

# The effectiveness of topical preparations for the treatment of earwax: a systematic review

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## SUMMARY

**Background:** Earwax is a common problem in both primary and secondary care. There is uncertainty as to the most effective topical treatment.

**Aim:** To assess the evidence concerning the efficacy of topical preparations used for treating earwax.

**Design of study:** Systematic review and meta-analysis.

**Method:** Searching for randomised controlled trials (RCTs) of relevant studies. Classification of preparations into three groups, enabling pooling of data and meta-analysis.

**Results:** Of the 18 RCTs included in the review, four were judged to be of high quality. Fifteen preparations including saline and plain water were studied. Oil-based and water-based preparations were equally effective at clearing earwax without syringing (odds ratio [OR] = 0.9, 95% confidence interval [CI] = 0.4 to 2.3) and facilitating successful syringing (OR = 1.0, 95% CI = 0.6 to 1.6). A non-water-, non-oil-based preparation appeared more effective than an oil-based preparation at both clearing earwax without syringing, and facilitating successful syringing. Immediate syringing after application of a preparation may be as effective as using eardrops for several days and delaying syringing.

**Conclusions:** On current evidence, there is little to choose between water-based and oil-based preparations; non-water-, non-oil-based preparations appear promising at both clearing earwax and facilitating successful syringing, but further large trials are needed. Although immediate ear syringing is effective and convenient for patients, it may be less cost-effective than using eardrops and perhaps avoiding syringing. Most of the evidence regarding such a common and time-consuming problem is not of high quality.

**Keywords:** ear wax; meta-analysis; topical administration; systematic review.

## Introduction

EARWAX is a common problem that can cause deafness, irritation, pain, tinnitus, dizziness, and vertigo.<sup>1-3</sup> In most instances earwax causes no symptoms at all, but it can prevent adequate examination of the tympanic membranes, and this can be a problem especially when examining ill children.

Preparations for clearing earwax have been used for centuries, and procedures for removing earwax go back to ancient Egyptian times.<sup>4</sup> Manual syringing has been historically the most common method of clearing earwax, but can lead to perforation of the eardrum and other complications, such as bleeding and otitis externa.<sup>5</sup> In the United Kingdom (UK), electric irrigators are recommended to avoid these problems.<sup>6</sup> Ear syringing is one of the most frequently performed procedures in primary care, and is usually delegated to nurses;<sup>7</sup> it is effective in improving hearing and the symptoms associated with earwax.<sup>8</sup>

Although there are many different preparations available for treating earwax, there is no agreement on which agent to use, or the optimal duration of treatment.<sup>9</sup> The *British National Formulary (BNF)* recommends sodium bicarbonate, olive oil, or almond oil.<sup>10</sup> The aim of this systematic review is to assess the evidence provided by randomised controlled trials (RCTs) on the effectiveness of topical earwax preparations in clearing earwax without syringing, and facilitating successful syringing.

## Method

We examined Medline, CINAHL, and the Cochrane Controlled Trials Register (last accessed January 2004) using the search terms 'ear and wax', 'earwax', 'cerumen', and 'trial'.<sup>11</sup> We also searched the National Research Register (June 2003) for ongoing studies and accessed Clinical Evidence (June 2003) for the most recent advice and references.<sup>9</sup> We scrutinised the references of the identified articles and also those of many review articles on the management of earwax and ear care. We contacted experts in the field, people currently doing research on earwax, some of the authors of the identified trials, the pharmaceutical companies manufacturing the preparations used in the UK, and two companies in the United States (US).

The authors included all randomised trials that evaluated drops used for treating earwax with no restriction on either date or language. Each trial was read independently to assess its eligibility and quality. We excluded non-randomised studies and assessed the quality of the RCTs using the following criteria:

- reported generation of allocation sequence,
- allocation concealment,
- inclusion of all randomised patients, and
- blinding of outcome assessors.<sup>12</sup>

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## HOW THIS FITS IN

### What do we know?

There are many different preparations available for treating earwax. There is no good evidence about which agent to use or the optimal duration of treatment.

