Clin. Otolaryngol. 1990, **15**, 7–10

A double-blind, randomized, prospective trial of a topical antiseptic versus a topical antibiotic in the treatment of otorrhoea

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Accepted for publication 6 September 1988

CLAYTON M. I., OSBORNE J. E., RUTHERFORD D. & RIVRON R. P. (1990) *Clin. Otolaryngol.* **15**, 7–10

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The clinical efficacy was assessed of a topical antiseptic (aluminium acetate) and a topical antibiotic (gentamicin sulphate) for the initial treatment of otorrhoea. Evidence of resistant organisms developing to either treatments after 9 and 21 days was also examined. 139 affected ears were entered into the trial and of these, 102 (74%) completed the study. Improvement in the otorrhoea occurred in 68% of ears treated with gentamicin and 67% of ears treated with aluminium acetate, with no significant difference between the two treatments. No resistant organisms to aluminium acetate were encountered. Twelve gentamicin-treated ears had gentamicin-resistant organisms at presentation and one patient developed a gentamicin-resistant *Pseudomonas* during treatment. We therefore recommend a topical antiseptic such as aluminium acetate rather than a topical antibiotic in the initial treatment of otorrhoea on the grounds of cost, avoidance of resistance and toxicity.

Keywords *topical antibiotics* *topical antiseptics* *otorrhoea*

There are an increasing number of bacteria emerging in the community which are resistant to first-line antibiotics.[1,2] These are posing enormous problems, especially to immunosuppressed patients and to burns units. Otorrhoea is a relatively trivial symptom and many microbiologists feel that topical use of first-line antibiotics should be avoided in view of the danger of encouraging the emergence of resistant strains.

This trial of a simple antiseptic (8% aluminium acetate) versus a local antibiotic (gentamicin) aimed to find out:

(1) Whether there was any difference between the clinical efficacy of either agent in the treatment of otorrhoea.

(2) Whether there was any evidence of antibiotic or antiseptic-resistant bacterial strains emerging following 9 days and 21 days treatment of otorrhoea.

Method

PATIENT SELECTION

Patients with otorrhoea caused by otitis externa, a discharging central perforation

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or mastoid cavity were selected subject to the following criteria:

(a) The patient had received no topical or systemic antibiotics in the previous three weeks.
(b) The patient had no clinical evidence of fungal infection within the ear.
(c) The patient had no history of drug sensitivity to the agents used (8% aluminium acetate and 0.3% gentamicin sulphate).
(d) Patients with acute middle ear disease or cholesteatoma were excluded.

Assessment and treatment regime

At enrolment, a bacterial swab was taken of the discharge to assess flora and sensitivities.

Patients were randomly allocated treatment with either aluminium acetate or gentamicin ear drops in a double-blind fashion. The medication codes were known only by the pharmacy. Patients were instructed to use 5 drops 3 times daily after self mopping. Patients were assessed every 3 days and treatment compliance monitored. The patient's ears were formally assessed and scored at 9 days and 21 days. Further bacterial swabs were taken at these visits.

Patients ears were scored from 0 to 4 using the following observations:

0: Dry ear.
1: Moist ear without otorrhoea noticed by the patient.
2: Otorrhoea noticed by patient with no oedema obscuring the tympanic membrane or mastoid cavity.
3: Otorrhoea noticed by patient with some oedema partially obscuring the tympanic membrane or mastoid cavity.
4: Otorrhoea with the tympanic membrane totally obscured by oedema or mastoid cavity lined by oedematous mucosa.

(A score of 0 is included as the same scale was used during the trial to assess the results of treatment.)

Patients who failed to attend clinics or failed to comply with the treatment regime were excluded.

Table 1. Treatment allocation of clinical condition

	Completed patients		*Excluded*
Condition	*Al. acetate*	*Gentamicin*	*patients*
Otitis externa	25	41	23
Mastoid cavity	13	8	9
Central perforation	4	11	5
Total	42	60	37

Microbiology

Swabs were sent in transport media and plated out on to blood, neomycin blood, chocolate and Sabouraud's agars. Aerobic and anaerobic incubation were performed for 48 h. Sensitivity of the isolates was tested for gentamicin and aluminium acetate. In the latter, Isosensitest medium (Oxoid Ltd) and chocolate agar plates containing 0.5% and 1% aluminium acetate were used.

