



## Efficacy and Safety of Dimeticone in the Treatment of Lice Infestation through Prophylaxis of Classmates

*\*Pietro FERRARA<sup>1</sup>, Francesca DEL BUFALO<sup>2</sup>, Valerio ROMANO<sup>1</sup>, Eloisa TIBERI<sup>1</sup>, Giorgia BOTTARO<sup>2</sup>, Lorenza ROMANI<sup>2</sup>, Monica MALAMISURA<sup>2</sup>, Francesca IANNIELLO<sup>1</sup>, Laura CENI<sup>3</sup>, Giovanni MOTTINI<sup>3</sup>, Antonio GATTO<sup>1</sup>*

1. Dept. of Paediatrics, "A. Gemelli" University Hospital, Rome, Italy

2. Service of Paediatrics, Campus Bio-Medico University, Rome, Italy

3. FAST, Campus Bio-Medico University, Rome, Italy

**\*Corresponding Author:** Tel: +92-21-5689860 Email: pferrara@rm.unicatt.it

(Received 23 Feb 2013; accepted 18 June 2013)

### Abstract

**Background:** We conducted a study to evaluate efficacy and safety of dimeticone 4%, a lotion with no conventional insecticide activity, to cure lice infestation and to prevent spread of infestation/reinfestation by prophylaxis of classmates.

**Methods:** The study is carried out between April 2008 and June 2008 in Petranova International Institute in Rome. A total of 131 children, aged 3 to 13 years (median age: 7 years) were included in the study. All participants received treatment with dimeticone 4% that was applied both to children with the infestation, to cure it, and to all classmates, to prevent the spreading of the infestation. They have been controlled after 7 and 30 days from the application of dimeticone.

**Results:** At baseline we found a positivity of lice infestation in 23/131 children (17.6%), whereas 108/131 (82.4%) children were free from lice. After 7 days of treatment with dimeticone 4%, 7/23 (30.4%) positive children still had lice infestation, with a cure rate of 69.6% (16/23). At 30 days 26/131 children (19.9%) were infested: 15 children were lice free at baseline whereas 11 had lice at both evaluations; the cure rate amounted to 52.2% (12/23). The reinfestation rate (percentage of positive children that showed negativity at baseline) was 5.3% (7/131) at 7 days and 11.5% (15/131) at 30 days.

**Conclusion:** The lower reinfestation rate showed in our trial suggests that this approach could be effective in reducing spreading of head lice in small communities. More studies are needed to confirm our findings.

**Keywords:** Head lice, School, Dimeticone

### Introduction

Infestation with lice, or pediculosis, is a widespread public health problem that affects people of all socio-economic backgrounds and ages, even though infection occurs primarily in children of school age (1). The condition has a strong impact on non-attendance at school and at work and if left untreated it can lead to inflammation and secondary infections (1). There is now strong evidence of the emergence of strains of

lice resistant to common pediculicides that leads to the failure to eradicate the infection in some patients and to an increased prevalence of pediculosis in many countries (2,3). It is important, however, to recognize that much treatment failure may result from reinfestation from an untreated classmate or follow the application of an inadequate quantity of pediculicide or an improper duration of treatment. Thus it is necessary

to evaluate a new approach to treat head lice aimed to prevent reinfestation after cure.

Treatment of lice infection is based on topical or oral drugs, physical agents and wet combing. The literature is reach of studies on efficacy of topical agents but the elevated rate of failure of this drugs leads to test the efficacy of new drugs (4). Among physical agents dimeticone lotion is a therapy for lice infestation and it seems less irritant than other treatments (2). Dimeticone belongs to topical non-neurotoxic agents and it is used also for the treatment of infant colic (4). In its class it was the first successful treatment for lice infestation in the UK. The main action of dimeticone seems to be coating the lice causing disruption of their ability to manage water; other proposed mechanism is the airway obstruction and suffocation (4).

In this study, we conducted a study to evaluate efficacy and safety of dimeticone 4%, a lotion with no conventional insecticide activity, to cure lice infection and to prevent spread of infestation/reinfestation by prophylaxis of classmates.

## Materials and Methods

The study is carried out between April 2008 and June 2008 into Petranova International Institute in Rome. A total of 131 children, aged 3 to 13 years (median age: 7 years) were included in this open prospective study and received treatment with dimeticone 4% lotion. Characteristics of age and presence/absence of lice at baseline are shown in Table 1. The study was performed in Petranova International Institute in Rome. First data collected were about age and previous use of pediculicides.

