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Otitis externa: what is the problem with getting it right? A mixed-methods study in primary and secondary care‡

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Main Article

Dr H Mohammed takes responsibility for the integrity of the content of the paper

‡This article has been updated since original publication. A notice detailing the change has also been published

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Abstract

Objective. Otitis externa accounts for 1.1–1.3 per cent of patient presentations in primary care and 25 per cent of urgent referrals to ENT. This study aimed to explore otitis externa clinical decision-making at the primary-secondary care interface, otitis externa prevalence and recent trends in antimicrobial resistance in otitis externa related bacterial isolates and ototopical prescribing.

Method. This is a mixed-methods study drawing on data from primary and secondary care and open National Health Service sources.

Results. A total of 101 general practitioner survey respondents reported frequently prescribing oral antibiotics for otitis externa. General practitioner consultations for otitis externa increased 25 per cent over 15 years. General practitioner ototopical preparations cost the National Health Service £7 410 440 in 2006 and £11 325 241 in 2016. A total of 162 consecutive hospital otitis externa-related bacterial isolates yielded 128 pseudomonas species, with 18 that were resistant to gentamicin and 7 that were resistant to ciprofloxacin. Ten guidelines reviewed showed systematic inconsistencies.

Conclusion. General practitioners reported regularly prescribing oral antibiotics for otitis externa. Antimicrobial drug resistance is common in otitis externa. The available guidance is suboptimal.

Introduction

Diffuse inflammation of the external auditory meatus (otitis externa) has been estimated to have an annual UK primary care prevalence of 1 per cent, with 3 per cent of sufferers referred to secondary care.[1] Key recommended treatments are ototopical drops, analgesia and avoidance of precipitating factors.[2]

We were concerned with the increased promotion of fluoroquinolone drops for the treatment of ear infections because they are still a key part of systemic therapy for necrotising otitis externa, and resistance driven by prior topical use may reduce efficacy in severe infection. In this study, we therefore aimed to explore the following. In primary care, we aimed to analyse: (1) otitis externa decision-making, guideline content, awareness and adherence, and (2) consultation rates and costs. In secondary care, we aimed to analyse: (1) otitis externa and necrotising otitis externa inpatient activity, and (2) the antimicrobial resistance profile of otitis externa-related bacterial isolates and content of available guidelines.

Materials and methods

Relevant components of the study were registered with the Clinical Effectiveness and Audit department of the Newcastle hospitals.

Data sources

Primary care

For primary care, the data sources were as follows. The first data source was from an otitis externa decision-making in primary care online survey (Figure 1) of a convenience sample of general practitioners and general practitioner trainees in North East England. It comprised research contacts in 12 clinical commissioning groups in North East England and North Cumbria. The office that distributed the questionnaire was not able to provide the total number of general practitioners to whom the questionnaire was sent. The questionnaire was designed based on the contents of the National Institute for Health and Care Excellence (NICE) clinical knowledge scenario. It was then discussed with and revised by the senior author and then piloted in a group of general practitioner trainees. The final version was posted online. A link to the survey was emailed to 500 general practitioner trainees in North East England.

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1. How many years of medical practice have you done including Foundation?

2. Did you hold an ENT post in your training rotation?
yes No

3. Would you swab the ear in otitis externa?
Always Occasionally
Often Never
Other (please specify)

4. If yes, when would you consider an ear swab? (Please tick all that apply)

In immune-compromised patients
If first choice treatment fails
Before start of treatment
If episodes are recurrent
Other (please specify)

5. Topical otitis externa treatment - which do you routinely prescribe? (Please tick all that apply)
I don't prescribe topical drops
Otomize spray
Earcalm spray
Sofradex
Chloramphenicol
Gentamicin
Gentasone HC
Betnesol N
Ciprofloxacin
Other (please specify)

6. Oral antibiotics treatment - Which do you routinely prescribe? (Please tick all that apply)
I don't prescribe oral antibiotics
Amoxicillin
Flucloxacillin
Clarithromycin
Ciprofloxacin
Amoxicillin-clavulanate
Other (please specify

7. Which of the following do you routinely recommend to patients with otitis externa (please tick all that apply)?
None
Do not use cotton buds
Keep ears dry when bathing/showering
Avoid swimming (or use ear plugs)
Other (please specify)

8. Which guidelines if any do you use for the management of acute otitis externa (please tick all that apply)?
None
Regional
NICE
Other (please specify)

Fig. 1. The otitis externa questionnaire for primary care. NICE = National Institute for Health and Care Excellence.

