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# Short Communication

# Distribution of ear drops using a non-aerosol spray delivery system

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**Abstract**

The distribution of ear drops in normal ears is variable. A new product Otomize® (Stafford-Miller) containing dexamethasone and neomycin has a non-aerosol spray mist delivery system.

This has been applied to normal ears and found to be superior in its distribution to generally available ear drops previously assessed.

## Introduction

Wilson *et al.*, (1991) demonstrated marked variation in the distribution of water- and oil-based ear drops in normal ears, the most viscous drops reaching the tympanic membrane and successfully covering it less often than other drops. The best drops were the least viscous.

Clearly a spray delivery system is likely to improve the distribution of drops, as the spray mist will not be wholly dependent on gravity, and therefore, unlikely to be affected by the position of the patient.

We have tested the recently available ear spray containing dexamethasane and neomycin otomize (Otomize®-Stafford-Miller Ltd), to determine the distribution in normal subjects.

## Materials and methods

Twenty normal ears were subjected to study. The ear canals cleared of wax and the tympanic membrane inspected. A liberal dusting of povidone powder was then applied and the ear reinspected to ensure total cover. The subject was then placed on their side, the cartilaginous meatus straightened and a single metered dose of Otomize, as suggested by the manufacturer, administered to the test ear. The subject remained lying for one minute, after which the tympanic membrane was reinspected. The position of any residual powder was noted and a line drawing made of the result.

Additionally the spray was tried both in the upright position and with two activations to see if this made any difference.

## Results

The spray reached the tympanic membrane in all cases. Nine ears showed total cover of the tympanic membrane whilst only four had less than 50% coverage (Table I).

These results were compared with the results of an earlier study using drops (Table I). Analysis by chi squared for each of the drops compared to 'Otomize' showed a significant difference between 'Locorten-Vioform' (Zyma) and 'Otomize' (Stafford-Miller) $0.001 < p < 0.01$ (3 degrees of freedom). No other results reached significance.

As most drop manufacturers state that two to three drops should be used, six ears had two metered doses of Otomize, and this provided complete cover in all ears.

Six ears also had the spray preparation instilled in the upright position, three of which attained complete cover, the remainder had over 50% coverage.

## Discussion

It has been shown in normal people that the distribution of ear drops is variable (Wilson *et al.*, 1991). The 'Otomize' spray would appear to improve the coverage of the tympanic membrane. This may be beneficial in the disease situation under which ear drops are normally used.

In clinical trials of 'Otomize' a greater number of patients were rated as having a 'good' outcome to treatment when using 'Otomize', when compared with another leading ear drop (Smith and Moodie, 1990b). Furthermore, when questioned about the acceptability of the spray, significantly more patients preferred the spray to drops (Smith and Moodie, 1990a).

A single metered dose of Otomize (0.06 ml) is approximately equivalent to a single ear drop (manufacturers data). This study has therefore compared a single drop of 'Otomize' with three drops of the other brands. If the study had used a similar amount as other ear drop manufacturers recommend, ie two to three drops, we would expect complete penetration to all parts of the

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TABLE 1
AREA OF TYMPANIC MEMBARNE COVERED BY OTOMIZE COMPARED TO DROPS

| | No: | Cover None | <50 per cent | >50 per cent | Complete |
|---|---|---|---|---|---|
| Otomize | 20 | 0 | 4 | 7 | 9 |
| Gentisone HC* | 15 | 0 | 6 | 7 | 2 |
| Locorten-Vioform* | 15 | 3 | 8 | 3 | 1 |

*Figures from previous trial (Wilson *et al.*, 1991)

normal ear (as was seen on the small number on which this was tried), and therefore improved delivery in the presence of disease.

Otomize spray appears the most expensive 'drop' tested. The basic cost of the various drops/spray is as follows (March 1991): Locorten-Vioform 7.5 ml £1.05, Gentisone HC 10 ml £3.99, Otomize 5 ml £3.95. This trial has compared three drops with one spray activation (as recommended by the various manufacturers), and when this is taken into account, we would expect one bottle of Locorten-Vioform to last 13 days, Gentisone HC 18 days and Otomize 27 days (based on: one drop = 0.06 ml, 3 drops three times daily against 1 activation three times daily). Otomize, therefore, compares favorably on cost with other commonly available preparations.

The authors feel that this new delivery system offers a significant advantage over the standard drop delivery method. It is easier to use, and more acceptable to patients. It is not gravity dependent and therefore obviates the need for prolonged recumbency, and the distribution (at least in normal ears) is superior to standard ear drop preparations.

The distribution of ear drops in the disease situation remains to be determined. Assuming the distribution of drops is important for the treatment of infective conditions of the ear, this delivery system would represent an advance in their treatment.

**Key words: Ear drops**

**References**

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