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# Management of granular myringitis: A systematic review

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#### **Abstract**

Introduction: Granular myringitis is a chronic disorder characterised by lateral squamous de-epithelialisation and granulation of the tympanic membrane. Untreated, granular myringitis can lead to post-inflammatory medial external auditory canal fibrosis, acquired canal atresia and inflammatory infiltration of the deep canal.

Aim: This study aimed to establish optimal management strategies which could be applied to clinical practice, through systematic review of the current literature.

Methods: Current literature was obtained by searching evidence-based medical databases, the Cochrane database, the Database of Abstracts of Reviews of Effects, the Cochrane controlled trials register, Ovid Medline, the various *British Medical Journal* imprint journals, individual journal websites and citation indexes, and by hand-searching current journals. Detailed inclusion criteria were set. Data were retrieved from the selected studies and checked for accuracy and consistency. The primary outcome measured was the effect of the proposed intervention on recurrence of granular myringitis, compared with empirical antibiotic therapy.

Results: Fifty-eight publications were identified, dating from 1964 to 2005; 46 of these were potentially relevant. After assessment using the preset inclusion criteria, only two studies remained. El-Seifi and Fouad (2000) found that surgical excision of granulation tissue resulted in an 80 per cent reduction in recurrence of granular myringitis when compared with conventional antibiotic therapy. However, Jung *et al.* (2002) demonstrated a 96 per cent reduction in granular myringitis recurrence when managed with dilute vinegar solution.

Conclusions: There was a reduced recurrence of granular myringitis in both studies' intervention groups, although neither study was randomised or blinded, making it difficult to assess the clinical relevance of the results. However, the following conclusions can be inferred. (1) Conventional topical antibiotic and steroid drops appear to be less efficacious and more likely to lead to recurrence of symptoms, compared with other proposed treatment modalities. (2) Treatment with dilute vinegar solution presents a logical, unharmful alternative to conventional antibiotic drops. Further research of high value is needed.

Key words: Myringitis; Otitis; Otitis Externa; Tympanic Membrane; Review

### Introduction

Granular myringitis is a chronic inflammatory disorder characterised by lateral squamous de-epithelialisation and granulation of the tympanic membrane in the absence of middle-ear disease. Studies estimate the prevalence to be around 1.2–1.8 per cent amongst adult otology out-patients. 1,4

The aetiology is unclear. A loss of squamous epithelium on the lateral surface of the tympanic membrane is accepted as one of the preliminary stages of granulation development. Gram-negative organisms are a common finding in affected ears, in particular, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Proteus mirabilis*. 6,7

Clinically, patients present with a combination of malodorous otorrhoea, intra-meatal itch and a feeling of aural fullness. <sup>1,5</sup> Granular myringitis does not classically produce a hearing deficit, but can lead to complications such as post-inflammatory medial canal fibrosis, canal atresia or stenosis, and inflammatory infiltration of the deep canal. <sup>2,8,9</sup> On otoscopic examination, focal, segmental, diffuse or polypoid, red granulation tissue on a thickened tympanic membrane may be visible. External auditory canal wall involvement and mucopurulent discharge may also be present. <sup>1,4,10</sup>

Three main treatment modalities are mentioned in the literature: topical antibiotic with steroid drops;

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cauterisation of granulations; and debridement of granulomatous tissue. However, there is no universal treatment which has proven effective in every case. to

Although granular myringitis appears to respond initially to topical antibiotic therapy, this does not prevent the condition from recurring. The condition typically has a relapsing and remitting course. Ineffective treatment prolongs the patient's misery and may lead to the aforementioned complications – hence the need for identification of successful, evidence-based treatment guidelines.

By conducting a systematic review of the current literature, this review aimed to determine a management plan to treat and prevent recurrence of granular myringitis, which could then be integrated into clinical practice. Our report will also highlight topics lacking research of high quantitative and qualitative value, indicating areas requiring further study.

