

Acidifying therapy, best choice in otitis externa?

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Abstract Literature was reviewed in order to define a rational therapy in otitis externa based upon aetiology and predisposing factors. In most cases a bacterial infection turned out to be present (mainly *Pseudomonas Aeruginosa* or *Staphylococcus Aureus*); also, an allergic contact dermatitis or mycosis can be present, particularly in chronic otitis externa. The medication of choice is Aluminium acetotartrate. Resistant cases can be treated with topical antibiotics or topical steroids. Combination of both drugs is not recommended. Research in general practice is needed to state the outcomes of using these guidelines.

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Introduction

Since 1976, a group of about 15 experienced general practitioners, staff members of the department of general practice in Nijmegen, meet once a month to discuss common problems in general practice. In 1992 some conferences were addressed to otitis externa and an orientation in literature was made. Otitis externa is defined as an inflammatory condition of the skin of the external ear canal. In the Netherlands, incidence-figures from general practice amount to 12-14 cases per 1000 patients per year. It almost equally affects all age groups and both sexes.¹⁻⁴ Otitis externa occurs most frequently in summer and in humid tropical areas. Patients complain of pain, itching, discharge and, less often, hearing loss or a plugged feeling. Otoscopy reveals erythema, edema and discharge or desquamation.⁵⁻⁸ Acute and chronic forms can be distinguished. Simple acidifying therapy is recommended for the acute form; there are no concrete recommendations for chronic otitis externa. Moreover, it is only in Dutch literature that a distinction between a dry and a wet form of otitis externa is made.⁹⁻¹¹ It is not clear whether this clinical distinction corresponds with different aetiological factors and, consequently, should be treated differently. In the Netherlands, daily practice does not seem to correspond with the advice for acidifying therapy, at least not according to daily practice of the members of the conferences. In order to reach consensus on the management more knowledge about the aetiology was required. Therefore a study of literature was conducted, in order to find the answers to the following questions:

- Which factors play a part in the aetiology of otitis externa?
- Is a treatment with acidifying eardrops justified in view of these factors?

Methods

Using otitis externa as a keyword, the literature of the last 10 years was screened referring to Medline (the automatized bibliographic data collection of the Index

Medicus) and Famli (the family medicine appendix of the Index Medicus). Literature references found in the selected publications were traced and two ENT textbooks were consulted. Articles were excluded from further study when they concerned one of the following subjects: malignant otitis externa; in vitro research; surgical therapy; CT-scan. Case-reports and reports concerning undefined otitis were also excluded. This procedure yielded 51 articles. First of all, these articles were scanned for information on aetiology. Secondly, reports from clinical trials were studied, comparing different drugs (and/or placebo) in the treatment of otitis externa. Reports of trials in which different brands of eardrops were compared, while each contained a combination of an antibiotic and a corticosteroid, were excluded.

Seven studies were found and critically reviewed according to the following criteria:¹²

- was the study based on an 'inception-cohort'?
- was the referral pattern described?
- were the exclusion-criteria described?
- has complete follow-up been achieved?
- were the demographic and clinical characteristics of patients and controls described?
- was the study designed as a randomized controlled trial?
- have patients and controls been matched for clinical characteristics?
- have objective outcome criteria been developed and used?
- was the outcome assessment 'blind'?

Aetiology

The ear canal is well protected against infections by the acidity (pH 5-5,7) of the meatal skin, by the water-resistant, bacteriostatic and bactericidal qualities of cerumen (thanks to the polyunsaturated fatty acids in cerumen), and by the outward migration of the meatal skin with about 1,5 mm per month.¹³⁻¹⁵ This natural protection can decrease as a result of:

- tissue maceration in case of high environmental temperature and humidity (tropical climate, swimming);
- damage of the skin, caused by for example scratching or syringing the ear, or a corpus alienum (hearing aids!);
- dermatological diseases, such as eczema, psoriasis;
- alkaline pH, caused by using soap;
- absence of cerumen, caused by vigorous cleaning of the ear canal, chronic inflammation, or long-term topical application of steroids;
- host resistance lowering conditions like diabetes, anemia;
- anatomical variants, such as a narrow ear canal.

