Comparison of the efficacy four treatment modalities for recurrent acute suppurative otitis media

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[5]**Abstract**

Practices differ on the medical management of recurrent acute suppurative otitis media (SOM). This study compares the efficacies of various modalities in terms of cessation of otorrhoea. The hypotheses were that topical ear dressing is more efficacious than oral antibiotics and that topical disinfectant and antibiotics will be comparable in outcome.

Prospective study comparing the efficacy of four selected modalities of treatment of recurrent acute suppurative otitis media in patients attending the University College Hospital, and the Bilal Medical Mission, Ibadan. The modalities were dropping ear medication at home, ear dressing with topical antiseptic, topical antibiotic and oral antibiotics. The patients were randomized into these 4 groups and followed up for 6 10 months.

Of the 368 acute SOM subjects followed up for 6 months, cessation of otorrhoea was achieved in 8 / 91 (8.8%) in those who applied ear drop at home, while otorrhoea ceased in 85/ 131 (64.9%), in the daily antiseptic topical wick dressing group, 79/101 (78%) in the daily antibiotics topical wick dressing group and 10/45 (22.2%) in those who had oral antibiotics.

Univariate analysis revealed that antiseptic dressing is better than home use of ear drops (OR=37.4; P = 0.000), also antibiotic ear dressing is superior to home use of ear drops (OR=62.5; P=0.001). However, topical ear dressing with antibiotics or antiseptic is superior to oral antibiotics (OR=63.6; P= 0.000).
Antibiotic ear dressing is superior to antiseptic ear dressing (OR=3.2; P=0.000).
From this study we conclude that topical ear dressing is superior to use of ear drops in the management of SOM and topical antibiotic dressing has better outcome than topical antiseptic dressing.

Key Words: Suppurative otitis media, cessation of otorrhoea, ear drop, topical ear dressing, oral antibiotics, difference

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Introduction

Otitis media is a major reason for paediatric consultation and the leading indication for antibiotic prescription in children[1, 2]. There is general agreement that aural toilet must be part of the standard medical treatment for chronic suppurative otitis media (CSOM)[1 - 5], although there is no consensus among general and specialist physicians with regard to the medical management of recurrent acute SOM. Use of oral antibiotic is still rampant and after its use a significant proportion still had a re infection or persistence of suppuration. This leads to the question of the relevance of use of oral antimicrobial therapy in the management. This study tested the hypothesis that oral antibiotics does not make significant change in the outcome of otorrhoea and that there is no significant difference in outcome between the use of topical disinfectant and topical antibiotics.

Materials And Method

Subjects

The patients were recruited from the General Out-patient department and the Otorhinolaryngology outpatient Clinic of the University College Hospital, and the Bilal Medical Mission, Ibadan. The inclusion criteria were children under the age of 12 years with recurrent acute mucoid and purulent otitis media using the reference of 2 weeks as cut off for acute OM as recommended by the World Health Organization[6]. The patients who had commenced any treatment for before the commencement of the study were excluded.

Informed consent was obtained from the parents and recruitment commenced. The subjects had history taken, and examination of the ear, nose and throat was done with a hand held otoscope and Shirom lamp and head mirror. After

diagnosis and recruitment into the study, all patients had nasal decongensants and suction ear toileting. Following this the patients were randomly assigned into 4 groups. First group were to use ear drops at home after teaching and demonstrating the method of ear dropping to the mothers and caregivers. Confirmation that the patients actually used the ear drop at home was done by estimating diminution in the volume of the medication in the bottle on presentation at follow up.

The second subject group was daily topical wick dressing with antiseptic ear medication (Flavine in spirit ear drop®) and third group was offered daily dressing with antibiotics ear drop (Ciprofloxacin hydrochloride) for 2 4 weeks.

The fourth group was offered oral antibiotics (Erythromycin®) for 1 week after ear suction toileting. All the patients were followed up for 6 10 months. At follow up, the ears were examined for persistent cessation of otorrhoea for at least 1 month which was taken as the measure of outcome.

The study had ethical approval including participants' consent for publication by the institution review board of the University of Ibadan and University College Hospital Ibadan (UI/IRC/07/0023).

Statistics

The main outcome variables was cessation of otorrhoea while the dependent variable were the modalities of ear dressing and the use or non use of oral antibiotics. The data was initially explored using the Stata software, variables were analysed by unpaired t-test both for equal and unequal variance using the variance ratio function of the Stata software to determine the appropriate use of the Satterthwaite's correction for the degrees of freedom. Level of statistical significance was at $p< 0.05$ for all the analyses.

