

Main Articles

Randomized trial on the treatment of oedematous acute otitis externa using ear wicks or ribbon gauze: clinical outcome and cost

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Abstract

Acute otitis externa is a common condition that can be extremely painful. When there is considerable canal oedema, packing is necessary to facilitate the passage of medication. The experience at the Royal Victoria Eye and Ear Hospital is that ear wicks generally require removal in two to three days by medical staff and can be labour intensive as they often involve serial removals following re-insertions. Alternatively, medicated ribbon gauze is cheap and can be removed by the patient at home. Ear wick and mediated ribbon gauze were investigated by a prospective randomized trial involving 94 patients.

Fewer out-patient visits were required for the ribbon gauze group (two *vs.* three, $p < 0.0001$) with considerably less material and labour costs than the wick group. Similar resolution rates were achieved (70 per cent *vs.* 64 per cent, $p = 0.58$). Following development of guidelines, the proportion of otitis externa patient reviews in the accident and emergency department declined from 49 per cent to 36 per cent.

Compared with the ear wick, medicated ribbon gauze is a cost-effective method of treating oedematous acute otitis externa.

Key words: Otitis Externa; Treatment Outcome; Healthcare Costs

Introduction

Otitis externa is a condition commonly encountered in both otolaryngological and general practice. It accounts for 20–30 per cent of consultations seen by otolaryngologists.¹ An audit by Raza *et al.* (1995) reported that one in six new referrals to the ENT casualty clinic were for otitis externa and these patients comprised 30 per cent of the review group.² On consideration of staff resources alone, this condition represents a significant portion of health services in the ENT sector.

The clinical presentation of acute otitis externa (AOE) is usually straightforward. Typically, patients present with symptoms of discharge, pain, hearing loss, itch and tinnitus in descending order of frequency.³ Occasionally, in severe cases of AOE where there is pinna cellulitis and occlusive canal oedema, it may be difficult to differentiate the condition from acute mastoiditis. Extreme tragal tenderness is usually a feature of the former.

The pathogenesis of otitis externa is complex and often multifactorial. Peterkin (1974) described four aetiological subgroups – genetic, environmental,

traumatic and infective.⁴ A narrow external auditory canal (EAC), excessive wax production and atopy can genetically predispose an individual to otitis externa. A hot and humid climate in the presence of water often precipitates the infection as well as habitual trauma with various household instruments. Often, the presentation is an interplay of all these factors.

The principles of management of AOE involve firstly the atraumatic cleaning of the EAC, paying particular attention to the anteroinferior recess where stubborn debris may lie unseen.⁵ Significant canal oedema can be physically addressed by packing with an ear wick or ribbon gauze. This will facilitate the passage of antibiotic medication and pH control.⁶ Systemic antibiotics are considered in the setting of auricular cellulitis with, or without, lymphadenitis. A single intramuscular dose of steroid medication may be effective in patients with severe pain and canal oedema.

At the Accident and Emergency Department of the study hospital, 14 389 ENT attendances were treated in 1998. Otitis externa accounted for 20 per

cent of new presentations and 44 per cent of review patients. A large proportion of these reviews were for ear wick changes, which consumed a considerable amount of personnel resources and contributed to lengthy waiting times for other patients in the department. Ear wicks are generally removed after two to three days as a prophylactic measure against toxic shock syndrome. This was performed in the casualty clinic as it was deemed inappropriate to refer these patients to their local practitioner for follow-up.

The purpose of this study is to assess the clinical effectiveness and comparative cost of treating patients with AOE, where packing is required for canal oedema. The standard ear wick management is compared with ribbon gauze treatment in a randomized trial.