### What does this paper add?

If syringing is performed for uncomplicated earwax, there is little to choose between water-based and oil-based preparations, and plain water may suffice. Applying a water-based or oil-based preparation 15–30 minutes prior to syringing is probably as effective as applying it for several days. Non-water-, non-oil-based preparations appear promising for clearing earwax, but several days' treatment is required. Further well-designed randomised studies comparing the three types of agents are needed to fill the current gaps in the evidence.



We used a three-point scale for each criterion (Supplementary Table 1) and defined a high-quality trial as having the maximum score on each of the four criteria. The very few differences in opinion were settled by negotiation.

We classified eardrops into three groups: water-based, oil-based, and non-water-, non-oil-based (Table 1). The classification is based on the physical and chemical properties of the preparations, as the mechanisms of action are probably different (M Whitefield, personal communication, 2002). The underlying assumption of the classification is that preparations with similar properties have similar mechanisms of action. There is evidence for this from *in vitro*

studies: water-based preparations have a cerumenolytic activity, whereas oil-based preparations have only a softening effect.<sup>13–21</sup> There have been no published *in vitro* studies using non-water-, non-oil-based preparations (SSL International PLC, personal communication, 2002).

When urea-hydrogen peroxide (carbamide peroxide, Exterol® [Dermal oratories Ltd], Otex® [DDD Ltd]) comes into contact with water, hydrogen peroxide is one of the main products. This has been shown to have powerful cerumenolytic activity *in vitro*. In the 1940s, both hydrogen peroxide (which breaks down into water) and water were shown to have cerumenolytic activity.<sup>15</sup> Cerumenolytics work by hydrating the desquamated sheets of corneocytes, which are the major constituent of cerumen plugs, and subsequently inducing keratolysis with disintegration of the wax.<sup>22</sup>

The main outcomes assessed were clearing earwax without syringing and successful syringing. Successful syringing was variably defined in studies, but included ease of syringing, clearance of wax, and the ability to see the tympanic membrane afterwards. Using a random effects model, we pooled the results of studies that compared water-based, oil-based, and non-water-, non-oil-based preparations where we could identify suitably similar outcomes, and when we were satisfied that the randomisation procedures were acceptable.<sup>23</sup>

## Results

The searches identified 39 possibly relevant papers. The reviewers identified 19 trials and found another five among referenced papers. Six were excluded as they were not RCTs,<sup>24–29</sup> including two trials that used quasi-random rather than random allocation.<sup>24,29</sup> This left 18 trials to

Table 1. Preparations used in trials.

Preparation	Constituents
<b>Water-based</b>	
Acetic acid	2.5% aqueous acetic acid
Cerumenex® (Purdue Frederick) (no longer marketed in UK)	10% triethanolamine polypeptide oleate-condensate
Colace® (Purdue Frederick) liquid (marketed as a laxative)	docusate sodium 10mg/ml, citric acid, D&C Red No.33, methylparaben, poloxamer, polyethylene glycol, propylene glycol, propylparaben, sodium citrate, vanillin, purified water
Hydrogen peroxide	3% solution
Molcer® (Wallace Manufacturing Chemists Ltd)	docusate sodium 5%
Sodium bicarbonate	sodium bicarbonate, glycerin 30 ml, purified water to 100 ml
Waxsol® (Norgine Ltd)	docusate sodium 0.5%, water-miscible base, mixed parabens in 2-phenoxyethanol 0.6%
Xerumenex® (formerly HR Napp Ltd) (no longer marketed in UK)	10% triethanolamine polypeptide oleate-condensate, propylene glycol, 0.5% chlorbutol, water
<b>Oil-based</b>	
Almond oil	
Cerumol® (LAB)	arachis oil 57.3%, chlorbutol 5%, para-dichlorobenzene 2%, oil of turpentine 10%, 3-methoxybutyl acetate (butoxyl) 10%, ortho-dichlorobenzene 14.5%, (benzocaine until 1971)
Diocetyl-medo® (Schwarz Pharma Ltd) (marketed as a laxative)	5% diocetyl sodium sulphosuccinate, maize (corn) oil
Earex® (SSL International plc) (same as Otocerol®)	arachis oil, almond oil, rectified camphor oil
Olive oil	
<b>Non-water-, non-oil based</b>	
Audax® (SSL International plc) (same as Earex Plus® [SSL International plc])	50% choline salicylate, glycerol (glycerin), ethyleneoxide-polyoxypropylene glycol, propylene glycol, 0.5% chlorbutol, water
Exterol® (Dermal Laboratories Ltd) (same as Otex® [DDD Ltd])	5% urea-hydrogen peroxide (carbamide peroxide), anhydrous glycerol, water-miscible base