**Table 1:** Presence/absence of lice at baseline

Age (years)	Presence of lice (% of all children)	Absence of lice (% of all children)	Total
3-5	6 (4.6)	34 (25.9)	40
6-10	8 (6.1)	53 (40.5)	61
11-13	9 (6.9)	21 (16)	30
Total	23 (17.6)	108 (82.4)	131

Investigators had been previously trained to perform hair examination by the means of a plastic detection comb, in accordance with a standard protocol.

The children of every classroom were evaluated in order to establish the presence or absence of head lice. Informed assent procedures were followed and all eligible children whose parents had signed informed consent were included in the study. We included children that had not underwent any treatment for pediculosis in the previous two weeks and whose curators assured not to use any other head louse treatment during the trial.

We excluded any children who had taken trimethoprim/sulfamethoxazole (TMP-SMX) or TMP alone during the four weeks preceding the study or who were taking the same antibiotics at moment of evaluation.

All participants that met inclusion criteria received treatment with dimeticone 4% that was applied both to children with the infestation, to cure it, and to all classmates, in order to prevent the spreading of the infestation.

We have so performed an open prospective study of the effectiveness and tolerability of dimeticone 4% on lice infection. In particular we evaluated its effectiveness at reducing reinfestation when used not only on infected children but also on their classmates.

Treatment was carried out at home. All the carers of children included in the study were provided with dimeticone 4%, supplied in 100 ml glass bottles, and with 30 ml bottles of a non-medicated shampoo. They were also instructed to apply the product accurately, following appropriate instructions of use. It had to be accurately applied to dry hair and scalp at least one hour before going to bed (to let it begin to evaporate), paying attention to cover carefully the whole head. Then it had to be left for 8 hours/overnight and at morning it had to be washed off using the shampoo provided and rinsed with water. The same regimen had to be repeated seven days after the first application.

Moreover, according to directions provided by the Cochrane review, parents were warned not to remove lice by combing after the treatment (1).

We fixed two end points: after 7 and 30 days from the first application of dimeticone. Investigators have rated patients through using plastic detection combs. The first end point was chosen to allow sufficient time for the treatment to be effective, the latter to enable any reinfestation to occur.

## Results

At baseline we found a positivity of lice infestation in 23/131 children (17.6%), whereas 108/131 (82.4%) children were free from lice.

At the first control, after 7 days of treatment with dimeticone 4%, 7/23 (30.4%) children had still lice infestation, 16/23 (69.6%) children were lice free with a cure rate (percentage of children cured) of 69.6% (16/23). Moreover at 7 days we found lice in 7 children that were negative at baseline increasing total positivity to 14/131 children (10.7%); this might be an indicator of reinfestation (Table 2).

**Table 2:** Presence/absence of lice at I control (7 days)

Age (years)	Presence of lice (% of all children)	Absence of lice (% of all children)	Total
3-5	2 (1.5)	38 (29)	40
6-10	4 (3.1)	57 (43.5)	61
11-13	8 (6.1)	22 (16.8)	30
Total	14 (10.7)	117 (89.3)	131

At 30 days 26/131 children (19.9%) were infested: 15 children were lice free at baseline whereas 11 had lice at both evaluations; the cure rate amounted to 52.2% (12/23) (Table 3).

**Table 3:** Presence/absence of lice at II control (30 days)

Age (yr)	Presence of lice (% of all children)	Absence of lice (% of all children)	Total
3-5	3 (2.3)	37 (28.2)	40
6-10	14 (10.7)	47 (35.9)	61
11-13	9 (6.9)	21 (16)	30
Total	26 (19.9)	105 (80.1)	131

The reinfestation rate (percentage of positive children that showed negativity at baseline) was 5.3% (7/131) at 7 days and 11.5% (15/131) at 30 days.

## Discussion

Louse infestation affects, each year, about 6 to 12 million people, mainly children, in the United States and a high prevalence is reported also in other countries (Israel, France, United Kingdom, Denmark, Sweden, Australia and Italy) (3).

A major concern consists in the rapid increase in insecticide resistance. From personal observation, Canyon and Speare report a significant increase in resistance to common pediculicides that brought in 2003 to an ineffectiveness of chemical head lice treatments in controlling the infection (80% resistance to permethrin and 30% resistance to malathion-containing products) (5). Furthermore, reinfestation is common even with treatments that prove successful if associates of the treated person are not treated concurrently. This occurrence is particularly frequent in small communities, as schools, where people are in close contact for long time.

With regard to this aspect of the issue, many of these communities adopt precautionary measures consisting of keeping children with nits in, resulting in school absenteeism and in psychological and social problems for children and their families. In 1998, 12 to 24 million days of school were lost secondary to no-nit policies.

