

# Treatment of otitis externa with miconazole nitrate

## A comparative study involving 85 cases

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### Summary

The hazards of neomycin in local preparations have recently been re-emphasized. Eighty-five patients with otitis externa were treated with one of two preparations between August 1980 and April 1982 — 54 were treated with a cream containing miconazole nitrate and hydrocortisone (Daktacort; Janssen) and 31 with a preparation containing neomycin (Kenacomb; Squibb); Sixty eight per cent of the patients were cured within 1 week with both preparations. Most treatment failures were due to a resistant *Pseudomonas aeruginosa*. The miconazole cream proved as effective as the preparation containing neomycin in the first-line treatment of otitis externa. A gentamicin-containing steroid ointment was effective against the *Pseudomonas* infection.

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The treatment of otitis externa varies, chiefly according to the attending physician's fancy, and the number of preparations commercially available and recommended therefore far outstrips the need. Most local agents for its treatment consist of drops or ointment containing a steroid and a broad-spectrum antibiotic.

It has recently once again been emphasized that neomycin sensitivity is a common cause of continued eczema in otitis externa,<sup>1</sup> with the corticosteroid in the preparation masking the acute allergic reaction.

The danger of the local application of an aminoglycoside antibiotic in combination with a steroid is therefore not only the induction of resistant organisms but also the increased risk of sensitization to the drug, making any later use systemically far more hazardous. For this reason it was decided to conduct a trial comparing the efficacy of a non-antibiotic-containing cream with that of a neomycin-containing preparation.

### Rationale for the trial

In tropical areas fungi are implicated in 80% of cases of otitis externa.<sup>2</sup> While the causes of otitis externa are legion,<sup>3</sup> the eczematous reaction and the high prevalence of fungal infections make these two constituents of the condition the most important to treat primarily. For this reason, two preparations were selected for the trial: (i) a preparation (Kenacomb; Squibb) containing triamcinolone (a steroid), nystatin (an antifungal agent), neomycin and gramicidin; and (ii) a cream (Daktacort; Janssen) containing hydrocortisone and miconazole nitrate (an antifungal agent). The difference between these two agents lies in the local antibiotic content of the former.

## Patients and methods

From August 1980 until April 1982 all patients with otitis externa seen at the otorhinolaryngology outpatient department at Tygerberg Hospital, Parowvallei, CP, were entered into the trial. Patients could not be selected on a double-blind basis, because, since he was applying the treatment himself, the doctor had to be aware what preparation he was using. To avoid selection, the first 54 patients seen were treated with the miconazole-containing cream and the 31 seen subsequently with the neomycin-containing preparation.

Following the clinical diagnosis of otitis externa, a swab was taken for culture and sensitivity studies and thorough cleansing of the ear was performed. A 0,65 cm ribbon gauze wick impregnated with the relevant preparation was then packed into the external auditory canal, and the patient was seen again 2 days later. The gauze wick was then removed and the patient was given a tube of ointment or cream to take home and apply to the ears morning and evening with a cotton bud. The patient was then seen again a week later.

## Results

### Miconazole group (54 patients)

**Pus swab results** (Table I). A variety of organisms were isolated from the pus swabs, with *Staphylococcus aureus* and *Pseudomonas aeruginosa* the most important. In 11 patients more than one organism was cultured, and a fungus was isolated in 6 cases only.

TABLE I. EAR SWAB CULTURES

Organism	Neomycin group	Miconazole group
<b>Bacteria</b>		
<i>Pseudomonas aeruginosa</i>	4	7
<i>Staphylococcus aureus</i>	6	15
<i>Proteus sp.</i>	3	6
$\beta$ -haemolytic streptococci	1	3
<i>Clostridium</i>		2
<i>Enterobacter</i>		1
No growth	4	6
Normal bacteria	6	10
Mixed growth	3	11
No swab results	7	3
<b>Fungi</b>		
<i>Candida albicans</i>	1	5
<i>Aspergillus niger</i>	1	1
No growth	20	30
No swab results	9	18

**Clinical results** (Table II). Fourteen patients did not present for follow-up examination. While one might assume that they stayed away because they no longer had symptoms, honesty demands that they be excluded from the trial. There were 2 patients with concomitant furunculosis who received a systemic antibiotic together with the local treatment. Although this was effective they were excluded from the series because of the combined treatment. There were therefore 38 patients left in the trial group. Of these 26 were free of disease within a week and 8 had improved by the first follow-up visit but were then lost to follow-up; in 4 treatment was regarded as having failed. Analysis of these 4 cases showed the following: 1 patient had a *Pseudomonas* culture and responded to local gentamicin and cortisone, another with a *Pseudomonas* culture was treated with a neomycin-containing ointment but was lost to follow-up, a third received further treatment with miconazole but was lost to follow-up, and the fourth was no better after 1 week and was then lost to follow-up.

TABLE II. CLINICAL RESULTS IN 85 PATIENTS

Category	Neomycin group		Miconazole group	
	No.	%	No.	%
Free of disease	17	68	26	69
Improved	4	16	8	21
Treatment failure	4	16	4	10
<b>Total</b>	<b>25</b>	<b>100</b>	<b>38</b>	<b>100</b>
No follow-up	3		14	
Concomitant furunculosis	3		2	
<b>Total</b>	<b>31</b>		<b>54</b>	

### Neomycin group (31 patients)

**Pus swab results** (Table I). *Ps. aeruginosa* and *Staph. aureus* were also cultured from a significant number of patients in this group. Fungi were cultured in 2 cases only.

**Clinical results** (Table II). Three patients did not present for follow-up examination, while another 3 received systemic antibiotics for concomitant furunculosis. Again these patients have been excluded from the series. Of the 25 patients remaining in the trial, 17 were free of disease within a week and 4 had improved by the first follow-up visit but were then lost to follow-up; in 4 cases treatment was regarded as having failed. Analysis of these 4 cases revealed the following: 2 patients had *Pseudomonas* infection responsive to local gentamicin and cortisone, 1 developed neomycin sensitivity responsive to local gentamicin and cortisone, and 1 responded to local miconazole treatment.

## Discussion

The empirical use of ointments containing neomycin, a corticosteroid, and often other agents is common in the treatment of otitis externa.<sup>4</sup> However, the adverse effects of these preparations have received widespread attention of late, and there is evidence that they are not necessarily required.

The results of the present trial have led to the conclusion that the treatment of otitis externa with a cream containing miconazole and hydrocortisone is in no way inferior to treatment with a preparation containing neomycin, gramicidin, nystatin and triamcinolone. In our experience addition of neomycin provided no therapeutic advantage.

An unexpected additional finding was that a *Pseudomonas* species was cultured from pus from the ears of half of the patients who did not respond to the first line of treatment. All these patients then responded well to a preparation containing gentamicin.

## Conclusion

Because of the known adverse effects of the local application of neomycin,<sup>5</sup> preparations containing this agent should not be used in the primary treatment of otitis externa. A preparation containing an antifungal agent, miconazole, and hydrocortisone has proved equally effective as a first-line treatment.

If a good response has not been achieved within a week the miconazole cream should be replaced by a gentamicin-containing steroid ointment, because secondary infection with *Ps. aeruginosa* is likely.

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