The second data source for primary care was the otitis externa workload estimated from a primary care diagnostic database in North West England[3] that covered 23 general practitioner practices with 152 238 patients. We assessed consultations over a 12-month period from 2015 to 2016 stratified by age: 0–18, 19–64 and over 65 years.

The second data source for primary care was the National Health Service Digital website,[4] which was interrogated for any trends in community prescription of otitis externa topical preparations in the British National Formulary.

Secondary care

For secondary care, the data sources were as follows. The first data source was Hospital Episode Statistics[5] data in England for secondary care of otitis externa and necrotising otitis externa admissions from 2002 to 2020.

The second data source was the antimicrobial resistance patterns of 162 consecutive bacterial otitis externa-related bacterial swab isolates at the Freeman Hospital, Newcastle upon Tyne, from 2 June 2017 to 29 June 2018. The sensitivity testing results were interpreted according to systemic breakpoints. When using topical therapy, the higher concentrations supplied to the ear can often overcome a degree of non-susceptibility, as long as there is some activity *in vitro*.

Guidelines

Ten online UK otitis externa guidelines were assessed for: (1) ease of use, (2) concordance, and (3) inclusion and quality of any prevention advice.

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Table 1. Summary of surveys of general practitioner trainees and general practitioners

Parameter	General practitioner trainees	General practitioners	Total
Respondents (*n*)	64	37	101
Post-graduate experience (mean; years)	6.7	14.5	9.6
Indications for ear swab (*n* (%))			
– Recurrent episodes	47 (73)	30 (81)	77 (76)
– Failure of first choice	38 (59)	23 (62)	61 (60)
Routinely prescribe (*n* (%))			
Otomize® spray	60 (94)	37 (100)	97 (96)
EarCalm® spray	10 (16)	13 (35)	23 (23)
Oral antibiotics	27 (42)	19 (51)	46 (46)
Follow guidelines (*n* (%))			
– National Institute for Health and Care Excellence	36 (56)	2 (5)	38 (38)
– Regional	22 (34)	15 (41)	37 (37)
– None	12 (19)	21 (57)	33 (33)
Advise patients (*n* (%))			
– Avoid use of cotton buds	51 (80)	35 (95)	86 (85)
– Keep ears dry when bathing or showering	47 (73)	32 (86)	79 (78)
– Avoid swimming or use ear plugs	50 (78)	29 (78)	79 (78)

Table 2. Incidence of otitis externa by age group*

Parameter	0–18 years Patients (*n* (%))	19–64 years Patients (*n* (%))	65+ years Patients (*n* (%))	All Patients (*n* (%))
Diagnosed in last 12 months	318 (0.21)	1147 (0.75)	433 (0.28)	1898 (1.25)
Diagnosed at any point in their lifetime	1852 (1.22)	10742 (7.06)	4467 (2.93)	17061 (11.21)

*North West Primary Care Data, *n* = 152 238

Results

Primary care

Otitis externa decision-making in primary care

Our 101 respondents (Table 1) showed that 42 per cent of general practitioner trainees and 54 per cent of general practitioners prescribe oral antibiotics, most often amoxicillin (14 of 27 trainees) and flucloxacillin (12 of 19 general practitioners). Systemic treatments were used similarly (40 per cent) among the 20 respondents who had an ENT trainee placement.

Workload of otitis externa

The primary care data are summarised in Table 2. The annual incidence of otitis externa in the North West primary care catchment area was 1.25 per cent. Extrapolation to the population of England in 2015 equates to around 700 000 patients.