### Methods

### Literature search

Current literature on granular myringitis was obtained by thorough searching of evidence-based medical databases, the Cochrane database of systematic reviews, the Database of Abstracts and Reviews of Effects, the Cochrane controlled trials register, Ovid Medline, the various British Medical Journal imprint journals, individual journal websites and citation indexes, as well as hand-searching of current journals to include new publications. Unpublished literature searches were performed using 'grey area' search engines, and generalised internet search engines were also used to increase search sensitivity. The search terms included 'granular myringitis' and synonyms, 'myringitis' and 'granular ear disease'. Reference lists of articles and relevant textbooks were consulted to optimise search sensitivity. The search was tested for reproducibility and updated throughout the duration of the study. The range of studies collected covered the years 1964 to 2005.

# Inclusion criteria protocol

Type of study. Randomised controlled trials, controlled case studies and observational reports were included in the initial screening process. The minimal acceptable number of patients per trial was 20.

Type of patient. The review included adults with a clinical diagnosis of granular myringitis of at least three weeks' duration, based on clinical history and examination. Inclusion required reported otoscopic findings of focal, diffuse or segmental granulation of the lateral tympanic surface. A diagnosis based on clinical history alone was deemed inappropriate and unreliable, due to the possibility of misdiagnosis with cholesteatoma or chronic suppurative ear disease. Patients suffering from co-morbid middle-ear disease were excluded.

*Types of intervention.* Any proposed management of granular myringitis was accepted, including medical topical or oral therapy and surgical management.

Types of outcome. The primary outcome assessed was recurrence of granular myringitis. Publications were screened for potential relevance and then further assessed by the preset inclusion criteria.

The studies which remained were critically appraised to expose any methodological flaws or biases. All studies were assessed with regards to randomisation, double-blinding and loss to follow up, and evaluated using the Oxford Centre for Evidence Based Medicine grading system.<sup>13</sup>

Data were retrieved from the selected studies and checked for accuracy and consistency throughout the paper. Any apparent losses to follow up were investigated and checked. The primary outcome sought was whether the proposed intervention reduced the risk of recurrence of granular myringitis.

#### Results

Fifty-eight publications were identified by the initial search, 46 of which were screened as being potentially relevant. However, after assessing each publication using the preset inclusion criteria, only two studies satisfying these criteria were found. A summary of the results at each stage of the search is shown in Figure 1.

The properties of the 44 studies which did not meet the inclusion criteria are given in Table I.

The properties of the two studies which met the inclusion criteria are tabulated in Table II.

### Quality assessment

The evidential value of each study was assessed according to the Oxford Centre for Evidence Based Medicine guidelines.<sup>13</sup> The study by Jung *et al.*<sup>6</sup> was considered to contain grade IIb evidence and the study by El-Seifi and Fouad<sup>4</sup> to contain grade IIc evidence.

These two studies were then appraised according to their methodological quality, taking into account: randomisation of subjects, accounting for all subjects, blinding of patients, blinding of treating physicians and additional sources of bias. These aspects are discussed for each study, below.

