Use of an Autoinflation Device Does Not Lead to a Clinically Meaningful Change in Hearing Thresholds in Children With Otitis Media With Effusion

Running title: Autoinflation for children with OME

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Disclosure statement

Hannah Cooper, Ilaria Grifa and Catriona Bryant declare that they have no conflicts of interest.

Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Abstract

Objectives

The objective of this study was to establish whether autoinflation was an effective intervention in a paediatric audiology service. The aims were to evaluate whether there was improvement in hearing thresholds following introduction of an autoinflation device, and whether there was a reduction in further audiology follow-ups, and in referrals to an ear, nose and throat specialist for consideration of ventilation tube insertion.

Design

This was a pragmatic retrospective study with historical controls using a paired availability design at a single paediatric audiology service in England.

Participants

All children seen in the clinic over a two-year period who were aged between 3 and 11 years and who had a type B tympanogram in at least one ear were included. The Otovent autoinflation device was available as a treatment option over the second year (Cohort B) but not the first (Cohort A). There were 976 children included in the study: Cohort A comprised 513 children, Cohort B comprised 463 children.

Results

There was a statistically significant improvement in hearing thresholds in Cohort B compared to Cohort A, however the improvements were clinically minimal with small effect sizes. There was no significant difference in improvement of tympanometry results between the two cohorts. Significantly more children in Cohort B (autoinflation group) were referred to an ear, nose and throat specialist after their second appointment compared to Cohort A.

Conclusions

It was feasible to introduce autoinflation into the care pathway, however there was no evidence of clinically meaningful improved outcomes for patients.

Key words

Hearing

Middle ear effusion

Autoinflation

Glue ear

Paediatric

Key points

- Autoinflation using a nasal balloon is a low-cost intervention which may promote resolution of otitis media with effusion.
- A recent NICE technical briefing suggested that autoinflation be used as a first-line option for glue ear during or after a watchful waiting period to help avoid the need for grommet surgery.
- We conducted a clinical evaluation of an autoinflation device to find out whether it improved hearing thresholds in a typical paediatric audiology clinic.
- There were clinically minimal improvements in hearing thresholds in the autoinflation group compared to controls, and significantly more children from the autoinflation group were referred to an ear, nose and throat specialist.
- The introduction of the autoinflation device was feasible and acceptable to patients, parents, and audiologists, however, we did not feel that it was helpful enough to continue to offer it to all patients with otitis media with effusion.

Introduction

Otitis media with effusion (OME) is characterised by fluid collection in the middle ear in the absence of acute infection. Conductive hearing loss is the main symptom and may be persistent or recurrent (1). Spontaneous resolution is common, however recovery is unpredictable and some children may experience significant impact on their speech perception, language development, educational outcomes, behavioural development and quality of life (2–6).

A period of watchful waiting is the usual course of action following OME diagnosis. Ventilation tube (VT) insertion is a common surgical intervention for children with persistent OME. However, there is little evidence of long-term benefit with no difference in hearing levels seen in those with VTs compared to controls at 12 and 18 months post-surgery (7).

Autoinflation using a nasal balloon is a low-cost intervention which may promote resolution of OME during the watchful waiting period. A recent randomised controlled trial (RCT) showed that autoinflation was an effective method of clearing middle ear effusion, as shown by improvement in tympanometry results, in children age 4-11 years at one and three months compared to standard care alone in a primary care setting (5). However, it is hearing loss, rather than OME in isolation, that is known to affect language and social development (4), and it has been suggested that audiometric assessment completed over a specific time period should be the primary outcome in assessing OME (7).

A systematic review evaluating the use of autoinflation for hearing loss in children with OME (8) suggested that it does not improve audiometry thresholds. However, study groups were small, which is particularly problematic considering the high spontaneous resolution rate. Adherence to using autoinflation was also variable (9,10). Parental perception of the device is that it is acceptable and appealing to children, and that it is possible to adhere to the treatment regimen by making the nasal balloon part of a child's daily routine (11).