examine (Supplementary Table 1).<sup>13,14,30-45</sup> The methods and results are summarised in Supplementary Tables 2 and 3. Four trials were classified as high quality.<sup>41,43-45</sup> but one of these trials used outcome measures that made comparisons with other studies impossible.<sup>43</sup> The remaining trials scored mostly 'A' or 'B' on the four quality measures. One of these trials contained insufficient information to make useful comparisons with other studies.<sup>40</sup>

### Clearing earwax without syringing

**Water-based compared with oil-based preparations and no treatment.** Keane *et al* compared sodium bicarbonate (water-based), Cerumol® (LAB) (oil-based), sterile water, and no treatment in older patients in hospital.<sup>39</sup> Complete clearance of wax occurred spontaneously in 5% of ears, with water and sodium bicarbonate in 21% of ears, and with Cerumol® in 23%. There was weak evidence that both water-based and oil-based preparations were more effective at completely clearing wax than no treatment (water-based odds ratio [OR] = 4.7, 95% confidence interval [CI] = 1.0 to 21.7; oil-based OR = 5.2, 95% CI = 1.0 to 26.0). There was no significant difference between them (OR = 0.9, 95% CI = 0.4 to 2.3).

**Non-water-, non-oil-based compared with oil-based preparations.** Lyndon *et al* compared a non-water-, non-oil-based preparation (Audax® [SSL International plc]) to an oil-based preparation (Earex® [SSL International plc]) for its ability to clear earwax and avoid syringing in general practice.<sup>37</sup> The non-water-, non-oil-based preparation was clinically more effective (39%) than the oil-based preparation (23%) in clearing earwax (OR = 2.1, 95% CI = 0.7 to 7.4), although this evidence is weak.

Dummer *et al* compared Audax® to another oil-based preparation (Cerumol®), but the outcomes they used did not include avoidance of syringing.<sup>38</sup> Both preparations reduced the amount of wax in more than 50% of ears (OR = 1.1, 95% CI = 0.5 to 2.4). There was weak evidence that Audax® was more effective in improving objective hearing (OR = 3.4, 95% CI = 0.6 to 35.1).

**Non-water-,non-oil-based compared with water-based preparations.** There were no trials comparing non-water-, non-oil-based preparations with water-based preparations.

**Water-based preparations compared.** Two trials compared different water-based preparations in both adults and children. Singer *et al* compared docusate sodium and triethanolamine polypeptide in an emergency department.<sup>41</sup> Syringing was avoided in 19% of ears with docusate sodium (Colace® [Purdue Frederick]) and 9% with triethanolamine polypeptide (Cerumenex® [Purdue Frederick]). The evidence that docusate sodium is more effective than triethanolamine polypeptide is weak (OR = 2.4, 95% CI = 0.3 to 27.2) as demonstrated by the wide confidence interval, which includes the figure one. Carr and Smith compared 10% aqueous sodium bicarbonate and 2.5% acetic acid in people attending a community family practice clinic.<sup>43</sup> No difference was found between the preparations in reducing the amount of cerumen, but they were more effective in children than in adults (average

change on an arbitrary scale 0.96 and 0.45, respectively,  $P = 0.001$ ).

Two trials compared water-based preparations with normal saline in children attending paediatric emergency departments.<sup>44,45</sup> Meehan *et al*<sup>44</sup> avoided syringing in 13% of children with both docusate sodium (Colace®) and normal saline, and 41% of children with triethanolamine polypeptide (Cerumenex®), but the differences were not statistically significant ( $\chi^2 = 5.0$ , degrees of freedom [df] = 2,  $P = 0.08$ ). Whatley *et al*,<sup>45</sup> using the same preparations, avoided syringing in 12% of children with docusate sodium, 13% with triethanolamine polypeptide, and 4% with normal saline. These differences were also not significant ( $\chi^2 = 1.8$ , df = 2,  $P = 0.4$ ).