Cost of topical preparations

From 2006 to 2016, there was a steady increase in total prescription costs for community otitis externa topical prescriptions, from £7 million to £11 million (Table 3). Expenditure on ciprofloxacin drops rose most rapidly, increasing 12-fold in 3 years.

Secondary care

Hospital Episode Statistics data

In-patient otitis externa admissions in England showed a 122 per cent overall increase from 2611 patients in 2002 to 5786 patients in 2020 (Table 4). In 2002 to 2003, the mean length of stay was two days. The 2019 to 2020 bed occupancy equates to approximately 3.1 million at £346 per day.[6] Necrotising otitis externa workload increased by 950 per cent in the same interval, at a cost of approximately £6.1 million.

Antimicrobial resistance profile

Pseudomonas species were isolated in almost 80 per cent (128 of 162) of the consecutive hospital swabs. *Staphylococcus aureus* was isolated from 41 swabs (25.3 per cent). Three out of five isolated streptococcus species were resistant to gentamicin. Multiple pathogens were grown from 20 swabs. One pseudomonas isolate was resistant to all antibiotics tested. Table 5 summarises resistance patterns in isolated bacteria according to the European Committee on Antimicrobial Susceptibility Testing guidelines for systemic antibiotic use.[7]

Guidelines

The guidelines reviewed (Table 6) show discrepancies in first line and second line recommendations. Some[8] lacked clarity

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Table 3. National Health Service indicative price of topical ear preparations ranked by 2016 total expenditure

Topical drug	NHS IP (£)	Volume (ml)	Price per ml (£)	Total expenditure (£)	
				2006 unless stated	2016
Otomize® (dexamethasone, acetic acid, neomycin sulfate) spray	3.27	5	0.65	2 983 774	4 297 422
Sofradex® (gramicidin, framycetin sulfate, dexamethasone) drops	7.50	8	0.94	1 502 165	2 657 946
Gentamicin 0.3% / hydrocortisone acetate 1% ear drops	26.19	10	2.62	712 190 (in 2015)	1 838 203
Gentisone HC® (gentamicin 0.3% / hydrocortisone acetate 1%) drops	4.76	10	0.47	1 418 689	16 108
Flumetasone 0.02%/clioquinol/1% drops	11.34	7.5	1.51	187 589 (in 2014)	1 751 250
Locorten-Vioform® (clioquinol, flumetasone pivalate) drops	1.76	7.5	0.23	453 339	3 987
Earcalm®* (glacial acetic acid) spray	7.99†	5	1.60	54 982	345 183
Ciloxan® (ciprofloxacin) drops	4.70	5	0.94	12 270 (in 2011)	145 557
Chloramphenicol 5% drops	63.69	10	6.37	4 081	90 147
Betnesol-N® (betamethasone and neomycin) drops	2.39	10	0.24	280 997	82 759
Chloramphenicol 10% drops	84.70	10	8.47	110	37 589
Aluminium acetate 8% drops	No Information	No information		16 370	31 506
Aluminium acetate 13% drops	75‡	No information	N/A	18 013	10 617
Otosporin® (hydrocortisone, polymyxin B, neomycin) drops	7.45	10	0.75	555 687	500
Total				7 290 455	11 308 777

*Available over the counter; †over the counter price; ‡price quoted from pharmacy. NHS = National Health Service; IP = indicative price

Table 4. Hospital Episode Statistics data for admissions with otitis externa and necrotising otitis externa

Year	Otitis externa (*n*)	Bed days* (*n*)	Necrotising otitis externa (*n*)	Bed days* (*n*)
2002–2003	2611	5312	107	1130
2019–2020	5786	9019	1127	15 346

*Finished consultant episode bed days

Table 5. Resistance patterns in 169 isolated bacteria

Bacteria	Antibiotic	Resistance (*n* (%))
Pseudomonas species*	Ciprofloxacin	7 (5.5)
	Gentamicin	18 (14)
	Meropenem	2 (1.5)
	Tazocin	2 (1.5)
Staphylococcus aureus†	Flucloxacillin	2 (4.7)
	Gentamicin	1 (2)
	Tetracycline	4 (10)
	Erythromycin	5 (12)

*$n = 128$; †$n = 41$

concerning prophylaxis (i.e. water exclusion from the ears). Some lacked specificity; for example, the local Hertfordshire guidelines[9] advise consideration of an oral antibiotic if otitis externa is 'severe' but without defining severity. Suspected tympanic membrane perforation was associated with considerable divergence: some guidelines[8] recommend non-ototoxic topical treatment while others[10,11] state any topical antibiotic class can be used for up to seven days.