A recent National Institute for Health and Care Excellence (NICE) technical briefing (12) examining the effectiveness of the Otovent (ABIGO Medical, Askim, Sweden) for OME suggested that autoinflation be used as a first-line option for glue ear during or after the watchful waiting period to help avoid the need for grommet surgery. Whilst RCTs are the "gold standard" for establishing efficacy and safety of new interventions they may not be representative of patient populations and routine clinical practice due to necessarily strict inclusion/exclusion criteria (13). RCTs also have extra resources for ensuring high levels of treatment compliance which are rarely available in clinic. The recent RCT (5) took place in a primary care setting and measured outcomes on tympanometry rather than the more clinical relevant outcome of hearing.

Here, we performed an analysis to establish whether autoinflation using the Otovent device led to an improvement in hearing thresholds in children with glue ear, and whether there was a reduction in further audiology follow-ups, and in referrals to an ear, nose and throat (ENT) specialist.

Materials and Methods

Study design and setting

The study took place at the Royal Berkshire Hospital NHS Foundation Trust (RBFT). This was a pragmatic retrospective study with historical controls using a paired availability design (14). This design reduced the possibility of selection bias as all eligible patients were compared in the period analysed, whether they received the device or not.

Ethical considerations

This study was categorised as a clinical service evaluation by the research and development department. Formal research ethics committee approval was therefore not required and it was not necessary to obtain written consent from patients or carers.

Participants

All children seen in the RBFT children's hearing assessment clinic between 23 February 2017 and 22 February 2019 who were aged between 3 and 11 years and had a type B tympanogram with normal ear canal volume in at least one ear were included in the analysis. Reasons for exclusions and numbers are shown in Figure 1. The final group for analysis comprised 976 patients. Two cohorts were identified: Cohort A (n=513) were between 23 February 2017 and 22 February 2018 and Cohort B (n=463) were seen between 23 February 2018 and 22 February 2019. Autoinflation was available as a treatment option for Cohort B and not for Cohort A.

Procedures

All children received routine care including history taking, otoscopy, tympanometry, and pure tone or play audiometry at each appointment. For children identified with OME, at least one period of watchful waiting was arranged with a follow-up appointment scheduled between three and six months depending on parental report, audiometry results and whether OME was unilateral or bilateral. Children with persistent bilateral OME and a hearing level in the better ear of 25–30 dB HL or worse averaged at 0.5, 1, 2 and 4 kHz were offered a choice between referral to ENT for consideration of surgical intervention (15) or temporary hearing aids.

Children in Cohort B were also offered an Otovent care pack. A care pack was not offered for children with a latex allergy, children who already had ventilation tubes, or children with active ear infections. The care pack consisted of an Otovent, a patient information leaflet (Using the Otovent – departmentally written and reviewed by the hospital patient panel), reward stickers and chart. Audiologists gave information about autoinflation by either demonstrating themselves, showing a video in clinic, or showing the instructions on the patient information leaflet. Patients could accept or decline the device at the appointment.

Patients were advised to use the device as specified by the manufacturers i.e. three times a day for the first week, then twice a day after that until the follow up appointment. Information was collected about reasons audiologists did not offer the Otovent. Parents of children who had received an Otovent pack were asked brief questions at the follow up appointment about compliance and issues with the device. All patients were either discharged, referred to ENT, or had a further appointment arranged in audiology.

Data Analysis and Missing Data

The study had a paired availability design i.e., all children who met the clinical criteria for receiving an Otovent were included in the analysis (not just those who received it) in order to reduce selection bias. However, results were also analysed for those who consistently used the device in order to see whether compliance affected the outcomes.

McNemar's test was used to evaluate change in tympanometry between the two time points for each group. An improvement in tympanometry was defined as a change from type B tympanogram to type A, A_s or C. Difference-in-difference (DiD) analysis (16) was used to measure the impact of the Otovent compared to standard care alone and regression modelling was used to examine differences between groups. Paired t-tests were applied to examine the difference in hearing thresholds over time. Regression modelling was used to evaluate differences between groups. Reduction in the number of audiology follow-ups and ENT referrals was evaluated using chi-square testing.

