Effectiveness of ear syringing in general practice: a randomised controlled trial and patients' experiences

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SUMMARY

Background: *Ear syringing is a common procedure performed for a variety of symptoms in primary care. Reports of its effectiveness vary considerably and no randomised controlled trials (RCTs) have been performed.*

Aim: *To estimate the effect of ear syringing on hearing thresholds, and on symptoms leading to ear syringing in general practice.*

Design of study: *Randomised single-blind controlled trial. Before-and-after self-assessments of symptoms.*

Setting: *Patients from three general practices in the Bristol area attending twice-weekly clinics dedicated to ear syringing over a 12-week period.*

Method: *Patients were randomly assigned to have their hearing tested before and after ear syringing, or twice before ear syringing. Changes in hearing threshold were measured by pure tone audiometry (PTA). All patients completed self-assessment forms of symptoms using Likert scales before, and one week after, ear syringing.*

Results: *Hearing threshold improved by 10 dB or more in 34% (95% confidence interval [CI] = 21% to 47%) of the intervention group and 1.6% of control group (number needed to treat = 3.1, 95% CI = 2.2 to 5.2,* P*<0.001). The levels of improvement in the intervention group ranged between 15 dB and 36 dB. The symptoms that most commonly improved included hearing on the phone, pain, a feeling of blocked ears, and hearing one-to-one. There was a strong relationship between the change in thresholds, as measured using PTA, and self-reports of hearing improvement. Secondary analysis was unable to identify predictors of objectively measured improvement.*

Conclusion: *Ear syringing improved hearing threshold in a substantial proportion of patients. An even larger proportion reported an improvement in symptoms. It was not possible to predict which patients would benefit.*

Keywords: *ear syringing; hearing; ear wax; randomised controlled trial.*

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Submitted: 30 November 2001; Editor's response: 18 February 2002; final acceptance: 25 May 2002.

Introduction

EAR syringing is a common clinical procedure in primary health care, but there is little, and conflicting, evidence as to its effectiveness and there has been no randomised controlled trial (RCT).[1] Many people have ear wax present without it causing symptoms. It can be removed to relieve many different symptoms, including tinnitus, earache, vertigo, a feeling of fullness of the ear, irritation, and hearing aid problems, as well as deafness.[2] Anecdotally, ear, nose and throat surgeons often feel that ear syringing does not help hearing, whereas general practitioners (GPs) and patients often feel that it does, perhaps reflecting the different patient populations seen. It is commonly stated that wax only affects hearing if it is 'impacted',[3] but the term is used in different ways and may simply imply the coexistence of wax obscuring the drum with symptoms in that ear.[1]

In the United States, 150 000 ear wax removals take place each week,[4] but there appears to be no national figure available for the United Kingdom. One study estimated that each GP sees on average nine patients per month who request removal of ear wax, with a large between-practice range of between five and 50.[5]

Although a common procedure, ear syringing is not without risks, including possible damage to the tympanic membrane and promotion of infection.[6] Despite the assertion that 'removal of earwax and subsequent improvement of hearing can be one of the most satisfying clinical experiences for patient and doctor alike',[7] there is disagreement concerning the detrimental effect of ear wax on hearing. Although some reports consider earwax to raise hearing thresholds by as much as 40 to 45 dB[2,8] others have observed that its removal may improve hearing only by 5 to 10 dB.[5,9]

Most studies concerned with measuring hearing do so using pure tone audiometry (PTA) which, when performed by an experienced audiologist with suitably sensitive instrumentation, can provide accurate objective measures of hearing thresholds of different frequencies.[3] Hanger and Mulley have suggested that audiometric measurement alone may not reflect the degree of impaired hearing experienced by the person concerned.[7] A complete evaluation of ear syringing should include supplementation of audiometric measurement by subjective reports of improvement of hearing and other symptoms.

This study aimed to estimate the effect of ear syringing on (a) hearing thresholds and (b) symptoms leading to ear syringing in general practice.

HOW THIS FITS IN

What do we know?

Ear syringing is performed in order to relieve a variety of symptoms. Reports of its effectiveness vary considerably and no RCTs have been performed.

What does this paper add?

Hearing threshold is improved by a large amount in a substantial minority of people. Subjective reports of improvement in hearing and blocked ears correlate well with objective measurement and patients report improvement in other symptoms.