Pooling the data of the three studies that compared docusate sodium with triethanolamine polypeptide,<sup>41,44,45</sup> docusate sodium was equally effective at clearing earwax (14%) as triethanolamine polypeptide (19%) (OR = 0.8, 95% CI = 0.2 to 2.8; Table 2). Pooling the data of the two studies that compared the preparations with normal saline,<sup>44,45</sup> triethanolamine polypeptide was more effective than normal saline (OR = 4.6, 95% CI = 1.1 to 18.5), whereas the evidence in favour of docusate sodium was weaker (OR = 1.9, 95% CI = 0.4 to 8.8). There was no strong evidence of statistical heterogeneity in these meta-analyses.

**Oil-based preparations compared.** One trial compared two similar oil-based preparations (Otocerol® and Cerumol®).<sup>36</sup> Syringing was avoided in 26% of people using Otocerol® and

Table 2. Effectiveness of preparations in clearing earwax.

Study	Docusate (water-based)	TEP (water-based)	Odds ratio (95% CI)
Singer <i>et al</i> <sup>41</sup>	5/27	2/23	2.4 (0.3 to 27.2)
Meehan <i>et al</i> <sup>44</sup>	2/15	7/17	0.2 (0.02 to 1.6)
Whatley <i>et al</i> <sup>45</sup>	4/34	4/30	0.9 (0.1 to 5.2)
Total	11/76	13/70	0.8 (0.2 to 2.8)
Heterogeneity	Woolf Q = 3.6, df = 2, $P = 0.2$		
Overall effect	$\chi^2 = 0.1$ , df = 1, $P = 0.7$		
	Docusate (water-based)	Saline (water-based)	
Meehan <i>et al</i> <sup>44</sup>	2/15	2/16	1.1 (0.07 to 16.9)
Whatley <i>et al</i> <sup>45</sup>	4/34	1/28	3.6 (0.3 to 183.7)
Total	6/49	3/44	1.9 (0.4 to 8.8)
Heterogeneity	Woolf Q = 0.6, df = 1, $P = 0.4$		
Overall effect	$\chi^2 = 0.7$ , df = 1, $P = 0.4$		
	TEP (water-based)	Saline (water-based)	
Meehan <i>et al</i> <sup>44</sup>	7/17	2/16	4.9 (0.7 to 55.4)
Whatley <i>et al</i> <sup>45</sup>	4/30	1/28	4.2 (0.4 to 212.0)
Total	11/47	3/44	4.6 (1.1 to 18.5)
Heterogeneity	Woolf Q = 0.01, df = 1, $P = 0.9$		
Overall effect	$\chi^2 = 4.6$ , df = 1, $P = 0.03$		

TEP = triethanolamine polypeptide. df = degrees of freedom. An extended version of this table can be found online (Supplementary Table 4).

11% using Cerumol<sup>®</sup> but the evidence that Otocerol is more effective is weak (OR = 2.8, 95% CI = 1.0 to 8.0).

Comparing all the studies that examined the clearance of earwax, there was a significant linear association ( $\chi^2$  for linear trend = 25.6, df = 1,  $P < 0.0001$ ) between the number of days' treatment and earwax clearance.<sup>36-39,41,43-45</sup> Four days' treatment was more effective (35%) than 1 day (14%), or 3 days' treatment (19%).

### Successful syringing

**Water-based compared with oil-based preparations.** Five trials compared water-based preparations (including plain water) with oil-based preparations.<sup>14,30,33,34,42</sup> Pooling the data of these trials, the success of syringing was virtually identical with either water-based (78%) or oil-based (79%) preparations (OR = 1.0, 95% CI = 0.6 to 1.6; Table 3). There was no evidence of statistical heterogeneity. If the three lower quality trials<sup>14,30,42</sup> are taken out of the analysis, the result is almost identical (OR = 1.0, 95% CI = 0.5 to 2.1), which supports the decision to pool the data from all the trials.