There were significantly more missing values for Cohort B at 0.5 and 2 kHz PTA at the second appointment compared to Cohort A (see Supplementary table A) and it was concluded that data were unlikely to be missing at random. Therefore, missing values were not replaced. To mitigate data loss, analyses included all the available data where possible.

Results

Participant characteristics and between group comparisons are shown in Table 1. Sex, age and tympanometry type were not significantly different between groups. Hearing thresholds were significantly poorer at all frequencies on the right and two frequencies on the left for Cohort B compared to Cohort A. The interval between appointments was significantly shorter for Cohort B compared to Cohort A. However, the differences were clinically minimal (maximum difference in hearing threshold was 2.48 dB) and small effect sizes were observed.

Four children were reported to have latex allergy and therefore were not offered the Otovent. The Otovent was offered to and accepted by 331 families. One hundred thirty-two children who had an appointment in 2018-19 did not receive an Otovent. Reasons for this included parents feeling their child would not be able to use the device, lack of stock at outstation clinics, clinician forgetting, and lack of time in the appointment. Of the 331 children who received the Otovent, 54 did not use it, 54 used it sporadically and 156 used it consistently. Information was not collected for the remaining 67. The majority of audiologists (83%) demonstrated the device by showing the available video.

Group Differences

Hearing thresholds

Results of audiometry at both time points are shown in Figure 2. There was significant improvement across frequencies ($p<.001$) between the two time points for each group with a mean improvement of 5.36 dB HL for Cohort A and 6.27 dB HL for Cohort B. Results of regression modelling are illustrated in Table 2 and show significantly greater improvements in hearing threshold in Cohort B at 2 kHz ($p=.032$) and 4 kHz ($p=.020$) on the right compared to Cohort A. This significant difference was maintained at 4 kHz (but not 2

kHz) on the right when considering only those who were consistent users of the Otovent in Cohort B (see Supplementary table B). Significantly more children met the NICE criteria for surgical consideration at the second appointment in Cohort B (19%) compared to Cohort A (12%; χ^2=4.55, *p*=.033).

Tympanometry

McNemar's test showed that there was a significant improvement in middle ear function between the first and second appointments as determined by change from type B tympanogram to type A, A_s or C in both groups (*p*<.001 for both groups). DiD analysis suggested that improvements were greater in the control group compared to the Otovent group (see Table 3). Results of regression modelling showed that there was no significant difference between groups when comparing rates of improvement for tympanometry. There was no substantial change in the results when evaluating only those who were consistent users of the Otovent in Cohort B.

Further Appointments

There was no significant difference between groups in the number of children who were seen for further audiology appointments (Cohort A: 50.5%, Cohort B: 52.3%; *p*=.645). However, significantly more children in Cohort B were referred to ENT following their second appointment in comparison to Cohort A (Cohort A: 15.6%, Cohort B: 29.6%; *p*<.001).

Issues with Device

Verbal comments from children and parents were recorded for 238 patients. Ninety-one parents or children reported that they had no problems using the device. Thirty reported that it was difficult to use the device at first but got easier with time. Difficulties inflating the balloon were reported for 55 children and pain or discomfort was reported for 16 children.

Other issues included the child having nasal congestion or other illness, the family having difficulties finding time to use the device, the child refusing or being scared to try, and the device getting lost.

Discussion

Our primary goal was to assess whether there was a difference in improvement in hearing thresholds in the autoinflation group compared to controls. We found significant improvements between first and second appointments across frequencies in both groups which was as expected given that OME is frequently a self-limiting condition with resolution rates of 56% by 3 months (17). Although there was significantly greater improvement in the autoinflation group at some frequencies, the improvements were less than 2 dB HL, which is not clinically significant, and effect sizes were small. Previous studies have suggested that autoinflation does not significantly improve hearing thresholds compared to controls (10,18) and although our study does suggest a significantly greater improvement at some frequencies for our autoinflation cohort, the functional gain was minimal.