The connection between swimming and otitis externa has been confirmed in controlled studies.¹⁶⁻¹⁹ No controlled studies regarding any of the other mentioned predisposing factors were found.^{5 8 9 14 15 20-34}

Infection is an important cause of otitis externa; *table 1* shows the results of cultures made of diseased and normal ears. In general, the micro-organisms predominantly isolated in otitis externa are *Pseudomonas aeruginosa* (17-64 per cent) and *Staphylococcus aureus* (11-46 per cent). Pathogenic bacteria are sporadically found in the healthy external ear canal of control persons.^{6 7 19 21 35-37} In Norway, during a whole year, a high incidence of *S. aureus* was found together with a low incidence of fungi and yeasts,⁷ whereas in swimmers and in subtropical areas a high incidence of *Pseudomonas* was found together with a moderate high incidence of fungi and yeasts.^{6 19} Fungi and yeasts also play a role in the following situations: chronic otitis externa; long-term treatment with eardrops containing a corticosteroid; prolonged prophylactic treatment with antibiotics; in immunocompromised patients.^{5-7 37 39 40}

In otitis externa of more than two months' duration, 18 per cent of the cultures showed no micro-organisms or a normal flora (*Staphylococci* other than *S.aureus*, *corynebacteria*).³⁷ In such cases an allergic contact dermatitis should be considered; for example caused by chemical substances in hearing aids, hair-dye,

Table 1 Cultures of patients with otitis externa and controls. Percentages

	Healthy ear canal			Otitis externa		
	Dibb ³⁸ n=77	Manni ⁶ n=21	Calderon ¹⁹ n=29	Dibb n=226	Manni n=54	Calderon n=29
Diphtheroids	32	38	86	86	48	81
Staphyloc. C-*	83	90		52		
<i>S. aureus</i>	4		8	34,1	18	11
<i>Pseudomonas aeruginosa</i>			22,1	38	50	
B-hemolyt. streptococ				15,5	4	
<i>Proteus</i> sp				3,5	9	
<i>Klebsiella</i> sp				5,3	11	3,7
<i>E.coli</i>				3,5		1,9
<i>Candida alb</i>			9,3	14		
<i>Aspergillus</i> sp.				24		
No growth	9	10	5	4,4	8	1,9

* C- = coagulase-negative, predominantly *S. epidermidis*

Table 2 Seven studies concerning comparative trials to the medication treatment of otitis externa

References	16	55	50	52	56	57	24
Number of patients	126	24	66	46	179	110	83
Therapeutics	(a)	(b)	(c)	(d)	(e)	(f)	(f)
1 Start cohort	+	+	+	+	+	+	+
2 Selection of patients	+	+	-	+	-	-	-
3 Exclusion criteria	-	+	+	+	-	+	+
4 Percentage patients followed	+	+	*	+	+	*	+
5 Characteristics							
- demographic	-	-	-	-	+	+	
- clinical	-	-	+	+	-	+	+
6 Randomized	+	+	+	+	+	+	+
7 Matching	-	-	‡	+	-	-	-
8 Criteria end-results	+	-	+	+	+	+	+
9 Double-blind	-	+	+	-	+	+	+

* drop-outs >20 per cent. ‡ matching was negative (groups were not corresponding).