Head lice have also important economic implications, in terms of both direct and indirect costs. Direct costs refer strictly to treatment expenses whereas indirect costs account for lost wages, school or nursing home monitoring programs and education programs designed to reduce infestation. Even though no formal pharmacoeconomic studies of such costs have been published, it is estimated that combined direct and indirect costs may be as high as \$1 billion per year (6).

In the space of last decades, many different insecticides have been studied to find a proper treatment for this infection and to overcome rising

resistances. Traditional pharmacological therapies have focused on 1 or 2 courses of various ovocidal and pediculicidal topical therapies. Nowadays the American Academy of Paediatrics recommends permethrin 1% as first-line treatment for head lice (7).

There are different main aspects we must weigh when considering a treatment, such as: application instructions, safety and toxicity, mechanism and prevalence of resistance.

One of the first pediculicides used was lindane, an organochloride with properties similar to dichlorodiphenyltrichloroethane (DDT) that showed a potent effect but was withdrawn because of its unfavourable safety profile (8).

Afterwards pyrethroids (permethrin and pyrethrins) have been developed and are the principal pediculicides available in the United States nowadays. They show a good safety profile for occasional use but resistance is widespread and increasing (9-11). This phenomenon brings families to a recurring use of these products that may pose a great risk of direct or cumulative toxicity.

An other widely used organophosphate insecticide is malathion, which is sold in a formulation comprising also isopropyl alcohol and terpeneol. Such product has proven to be very efficacious, even superior to permethrin, but efficacy is attributed to the triple formulation. Unfortunately, some misconceptions about the safety of malathion in an isopropyl alcohol vehicle, negative publicity and statements about its toxicity caused it lot of unpopularity. Nevertheless its safety and efficacy have been well documented (12). The United Kingdom Committee on Safety of Medicine stated that "there is no evidence to suggest that serious systemic adverse reactions are associated with topical malathion". Unfortunately resistance to malathion also has been widely reported (13,14).

Meinking et al. recently reported a significant reduction of the efficacy rate of common over the counter pediculicides in the United States compared with rates described only 2 years ago (15). Such resistance to common agents, proven in many countries all over the world (16-18), has spurred the search for new alternative treatments.

Two possible options are represented by oral drugs such as ivermectin and TMP-SMX (12, 19). Ivermectin is a lactone with pediculicidal effect only. Its efficacy is limited by the fact that we still don't know the rational dosing needed in lice infection and that three treatment course are necessary. Moreover its use is contraindicated in children who weigh <15 kg, because it can cross the blood brain barrier and it has not been approved by the Food and Drug Administration (FDA) for the treatment of head lice infestation (7). No resistance has been reported to date (9,12,19).

As ivermectin, TMP-SMX is not ovocidal. Its mechanism of action is not clearly known yet, since studies show different results and hypothesis. Its efficacy is controversial, since Hipolito et al. study shows significant benefit (20) while Sim et al. report no benefit by its use (21). Because of its rare but important side effects (toxic epidermal necrolysis, Stevens-Johnson syndrome, aplastic anemia and blood dyscrasias) and of its uncertain efficacy, TMP-SMX is not recommended as first line therapy, as suggested in last international guidelines (3).

Nonpharmacologic approaches involve occlusion therapy (vinegar, mayonnaise, petroleum jelly, butter and other similar substances submersion), essential oils, nit combing, hot air and hair removal. Even though some studies show little efficacy of these treatments, none of them have been approved and they are listed as "Treatments not recommended" in the international guidelines (3). Shaving the head is not recommended because of its psychological consequences on children. Moreover its efficacy has never been proved and is only anecdotal. Goates et al. report a significant efficacy of hot hair treatments, but their results vary widely (efficacy 10%-80%) and there are no comparisons with standard methods (22). Canyon and Speare compared several botanical and synthetic substances to clarify their value and found out that none of them showed sufficient preventative efficacy to be approved (5). With regard to nit combing as monotherapy numerous studies and observations prove its success rates to be far from perfect. In 2000 Roberts et al. compared wet combing with malathion and showed that

malathion was twice as effective as combing (23). On the contrary Hill et al. report a significant effectiveness of “Bug Buster kit” (wet combing with conditioner) (24). In their randomised trial it proves to be four time more effective than common pediculicides, with a cure rate of 57% versus 13% of pediculicides. However it must be noted that this study was conducted in the United Kingdom, where resistance to common pediculicides is very high. Beside its efficacy, to be effective nit combing must be performed for 30 minutes everyday or every second day, which is not practical and is criticised as unfeasible. Therefore the International guidelines recommend that “combing should always be an integral part of any pediculicidal treatment in order to remove live and dead lice, eggs and nits” (3). Moreover, combing has proven to be more effective than visual inspection for diagnosis of head louse infestation (25,26).

