lice, *Pediculus capitis*: a new technique. *Med. Entomol.* 16, 82-3, 1979.
- 3) Downs A.M.R., Stafford K.A., Coles G.C. - Head lice: prevalence in schoolchildren and insecticide resistance. *Parasitol. Today* 15, 1-4, 1999.
- 4) Maunder J.W. - Resistance to organochlorine insecticides in head lice and trials using alternative compounds. *Med. Officer.* 125, 27-9, 1971.
- 5) Meinking T.L. - Infestations. *Curr. Probl. Dermatol.* 11, 73-120, 1999.
- 6) Meinking T.L., Entzel P., Villar M.E., et Al. - Comparative efficacy of treatments for pediculosis capitis infestations: Update 2000. *Arch. Dermatol.* 137, 287-92, 2001.
- 7) Meinking T.L., Serrano L., Hard B., et Al. - Comparative in vitro pediculicidal efficacy of treatments in a resistant head lice population in the United States. *Arch. Dermatol.* 138, 220-4, 2002.
- 8) Meinking T.L., Taplin D. - Infestations. In: Schachner L.A., Hansen R.C. eds. - *Pediatric Dermatology*. Mosby, 2003 Elsevier Limited.
- 9) Mumcuoglu K.Y., Zias J. - How the ancients deloused themselves. *Bibl. Archaeol. Rev.* XV(6):66, 1989.
- 10) Mumcuoglu K.Y., Hemingway J., Miller J., et Al. - Permethrin resistance in the head louse *Pediculus capitis* from Israel. *Med. Vet. Entomol.* 9, 427-32, 447, 1995.
- 11) Taplin D., Meinking T.L., Castillero P.M., et Al. - Permethrin 1% Creme Rinse (NIX) for treatment of *Pediculus humanus var. capitis* infestation. *Pediatr. Dermatol.* 3, 344-8, 1986.