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Main Articles

Accuracy of patient self-medication with topical eardrops

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Abstract
Topical eardrops are commonly prescribed by otolaryngologists and general practitioners and many believe that patient compliance is poor, although this has not been studied in a properly controlled manner. Thirty-nine patients with otitis externa were reviewed four times during a two-week course of topical eardrops and their treatment compliance studied. The patients tended to undermedicate themselves, and this tendency increased over the two-week period. Patients were administering significantly fewer drops by the end of day 11 than by the end of day 3 ($p = 0.2$). Compliance patterns were extremely poor, in that only 40 per cent of patients were managing to self-medicate within a 25 per cent error margin by the end of day 3. These findings may have future implications in the ongoing debate on eardrop use.

Key words: Otitis externa; Drug therapy; Patient compliance

Introduction

Self-medication with topical aminoglycoside-containing eardrops is commonly used in the management of many infective ear conditions. Recently there has been much debate concerning the risk of ototoxicity caused by their use.[1] ENT surgeons continue to use these medications for periods of up to two weeks, arguing that their use is rapidly effective in treating a condition which itself can produce permanent cochlear or vestibular damage.

Treatment regimens generally involve the application of a set number of drops to the affected ear, self-administered by the patient. This is not a straightforward procedure, as many patients find it difficult to know how many drops have entered the ear canal. This may lead to under- or over-medication. The purpose of this study was to look at the accuracy of patient self-medication.

Materials and methods

After ethical approval had been given for the study 39 patients took part. Each had unilateral otitis externa, with no middle-ear pathology and an intact tympanic membrane. At the commencement of the trial the best method of instilling the drops was demonstrated to each patient individually by the assessing doctor. Each patient was prescribed a 14-day course of three drops three times a day into the affected ear, and asked to reattend after using the drops for three, seven and 11 completed days (i.e. nine, 21 and 33 applications, respectively). Each patient was prescribed Vistamethasone N drops. The full drop bottle weight was recorded and stored by the pharmacy department on initial prescription.

Patients were requested to bring their bottles with them at each subsequent visit, although the reason was not explained, and they were weighed again by a second doctor without the patients' knowledge. The assessing doctor was blinded as to the weight results. At the end of the trial the mean weight of the three drops was calculated by weighing 10 sets of three drops from three different bottles. Using these data and the trial bottle weights, the accuracy of self-medication was studied.

TABLE I
DESCRIPTIVE STATISTICS OF DROP INSTILLATION COMPARED TO AMOUNT PRESCRIBED

Day	Number of patients measured	Mean percentage of prescribed drop instilled	Standard deviation (%)
3	20	97	0.42
7	23	91	0.43
11	19	71	0.36

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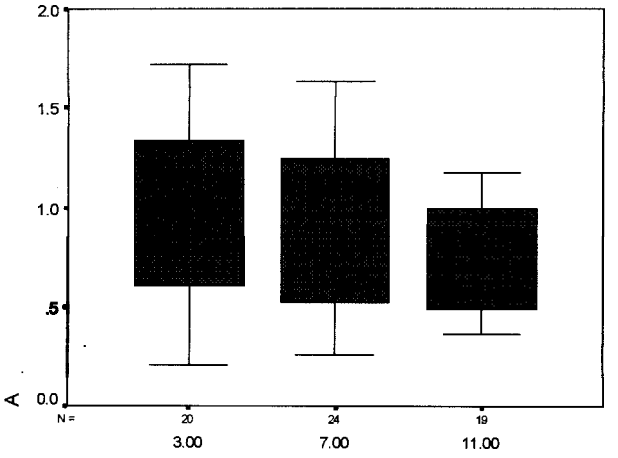

FIG. 1

Box plot illustrating self-medication tendency during treatment course.

Results

Of the total 156 expected weights only 99 were obtained (63.5 per cent), owing to failure to weigh the bottle at initial prescription on one occasion (0.6 per cent), failure to attend on eight occasions (5.1 per cent), and failure to attend with the medication bottle on 49 occasions (31.4 per cent). Overall, patients tended to undermedicate themselves, and this tendency increased over the course of the treatment (Table I, and Figure 1). Wilcoxon's signed-ranks test revealed that the amount of medication being administered by day 11 differed significantly from that administered by day 3 ($p = 0.02$).

Discussion

When assessing these results it should be remembered that all the patients were instructed on how best to instill the drops, and all patients were seen on numerous separate occasions. Therefore, the results will tend to reflect a more accurate pattern of self-medication as the sample is biased towards a highly motivated group. When applying the results to the population as a whole, therefore, it is likely that the trend towards undermedication would be more marked. The results are particularly interesting as previous work has found that when nasal drops are prescribed the tendency is towards overuse.[2]

As well as the tendency towards undermedication, the spread of compliance is broad. If acceptable compliance is arbitrarily defined as 100 per cent ± 25 per cent, then the percentage of patients complying acceptably was 40 per cent, 43 per cent and 32 per cent on days 3, 7 and 11, respectively. This marked failure to comply accurately suggests that the instillation of a prescribed dose of topical eardrops is difficult. Medications administered by spray applicators have been shown to coat the ear canal more effectively, and to be better tolerated and simpler to use.[3,4] Their use may improve patient compliance, although there are as yet no studies looking at this.

The debate concerning the safety of topical aminoglycoside eardrops will no doubt continue. There is no question as to the potentially ototoxic effect of their use. However, most of the research in this area involves animal models using animals with markedly different middle-ear architectures, and many believe such cross-species generalization is invalid.[5] The evidence that the topical use of aminoglycosides in acute and chronic suppurative otitis media (CSOM) is cochleotoxic is 'strengthened' by a series of sporadic reports detailing cochlear damage in cases of active CSOM treated in this way.[6] In these situations it is hard to know whether the topical preparation or the infective process has produced the damage. In addition, there are large studies available in which no detrimental effect has been caused by the use of topical aminoglycosides.[7] With no solid evidence base to these suppositions, we should naturally remain aware of the potential risk and use such treatments cautiously. The fact that patients tend to undermedicate, however, should also be borne in mind.

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