- (a) aluminium acetate with a combination preparation (combination of an antibiotic and steroid)
- (b) a solution of boric acid 4% and alcohol 25% with two combination preparations
- (c) aluminium acetate with a topical antibiotic
- (d) hydrocortisone-butyrate with a combination preparation
- (e) acetic acid 2% in aluminium acetate with VoSoL(R) (chemical composition: 2% acetic acid in a propylene-glycol vehicle of 3% propylene-glycol-diacetate, 0.02% benzethonium-chloride en 0.015% sodium-acetate) and VoSoL-hydrocortisone (VoSoL-HC) with a combination preparation
- (f) VoSoL-HC with a combination preparation

Management of otitis externa in daily general practice

- *Cleaning of the ear canal.* Advise patients not to do this themselves.
- *Inspection,* with special attention to the ear drum (otitis media, cholesteatoma, perforation).
- *Medication treatment:* aluminium acetotartrate 6 dd 2 eardrops during 1 week (anti-microbial, dries the external canal, not ototoxic); in case of edema or discharge, first place a cotton plug in the canal and keep it wet with the aluminium acetotartrate drops for 24 hours.

In case of obvious improvement in the first week of use, patient continues the same treatment until the symptoms have disappeared (max. 2-3 weeks).

If symptoms persist after 1 week, ask patients to return. Otoscopic inspection reveals:

- 1 No improvement and discharge: again cleaning, start topical antibiotics.

- 2 No improvement and itching or a dry, scaly ear canal: start corticosteroid containing eardrops.

A small number of patients will keep symptoms. In case of chronic otitis externa the following points ought to be considered:

- Avoid a warm humid environment (swimming), leave off hearing aids (temporarily).
- Culture for fungi and yeasts, especially in patients who have received topical steroids for a long time, immunocompromised patients or patients who have received prolonged prophylactic treatment with antibiotics.
- Consider allergic contact dermatitis and its predisposing factors.
- Consider reference to an ENT specialist, if middle ear disease can not be excluded or surgical correction of a narrow ear canal may be necessary.

chromate in match-heads (used for picking the ear!) and eardrops containing neomycine.^{5 9 23 28 41-43} Also, diseases like eczema, psoriasis, and diabetes mellitus, and habits like ear-picking, can account for chronic forms of otitis externa.^{10 28 42-45} Chronic otitis externa is more often attended by itching, the acute form more often by pain, hearing loss and discharge.³⁷ As a result of chronic otitis externa irreversible skin changes are described with narrowing of the ear canal.^{27 32} Malignant otitis externa is an extremely rare, but serious form of otitis externa.⁴⁶

Therapy

All authors recognize the importance of cleaning the ear canal ('aural toilet') for inspection and application of local therapy.^{47 48} Acidifying eardrops are often recommended as first choice of therapy. They have an antibacterial effect by lowering pH, and restore the natural barrier against micro-organisms.^{21 49} Topical antibiotics are indicated in cases of perforation of the

eardrum and in cases where acidifying therapy has no effect. Disadvantages of topical antibiotics are the development of sensitisation, drug resistance, and ototoxicity.^{5 8 9 11 22 27 28 42 44 50 51} Oral antibiotics are indicated when the infection spreads to the surrounding tissues outside the ear canal and systemic signs of infection develop, and in cases of serious and progressive otitis externa.^{8 9 14 44} Especially in the Netherlands, eardrops containing corticosteroids are recommended for the treatment of all dry, itchy forms of chronic otitis externa.^{5 10 11 23} Recently, no difference could be found between the efficacy of a topical corticosteroid and a combination of a topical corticosteroid with antibiotics; *S. aureus* infections were even more successfully treated by the topical corticosteroid only.⁵² In theory, repeated or prolonged use of steroids can cause atrophy of the skin.^{9 44 52} Only a few authors recommend eardrops that combine corticosteroids and antibiotics as first choice.^{23 26 31 53} Others warn against the use of such combinations, as they could mask

a superinfection caused by resistant organisms and could cause hypersensitivity to one of the antibiotics.^{8 9 11 44} In the USA, eardrops containing both an acidifying solution and a corticosteroid are recommended in case of otitis externa in patients with eczema or psoriasis.⁵⁴