With regard to resistance it is important to notice that every country may have its particular strain of head lice with its peculiar resistances, because of different courses of natural selection and variation among every population. This evidence leads to the necessity of performing trials to assess efficacy of various treatment protocols in each country.

We performed a trial to assess efficacy of a new treatment protocol based on a new pediculicidal agent: dimeticone. This is an insecticide-free lotion with a silicon solvent that has been specifically created for head louse treatment and has shown a high in vitro efficacy (27). It acts by immobilising lice that are left coated by a layer of dimeticone as solvent evaporates and die (28). Therefore its action is exclusively physical and it is not absorbed transdermally. These features are responsible of its safety and no adverse events were reported in our trial, showing that it can be applied many times with a very low risk of adverse events. No resistant strains to dimeticone have been reported to date. We selected dimeticone on the basis of data regarding its efficacy, its non-toxicity and on the basis of increases resistance of lice to other drugs.

A single-blind randomised controlled study was performed by Burgess et al. to compare the effi-

cacy of dimeticone versus phenothrin. This trial shows that the two agents are equivalent to within 20%, proving that dimeticone is efficacious at treating head louse infestation (2). In a second randomised, controlled, assessor blind trial Burgess compared dimeticone 4% versus malathion 0.5% and showed that dimeticone is significantly more effective than malathion (with a cure rate of 76.9% versus 34.5%) (29). Other randomised controlled trials, performed in Turkey and Brazil, proved the high efficacy of dimeticone lotion (30,31).

Our study evaluates the efficacy of this new treatment, especially in preventing reinfestation, by the application of dimeticone 4% lotion both to infested children and to their negative classmates. To our knowledge, this is the first study that evaluates prophylaxis of classmates to prevent reinfestation. At 7 days we found an efficacy rate of 69.6% that decreased, at 30 days, to 52.2%. The reduction in the cure rate at 30 days and the finding of lice in 15 previously negative children are indicator of the reinfestation. Our reinfestation rate amount to 5.3% at 7 days and 11.5% at 30 days. Heukelbach et al. showed higher reinfestation rate at 7 days, both in the dimeticone (33.3% - 24/72) and in permethrin groups (18.6% - 13/71) (31). In the light of these results it is mandatory promote other studies to obtain more encouraging results.

## **Conclusion**

The lower reinfestation rate showed in our trial suggests that treatment with dimeticone 4% could be effective in reducing spreading of head lice in small communities. More studies are needed to confirm our findings.

## **Ethical considerations**

Ethical issues (Including plagiarism, Informed Consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc) have been completely observed by the authors.



## Acknowledgements

The authors declare that there is no conflict of interests and that this study was not funded.