No significant difference in improvement in tympanometry was observed between the two cohorts. This is in contrast to an RCT which showed significantly more improvement in tympanometry results for an autoinflation group compared to controls (5). There may be several reasons for this. Firstly, there was a longer time period between the first and second appointments in the current study. As the spontaneous resolution rate of OME increases over time (17), it may be that any short term advantage of autoinflation was lost over a longer time period. Secondly, the compliance rate for the current study was lower compared than the RCT (5) and, as all eligible children were included in the primary analysis, this may have led to an underestimation of the effect of autoinflation. However, further analysis evaluating only children who were consistent users did not substantially change the results. The compliance

rates in the current study are similar to another study (10) and may more accurately reflect use of the device in a clinical setting outside of an RCT.

Significantly more children in the autoinflation group were referred to ENT compared to controls. This may have been due to there being significantly more children in the autoinflation group who met the NICE criteria for consideration for surgery at the second appointment. However, only 19% of the autoinflation cohort met the NICE criteria whereas 29.6% of the cohort were referred to ENT. It is speculated that at least some of these additional referrals may have been due to the possibility that both parents and audiologists were less likely to find a further period of watchful waiting acceptable as an intervention had taken place and had not resulted in resolution of the child's OME.

Limitations

This study has several limitations. This was a retrospective evaluation with historical controls and therefore risked selection bias. There was also more missing data than may be anticipated in other study designs such as RCTs. However, the aim was to obtain information about how effective autoinflation was in a typical paediatric audiology clinic. A paired availability design was used in order to reduce selection bias, and a full calendar year per cohort was evaluated in order to control for known effects of seasonality in OME (19). A further possible issue was that the cohorts differed significantly on several variables at the first appointment meaning that it is difficult to say that the two groups were drawn from the same population. However, the sample size was large (976 children), and therefore small differences became significant. For example, there was a significant difference in interval between appointments but this was around 10 days and is unlikely to have had a large impact on resolution rates.

Conclusion

This study found that introducing autoinflation into a paediatric audiology clinic for the management of OME is feasible and acceptable to children, parents and audiologists. Although there were significantly greater improvements in hearing thresholds in the autoinflation cohort compared to controls, these were not clinically meaningful, and there were no significant improvements in tympanometry and significantly more children in the autoinflation group were referred to ENT. Our data do not support routine use of the Otovent device in children who present with OME. It is possible that some subgroups will benefit from this device, and future studies may look to define such cohorts.

References

1. Cai T, McPherson B. Hearing loss in children with otitis media with effusion: a systematic review. Int J Audiol [Internet]. 2017 Feb 14 [cited 2021 Mar 16];56(2):65–76. Available from: https://www.tandfonline.com/doi/full/10.1080/14992027.2016.1250960
2. Bennett KE, Haggard MP, Silva PA, Stewart IA. Behaviour and developmental effects of otitis media with effusion into the teens. Arch Dis Child. 2001;85(2):91–5.
3. Maw R, Wilks J, Harvey I, Peters TJ, Golding J. Early surgery compared with watchful waiting for glue ear and effect on language development in preschool children: A randomised trial. Lancet. 1999 Mar 20;353(9157):960–3.
4. Roberts J, Hunter L, Gravel J, Rosenfeld R, Berman S, Haggard M, et al. Otitis media, hearing loss, and language learning: controversies and current research. J Dev Behav Pediatr. 2004/04/15. 2004;25(2):110–22.
5. Williamson I, Vennik J, Harnden A, Voysey M, Perera R, Breen M, et al. An open randomised study of autoinflation in 4- to 11-year-old school children with otitis media with effusion in primary care. Health Technol Assess (Rockv). 2015;19(72):1–149.
6. Tomlin D, Rance G. Long-term hearing deficits after childhood middle ear disease. Ear Hear. 2014;35(6):e233–42.
7. Browning GG, Rovers MM, Williamson I, Lous J, Burton MJ. Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children. In: Browning GG, editor. Cochrane Database of Systematic Reviews [Internet]. Chichester, UK: John Wiley & Sons, Ltd; 2010 [cited 2017 Aug 22]. Available from: http://doi.wiley.com/10.1002/14651858.CD001801.pub3
8. Perera R, Glasziou PP, Heneghan CJ, McLellan J, Williamson I. Autoinflation for