Method

Between March 1999 and March 2000, 94 consecutive candidates were enrolled into a single blinded randomized trial from the Accident and Emergency Department of the Royal Victorian Eye and Ear Hospital, a tertiary teaching hospital with a state-wide catchment area. These patients were primarily either 'walk-in' cases or referred by the general practitioner. They were assessed for incident cases of oedematous AOE based on the relevant criteria and consented for enrolment into the study. An ear swab was taken and gentle aural toilet performed prior to randomization. This is to minimize any treatment bias as cleaning of the EAC is generally regarded as an important step in the overall management. Following this, the patient was allocated into one of two treatment groups. Oral antibiotics were given for pinna cellulitis with, or without, lymphadenitis, and intramuscular steroids were administered for severe painful canal oedema.

Selection

Selection was performed by a single ENT Registrar to ensure uniformity of diagnosis. Enrolment was based on clinical features of acute otitis externa (otalgia, otorrhoea, hearing deficit, and itchiness) in the presence of an oedematous external canal with less than 3 mm patency. Patients with the onset of symptoms longer than two weeks or co-existing middle ear pathology were excluded. Factors such as demographic details, diabetes, aural dermatitis, recent AOE in the last two months, previous treatment, water exposure, and cotton bud trauma were recorded. A pilot study was performed on eight patients.

Randomization

Block randomization was employed to ensure equivalent numbers in each of the two treatment arms. Six permutation groups each containing four treatment codes (AABB, ABAB, ABBA, BBAA, BABA, BAAB) were assigned a number. A random number generator provided the order sequence that was transcribed into non-transparent sealed envel-

opes. Consecutive patients who were eligible and consensual were then assigned the contents of the envelope.

Treatment 'A' comprised insertion of an ear wick accompanied by regular topical antibiotic/anti-inflammatory drop therapy ('Sofradex', 'Otodex' or 'Locacorten Vioform'). Patients were given a review appointment in two to three days for wick removal and reassessment.

Treatment 'B' comprised insertion of ribbon gauze impregnated with antibiotic/anti-inflammatory ointment ('Soframycin' or 'Otocomb') into the EAC. This was removed by the patient after three days and topical antibiotic/anti-inflammatory drops commenced. Review was at one week.

Follow-up

All reviews were performed by clinicians other than the initial case selector. At the time of initial consultation, patients were informed that a survey was currently being conducted and that they would be contacted by telephone in three to four weeks for a progress check.

Outcome measures

The primary outcomes under investigation were:

- (1) resolution of AOE at two weeks as defined by the absence of otalgia, otorrhoea and restoration of hearing. This was assessed by telephone survey three to four weeks following presentation.
- (2) the total number of visits to the accident and emergency department for treatment of the AOE episode.

Other factors were measured to control for confounding and used in a regression model. These comprised age, sex, nationality, recent otitis externa in the last two months, diabetes, aural dermatitis, cotton bud use, water exposure from sources such as shower, spa, swimming pool, sea, lake, syringing and previous treatment prior to presentation.

Statistical analysis

Symptomatic resolution was tested for significance using Chi-squared test. Fischer's exact test was used for the total number of visits. The *t*-test was used for continuous data. Univariate and multivariate logistic regression was used to create a model with resolution as the outcome variable.

Sample size calculation

Using STATA, a sample size of 43 in each group was obtained to give a power of 90 per cent and an alpha value of 0.01 to detect a difference of one out-patient visit. A standard deviation of 1.2 was assumed for each treatment group.

Results

Overall patient characteristics between the two treatment groups were very similar (Table I). The mean age was in the fourth decade of life, and there