Method

Study population and design

The study population comprised all patients who attended clinics dedicated to ear syringing at three general practices in the Bristol area during the period April to September 2000. The clinics were held twice weekly over a 12-week period in each of the practices. The practices were situated in urban and rural areas serving 33 336 patients from a range of socioeconomic backgrounds. Inclusion and exclusion criteria were based on the general practices' existing protocols. These varied slightly in detail in; for example, whether patients could refer themselves directly to the treatment room nurse, but were agreed on (a) only syringing the ear when the ear drum was completely obscured by wax and (b) the need to use oily ear drops for at least three days before syringing. This is the current standard practice, although a recent study showed that instillation of water and waiting 15 minutes was equally effective.[10]

The design of the study was a single-blind randomised controlled trial comparing the effects on hearing of ear syringing versus no treatment. Blinding of the patients was not possible but the audiologist conducting the tests was unaware of the treatment arms to which the patients had been assigned. The intervention group had their hearing tested before and after ear syringing, whereas the control group had their hearing tested twice before their ears were syringed. Hearing thresholds were tested using PTA with a Kamplex KLD21 machine, by fully qualified audiologists according to British Society of Audiology recommendations,[3] including masking where appropiate. It was carried out in a quiet room in each practice using background sound attenuating headphones.

In addition, patients were asked for their self-reports on symptoms. Because syringing could not be denied to control patients for the period necessary to assess perceived changes in symptoms, all patients in both arms of the RCT completed these forms.

Recruitment and assignment

Only those patients who were able to attend at specific times when the audiologist and research assistant were present were entered into the study. For the purposes of baseline comparison, those who attended at other times (non-participants) were asked to complete a baseline questionnaire and a symptom self-assessment form. Nurses used the individual practice's protocol to confirm whether and which ear(s) were to be syringed. Those who were not to be treated were excluded from the study. Stratified random sampling, using blocks of four, with separate strata for single and bilateral syringing for each of the three practices, were prepared in advance by a team member who had no contact with the patients. Random number tables were used to generate the blocks. Immediately after being informed regarding their treatment, participants were allocated using sealed envelopes. They were instructed that the audiologist should not know to which group they had been allocated.

All participants had a first hearing test. Those in the intervention group then had their ear(s) syringed, waited until they were dry and had a second hearing test. Control patients waited an equivalent time before being retested and then had their ears syringed. Baseline questionnaires and symptom self-assessment forms were completed during the waiting times. A second self-assessment form was posted to all participants to reach them one week after attending the study clinic. Patients who had not oiled their ears to soften the wax did not receive treatment (as per practice protocol) but were asked to reattend. If they could reattend during one of the study clinics then they were enrolled into the study at that time. If the patient had to reattend because the first treatment was not effective in clearing the earwax the assessments were made after the successful completion of the treatment.

Outcome measurement

The primary outcome measure was the proportion of people with an improvement in hearing threshold of 10 dB or more, measured using PTA. Hearing improvement was defined as the average change across four frequencies (500 Hz, 1 kHz 2 kHz and 4 kHz) in the syringed ear or, if both ears were syringed, in the ear that improved more. This definition was intended to identify individuals, rather than ears, who benefited clinically. The minimum improvement regarded as both clinically significant and reliably detected using PTA is 10 dB.[3] Secondary outcome measures were improvements in hearing threshold at each of the four frequencies in each ear and changes in symptoms.

Participants completed a baseline questionnaire that included questions on why they were having their ears syringed, frequency of previous ear syringing, underlying hearing problems, age, and sex. They also completed self-assessments of symptoms using a form that was devised for the study. This asked them to rate three aspects of hearing (one-to-one conversation, group conversation, and telephone usage)[11] and other common symptoms for which ear syringing is requested (as identified by a pilot survey) using a four-point Likert scale. Pilot work showed this to have good test-retest reliability (0.92 over a one week) in people both with and without hearing difficulties (n = 11 and n = 13 respectively), who were not having their ears syringed. There was no suitable comparator against which to judge validity, although ease of completion indicated good face validity.

Other outcomes were obtained from before-and-after self-

assessment forms. An improvement was defined as the lessening of severity by at least one level. The analyses examined the relationship between objective measurement and the self-reports of subjective change in hearing and/or blocked ears and other symptoms. Finally, the data were inspected for predictive features in terms of demographic variables and baseline characteristics, including hearing levels.