Discussion

This study is a multi-method review of several facets of the diagnosis and management of otitis externa. It included prospectively assessed data from general practitioners, national level data for both primary and secondary care, and detailed investigations into the microbiology and cost implications of otitis externa.

The 101 general practitioners who responded to the survey reported frequently prescribing oral antibiotics for otitis externa. General practitioner consultations for otitis externa increased 25 per cent over 15 years. General practitioner ototopical preparations cost over £11.3 million in 2016. The 1.25 per cent otitis externa prevalence we estimated in North West England is similar to a prior UK report[1] and higher than the prevalence in the USA.[12] Hospital admissions for necrotising otitis externa increased 700 per cent over 14 years, and otitis externa admissions increased in number and duration.

Our survey of general practitioners and general practitioner trainees highlighted a number of significant issues around implementing otitis externa guidelines, which have also been noted in the USA.[13] Most of our respondent general practitioners report having accessed guidelines, yet 42 per cent of surveyed general practitioner trainees and 51 per cent of general practitioners would prescribe oral antibiotics, which is notably higher than previous surveys[1,14,15] and contrary to most guidance. Not only is oral treatment less effective than topical treatment,[16] it encourages the development of antimicrobial resistance.[17] There was also some variation in terms of prescription of topical agents and the type of agent prescribed. A number of factors could influence the selection of topical agent in primary care, such as being mentioned in

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Table 6. Comparison of 10 commonly used otitis externa UK guidelines

Guideline	First line recommendations	Second line recommendations	Detailed prophylaxis	Data source
NICE CKS[25]	Avoiding aggravation factors. Cleaning ear canal and analgesia. Then antibiotics and steroid drops. Acetic acid stated to be equivalent to topical antibiotics in week 1	Not mentioned	Detailed advice including recommendation of using ear plugs	BMJ; Cochrane American
BMJ best practice[8]	Topical antibiotic solutions, non-ototoxic (quinolones) if TM perforation suspected and based on patient preference	Not mentioned	Prevention of water ingress	Cochrane American and other references
North American[24]	Topical and systemic analgesia, topical non-ototoxic antibiotics and steroids. Systemic antibiotics if infection extends beyond ear canal or if specific host factors exist	Not mentioned	Yes, including cotton wool with Vaseline®	Cochrane and other references
Public Health England[26]	Analgesia for pain relief. Apply localised heat (e.g. a warm flannel). Systemic antibiotics if systemic symptoms or spreading cellulitis	Topical acetic acid or neomycin sulphate with corticosteroid	Nil	American, NICE CKS and Cochrane
North Yorkshire*[11]	Acetic acid 2% spray for 7 days and analgesia. Topical antibiotics could be used in case of TM perforation for less than 10 days if infection is present. Systemic antibiotics if systemic symptoms or spreading cellulitis	Locorten-Vioform®	Nil	NICE CKS
North East London*[27]	Acetic acid 2%	Neomycin sulphate with corticosteroid	Nil	NICE CKS and public health
Hertfordshire[9]	Adequate analgesia. Do not prescribe topical quinolones (unlicensed)	Acetic acid 2% spray. In more severe otitis externa, topical antibiotics with or without steroids. Oral antibiotics for severe cases	Nil	NICE CKS
North Tyneside[28]	Consider 2% acetic acid ear drops if mild symptoms (over the counter). Topical antibiotic and steroid drops	Refer to nurse practitioner ear care clinic	General advice (do not poke or let shampoo or soap into ears)	Nil
Northern Lincolnshire[29]	Acetic acid 2%	Neomycin sulphate with corticosteroid (maximum 2 weeks)	Not mentioned	NICE CKS
North Cumbria referral guidelines[10]	Swab and dry-mop. Topical treatment drops or spray (topical antibiotics could be used in case of TM perforation for less than 10 days if infection is present). If pinna involved, oral antibiotics long-term or as prophylaxis	Not mentioned	Consider underlying skin condition, close diabetic control, water precautions, review shampoo, regular (acetic acid)	Nil

