

## Main Articles

# Duration of antibacterial effectiveness of gentamicin ear drops in external otitis

YOSEPH RAKOVER, M.D., AMNON SMUSKOVITZ, M.D., RAUL COLODNER, M.Sc.\*,  
YORAM KENESS, Ph.D.\*, GABRIEL ROSEN, M.D., F.A.C.S.

### Abstract

The recommendation of Anderson and Steele, for the use of ear drops four times a day, has not been changed since 1948. In order to re-evaluate the frequency of using ear drops, we examined the duration of the effectiveness of the antibacterial activity of gentamicin ear drops in external otitis.

Seventeen patients (25 ears) with external otitis were studied. We took 18 samples from each ear at 0, 1, 2, 3, 6, 8, 10, 12 and 14 hours and measured the concentration of gentamicin on the wick and in the ear canal. We found that the concentration of gentamicin began to decrease only after 12 hours and a more significant decrease was detected after 14 hours of treatment. We have shown that the antibiotic used on the wick is effective for 12 hours.

In conclusion, we recommend using ear drops twice a day on a wick as routine therapy for external otitis.

**Key words:** Otitis Externa; Drug Delivery Systems; Gentamicin

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### Introduction

External otitis is an infection involving the external auditory canal. Physical examination shows oedema of the auditory canal. If the canal is sufficiently open for examination, a small amount of purulent exudate may be seen. Damaged tissue and purulent exudate tend to increase the formation of debris in the external auditory meatus. Accumulation of this debris then causes further inflammation, irritation and damage. The cycle needs to be broken and this is best accomplished by aggressive cleansing and suction with placement of a gauze wick. Whatever the original pathology, infections occur in almost every case of external otitis. The resulting exudate forms an ideal site for microbial growth. Commonly occurring bacterial pathogens are *Pseudomonas aeruginosa* and *Staphylococcus aureus*<sup>1–3</sup> Ear drop medications applied to the wick inserted into the external auditory canal draw the drops into the inflamed canal. This is a useful therapeutic approach in that it provides enhanced efficacy at the affected site while avoiding the side-effects that accompany systemic administration of the drug.

Since 1948, when Anderson and Steele<sup>4</sup> recommended the use of ear drops in the affected ears, four times a day, this recommendation has not been

updated.<sup>2</sup> We were unsuccessful in our search for the duration of the antibacterial effectiveness of ear drops. In a local survey carried out among otorhinolaryngologists and family physicians, we found variations in the orders given by them for the use of ear drops, ranging from four to 10 times a day.

In order to re-evaluate the frequency of use of ear drops, we examined the duration of the effectiveness of antibacterial activity of gentamicin ear drops in external otitis.

### Patients and methods

Seventeen patients (25 ears) with severe external otitis were hospitalized in Ha'Emek Medical Center in Afula and were studied. The local human ethical committees approved the study.

Swabs were taken from each ear for bacteriological study before treatment. The microbiological findings from the 25 ears with external otitis were as follows: *Pseudomonas aeruginosa*: 11 ears; mixed culture of *Pseudomonas aeruginosa* and *Staphylococcus coagulase neg*: seven ears; mixed culture of *Pseudomonas aeruginosa* and *Candida albicans*; five ears; mixed culture of *Pseudomonas aeruginosa* and *Proteus mirabilis*; two ears. The treatment included the insertion of a ribbon gauze wick with five

drops of gentamicin sulphate ophthalmic solution (3 mg/ml) (Shearing Corp., Kenilworth, N.J.). The follow up of the 25 ears showed no deviation in the clinical course compared with the other patients with external otitis in our department.

#### *Measurement of the concentration of antibiotic used in the ear canal*

Samples for measuring gentamicin sulphate concentration in the ear canal were taken from each ear at the following intervals: 0, 1, 2, 3, 6, 8, 10, 12 and 14 hours post-placing the drops. Following each sampling, the time count began again. The total time for taking samples from each ear was 56 hours. After the wick was removed for the microbiological assay, the affected ear was cleansed by suction and another wick was inserted according to the protocol of treatment in our patients with external otitis.

Two different samples were taken from each ear in the following way:

- (1) The wick was taken out, rinsed in 2 ml of sterile normal saline (0.9 per cent NaCl). Twenty microlitres were taken from the solution as the 'wick sample'.
- (2) After removing the wick, the ear canal was rinsed with 2 ml of sterile normal saline (0.9 per cent NaCl). Twenty microlitres were taken from the solution as an 'ear canal sample'.