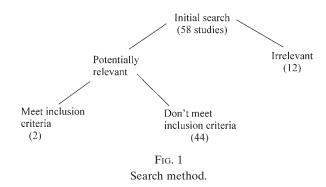


TABLE I
CHARACTERISTICS OF EXCLUDED STUDIES

Study	Design	Subjects	Interventions	Outcomes	Reason for exclusion
Hwang et al. <sup>14</sup>	Prospective observational	221 (118 male, 103 female)	Nil	Organisms isolated	Not relevant
Hwang et al. <sup>7</sup>	Prospective bacteriological	161 out-patients with otorrhoea	Nil	Organisms isolated	Not relevant
Fechner et al. <sup>15</sup>	Retrospective case series	13 children (6–14 yrs)	CO <sub>2</sub> laser	Resolution of GM	No control cases Previous middle-ear disease
Hannley et al. <sup>16</sup> Khalil & Windle-Taylor <sup>17</sup>	Consensus panel report Retrospective case note review	Nil formal 101	Nil formal CWD mastoidectomy	Nil formal Frequency of OPD visits Clinical problems % Discharged	Not relevant Not relevant
Slattery & Saadat <sup>8</sup>	Retrospective chart review	24 with post-inflammatory medial canal stenosis	Surgery vs medical	Hearing threshold Recurrence	Not relevant
Lavy & Fagan <sup>9</sup>	Review of chronic stenosing external otitis	Nil formal	Nil	Nil formal	Not relevant
Lundy & Graham <sup>18</sup>	Survey of otolaryngologists	Otolaryngologists	Nil	Treatments used	Not relevant
Albers <sup>19</sup> Jang & Park <sup>20</sup> MacFadyen <i>et al.</i> <sup>21</sup>	Retrospective follow up Retrospective review RCT	23, complications of OM 88, otorrhoea, CSOM 427 Kenyan school- children	Diagnostic/therapeutic Nil Ciprofloxacin vs boric acid	Morbidity/mortality Causal organisms Resolution of discharge	Not relevant Not relevant Not relevant
Wai & Tong <sup>22</sup>	Review	Nil formal	Nil	Nil	Not relevant
Indorewala <sup>23</sup>	Retrospective review	210	Tympanoplasty: fascia lata vs temporal	Residual or recurrent disease	Not relevant
Dohar <sup>24</sup> Roland <sup>25</sup>	Historical review RCT	Nil 90 children	Nil Quinolone vs quinolone + steroid	Nil Resolution of granulation tissue	Not relevant Not specific to granular myringitis/TM
Aminifarshidmehr <sup>26</sup>	Prospective observational study	96, CSOM	Acetic acid solution	Resolution Recurrence	Middle-ear disease GM not investigated
Schapowal <sup>27</sup>	Clinical overview	Nil	Nil	Nil	Not relevant
Tos <sup>28</sup>	Prospective bacteriological	19 (3 male, 16 female)	All had post- inflammatory atresia	Recurrence Side effects	Not relevant
Ong & Chee <sup>29</sup> Coates <i>et al.</i> <sup>30</sup>	Review	Nil	Nil	Nil	Not relevant
	Case discussions	Sample from clinical experience	Nil	Personal experience	Not relevant Not valid
Zapalac et al. <sup>31</sup>	Retrospective review	90 children	Nil	Suppurative complications of AOM	Not relevant
Hoshino et al. <sup>32</sup>	Case report	5	Cautery of granulation	Time to healing Recurrence	Acute not chronic GM Large bias
Giridharan <i>et al.</i> <sup>33</sup> Morais <i>et al.</i> <sup>34</sup>	Case report	1 female	Nil	Investigations, recovery	Not relevant
Morais et al. <sup>34</sup>	Case report	2	_	Resolution	Not relevant Inadequate size Inadequate information
Kashiwamura et al. <sup>35</sup>	Prospective clinical	48	Burow's solution	Resolution	No controls Inadequate information

TABLE I Continued

Study	Design	Subjects	Interventions	Outcomes	Reason for exclusion
Roland et al. <sup>11</sup>	RCT	90	Ciprofloxacin/ dexamethasone <i>vs</i> ofloxacin	Granulation tissue compared with baseline	Not specific to GM Patients had middle-ear disease
Makino et al.36	Retrospective review	40 cases of GM	Nil	Clinical features	Not relevant
Wolf et al. <sup>37</sup>	Prospective study	9 children (5 boys,	Topical	Clinical features	Not relevant
	1	4 girls)	1	Recurrence	No controls
20					Wrong population
Jang et al. <sup>38</sup>	Retrospective review	21 (7 men,	Endoscopy-aided laser	Response to	No control group
		14 women)	therapy	treatment	Variables mentioned but not accounted for
Puls <sup>39</sup>	Retrospective	74 myringoplasties	Xenograft vs temporalis	Results	Not relevant
2	case review		fascia	Perforation	
Kunachak <sup>3</sup>	Review	Nil	Nil	Nil	Not relevant
Stoney et al. 40	Review	Nil	Nil	Nil	Not relevant
Yinglin <sup>41</sup>	Case report	3	Formalin	Resolution	Large bias Small population No control
<i>-</i>					Not relevant
Basterra & Schneider <sup>5</sup>	Retrospective study	1	Nil	Morphology	Not relevant Insignificant
Zhu et al. <sup>42</sup>	Retrospective	52	Tympanoplasty vs	Hearing	Not specific to GM
	•		tympanoplasty with mastoidectomy	improvement	Cholesteatoma & middle-ear disease present
Schroeder & Darrow <sup>43</sup>	Review	Nil	Nil	Nil	Not relevant
Jung et al. 44	Case-control	_	_	_	Repeated study within review
Eliashar <i>et al.</i> <sup>45</sup>	Retrospective case review	13	Investigative	Audiometric results	Acute myringitis not chronic GM Irrelevant
Terayama et al.46	Retrospective	21, 25 ears	Burow's solution	Cure, time to cure	Only 2 patients with GM
					Inadequate description No randomisation No control
Sade <sup>47</sup>	Case reports	_	_	_	Not relevant to GM Inadequate information
Ramsev <sup>48</sup>	Review	Nil	Nil	Nil	Not relevant
Ramsey <sup>48</sup> Boedts <sup>49</sup>	Review	_	_	_	Not relevant
Fitzgerald <sup>50</sup>	Comment	Nil	Nil	Nil	Not formal study
Lien & Chang <sup>51</sup>	Retrospective	14 (6 male, 8 female)	TM graft	Recurrence	Does not assess treatment modality
Lien & Chang <sup>52</sup>	Retrospective	23 adults	Otozambon + steroid	'Cure'	No controls, no objective measure