**Water-based preparations compared.** Four trials compared docusate sodium with triethanolamine polypeptide.<sup>14,41,44,45</sup> Pooling these data, there is weak evidence that docusate sodium (64%) is more effective than triethanolamine polypeptide (50%) (OR = 1.9, 95% CI = 0.7 to 5.0; Table 3) but there is evidence of statistical heterogeneity. If Fraser's lower quality trial is removed from the analysis, the result is unchanged (OR = 1.8, 95% CI = 0.5 to 6.8). Singer *et al* found docusate sodium particularly effective in children aged 5 years or less.<sup>41</sup>

Meehan *et al* and Whatley *et al* used normal saline as a control. Pooling these data, there is weak evidence that both triethanolamine polypeptide (45%) (OR = 0.5, 95% CI = 0.2 to 1.2; Table 3) and docusate sodium (47%) (OR = 0.5, 95% CI = 0.2 to 1.2; Table 3) are less effective than normal saline (61%). There is no evidence of statistical heterogeneity in either analysis.

**Oil-based preparations compared.** Two trials examined 5% dioctyl sodium sulphosuccinate (Dioctyl-medo<sup>®</sup> [Schwarz Pharma Ltd]) and compared it to its maize oil base.<sup>31,32</sup> Fraser compared the same preparation with olive oil.<sup>14</sup> Pooling these data, dioctyl is of similar efficacy (68%) to the oil (71%) (OR = 0.6, 95% CI = 0.2 to 2.4; Table 3); there is evidence of statistical heterogeneity. If Fraser's lower quality trial is removed from the analysis, the result is similar (OR = 0.8, 95% CI = 0.1 to 4.2).

Fraser compared olive oil and Cerumol<sup>®</sup>.<sup>1</sup> Syringing was effective in 92% of ears with olive oil and 96% with Cerumol<sup>®</sup> (OR = 0.5, 95% CI = 0.008 to 10.4). Fraser also compared Cerumol<sup>®</sup> with dioctyl.<sup>14</sup> Syringing was slightly less effective (80%) with dioctyl, but evidence that Cerumol<sup>®</sup> is more effective is weak (OR = 5.8, 95% CI = 0.6 to 283.5).

One trial compared two oil-based preparations (Otocerol<sup>®</sup> and Cerumol<sup>®</sup>).<sup>36</sup> Syringing was successful in 77% of subjects using Otocerol<sup>®</sup> and in 72% using Cerumol<sup>®</sup> (OR = 1.3, 95% CI = 0.5 to 3.4).

**Non-water-, non-oil-based compared with oil-based preparations.** Lyndon *et al* found a non-water-, non-oil-based preparation (Audax<sup>®</sup>) (97%) to be clearly superior to an oil-based preparation (Earex<sup>®</sup>) (63%) in facilitating successful syringing after applying twice a day for 4 days (OR = 21.4, 95% CI = 2.6 to 178.6).<sup>37</sup>

Table 3. Effectiveness of preparations in facilitating successful syringing.