Once in the laboratory, the samples were homogenized and three 0.025 ml aliquots from each sample were soaked onto three 6 mm paper disks (Schleicher and Schuell, Dassel, Germany). The disks were placed on Mueller Hinton agar (Difco Laboratories, Detroit, MI, USA) 90 mm plates containing an inoculum of  $10^6$  CFU/ml of *Bacillus subtilis* (ATCC #6633, a strain widely used for antibiotic screening procedures), in a three-disk-per-plate setting.

After overnight incubation at 37°C, plates were examined and the inhibition zone diameter around the disks was measured.

Measuring inhibition zone diameters produced by serial dilutions of gentamicin every working day produced a calibration curve. Every single dilution was tested in triplicate and the averages of all dilutions plotted.

The remaining gentamicin levels in patient samples of the same day was calculated by interpolation of the average of the three-disk inhibition diameter in the same day calibration plot. The results obtained in this way showed the concentration of the gentamicin in units of micrograms/ml.

#### *Control group*

Five volunteers (10 ears) with ears free of diseases of the canal or the middle ear were chosen. The ear canals were washed with 2 ml of sterile normal saline (0.9 per cent NaCl). Twenty microlitres were taken from the solution in the ear canal and tested as described before. We found that in all 10 samples of the control group there was no inhibition of the growth of *Bacillus subtilis*.

TABLE I  
AVERAGE CONCENTRATION OF GENTAMICIN SULPHATE IN 25 EARS  
PER TESTING TIME

Period of time (hours)	Average concentration of 25 ear samples, from the rinsed wick solution ( $\mu$ grams/ml)	Average concentration of 25 ear samples, from the ear canal solution ( $\mu$ grams/ml)
0	100	40
1	100	42.5
2	100	42.5
3	100	40
6	100	45
8	100	40
10	100	37.5
12	80	20
14	40	5

#### Results

We took 18 samples from each ear. All 450 samples produced a growth inhibition zone in the *Bacillus subtilis* lawn. The average concentrations of the gentamicin sulphate in 25 samples per each time of testing are shown in Table I.

From the table we have seen that the concentration of gentamicin sulphate began to decrease only after 12 hours of treatment and more significantly, following 14 hours of treatment.

#### Discussion

It has been said by McDowall<sup>1</sup> that 'there is nothing new in otitis externa, but it is often valuable to restate the fundamental principles in the management of these cases particularly when so many of them are referred to hospital because of the failure of previous treatments and the frequency of recurrences'.

In our practice, we routinely clean the ear and then insert a ribbon gauze wick with ear drops. The wick should fill the ear canal well and should be inserted as near the tympanic membrane as possible. The fit should be snug but not tight so as to enable the drops that the patient will use at home to penetrate the wick. The wick serves two purposes: it keeps the solution in contact with the bacteria in the ear, particularly useful in an inflamed oedematous meatus and it prevents conscious and unconscious scratching of the ear by the patient.

Barr and Al-Khabori,<sup>5</sup> recommended a technique by which the external auditory canal is filled with ointment, 'the sump-filling technique' and leaving the ear rest for one week. They claimed that this technique might be useful in patients who find difficulty in applying ear drops four times a day.

In contrast to Barr and Al-Khabori,<sup>5</sup> Peterkin<sup>6</sup> declared that 'powders and pastes should never be applied to the meatus, as they can form concretions in the outer ear analogous to the cement formed by the insufflation of sulphonamide powder that was once used'. McDowall<sup>1</sup> said that repeated examination is necessary during treatment to ensure that the meatus remains clear and does not become clogged by a mixture of discharge, desquamated epithelium and therapeutic agent.

In our study, we have shown that the antibiotic in the wick is effective for 12 hours so that there is no need to use the drops more than twice a day. This will further contribute to the patient's compliance.

The limiting factor in using the 'sump-filling technique' is that there needs to be enough space in the ear canal to act as a sump (i.e. half the tympanic membrane should be seen).<sup>5</sup> The wick technique is particularly useful for an oedematous meatus, commonly seen in external otitis.

### In conclusion

We have shown that antibiotic usage on the wick in external otitis is effective for 12 hours or so that there is no need to use the drops more than twice a day. We, therefore, recommend a twice daily application of ear drops on a wick as routine therapy for external otitis.

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Address for correspondence:

Y. Rakover,  
Department of Otorhinolaryngology,  
Ha' Emek Medical Center,  
Afula,  
Israel.

Fax: 972-6-6524310

E-mail: rakover@clalit.org.il

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