Yrs = years; GM = granular myringitis; CWD = canal wall down; OPD = out-patients department; OM = otitis media; CSOM = chronic suppurative otitis media; RCT = randomised, controlled trial; TM = tympanic membrane; AOM = acute otitis media

TABLE II
CHARACTERISTICS OF INCLUDED STUDIES

Study	Disease of	Sample	Меап	M·F	Setting	Decian	Rlinded?	Follow up	I oee to	Intervention	Control aroun Quitcome	Outcome
, and	Execuse of sample present interest size $(n)$ age $(y_1)$	size $(n)$	age (yr)	1.1.1	grimg	Caign		(Range, (mean)) follow up group	dn wolloj	group	droig como	
Jung et al. <sup>6</sup> GM	GM	30	38.4	7:23	7:23 2° care	Case-control No	No	Min 6 mth, max Nil not given	Nil	2-3/day vinegar	2-3/day vinegar Topical ofloxacin* Time to healing Recurrence	Time to healing Recurrence
El-Seifi & Fouad <sup>4</sup>	GM	74	29	49:45	49:45 3° referral centre & private otology	& Case series	No	6 mth-12 yr (6.25 yr)	ij	Surgical excision of granular	Acetic acid + antibiotic steroid drops*	
					Fraccion							

Standard therapy. Yr = years; M:F = male/female ratio; GM = granular myringitis; 2° = secondary; min = minimum; mth = months; max = maximum; 3° = tertiary

# Description of studies

Jung et al.<sup>6</sup> This study selected 30 patients with diagnosed granular myringitis (23 women, 7 men), over a seven-year period, for non-blinded assignment into two groups of 15. The control group received conventional treatment with ofloxacin ear drops two to four times daily. The intervention group received aural toilet with vinegar solution once or twice daily. All patients were treated until otoscopy showed a dry tympanic membrane with no granulations. Patients were followed up for six months, and the outcomes measured included recurrence rate, recovery time, therapeutic efficiency and tolerance of therapy.

El-Seifi and Fouad.<sup>4</sup> This study retrospectively reviewed 94 patients (49 men, 45 women) presenting with granular myringitis over a period of 28 years. All 94 patients were assessed with regards to possible aetiology and symptoms, but only 74 were included in the treatment case series due to inclusion criteria conditions. Twenty-six patients were treated conservatively, with the centre's protocol of thrice daily irrigation with 1.5 per cent acetic acid, followed by drying of the ear and application of either gentamicin or neomycin with dexamethasone steroid drops. Patients were seen every few days to clean the discharge and debris and to apply a steroid anti-fungal cream. If granular myringitis persisted, the granulations were cauterised with 50 per cent trichloracetic acid and an oral quinolone given. Surgical management entailed excision of all granular material from the tympanic membrane and the meatal wall. The area was grafted using underlay cartilage from the tragus. Routine follow up comprised monthly review for six months and then annual review as required. The follow-up time ranged from six months to 12 years, depending on recurrence. The primary outcome measured was the recurrence rate.