hearing loss associated with otitis media with effusion. In: Perera R, editor. Cochrane Database of Systematic Reviews [Internet]. Chichester, UK: John Wiley & Sons, Ltd; 2013 [cited 2017 Aug 22]. Available from: http://doi.wiley.com/10.1002/14651858.CD006285.pub2

9. Arick DS, Silman S. Nonsurgical home treatment of middle ear effusion and associated hearing loss in children. Part I: clinical trial. Ear Nose Throat J [Internet]. 2005 Sep [cited 2017 Aug 22];84(9):567–8, 570–4, 576 passim. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16261757
10. Blanshard JD, Maw AR, Bawden R. Conservative treatment of otitis media with effusion by autoinflation of the middle ear. Clin Otolaryngol Allied Sci. 1993;18(3):188–92.
11. Vennik J, Williamson I, Eyles C, Everitt H, Moore M. Nasal balloon autoinflation for glue ear in primary care: a qualitative interview study. Br J Gen Pract. 2019 Jan;69(678):e24–32.
12. National Institute for Health and Care Excellence. Otovent nasal balloon for otitis media with effusion (NICE Medtech innovation briefing No. MIB59). NICE; 2016.
13. Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician. Adv Ther [Internet]. 2018;35(11):1763–74. Available from: https://doi.org/10.1007/s12325-018-0805-y
14. Baker SG. Rethinking historical controls. Biostatistics. 2001;2(4):383–96.
15. National Institute for Health and Care Excellence. Otitis media with effusion in under 12s: surgery (NICE Clinical Guideline No. CG60). NICE; 2008.
16. Columbia Public Health. Difference-in-Difference Estimation [Internet]. [cited 2020 Nov 30]. Available from: https://www.publichealth.columbia.edu/research/population-health-methods/difference-difference-estimation

17. Rosenfeld RM, Kay D. Natural history of untreated otitis media. Laryngoscope. 2003;113(10):1645–57.

18. Fraser JG, Mehta M, Fraser PA. The medical treatment of secretory otitis media. A clinical trial of three commonly used regimes. J Laryngol Otol [Internet]. 1977 Sep [cited 2017 Aug 22];91(9):757–65. Available from: http://www.ncbi.nlm.nih.gov/pubmed/335005

19. Lous J, Fiellau-nikolajsen M. Epidemiology of middle ear effusion and tubal dysfunction. A one-year prospective study comprising monthly tympanometry in 387 non-selected 7-year-old children. Int J Pediatr Otorhinolaryngol. 1981;3:303–17.

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Table 1 Participant characteristics and between group comparisons