## References

1. Dodd CS (2007). Interventions for treating head-lice. *Cochrane Database Syst Rev*, 18 (4): CD001165.
2. Burgess IF, Brown CM, Lee PN (2005). Treatment of head louse infestation with dimeticone lotion: randomised controlled equivalence trial. *BMJ*, 330 (7505): 1423-1426.
3. Mumcuoglu KY, Barker SC, Burgess IE et al. (2007). International guidelines for effective control of head louse infestations. *J Drugs Dermatol*, 6 (4): 409-414.
4. Tebruegge M, Pantazidou A, Curtis N (2011). What's bugging you? An update on treatment of head lice infestation. *Arch Dis Child Educ Pract Ed*, 96 (1): 2-8.
5. Canyon DV, Speare R (2007). A comparison of botanical and synthetic substances commonly used to prevent head lice (*Pediculus humanus var. capitis*) infestation. *Int J Dermatol*, 46 (4): 422-426.
6. Hansen RC, O'Haver J (2004). Economic considerations associated with *Pediculus humanus capitis* infestation. *Clin Pediatr*, 43 (6): 523-527.
7. Frankowski BL, Weiner LB, Committee on School Health the Committee on Infections Diseases, American Academy of Pediatrics (2002). Head lice. *Pediatrics*, 110 (3): 638-643.
8. Diamantis SA, Morrell DS, Burkhart CN (2009). Treatment of head lice. *Dermatol Ther*, 22 (4): 273-278.
9. Jones KN, English JC III (2003). Review of common therapeutic options in the United States for the treatment of *Pediculosis capitis*. *Clin Infect Dis*, 36 (11): 1355-1361.
10. Kristensen M, Knorr M, Rasmussen AM, et al. (2006). Survey of permethrin and malathion resistance in human head lice populations from Denmark. *J Med Entomol*, 43 (3): 533-538.
11. Burgess IF, Brown CM, Peock S et al. (1995). Head lice resistance to pyrethroid insecticides in Britain. *BMJ*, 311 (7007): 752.
12. Lebwohl M, Clark L, Levitt J (2007). Therapy for head lice based on life cycle, resistance, and safety considerations. *Pediatrics*, 119 (5): 965-974.
13. Downs AMR, Stafford KA, Harvey I et al. (1999). Evidence for double resistance to permethrin and malathion in head lice. *Br J Dermatol*, 141 (3): 508-511.
14. Hunter JA, Barker SC (2003). Susceptibility of head lice (*Pediculus humanus capitis*) to pediculicides in Australia. *Parasitol Res*, 90 (6): 476-478.
15. Meinking T, Serrano L, Hard B et al. (2002). Comparative in vitro pediculicidal efficacy of treatments in a resistant head lice population in the United States. *Arch Dermatol*, 138 (2): 220-224.
16. Downs AM, Stafford KA, Hunt LP et al. (2002). Widespread insecticide resistance in head lice to the over-the-counter pediculocides in England, and the emergence of carbaryl resistance. *Br J Dermatol*, 146 (1): 88-93.
17. Durand R, Millard B, Bouges-Michel C et al. (2007). Detection of pyrethroid resistance gene in head lice in schoolchildren from Bobigny, France. *J Med Entomol*, 44 (5): 796-798.
18. Bartels CL, Peterson KE, Taylor KL (2001). Head lice resistance: itching that just won't stop. *Ann Pharmacother*, 35 (1): 109-112.
19. Gratz NG (1997). Human Lice: Their Prevalence, Control and Resistance to Insecticides. A Review 1985-1997. Geneva: World Health Organization. [whqlibdoc.who.int/hq/1997/-WHO\\_CTD\\_WHOPE97.8.pdf](http://whqlibdoc.who.int/hq/1997/-WHO_CTD_WHOPE97.8.pdf).
20. Hipolito RB, Mallorca FG, Zuniga-Macaraicq ZO et al. (2001). Head lice infestation: single drug versus combination therapy with one percent permethrin and trimethoprim/sulfamethoxazole. *Pediatrics*, 107 (3): E30.
21. Sim S, Lee IY, Lee KJ et al. (2003). A survey on head lice infestation in Korea (2001) and the therapeutic efficacy of oral trimethoprim/sulfamethoxazole adding to lindane shampoo. *Korean J Parasitol*, 41 (1): 57-61.
22. Goates BM, Atkin JS, Wilding KG et al. (2006). An effective nonchemical treatment for head lice: a lot of hot air. *Pediatrics*, 118 (5): 1962-1970.
23. Roberts RJ, Casey D, Morgan DA et al. (2000). Comparison of wet combing with malathion for treatment of head lice in the UK: a prag-

- matic randomised controlled trial. *Lancet*, 356 (9229): 540-544.
24. Hill N, Moor G, Cameron MM et al. (2005). Single blind, randomised, comparative study of the Bug Buster kit and over the counter pediculicide treatments against head lice in the United Kingdom. *BMJ*, 331 (7513): 384-387.
  25. Balcioglu C, Burgess IF, Limoncu ME et al. (2008). Plastic detection comb better than visual screening for diagnosis of head louse infestation. *Epidemiol Infect*, 136 (10): 1425-1431.
  26. Mumcuoglu KY, Friger M, Ioffe-Uspensky I et al. (2001). Louse comb versus direct visual examination for the diagnosis of head louse infestations. *Pediatr Dermatol*, 18 (1): 9-12.
  27. Oliveira FA, Speare R, Heukelbach J (2007). High in vitro efficacy of Nyda L, a pediculicide containing dimeticone. *J Eur Acad Dermatol Venerol*, 21 (10): 1325-1329.
  28. Burgess IF (2009). The mode of action of dimeticone 4% lotion against head lice, *Pediculus capitis*. *BMC Pharmacol*, 9: 3.
  29. Burgess IF, Lee PN, Matlock G (2007). Randomised, controlled, assessor blind trial comparing 4% dimeticone lotion with 0.5% malathion liquid for head louse infestation. *PLoS One*, 2 (11): e1127.
  30. Kurt Ö, Balcioglu IC, Burgess IF et al. (2009). Treatment of head lice with dimeticone 4% lotion: comparison of two formulations in a randomised controlled trial in rural Turkey. *BMC Public Health*, 9: 441.
  31. Heukelbach J, Pilger D, Oliveira FA et al. (2008). A highly efficacious pediculicide based on dimeticone: randomized observer blinded comparative trial. *BMC Infect Dis*, 8: 115.