# Methodological quality

Jung et al.<sup>6</sup> Although this study was a case-controlled trial, there was no mention of randomisation of patients. It was therefore considered to be nonrandomised, introducing a possible source of bias. It was also a relatively small study, with only 30 subjects overall.

The diagnostic inclusion criteria were very precise, thus ensuring the correct diagnosis in all subjects. All subjects had malodorous otorrhoea, granulation tissue on the tympanic membrane under microscopic examination and a type A tympanogram. To ensure correct diagnosis, patients with chronic otitis media, tympanic membrane perforations, type B or C tympanograms, or the presence of middle-ear disease on imaging were excluded.

All subjects who started the trial were accounted for in the results section and were followed up for six months; however, there was no blinding of patients or physicians.

Another potential source of bias arose from the drainage and drying of the external ear canal with a hairdryer for one minute after instillation of the 8 L J NEILSON, S S M HUSSAIN

treatment in the intervention group, whereas this treatment was not mentioned in the control group. This therefore added another variable which could have introduced bias to the results.

The researchers in this study had actively attempted to exclude bias with regards to the concentration of vinegar solution used: 10 ml of initial solution of pH  $2.25 \pm 0.02$  was added to 30 ml of water, with a resultant solution pH of  $2.43 \pm 0.02$ .

El-Seifi and Fouad.<sup>4</sup> This non-randomised, retrospective study reported follow up for all patients, but was obviously not blinded due to its retrospective nature. The control group of 26 subjects was also outweighed by the intervention group of 48 subjects; however, the same outcome – recurrence rate – was measured for all subjects.

This study also used strict diagnostic inclusion criteria. Patients were assessed according to clinical history and examination, otoscopic examination, tympanic membrane microscopy and pure tone audiometry, in order to eliminate concomitant middle-ear disease (including cholesteatoma and chronic suppurative otitis media).

### Analysis of study results

After collection and analysis of results, it was considered inappropriate to conduct a formal meta-analysis due to the heterogeneity seen across both studies and the risk of producing a spurious result. However, the results of both studies were tabulated and analysed in order to determine absolute indicators of optimal treatment.

Jung et al.<sup>6</sup> The primary outcome of this study is shown in Table III. As these results show no recurrence in the intervention group, it is not possible to calculate an odds ratio or risk ratio. In this case, the results have been analysed to produce a risk difference and number needed to treat, to prevent introduction of more bias. According to this study, there was an 80 per cent increased chance of recovery without recurrence of granular myringitis following treatment with dilute topical vinegar solution, compared with ofloxacin ear drops. The number of patients requiring treatment in order for one patient to benefit was calculated as 1.25.

Regarding secondary outcomes, Jung *et al.* also published the time to resolution of symptoms and of granulation tissue. These results are shown graphically in Figure 2. The instillation of dilute vinegar solution into the external auditory meatus appeared to reduce the time to resolution of symptoms, compared with conventional antibiotic treatment. By the end of

TABLE III
RESULTS: JUNG ET AL. 6

	No recurrence	Recurrence	Total
Intervention group	15	0	15
Control group	13	2	15

TABLE IV
RESULTS: EL-SEIFI & FOUAD<sup>4</sup>

	No recurrence	Recurrence	Total
Intervention group	46	2	48
Control group	0	26	26

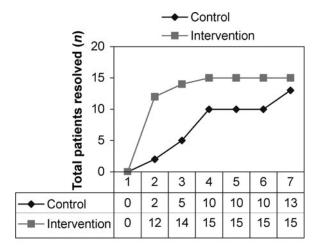
week one in the intervention group, 12 patients (80 per cent) had achieved resolution of symptoms, compared with two patients (13 per cent) in the control group. Another important secondary outcome explored by this study was the experience of side effects in the intervention group. Two patients experienced mild ear discomfort and one patient had an episode of mild dizziness. No information is given on the side effects of treatment with ofloxacin and, although these have been described elsewhere, 53 other studies do not give a comparative result in this population with granular myringitis.