Results

One hundred and thirty-nine affected ears were entered into the trial; of these, 102 (74%) completed the study. In 15 ears complete resolution of the otorrhoea occurred between 10 and 21 days. Thirty-seven (26%) failed to complete the study owing either to failure to attend or to inadequate compliance with treatment. The underlying condition of the 139 ears entered are shown in Table 1. Because of the elimination of cases there are significantly more ears with otitis externa treated with gentamicin ($\chi^2 = 8.54$, $P = 0.003$).

Table 2. Clinical grading at enrolment

Grade (1–4)	*Gentamicin*	*Al. acetate*
4	14	4
3	28	18
2	14	9
1	1	11
Total	60	42

Table 3. Improvement with treatment

Clinical condition	*Gentamicin*			*Al. acetate*		
	N	*I*	%	*N*	*I*	%
Otitis externa	41	31	76	25	18	72
Mastoid cavities	8	3	37	13	8	62
Central perforation	11	7	64	4	2	50
Total	60	41	68%	42	28	67%

$\chi^2=0.001$, $P=0.97$, NS.
N, number; *I*, improved.

The grade of discharge at presentation is shown in Table 2. Again there is a significant bias ($p=0.0002$) of more grade 1 scores in the aluminium acetate group.

The criteria for improvement of an ear following treatment were that there was an improvement in the score of 2 or more, or that the ear was clinically dry (score 0) at 21 days. The improvements in the scores are summarized in Table 3 and show that 68% of ears improved with gentamicin and 67% with aluminium acetate. There was no significant difference between the two treatments. ($\chi^2=0.001$, $P=0.97$). There was no significant difference in the response rates in the three conditions. Bacterial isolates were obtained in over 88%. The predominant organisms are listed in Table 4. There was no association between the severity of the condition and the clinical outcome.

No resistance was encountered with aluminium acetate although some yeasts grew on 0.5% concentration. This was not thought significant as the solution used by the patients was 8%.

Twelve patients treated with gentamicin showed resistant organisms at the onset of the trial:

B Haemolytic streptococci	3
Yeasts	5
Pseudomonas spp.	3
Bacteriodes spp.	1

Clinically, only 2 of these 12 cases failed to improve. Only one case of resistance emerged during the trial period using gentamicin and that was to a *Pseudomonas* organism. The use of the antibiotic appeared to encourage the emergence of yeasts.

Table 4. Microbiological flora

	%
Gram +ve	
Staphylococcus aureus	19.4
Staphylococcus coagulase −ve	9.8
Haemolytic streptococci	5.9
Gram −ve:	
Coliforms	27.4
Pseudomonas spp.	13.7
Anaerobes	4.0
Yeasts	5.9
Fungi	2.0
Non-recovery	11.7

Discussion

Our finding that there was no overall difference between the clinical efficacy of either agent agrees with a previous study comparing aluminium acetate with Otosporin[3] where no significant difference was found in the treatment of otitis externa.

The commonest pathogens isolated were Gram-negative coliforms and *Pseudomonas* spp. which is similar to several other reports.[3–6] Adequate aural toilet is an important part of the management of otorrhoea[7,8] and both groups were instructed as to how to perform it. It is of interest that 10 out of the 12 ears with resistant organisms to gentamicin improved, as did the patient in which the resistant strain of *Pseudomonas* emerged.

Although studies have found gentamicin to be an effective local agent in the treatment of chronic otitis media,[4,5,9] Browning *et al.*[10] in a small study found that the steroid component of gentamicin/steroid combination was the more important in the clinical outcome.

As there was no difference in the effectiveness of the agents in the treatment of otorrhoea it is recommended that an antiseptic such as aluminium acetate be used instead of an antibiotic as an initial treatment on the grounds of cost, avoidance of resistance, and toxicity.[2,11]

Acknowledgements

We would like to acknowledge the help and encouragement of Mr D. R. Hanson and

Mr J. D. Fenwick, Consultant ENT Surgeons, Leeds General Infirmary, and Professor R. W. Lacey, Department of Microbiology, University of Leeds.

Also, the ENT OP Sister S. Longbottom for her help in supervising patient reviews.

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