Statistical analysis was performed using STATA software. The primary analysis compared the proportions of patients experiencing hearing improvements of at least 10 dB, using Pearson's χ^2 test. Secondary analyses compared these proportions, while adjusting for baseline audiometry and age, using logistic regression. Other secondary analyses examined changes in audiometric thresholds as continuous variables, using Student's *t*-test to compare trial arms and, when adjusting for baseline audiometry and age, using linear regression. Baseline continuous variables with skewed distributions were compared using the Kruskal–Wallis test. Baseline predictors of audiometric improvement were examined, in the syringing arm only, using multiple linear and logistic regression. One hundred patients (50 in each study arm) was calculated in advance to be sufficient to detect a difference of 20% in the proportion of patients having an increase of at least 10 dB in acoustic threshold (i.e. 20% in the intervention arm and 0% in the control arm) at the 5% significance level and with 80% power.

Ethical approval for the study was obtained from the Local Research Ethics Committees.

Results

Characteristics of the sample

Of 185 patients requesting ear syringing within the study period, 116 were included in the study with 50 unable to attend at clinic times and 19 being unsuitable for ear syringing because their ear drums were not completely obscured (Figure 1). Each practice provided similar numbers of patients. The final analysis was based on 53 in the intervention arm and 61 in the control arm. The discrepancy of numbers in each arm was owing to the block randomisation sequences (which were stratified by practice and for unilateral or bilateral syringing) and because two intervention arm participants had to be excluded from the study after randomisation because they could not have a second hearing test before the end of the designated clinic time. Forty-four had one ear syringed and 70 had both ears syringed. Separate randomisation for single and bilateral syringing ensured that they were distributed evenly between the two arms.

The 50 non-participants were slightly, but not significantly, younger than participants (mean age = 54 years [95% CI = 48 to 60] and 60 years [95% CI = 57 to 63], respectively) with a similar sex distribution. There were also no significant differences regarding reported symptoms, usual hearing problems, and pattern of attendance for ear syringing.

Table 1 gives the profile of intervention and control arms. Despite baseline differences in age and audiometry, multivariable adjustments to effect estimates did not influence the magnitude or precision of these estimates, suggesting that these baseline differences were not confounders. Symptom prevalences were not systematically different between the two.

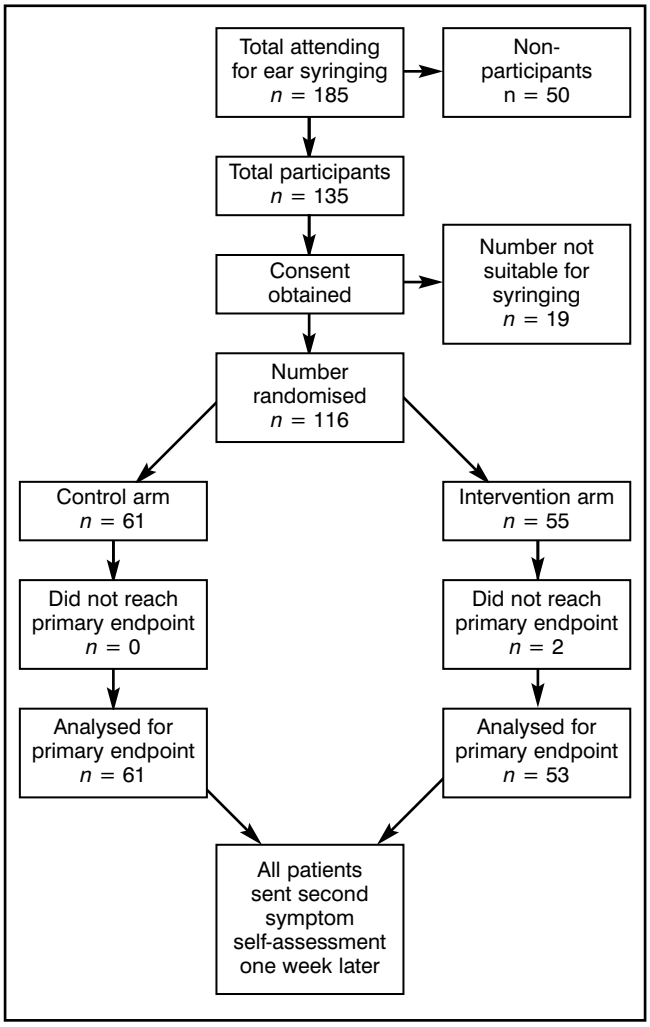

Figure 1. Progress of participants through the trial.