El-Seifi and Fouad.<sup>4</sup> Table IV shows the primary outcomes of this study. As these results contained a zero, they were analysed as risk difference and number needed to treat. Patients in this study had a 96 per cent increased chance of recovery from granular myringitis without recurrence after surgical excision of all granular tissue, compared with conservative topical antibiotic and steroid drop therapy. The number of patients requiring treatment in order for one patient to benefit was calculated as 1.04.

### Discussion

Jung *et al.* demonstrated a 96 per cent absolute reduction in recurrence of granular myringitis following treatment with a dilute vinegar solution, compared with ofloxacin ear drops.

Several studies have acknowledged high pH in the external auditory meatus as a possible aetiological factor in the precipitation and maintenance of granular myringitis. This supports Jung and colleagues'



Weeks (n)

 $${\rm Fig.}~2$$  Time to resolution of granular myringitis, Jung  $\it et~al.^6$ 

study of vinegar treatment. The use of daily irrigation of the external auditory canal with vinegar and water has been suggested by Lee. 12 There are no published case reports which confirm the results of this study. However, a retrospective report describing the positive effect of the acidic Burow's solution (aluminium acetate) in two patients with granular myringitis gives a little support to the theory of low pH as an aid in preventing recurrence.<sup>46</sup>

El-Seifi and Fouad demonstrated that surgical excision of granulation tissue reduced recurrence of granular myringitis by 80 per cent, compared with conventional antibiotic therapy. A retrospective, non-controlled case study published in the latter stages of the present review supports the hypothesis posed by El-Seifi and Fouad, i.e. that complete excision of all granulation tissue may have a place in the long term management of granular myringitis. This study investigated endoscopy-aided laser ablation of granulations, which led to resolution in 18 of 21 cases after a single treatment.<sup>38</sup> However, treatment of the control group with acetic acid may explain why the majority of subjects did not respond, as acetic acid is a known irritant of inflammatory tissue and may itself cause aural discomfort.

The evidential and methodological value of each study must be taken into consideration when interpreting the results. Although both studies showed a greater than 80 per cent reduced risk of recurrence in the intervention group, it must be noted that neither study was randomised or blinded, making it difficult to assess the clinical relevance of the results. Both studies were also of modest evidential

With regards to ethical considerations and clinical decision-making, the surgical technique described by El-Seifi and Fouad<sup>4</sup> may reduce granular myringitis recurrence, but the general risks associated with surgery and anaesthesia must be taken into consideration before applying the results in practice. The use of endoscopy-aided laser therapy to debride granulations may be a useful development in the future; this technique ablates granulations without the need for anaesthesia, and case reports have shown it to be effective in a number of patients. 15,38

Although granular myringitis is a troublesome condition, the complications of surgery may be far worse than the symptoms of the disease. Therefore, surgical debridement would be of optimal use in intractable, symptomatic patients.

Both studies<sup>4,6</sup> showed that their respective techniques were superior to topical antibiotic therapy in treating and preventing recurrence of granular myringitis. Therefore, the main clinical implication of this review is that alternative therapies should be considered when granular myringitis is encountered.

On another topic, other studies have made clear that inadequate clinical assessment often leads to a misdiagnosis of granular myringitis as chronic suppurative otitis media. <sup>10</sup> The present review, and the studies it included, each used strict inclusion criteria for the identification of patients with granular myringitis; these criteria represent potentially useful diagnostic tools in clinical practice.

### **Conclusions**

From this limited review, we draw the following conclusions.

Firstly, in the management of granular myringitis, conventional topical antibiotic and steroid drops appear to be less efficacious and more likely to lead to recurrence of symptoms, compared with other proposed treatment modalities.

Secondly, there is at present insufficient high quality evidence to support any particular management plan or treatment protocol for patients suffering from granular myringitis. However, treatment with dilute vinegar solution presents a logical, unharmful alternative to conventional antibiotic drops.

Thirdly, further research of high value (i.e. randomised controlled trials) is needed to further assess and identify management strategies which both resolve granular myringitis and prevent its recurrence (e.g. surgical debridement, endoscopyaided laser therapy, cautery and topical application of low pH solutions).

Fourthly, a standard protocol for diagnosis of granular myringitis is required in order to avoid misdiagnosis and to prevent inappropriate management.

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