Study	Water-based	Oil-based	Odds ratio (95% CI)
Dubow <sup>30</sup>	21/40	8/19	1.5 (0.4 to 5.3)
GP Research Group <sup>33</sup>	39/47	48/60	1.2 (0.4 to 3.8)
Fraser <sup>14</sup>	147/174	66/74	0.7 (0.2 to 1.6)
Chaput de Saintonge and Johnstone <sup>34</sup>	21/35	20/32	0.9 (0.3 to 2.7)
Eekhof <i>et al</i> <sup>42</sup>	21/22	19/20	1.1 (0.01 to 90.8)
Total	249/318	161/205	1.0 (0.6 to 1.6)
Heterogeneity	Woolf Q = 1.7, df = 4, <i>P</i> = 0.8		
Overall effect	$\chi^2$ = 0.02, df = 1, <i>P</i> = 0.9		
	Docusate (water-based)	TEP <sup>b</sup> (water-based)	
Fraser <sup>14</sup>	23/26	19/24	2.0 (0.3 to 14.5)
Singer <i>et al</i> <sup>41</sup>	17/23	6/21	7.1 (1.6 to 33.1)
Meehan <i>et al</i> <sup>44</sup>	5/15	8/17	0.6 (0.1 to 2.9)
Whatley <i>et al</i> <sup>45</sup>	18/34	13/30	(0.1 to 2.9)
Total	63/98	46/92	1.9 (0.7 to 5.0)
Heterogeneity	Woolf Q = 6.8, df = 3, <i>P</i> = 0.08		
Overall effect	$\chi^2$ = 1.53, df = 1, <i>P</i> = 0.2		
	Docusate (water-based)	Saline (water-based)	
Meehan <i>et al</i> <sup>44</sup>	5/15	8/16	0.5 (0.09 to 2.6)
Whatley <i>et al</i> <sup>45</sup>	18/34	19/28	0.5 (0.2 to 1.7)
Total	23/49	27/44	0.5 (0.2 to 1.2)
Heterogeneity	Woolf Q = 0.004, df = 1, <i>P</i> = 0.9		
Overall effect	$\chi^2$ = 2.3, df = 1, <i>P</i> = 0.1		
	TEP (water-based)	Saline (water-based)	
Meehan <i>et al</i> <sup>44</sup>	8/17	8/16	0.9 (0.2 to 4.3)
Whatley <i>et al</i> <sup>45</sup>	13/30	19/28	0.4 (0.1 to 1.2)
Total	21/47	27/44	0.5 (0.2 to 1.2)
Heterogeneity	Woolf Q = 1.0, df = 1, <i>P</i> = 0.3		
Overall effect	$\chi^2$ = 2.35, df = 1, <i>P</i> = 0.1		
	Dioctyl (oil-based)	Oil (oil-based)	
GP Research Group <sup>31</sup>	54/77	42/73	1.7 (0.8 to 3.6)
Burgess <sup>32</sup>	19/34	33/41	0.3 (0.1 to 1.0)
Fraser <sup>14</sup>	20/25	23/25	0.3 (0.03 to 2.5)
Total	93/136	98/139	0.6 (0.2 to 2.4)
Heterogeneity	Woolf Q=9.0, df=2, <i>P</i> =0.01		
Overall effect	$\chi^2$ =0.5, df=1, <i>P</i> =0.5		

df = degrees of freedom. TEP = triethanolamine polypeptide. An extended version of this table can be found online (Supplementary Table 5).

*Non-water-, non-oil-based compared with water-based preparations.* Amjad and Scheer compared a non-water-, non-oil-based preparation (carbamide peroxide) to a water-based preparation (Cerumenex®) applied 30 minutes prior to syringing.<sup>35</sup> Cerumenex® was significantly more effective (88%) than carbamide peroxide (18%) (OR = 33.0, 95% CI = 9.5 to 114.3) at facilitating removal of all or most of the wax.

*Water-based preparations compared with no treatment.* Harris compared Xerumenex® (formerly HR Napp Ltd) with no treatment.<sup>13</sup> The subjects applied the water-based preparation before going to bed and syringed their own ears the following morning. Syringing after using the preparation was much more successful (75%) than using no preparation (5%) (OR = 60.0, 95% CI = 6.6 to 547.3).

*No treatment.* In one study prior to randomisation, immediate syringing of all eligible subjects with no preparation was successful in 70% of subjects (74% of ears).<sup>42</sup>

Comparing all the studies that examined successful syringing, there was no association between the number of days' treatment and the success rate ( $\chi^2$  for linear trend = 0.4, df = 1,  $P = 0.5$ ).<sup>13,14,30-35,37,41,43-45</sup> Applying a preparation, including plain water, for 15–30 minutes was as successful as several days' treatment.

*Children compared with adults.* In the two studies that included children as well as adults, docusate sodium, sodium bicarbonate, and acetic acid appeared more successful in children.<sup>41,43</sup> It was not possible to combine the data across the studies as the outcomes measured were different.

## Discussion

### Summary of main findings

Water-based and oil-based preparations are equally effective in clearing earwax, and they are probably more effective than no treatment. Comparisons between different water-based or oil-based preparations do not demonstrate any major advantages of one preparation over another. One non-water-, non-oil-based preparation appeared superior to an oil-based preparation in clearing earwax, but this was confined to one small study and the evidence was weak. Whichever of the preparations is used, several days' treatment is required to achieve clearance rates of up to 40%.

Water-based and oil-based preparations are equally effective in facilitating successful syringing, and they are probably more effective than no treatment. Success rates of up to 97% are achievable. Docusate sodium appears more effective than most other water-based preparations, but saline is equally, if not more, effective. Immediate treatment with either a water-based (including plain water) or oil-based preparation followed by syringing 15–30 minutes later, would appear to be as successful as applying eardrops for several days and delaying syringing. Non-water-, non-oil-based preparations do not appear as successful in this situation. When applied for several days, however, one non-water-, non-oil-based preparation was clearly superior to an oil-based preparation.