Medical treatment of otitis externa was the first subject of 17 of the 51 selected articles. Of these 17 articles, 6 were reviews for postgraduate education, 2 were follow-up studies of one treatment, 2 were studies of the effects of cleaning the external auditory canal,^{47 48} and 7 were clinical trials comparing different medications. These 7 were studied according to the previously formulated criteria. The results are summarized in *table 2*: all trials meet at least 5 of the criteria; two meet 8 criteria;^{24 52} in four trials there is no mention of clinical criteria for the diagnosis acute otitis externa;^{24 52 56 57} one includes only 24 patients;⁵⁵ two have a high percentage of drop-outs.^{50 57} The four clinical trials in which acidifying therapy for otitis externa was one of the treatments can be summarized as follows:

- In a Family Medical Centre in Cyprus, 126 patients were studied. No significant differences were found between Aluminium Acetate eardrops and Polymyxine-neomycine-hydrocortisone eardrops (Otosporin®).¹⁶
- In England, in 24 patients referred to an ENT specialist, no significant differences were found between a solution of boric acid 4% and alcohol 25% on the one hand and polymyxine-fluocinolone-acetonide-econazol-methanol-glycerol-polyethylene-glycol eardrops on the other.⁵⁵
- In England, in 66 outpatients of an ENT department, no significant differences were found between Aluminium Acetate eardrops and gentamicin eardrops.⁵⁰
- In the USA, in 179 outpatients, 40 otitis externa ears were treated with acetic acid 2 per cent in Aluminium acetate, 40 were treated with VoSoL (a non-aqueous acid solution); the remaining ears, showing complications (eczema, allergic reactions), were treated with VoSoL combined with hydrocortisone (VoSoL-HC) or colistin-neomycin-hydrocortisone eardrops. In

the first group 80 per cent of the treated ears was cured within one week: pain was gone in 92,5 per cent, itching in 60 per cent; with VoSol the results were even better. In the ears with complications no differences were found between the two treatments.⁵⁶ The latter was also found in other trials.^{24 57}

A new development concerns artificial cerumen.³⁰ The first experiences are promising, but further research is needed.

For chronic otitis externa, reference to an ENT specialist is recommended if the presence of chronic middle ear disease can not be ruled out or if – rarely – one considers surgical correction of acquired stenosis of the external ear canal.^{10 14 29 32}

As a spin-off from the literature-study, some guidelines are proposed for the management of otitis externa in daily general practice (*page 33*).

Discussion

The epidemiology, aetiology and therapy of acute otitis externa is well documented in literature. Nevertheless, in the Netherlands and particularly in general practice the clinical picture has hardly been studied. Therefore, results can not simply be generalized to the situation of the Dutch general practitioner. With regard to chronic otitis externa things are less clear: there are no consistent definitions for the disease and the aetiology is much more complicated. The role of endogenic predisposing factors (dermatological diseases as eczema and psoriasis, systemic conditions, narrow ear canal) and of exogenic factors (allergic contact dermatitis, ear-picking) is insufficiently investigated; 20 per cent of the cultures (bacteria and fungi) is negative. Also, aetiological factors corresponding with dry and wet forms of otitis externa were not found in literature. Research does not seem to provide a reliable answer to the question whether these predisposing factors have consequences for therapy. Of course, in case of allergic contact dermatitis, contact with the allergen will be avoided, so the use of eardrops can be discontinued. But it remains unclear

whether a different treatment is required if a bacterial infection is the probable cause of otitis externa than if eczema is the probable cause.

Concerning the second question, there is little scientific research to the efficacy of acidifying therapy that meets the previously stated criteria of quality. Nevertheless, the results were remarkably similar: acidifying therapy equalizes the efficacy of the topical use of antibiotics or combinations of antibiotics and corticosteroids. It is concluded that an acidifying therapy is the first choice in the treatment of otitis externa; it is as effective as topical antibiotics and corticosteroids are, but does not entail the risk of complications, and it is cheap.

Publication-bias may have played a role in these positive results: negative results are more likely to remain unpublished. A second marginal note is the fact that a number of trials concerned patients of ENT specialists. This population is a selection of the more complicated and therapy-resistant cases, and therefore not representative for the general practice patients with otitis externa. Further research in family practice is necessary to evaluate the acidifying therapy.

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