Result

The subjects included 259 children with 368 ears diagnosed as acute OM and followed up for at least 6 month. They were made of 132 males and 127 females (some subjects had bilateral ear involvement), between the ages of 6 months and 9 years, mean of 6.5 years (SD =2.2).

The otorrhoea was purulent in 202(55%) and mucoid in 166 (45%). Cessation of otorrhoea was achieved in 8 out 91 (8.8%) antiseptic ear drop at home, antiseptic topical wick dressing was done in 131 with cessation of otorrhoea in 85 (64.9%), antibiotics topical wick dressing was done in 101 with cessation of otorrhoea 79 (78%). In the group with oral antibiotic, cessation of otorrhoea was achieved in 10/45 (22.2%).

Univariate analysis revealed antiseptic dressing is better than ear dropping at home (OR=37.4; P = 0.000), also antibiotic ear dressing is superior to ear dropping at home (OR=62.5; P=0.001). However, topical ear dressing with antibiotics/antiseptic is superior to oral antibiotics (OR=63.6; P= 0.0000). Antibiotic ear dressing is superior to antiseptic ear dressing (OR=3.2; P=0.000).

Discussion

The main findings from this study were that topical wick dressing was superior to ear drop and there was no benefit associated with the addition of oral antibiotics in the resolution of suppurative otitis media. Similarly it has been reported that aural toilet alone was not significantly better in resolving otorrhoea (OR = 0.63, 95% CL = 0.36, 1.12) and in healing perforations (OR = 1.04, 95%CL = 0.46, 2.38) than no treatment[4,5]. The superiority of ear dressing question the recommendation of WHO for the developing countries[1] which recommended teaching the mothers how to drop ear medication for children at home. They based this on the paucity of health personnel trained in otologic care. In this study, this modality of treatment yielded good outcome in only 8 out 126. This could be due to poor understanding of the instruction on how to put ear drops into the ear or simple refusal to comply. However it might also be attributed to advanced infection which also involved the mastoid bone, thus making effective drainage difficult. However, application of ear drop at home might also not be properly understood or not done as prescribed. In support of our finding, most otolaryngologists recommend topical antibiotic therapy in preference to oral antibiotics and point out the poor penetration by most antibiotics into a devascularized middle ear mucosa marked with subepithelial scarring and thickening[7-9].

The Cochrane review found that topical antibiotics were more effective than systemic antibiotics in resolving otorrhoea and eradicating middle ear bacteria (OR = 0.46, 95%CL = 0.30, 0.68). Six studies[10-15] used gentamicin, chloramphenicol, ofloxacin, and ciprofloxacin as topical antibiotics; hydrogen peroxide and boric acid with iodine powder as topical antiseptics; and

cephalexin, flucloxacillin, cloxacillin, amoxycillin, coamoxiclav, erythromycin, metronidazole, piperacillin, ciprofloxacin, azactam, trimethoprim-sulfa, ofloxacin, and intramuscular gentamicin as systemic antibiotics. In this study the antiseptic used was flavine in spirit while the topical and systemic antibiotics were similar to the ones reported above. However, some are also of the opinion that suction out and culture the discharge, prescribe oral antibiotics, and adjust according to sensitivity results. Ludman[2] and Nelson[3] advocated similar approaches and cited potential ototoxic effects as a major disadvantage of topical antibiotics. In addition, superior efficacy of topical dressing over systemic antibiotics suggested that suppurative otitis media was a local disease, although the aetiopathogenesis may be due to systemic factors such as malnutrition and dysfunction in the immune response. This study was a comparative analysis of the treatment modalities, it assumed that the disease was comparable in all the subjects, however, a randomized control trial will be better to determine the relative efficacy of the antibiotic or antiseptic ear drop. This is important because of cost and availability. The antiseptic ear drops used in this study were prepared locally in out hospitals hence cheaper and more easily available to patients.

However, it is concluded from this study that topical ear dressing is superior to the other modalities of management and topical antibiotic dressing has better outcome than topical antiseptic dressing. This study established the need to intensify the training of general practice physician and first contact health workers in comprehensive centres in basic skills in otologic care. In addition precaution should be exercised in the use of oral or systemic antibiotic in the treatment of recurrent suppurative otitis media.

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