The reasons for seeking care were blocked ears (78% of all participants), hearing problems (72%), noises in ears (33%), itchy ears (29%), dizziness (16%), and ear pain (14%). Both hearing problems and blocked ears were reported by 70%, while only 13% gave neither of these as reasons for attending for ear syringing.

Audiological measurements

Table 2 shows the proportion of people in intervention and control groups whose hearing threshold improved by 10 dB or more in the syringed ear or, if both ears were syringed, the more improved ear. This is graphically represented in Figure 2, which clearly shows the greater levels of improvement in the intervention group.

Objectively measured improvements in hearing of 10 dB or more were experienced by 18 out of 53 (34% [95% CI = 21% to 47%]) in the intervention group, compared with 1 out of 61 (1.6% [95% CI = 0% to 4.7%]) of the control group (Table 2). The number needed to treat for each patient who demonstrated improvement of at least 10 dB was thus 3.1 (95% CI = 2.2 to 5.2). The difference in mean improvement in hearing between intervention and control groups was 6.9 dB (95% CI = 3.8 to 10.1), which was small because of the

Table 1. Baseline characteristics of patients in intervention and control arms.

	Syringe arm (n = 53)		Control arm (n = 61)		P-value
Continuous variables[a], median (interquartile range)					
Age	63	42–71	62	57–77	0.07[b]
Right ear average audiometry[d]	32	20–54	24	14–41	0.02[b]
Left ear average audiometry[d]	36	20–50	28	14–46	0.14[b]
Categorical variables, n (%)					
Sex (male)	25	47.2	36	62.3	0.13[c]
Hearing aid (always or sometimes)	43	81.1	59	96.7	<0.001[c]
Referred to GP for ear syringing	29	54.7	24	45.3	0.35
Ears syringed					
Both	32	60.4	38	62.3	
Right	13	24.5	14	23.0	
Left	8	15.1	9	14.8	0.98
Symptoms					
Difficulty hearing one-to-one	34	64.1	36	59.0	0.57
Difficulty hearing in a group	41	78.9	42	58.9	0.23
Difficulty hearing on the phone	34	65.4	22	36.7	0.002
Blocked ear	46	86.6	58	95.1	0.12
Itchy ear	25	47.2	28	45.9	0.89
Ear pain	13	24.5	18	29.5	0.55
Noises	32	61.5	32	52.5	0.33

[a]Skewed distributions; [b]P-value from Kruskal–Wallis test; [c]P-value from χ^2 test; [d]average improvement for all frequencies for the same ear.