Variable	Cohort A (n=513) M (SD)	Cohort B (n=463) M (SD)	Statistic	*p*	Effect size	95% CI
Sex	234F:279M	201F:262M	$\chi^2 = 0.48$	.490	1.12	-
Age at appointment 1 (years)	5.26 (1.49)	5.38 (1.71)	*t* =-1.31	.191	-0.08	[-0.32, 0.06]
Age at appointment 2 (years)	5.71 (1.53)	5.88 (1.70)	*t*=-1.56	.120	-0.10	[-0.37, 0.04]
Interval between appointments (months)	4.54 (1.95)	4.20 (2.03)	*t*=2.07	**.040**	0.13	[0.01, 0.52]
Right tympanometry type A:A_s:B:C	58:7:399:49	41:6:376:40	$\chi^2 = 3.62$	.306	1.36	-
Left tympanometry type A:A_s:B:C	62:7:397:47	35:8:375:45	$\chi^2 = 5.95$	.114	1.48	-
Right ear hearing thresholds						
500 Hz (dB HL)	27.39 (10.26)	29.02 (11.05)	*t*=-2.22	**.027**	-0.15	[-3.64, -0.13]
1000 Hz (dB HL)	25.27 (11.02)	27.09 (11.91)	*t* =-2.34	**.020**	-0.16	[-3.35, -0.29]
2000 Hz (dB HL)	17.09 (11.28)	18.97 (12.01)	*t* =-2.11	**.035**	-0.16	[-3.64, -0.13]
4000 Hz (dB HL)	23.51 (13.44)	25.99 (13.49)	*t* =-2.68	**.008**	-0.18	[-4.30, -0.66]
Left ear hearing thresholds						
500 Hz (dB HL)	26.37 (10.85)	28.47 (10.44)	*t* =-2.84	**.005**	-0.20	[-3.55, -0.65]
1000 Hz (dB HL)	25.17 (11.90)	26.79 (11.08)	*t* =-2.05	**.040**	-0.14	[-3.17, -0.07]
2000 Hz (dB HL)	17.77 (11.86)	18.74 (10.47)	*t* =-1.14	.255	-0.09	[-2.66, 0.70]
4000 Hz (dB HL)	24.41 (13.32)	25.54 (13.02)	*t* =-1.24	.214	-0.09	[-2.91, 0.65]

All comparisons on scale data were *t* tests. Group comparisons on sex and tympanometry type were done using chi-square tests (one-sided). Significant comparisons ($p < .05$) are shown in boldface. Effect size = Cohen's d for *t* tests, and odds ratio (OR) for chi-square tests. CI = confidence interval.

Table 2 Regression modelling for audiometry improvements over time

	Cohort A (n=513)	Cohort B (n=463)		
	Reduction in threshold over time (dB HL)	Reduction in threshold over time (dB HL)	Beta (SE)	*p*
Right ear hearing thresholds				
500 Hz	5.18	5.62	-0.7 (0.8)	.373
1000 Hz	5.67	6.05	-0.6 (0.8)	.484
2000 Hz	4.28	5.95	-1.9 (0.9)	**.032**
4000 Hz	6.05	7.42	-2.2 (0.9)	**.020**
Pure tone average	5.29	6.26	-0.9 (0.8)	.265
Left ear hearing thresholds				
500 Hz	4.72	5.18	-1.4 (0.7)	.053
1000 Hz	5.60	7.01	-1.0 (0.8)	.225
2000 Hz	4.99	5.54	-0.9 (0.9)	.275
4000 Hz	6.36	7.41	-1.4 (0.9)	.121
Pure tone average	5.42	6.28	-1.0 (0.8)	.180

SE = standard error. Significant comparisons ($p < .05$) are shown in boldface.

Table 3 Tympanometry resolution by cohort

Variable	Cohort A (n=513) n (%)	Cohort B (n=463) n (%)	DiD	OR (95% CI)	*p*
Right tympanic resolution	203 (51%)	187 (50%)	-2.2	0.81 (0.36-1.8)	.608
Left tympanic resolution	194 (49%)	164 (44%)	-5.2	0.95 (0.44-2.05)	.893

Tympanic resolution defined as change from type B to A, A_s or C. DiD = difference-in-difference analysis. OR = odds ratio.