TABLE I
CHARACTERISTICS BY TREATMENT GROUP

	Ear wick group (n = 47)	Ribbon gauze group (n = 47)	Test statistic	p-value
Mean age, years* (sd, range)	38.2 (12.8, 11–68)	39.5 (17.9, 19–87)	–0.38	0.70
Sex			0.045	0.83
male	28 (59.6)	29 (61.7)		
female	19 (40.4)	18 (38.3)		
Nationality			0.72	0.3
1 = Anglo Saxon	20 (42.6)	23 (48.9)		
2 = European	20 (42.6)	16 (34.0)		
3 = Other	7 (8.5)	8 (17.0)		
Diabetes	4 (8.5)	2 (4.3)		0.33
Aural dermatitis [#]	3 (6.4)	4 (8.5)		1.00
Recent otitis externa	6 (12.8)	9 (19.1)	0.71	0.40
Previous treatment	36 (76.6)	38 (80.9)	0.25	0.61
Water exposure	23 (48.9)	23 (48.9)	0.00	1.00
Cotton bud use	22 (46.8)	30 (63.8)	2.76	0.10
Ear laterality			2.73	0.10
R	27 (57.4)	19 (40.4)		
L	20 (42.6)	28 (59.6)		
Treatment subtypes			0.25	0.97
1 = topical only	23 (48.9)	25 (53.2)		
2 = topical + oral antibiotic	9 (19.1)	9 (19.1)		
3 = topical + IM steroid	5 (10.6)	4 (8.5)		
4 = topical + oral antibiotic + IM steroid	10 (21.3)	9 (19.1)		

All significance tests performed by Chi-square except.

[#]Fisher's Exact test.

*t-test.

was a predominance of males (~60 per cent) in both groups. The majority of patients were from European backgrounds, and over 75 per cent had received previous treatment before presenting to the hospital emergency department. Aural dermatitis was rare, and this may reflect the fact that chronic cases lasting longer than two weeks were excluded. The wick group treated more right ear diseases than the gauze group although this was not significant. Each group comprised cases with similar degrees of severity as indirectly indicated by the treatment subtypes given in Table I.

The median number of visits for the medicated ribbon gauze group was significantly different to the ear wick group (Figure 1). Four patients in the gauze group did not attend the follow-up appointment because their symptoms had already resolved within a week of treatment. However, the overall resolution rate as assessed at two weeks by telephone interview was not significantly different between the two groups – 33 in the gauze group versus 30 in the ear wick group (Figure 2).

Univariate and multi-variate logistic regression analysis did not reveal any significant predictors for resolution outcome.

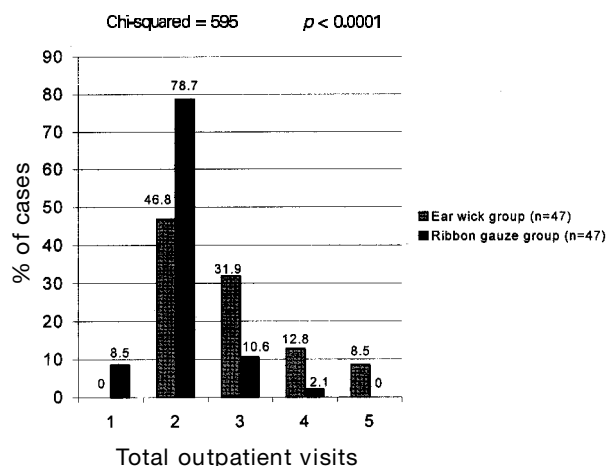


FIG. 1
Total visits by treatment group.

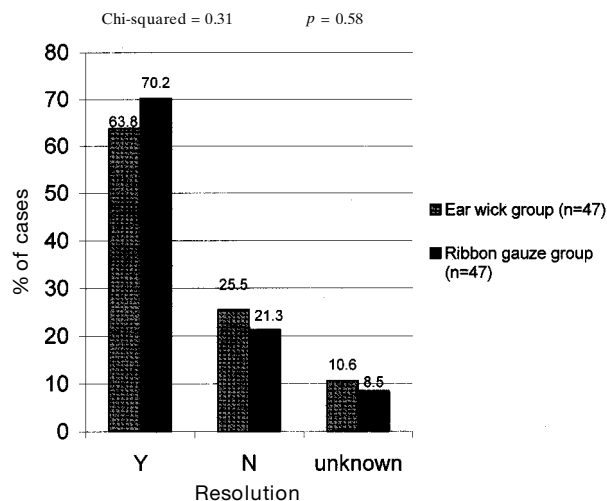


FIG. 2
Resolution at 2 weeks by treatment group.