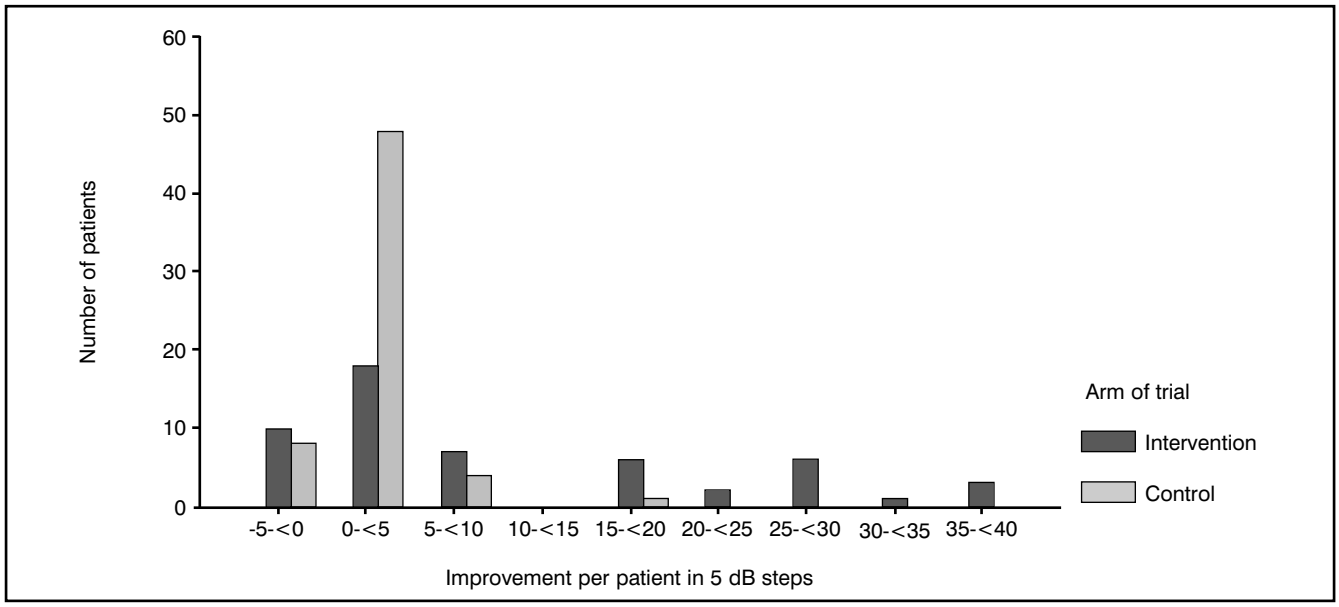

Figure 2. Improvement in audiometric thresholds in dB.

majority who did not improve after syringing. However, the improvement for those whose hearing improved by at least 10 dB was large, ranging from between 15 and 36 dB with a mean of 24 dB (95% CI = 11.6 to 37.4).

Of those people in the intervention group who were having their ears syringed because of a hearing problem, 16 out of 39 (41% [95% CI = 26 to 56]) had a 10 dB or more improvement. In a secondary analysis, adjustment for use of hearing aids (which was more common in the control group) strengthened the association between the intervention and an average improvement of more than 10 dB in both ears (adjusted odds ratio = 38 [95% CI = 4.8 to 302]).

Changes in symptoms

All participants had their ears syringed before returning the second questionnaire; therefore the data for subjective differences refer to participants from both arms. One hundred and five post-syringing self-assessment reports of symptoms were returned (response rate = 92%) with very few missing data. Table 3 shows the baseline prevalence of problems and the proportion of people who reported at least one level improvement for each scale. Participants initially presenting with difficulty hearing on the phone, or with ear pain were most likely to improve, while those presenting with itch or dizziness were least likely to improve. Improvements of at least 10 dB on audiometry were significantly associated with reported improvements in hearing one-to-one (P<0.001), hearing in a group (P = 0.011), hearing on the telephone (P<0.001), and blocked ears (P = 0.034).

Potential baseline predictors of audiometric improvement

Table 2. Proportion of patients in intervention and control arms showing increased hearing thresholds of at least 10 dB.

	Syringe (n = 53)		Control (n = 61)		NNT	95% CI	OR	95% CI	P-value
	n (%)	95% CI	n (%)	95% CI					
Head[a]	18 (34.0)	21.5–48.2	1 (1.6)	0.0–8.8	3.1	2.2–5.2	30.9	3.9–241	<0.001
Right ear average[b]	7 (13.2)	5.5–25.3	1 (1.6)	0.0–8.8	8.6	4.7–52.3	9.1	1.1–76.8	0.042
Left ear average[b]	14 (26.2)	15.3–40.3	0 (0)	0–5.9[d]	3.8	2.6–6.9		–	<0.001[c]

[a]Average improvement for all frequencies in the syringed ear or, if both ears were syringed, in the ear that improved more; [b]average improvement for all frequencies for the same ear; [c]P-value from χ^2 test; [d]one-sided; 97.5% CI.

Table 3. Subjective reports of change in symptoms.

Symptom	Number experiencing improvement/number with symptom	% experiencing improvement (95% CI)
Difficulty hearing on the phone	42/56	75 (64–86)
Pain	22/31	71 (55–87)
Blocked ears	65/104	62 (52–72)
Difficulty hearing one-to-one	43/70	61 (49–73)
Difficulty hearing in a group	46/83	55 (44–66)
Noises	32/64	49 (37–61)
Dizziness	11/23	48 (28–68)
Itchy ears	21/53	39 (26–51)

were examined. There were no significant predictors of having an improvement of at least 10 dB among the syringing arm. Patients presenting with blocked ears or hearing difficulties were three to four times more likely to have such an improvement but these associations were not significant.

