Randomised controlled trial of treatment of chronic suppurative otitis media in Kenyan schoolchildren

Abstract:

BACKGROUND: The outcomes of treatment of chronic suppurative otitis media (CSOM) are disappointing and uncertain, especially in developing countries. Because CSOM is the commonest cause of hearing impairment in children in these countries, an effective method of management that can be implemented on a wide scale is needed. We report a randomised, controlled trial of treatment of CSOM among children in Kenya; unaffected schoolchildren were taught to administer the interventions. METHODS: We enrolled 524 children with CSOM, aged 5-15 years, from 145 primary schools in Kiambu district of Kenya. The schools were randomly assigned treatments in clusters of five in a ratio of two to dry mopping alone (201 children), two to dry mopping with topical and systemic antibiotics and topical steroids (221 children), and one to no specific treatment (102 children). Schools were matched on factors thought to be related to their socioeconomic status. The primary outcome measures were resolution of otorrhoea and healing of tympanic membranes on otoscopy by 8, 12, and 16 weeks after induction. Absence of perforation was confirmed by tympanometry, and hearing levels were assessed by audiometry. 29 children were withdrawn from the trial because they took non-trial antibiotics. There was no evidence of differences in timing of withdrawals between the groups. FINDINGS: By the 16-week follow-up visit, otorrhoea had resolved in a weighted mean proportion of 51% (95% CI 42-59) of children who received dry mopping with antibiotics, compared with 22% (14-31) of those who received dry mopping alone and 22% (9-35) of controls. Similar differences were recorded by the 8-week and 12-week visits. The weighted mean proportions of children with healing of the tympanic membranes by 16 weeks were 15% (10-21) in the dry-mopping plus antibiotics group, 13% (5-20) in the dry-mopping alone group, and 13% (3-23) in the control group. The proportion with resolution in the dry-mopping alone group did not differ significantly from that in the control group at any time. Hearing thresholds were significantly better for children with no otorrhoea at 16 weeks than for those who had otorrhoea, and were also significantly better for those whose ears had healed than for those with otorrhoea at all times. INTERPRETATION: Our finding that dry mopping plus topical and systemic antibiotics is superior to dry mopping alone contrasts with that of the only previous community-based trial in a developing country, though it accords with findings of most other trials in developed countries. The potential role of antibiotics needs further investigation. Further, similar trials are needed to identify the most cost-effective and appropriate treatment regimen for CSOM in children in developing countries. PIP: 524 children aged 5-15 years with chronic suppurative otitis media (CSOM) were enrolled in a study to determine the effectiveness of different treatment regimens. The subjects were from 145 primary schools in Kenya's Kiambu district. 201 children received dry mopping treatment, 221 received dry mopping with topical and systemic antibiotics and topical steroids, and 102 received no treatment. Participating schools were matched on factors thought to be related to their socioeconomic status. 29 children were withdrawn from the trial for taking non-trial antibiotics, with no evidence observed of differences in the timing of withdrawals between the two groups. At 16 weeks of follow-up, otorrhoea had resolved in a weighted mean proportion of 51% of children who received dry mopping with antibiotics, 22% of children who received dry mopping alone, and 22% of untreated children. Similar differences were observed at 8 and 12 weeks of follow-up. The weighted mean proportions of children with healing of the tympanic membranes

by 16 weeks were 15% in the dry-mopping plus antibiotics group, 13% in the dry-mopping alone group, and 13% in the control group. Hearing thresholds were significantly better for children with no otorrhoea at 16 weeks than for those who had otorrhoea, and were also significantly better for those whose ears had healed than for those with otorrhoea at all times