TABLE II
COST ANALYSIS

	Ear wick treatment	Medicated gauze treatment
Materials	\$6.40 (2 wicks)	\$0.02 per 10cm strip
Ear ointment		\$0.13 (\$1.47 per tube lasting 11 doses)
Ear drops	same	same
Labour		One less out-patient visit

Discussion

This study indicates that medicated ribbon gauze treatment achieves a similar resolution rate to the ear wick but with fewer out-patient visits. The material cost is also significantly less when comparing two Pope wicks with 10 cm of gauze (Table II).

One potential source of bias is the type of topical medication used with the initial packing protocol. The ear wick patients used either 'Sofradex', 'Otodex' or 'Locacorten Vioform' drops whereas the ribbon gauze group received either 'Soframycin' or 'Otocomb' ointment. Although biochemically similar, the different medications used may have resulted in the observed outcome.

Otitis externa is a painful condition that requires prompt treatment with gentle, meticulous aural toileting, and antibiotic therapy. The key to topical treatment is in the delivery of medication either in the form of drops, sump-filling with ointment or packing, or a combination of each. If ear wicks are used, the patient may require several out-patient visits for packing changes since canal oedema may not have resolved after the initial wick is removed. The authors' experience is that valuable staff resources are sequestered.

In the situation where the EAC is open, ear drop or sump-filling treatments are satisfactory. Dekker (1991) described sump-filling of ointment by a syringe and suction tip, which provides continuous

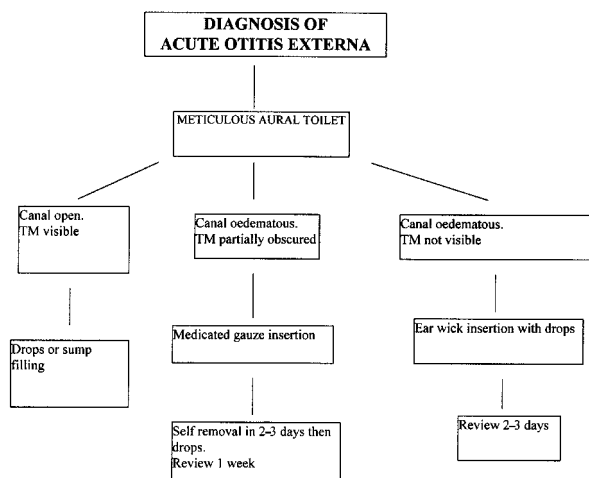
contact of the medication and does not require frequent reviews.^{7,8} However, this reduces hearing temporarily, and staged removal is often necessary.

Moreover, in the case of oedematous EAC, there is no cavity present to house the ointment. Ear drops require patient compliance and it has been suggested that contact time to canal skin is limited and distribution is highly variable.⁹

Where the EAC is oedematous to the extent of obscuring or obliterating the tympanic membrane view, the above treatment options alone are inadequate, and packing is required to reduce oedema and facilitate delivery of topical medication. The added benefit of packing is that it prevents further self-inflicted trauma, that can often potentiate the disease process.

One form of packing is the ear wick which, in combination with drop medication, is simple to use. However, care must be taken to ensure adequate toileting of the deep EAC otherwise residual debris will be impacted medially. The wick is generally removed after two to three days as a prophylactic measure against toxic shock syndrome.

Medicated gauze packing is another option. Ribbon gauze customized to the correct length and impregnated with the appropriate antibiotic ointment is gently placed into the canal using alligator forceps. The degree of pressure can be adjusted by the amount of material inserted and patients can remove the pack after two to three days when ear drop therapy is commenced. The advantages are that it does not require patient compliance for the initial period as regular ear drops are not necessary and it also provides continuous exposure to the medication. On removal, the gauze carries with it any remaining pus and debris.