Discussion

The study shows that one-third of patients had clinically significant improvements in hearing as a result of ear syringing. The difference in mean improvement was small (6.9 dB) and compares with the non-randomised study of Sharp *et al*, which found a mean improvement of 5.45 dB in ear, nose and throat hospital outpatients.[5] However, this disguises the fact that the improvement for those who benefited was large. The contrast between this large improvement in one-third and the absence of effect in two-thirds of people, also helps explain the previous polarised debate regarding the effect of ear syringing on hearing.

We have confirmed that ear syringing is a common procedure in primary care and that an RCT of its effectiveness is thus long overdue. A strength of this study is that it was a pragmatic trial, based in general practices, using consecutive patients attending for ear syringing and normal practice protocols. We identified 185 people from a combined list size of 33 336 over the 12 weeks. Assuming the practices are typical, extrapolation to the whole British population (56 million), suggests that over 25 000 patients every week visit their general practices for ear syringing. However, the generalisability of this finding may be limited, as all three general practices were large, well organised GP training practices allowing relatively easy patient accessibility to nurses for ear syringing.

The study showed that the most common reasons for attending for ear syringing were hearing problems and/or blocked ears, with very few patients complaining of blocked ears without hearing problems. It was therefore reasonable to use objective improvement in hearing as the primary outcome measure. The threshold of change (10 dB or more) was justified as appropriate when considering the level of change needed before any change is detectable by individuals in everyday life situations. The greater proportion of people reporting subjective improvement than those shown to have benefited using objective measurement supports the concept that hearing involves more than what is measured by PTA.

Limitations of the study should be considered. First, the fact that there was no available placebo procedure for ear syringing meant that participants could not be blinded. However, this would be unlikely to influence their audiometric performance, as iterative audiometric procedures are designed to avoid patient bias. Secondly, the measurement of subjective improvement in symptoms was not done within a randomised controlled trial. This was because the subjective benefits of ear syringing, unlike audiometry, would not necessarily be immediately apparent. We made the pragmatic decision that asking participants (if they were in the control group) to wait a week after randomisation to have their ears syringed would seriously diminish recruitment to the trial. The fact that participants were not blinded would also be more important for this part of the study. This part of the study does suggest that there is subjective improvement in a range of other symptoms, including hearing, and the strong correlation between objective and subjective improvements in hearing mutually support the validity of both measures.

Thirdly, because the study was based in general practices using quiet (but not soundproof) rooms, the level of background noise precluded optimal audiometric measurement. However, the conditions matched those commonly used in community clinical practice and the patients in control group, who had two hearing tests before ear syringing, showed high levels of test-retest reliability (Pearson's correlation coefficient at least 0.96 at each frequency).

The sample size was calculated on the basis of being sufficient to test the efficacy of ear syringing. Consequently, the numbers were too small to comment conclusively on adverse effects, such as damage to the tympanic membrane, although no patients in this study had a deterioration of more than 5 dB, and there were very few subjective reports of pain, noises, itchiness, and dizziness in their second assessments when the symptom had not previously been reported.

We were not able to predict statistically which people would benefit from ear syringing. There were no clear relationships between improvements and the reason for requesting ear syringing or other factors, such as underlying hearing problem, and frequency of having ears syringed previously. These negative findings may have been owing to the relatively small numbers involved in the study.

In summary, this study has shown that ear syringing is a common procedure in primary care and that it improves hearing in a substantial proportion of patients. From this small study, it is not obvious in advance which patients would benefit and future studies should focus on identifying baseline characteristics associated with likely improvement. Although the materials and equipment used are inexpensive, the amount of time spent in ear syringing by practice nurses is considerable. It would be useful to look at the use of ear drops/wax softeners alone compared with ear syringing, and the cost effectiveness of various strategies for managing patients with ear wax, such as direct patient access to nurses in a one-stop clinic for ear syringing.

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Acknowledgements

We would like to thank the reception staff and the nurses at the three general practices for the positive way in which they addressed recruitment and disruption to routine, and the audiology team from United Bristol Healthcare Trust, especially Mike Coleman and Pat Smith. We are especially grateful to all the patients who participated and gave their patience and time. Funding was provided by the RCGP Scientific Foundation Board. Air Balloon Surgery and the Backwell and Nailsea Medical Group are research general practices funded by the national R&D Support for NHS Providers Scheme.