



Community-based, multicenter, double-blind, randomized, controlled trial comparing the effectiveness of topical ciprofloxacin and Sofradex as treatments for chronic suppurative otitis media in Aboriginal children

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Many Aboriginal communities in rural and remote western Australia have rates of chronic suppurative otitis media (CSOM) 10 times the rate that the World Health Organization deemed as a massive public health problem in the child population. The recognition by Aboriginal leaders that the treatment of CSOM is a priority area has led to this issue being highlighted in Australia's National Aboriginal Health Strategy. In Aboriginal children, the disease usually commences in infancy within a few weeks of birth, causes hearing loss, is recurrent, can persist into adulthood, and may impact adversely on child development.

Our trial aimed to compare the effectiveness of topical ciprofloxacin (0.3%) and framycetin (0.5%), gramicidin, dexamethasone (FGD, Sofradex) as treatments for CSOM in Aboriginal children. The trial was the first community-controlled, multicenter, double-blind, randomized, controlled trial in Aboriginal children across the north of Australia.

Materials and methods

One hundred forty-seven children (under 15 years of age) were recruited from eight Aboriginal communities. Treatments were randomly assigned, and both health workers and parents or guardians were blinded as to treatment. Treatment consisted of five drops twice daily for 9 days, and ear toilets were administered prior to instillation of eardrops, ceasing on clinical cure. Standardized clinical assessments were conducted at baseline and at regular periods up to 21 days. The primary outcome was the resolution of otorrhea (clinical cure), and secondary outcomes included the

proportion of children with healed tympanic membranes and improved hearing thresholds.

Results

Cure of CSOM was observed in 71 of 111 (FGD, 29/56; ciprofloxacin, 42/55) of the children and was significantly greater in the ciprofloxacin group ($p = .009$), with an absolute difference of 24.6% (95% CI 15.8–33.4%). No clinically significant difference was found in the size of tympanic membrane perforation or in the level of hearing impairment when compared before and after treatment. None of the persistent bacterial pathogens following treatment had become resistant to ciprofloxacin.

Conclusions

Twice-daily ear toilets and topical antibiotics administered by both parents and health workers are effective in achieving cure when administered at the community level. Serious consideration needs to be given to increasing the accessibility of twice-daily ciprofloxacin as a first-line option for the nonsurgical treatment of CSOM in Aboriginal children in Australia.¹

References

1. Couzos S, Lea T, Mueller R, Murray R, Culbong M. Chronic suppurative otitis media in Aboriginal children and the effectiveness of ototopical antibiotics: a community-based, multicentre, double-blind randomized controlled trial. *Med J Aust* 2003;179:185–90.