CONSIDER:

- Oral antibiotics for pinna cellulitis and/or lymphadenitis.
- IM dexamethasone for painful canal oedema.

FIG. 3

Guidelines for the treatment of acute otitis externa.

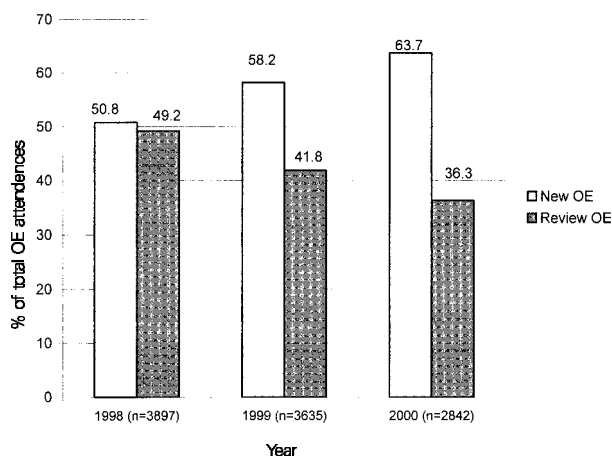


FIG. 4

'New' and 'review' cases of otitis externa by year.

Compared to ear wick treatment, ribbon gauze is much cheaper in both material and labour costs (Table II). An average cost difference per treatment episode is AUS\$ 6.25 plus one out-patient visit. If every new AOE patient presenting to the Accident and Emergency department of the study hospital required packing, the annual cost saving would be AUS\$ 12 500 and approximately 2000 visits. Anecdotally, gauze insertion may require more expertise to perform and if the EAC is completely occluded, it may be painful. In this situation, the ear wick is probably more appropriate.

Following completion of the study, a guideline for the treatment of acute OE was constructed (Figure 3) with the aim of standardizing management in the accident and emergency department. This was formally introduced in 2000 to reduce the indiscriminate use of ear wicks. Consequently, during both the study year of 1999 and 2000, a significant decline in the percentage of review cases of otitis externa was seen (Figure 4).

The treatment of oedematous AOE is a commonly encountered problem for both the otolaryngologist and general practitioner. If time and cost are important issues, the medicated ribbon gauze method offers a cost-effective way of managing the condition without compromising resolution outcome.

References

- 1 Hawke M, Wong J, Kraiden S. Clinical and microbiological features of otitis externa. *J Otolaryngol* 1984;**13**:289–95
- 2 Raza SA, Denholm SW, Wong JC. An audit of the management of acute otitis externa in an ENT casualty clinic. *J Laryngol Otol* 1995;**109**:130–3
- 3 Agius AM, Pickles JM, Burch KL. A prospective study of otitis externa. *Clin Otolaryngol* 1992;**17**:150–4
- 4 Peterkin GAG. Otitis externa. *J Laryngol Otol* 1974;**88**:15–21
- 5 Briggs RJ. Otitis externa. Presentation and management. *Aust Fam Phys* 1995;**24**:1859–64
- 6 Bojrab DI, Bruderly T, Abdulrazzak Y. Otitis externa. *Otolaryngol Clin North Am* 1996;**29**:761–82
- 7 Dekker PJ. Alternative method of application of topical preparations in otitis externa. *J Laryngol Otol* 1991;**105**:842–3
- 8 Wilde AD, England J, Jones AS. An alternative to regular dressings for otitis externa and chronic suppurative otitis media? *J Laryngol Otol* 1995;**109**:101–3
- 9 Wilson PS, Grocutt M, Dingle A, Reid AP. Distribution of ear drops in normal ears. *J Laryngol Otol* 1991;**105**:359–61

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Dr F. Pond takes responsibility for the integrity of the content of the paper.

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