

EM Journal Club  
 EVMS Journal Club  
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Your wife teaches at a local elementary school. She was informed by the school nurse that a child in her class as well as siblings in other classes have been identified as index cases of lice. Two months later after multiple attempts to eradicate the family of lice with standard therapy, the children continue to have active infestations. You wife EXTREMELY frustrated by the contact precautions required to be enforced in 7 y/o kids wants to know if there is “another way” [true story]

Search Strategy: lice, treatment, resistant, recurrent,

Citation: Chosidow O, et al. **Oral Ivermectin versus Malathion Lotion for Difficult-to-Treat Head Lice.** N Engl J Med 2010; 362: 896 – 905.

<b>I. WHAT IS BEING STUDIED?</b>	
1. Study Objective	In patients with difficult-to-treat head lice (treatment failure with topical insecticide) how does oral ivermectin (400 ug/kg) compare to 0.5% malathion lotion
2. Study Design	March 9 – September 14, 2009 in 7 study centers (UK, Ireland, France, Israel) 812 patients from 376 households Multicenter, cluster-randomized, double-blind, double-dummy, controlled trial
3. Inclusion Criteria	Age >2, Wt >15 kg, head lice infestation Previously failed treatment 2 – 6 weeks prior to start of study day 1
4. Exclusion Criteria	Pregnant or breastfeeding, active scalp disease (bacterial infection), pediculicidal use within 2 weeks of study, hair style precluding fine-toothed combing or dye or perm within 2 weeks of study, prior residence in Africa endemic for microfilaremic disease, known/suspected intestinal helminth infection, known hypersensitivity to treatment agents
5. Interventions Compared	Oral ivermectin 400 um/kg 0.5% malathion lotion Given on days 1 and 8
6. Outcomes Evaluated	Primary – absence of live head lice on day 15 (standardized combing)

	Secondary – absence of live head lice on days 2 and 8, days 22 and 29 for extension stage, treatment preference
<b>II. Are the results of the study valid?</b>	
1. Was the assignment of patients randomized	Permuted blocks of four, random assignment was by households (not patients) to receive ivermectin or Malathione in a 1:1 distribution.
2. Have the authors identified all important confounding factors?	Cluster randomization to avoid reinfestation, both study treatments administered on site on day 1 and 8, sufficient amount of malathion lotion applied, **malathion resistance
3. Were all patients who entered the trial properly accounted for and attributed at its conclusions?	11 (1.3%) did not meet inclusion criteria 35 (4.3%) lost to follow-up 53 (6.5%) did not complete the study
4. Was follow-up complete?	No further follow up past day 15 or day 29 for extension group
5. Were patients, health workers and study personnel “blind” to treatment?	Double-dummy technique All patients given both pill and lotion Ivermectin vs. placebo cellulose Malathion vs. placebo lotion isopropanol
6. Were study groups similar at the start of the trial	Yes. Accounted for household size, infestation, age, sex, weight, race, hair density, hair length, number of live lice
7. Aside from the experimental intervention, were the groups treated equally?	Yes. All patients given treatment at study center on days 1 and 8. If infestation still present on day 15 patients entered extension stage with alternative treatment on day 15 and 22
<b>III. What were the results?</b>	
1. How large was the treatment effect? (difference between treatment and control group).	378/397 patients (95.2%) free of head lice in ivermectin compared to 352/414 patients (85%) in malathion group 171/185 households (92.4%) vs. 151/191 (79.1%) lice free 30/31 (96.8%) vs. 8/8 lice free in extension groups
2. What was the estimated treatment effect at a 95% confidence interval?	Absolute difference ITT 10.2% [4.6 – 15.7] in patients Absolute difference PPP 7.3% [2.8 – 11.8] in patients Absolute difference 13.4% [6.4 – 20.4] in households

<b>IV. Will the results help me in caring for my patients? (Applicable?)</b>	
1. Were all clinically important outcomes considered?	Accounted for head-lice free, treatment failure, patient preference, adverse side effects
2. Are treatment outcomes worth the potential harms?	3 serious adverse events – 1 ivermectin was seizure. 2 in malathion were severe headache. Any adverse event 91 (22.9%) in ivermectin, 100 (24.2%) in malathion

Frankowski, B, et al. **Head Lice**. Pediatrics Vol 126 No. 2 August 2010, pp. 392 – 403

**\*\* Unless resistance to these products has been proven in the community, 1% permethrin or pyrethrins can be used for treatment of active infestations.**

**\*\* Benzyl alcohol 5% can be used for children older than 6 months, or malathion 0.5% can be used for children 2 years old or older, in areas where resistance to permethrin or pyrethrins has been demonstrated or for a patient with a documented infestation that has failed to respond to appropriately administered therapy with permethrin or pyrethrins.**

Bottom Line: Permethrin is still drug of choice for initial treatment for head lice. If after 2 treatments there is still evidence of lice infestation AAP recommends benzyl alcohol or malathion. Ivermectin is not approved by the FDA for the treatment of head lice (risk of crossing blood brain barrier). Safety has not been established at these larger doses though Ivermectin is used worldwide usually @ lower doses. Another Cochrane review is pending for further treatment recommendations. Parental reassurance is important in dealing with this “disease.” AAP recommends children are not to be sent home from school if lice found and removal of “No-Nit” policies in schools. In the ED we are likely to continue recommending permethrin treatment since some treatment failure is attributed to patient application. We are unlikely to use off label Ivermectin until further recommendations endorsing this drug are published.