*This is prescription guidance. NICE CKS = National Institute for Health and Care Excellence Clinical Knowledge Scenario; BMJ = British Medical Journal; TM = tympanic membrane

available guidance, cost and availability in local formularies. In total, around a quarter will routinely prescribe EarCalm® spray (acetic acid). It is possible that its cost (£6–8 per bottle) might be a contributing factor as it is relatively expensive in comparison to other topical preparations as shown in Table 3.

- Otitis externa is the commonest cause of ear discharge in adults
- Otitis externa carries a significant financial burden
- Recommended first line treatment for otitis externa is with topical preparations
- Otitis externa incidence and rate of complications are increasing
- Oral antibiotics in primary care are used commonly for treatment
- Available guidance is inconsistent

Hospital Episode Statistics data confirm a marked increase in otitis externa secondary care referrals. Potential factors may include increased antimicrobial resistance including to neomycin (Otomize®),[18] the observed steady increase of earphone or headphone users in the UK from 12 million in 2013 to 16 million in 2016,[19] and the increased popularity of showering which may allow more water ingress into the external auditory canal.

The frequency of resistance to gentamicin (18 per cent of pseudomonas species) is noteworthy as it is one of the more widely prescribed ototopical agents. Resistance to ciprofloxacin (7 per cent in this study) was higher than in a previous report.[20] As otitis externa is so common, guideline adherence is important to achieve good antimicrobial stewardship.[21] The rapidly expanding use of ciprofloxacin drops (National Health Service Digital prescribing data) is concerning. The use of topical fluoroquinolones is being actively promoted by pharmaceutical companies on the basis of a relatively low ototoxicity compared with aminoglycoside preparations[22] and the fact that non-specialists may find it difficult to exclude a tympanic membrane perforation. However, such increased use will increase the risk of evolved resistance to fluoroquinolones. This would deprive clinicians of one of very few oral treatments for necrotising otitis externa,[23] potentially leading in turn to longer in-patient admissions for intravenous therapy.

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We found marked variation in guidelines. NICE has a 'clinical knowledge skills document' rather than formal guidelines. This less structured format leaves more room for interpretation. Neither NICE nor the North American guidelines recommend topical antibiotics as first line treatment, while five of six local and regional guidelines more explicitly recommended acetic acid as a first line treatment. Avoidance of topical antibiotics aligns with the UK Commissioning for Quality and Innovation initiative to tackle antimicrobial resistance.[24] Prophylactic measures against otitis externa are alluded to only in some of the available guidelines.[10,12] Even where the use of earplugs or cotton wool smeared with water repellent materials, such as Vaseline® (petroleum jelly)[8] are referred to, consistency and adequate explanation are lacking.[25]

Limitations

We sampled selected guidelines and were not in a position to explore the reasons behind their variation, although lack of robust evidence is a likely contributor both to their deficiencies and to lack of adherence by community healthcare professionals. A further limitation is the local nature of the microbiological data, which may not be reflected nation-wide, but could form the basis for similar studies at other institutions.

Conclusion

In this study, we highlighted a number of important issues in otitis externa practice, including the increasing disease burden, complications and cost of topical treatment, the overuse of oral antibiotics in primary care and the promotion of broad-spectrum topical quinolone antibiotics in the community. The proportion of otitis externa isolated with an antibiotic resistant pathogen in this study is greater than has been reported in other studies. There is a need for improvement in evidence-based guidelines and their implementation in otitis externa, especially in terms of the avoidance of oral antibiotics.

Further research is needed to explore the perceptions of stakeholders concerning the misuse of systemic and topical antibiotic preparations, and the optimal methods of prevention.

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