In general, trials excluded people who had associated complications, such as otitis externa, and so the findings are

only applicable to straightforward cases. In trials where syringing was performed, none used electric irrigators that are now recommended in primary care.

### Strengths and limitations

Most of the trials were performed over 10 years ago, the earliest being in the 1950s. Four trials were judged to be high quality ('A' in all four categories), and they were conducted recently. Six of the remaining trials did not score 'C' in any category. Many of the trials, including some recent high quality trials, had insufficient numbers of participants to demonstrate clinically important differences in effectiveness.

Initially, comparisons between studies were difficult because of the large number of preparations used. However, by classifying preparations into three categories based on their physical and chemical properties, it was possible to pool data and compare outcomes in a clinically plausible way. As most of the analyses did not show any evidence of statistical heterogeneity, this provides some support for this approach. Although the mechanism of action of the non-water-, non-oil-based preparation Audax® is not published, it seems sensible to continue to separate such preparations from water-based and oil-based preparations as other mechanisms of action are likely to be operating.

The length of time for which the preparations are applied prior to syringing appears less crucial than for clearing earwax. This may well be because of the large number of children with soft wax that were included in the later trials. In only one study were adjustments made for baseline differences between the treatment arms for factors that might make earwax either more difficult to clear or to soften.<sup>40</sup> Wax becomes harder with age, and this is reflected in the two studies demonstrating that preparations are more effective in children than in adults.<sup>41,43</sup>

Wax that causes symptoms may be more difficult to treat than that found on routine examination. Pooling data between studies where earwax is a chance finding, and studies where there is a clinical indication for removal may potentially be inappropriate. Objective improvement in hearing was measured in only one trial,<sup>38</sup> although loss of hearing is one of the main presentations of symptomatic earwax.<sup>8</sup>

### Comparison with existing literature

A Cochrane Review has recently appeared in the Cochrane Library that differs from our study in three important respects.<sup>46</sup> First, the authors have not sought to categorise the preparations in the way we have done, and have therefore not been able to pool data. Secondly, they have included trials in which the allocation is non-random, which we have omitted from our study.<sup>29</sup> Thirdly, they appear not to have found a number of early trials that we found by pursuing referenced papers.<sup>24,25,30</sup> The reviewers concluded that saline or water are as effective as any proprietary agent, but they appear to have missed the therapeutic potential of non-water, non-oil-based preparations. We are in general agreement with the authors of the review that overall the studies are not of high quality. However, removing trials of poorer quality from the analyses does not change the overall findings.

## Implications for clinical practice and future research

Immediate syringing without any preparation is successful in approximately three out of four ears of those people attending either for a routine medical or for problems with earwax.<sup>24,42</sup> This strategy would appear to offer patients a more convenient option if they attend, but it might entail a wait if it fails. However, applying eardrops and waiting a further 15–30 minutes for the wax to dissolve or soften will result in successful syringing in nearly all cases. Self-syringing without any preparation would appear to be ineffective but the evidence is very limited.<sup>13</sup> Self-syringing is more popular in continental Europe, and its success rate after using a preparation is not known.

Ear syringing takes up a great deal of professional and patient time, and can have medicolegal consequences.<sup>47</sup> Some authorities have questioned whether we need to syringe ears at all.<sup>48</sup> Providing specialist nurses to administer care for ear problems is a cost-effective service,<sup>49</sup> and some practitioners have found that with regular ear care every 6–12 months the amount of syringing performed decreases significantly.<sup>50</sup> For uncomplicated earwax, it may be even more cost-effective to use eardrops and avoid consulting a health professional at all. Non-water-, non-oil-based preparations appear promising in this regard, although we do not know which preparation is the most effective. Further large, well-designed randomised trials are needed to determine whether non-water-, non-oil-based preparations are really more effective than water-based and oil-based preparations, including plain water itself.

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## Supplementary Information

Additional information accompanies this paper at: <http://www.rcgp.org.uk/journal/index.asp>

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