Supplementary table A PTA missing data and between group comparisons

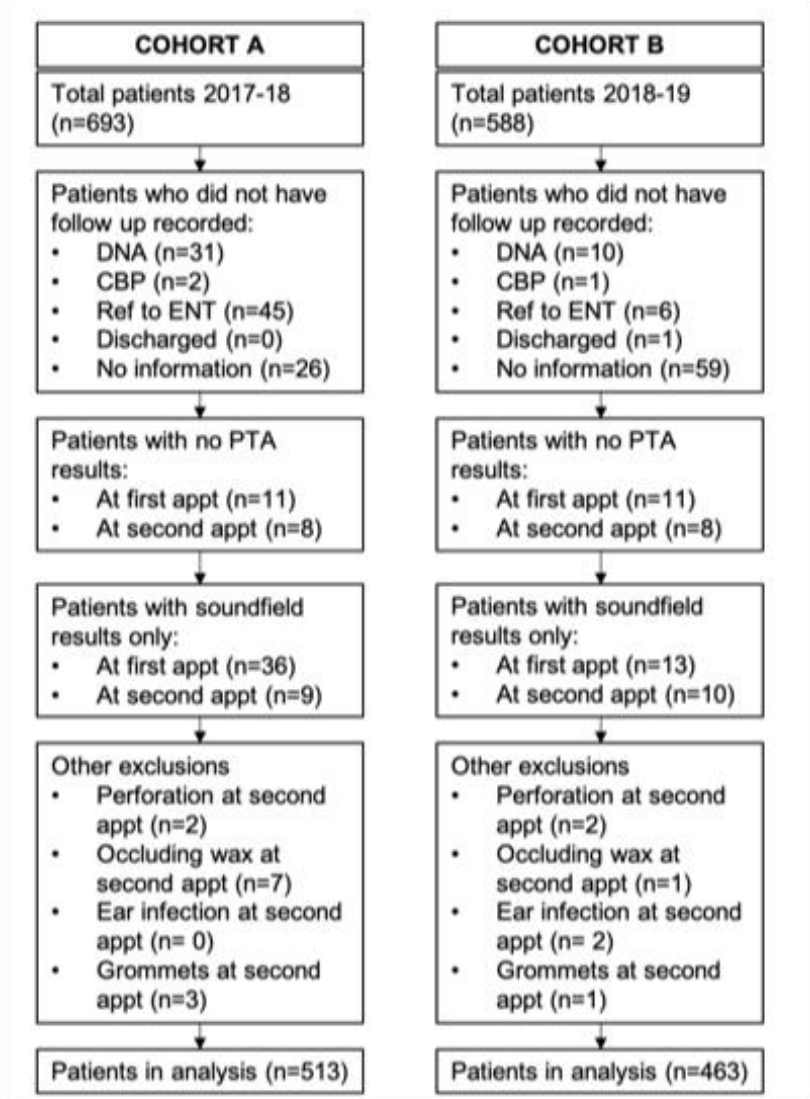
	Cohort A (n=513) n (%)	Cohort B (n=463) n (%)	χ^2	*p*
Appointment 1				
Right ear pure tone thresholds				
500 Hz	22 (4%)	28 (6%)	1.55	.213
1000 Hz	3 (0.6%)	1 (0.2%)	0.81	.368
2000 Hz	89 (17%)	102 (22%)	3.39	.066
4000 Hz	2 (0.4%)	4 (0.9%)	0.90	.344
Left ear pure tone thresholds				
500 Hz	25 (5%)	27 (6%)	0.44	.506
1000 Hz	5 (1%)	2 (0.4%)	1.01	.316
2000 Hz	92 (18%)	102 (22%)	2.56	.109
4000 Hz	3 (0.6%)	5 (1%)	0.73	.392
Appointment 2				
Right ear pure tone thresholds				
500 Hz	4 (0.8%)	17 (3.7%)	9.67	**.002**
1000 Hz	2 (0.4%)	0 (0%)	1.81	.179
2000 Hz	22 (4%)	46 (10%)	11.97	**<.001**
4000 Hz	0 (0%)	1 (0.2%)	1.11	.292
Left ear pure tone thresholds				
500 Hz	1 (0.2%)	10 (2%)	8.43	**.004**
1000 Hz	2 (0.4%)	0 (0%)	1.81	.179
2000 Hz	22 (4%)	47 (10%)	12.73	**<.001**
4000 Hz	1 (0.2%)	2 (0.4%)	0.45	.504

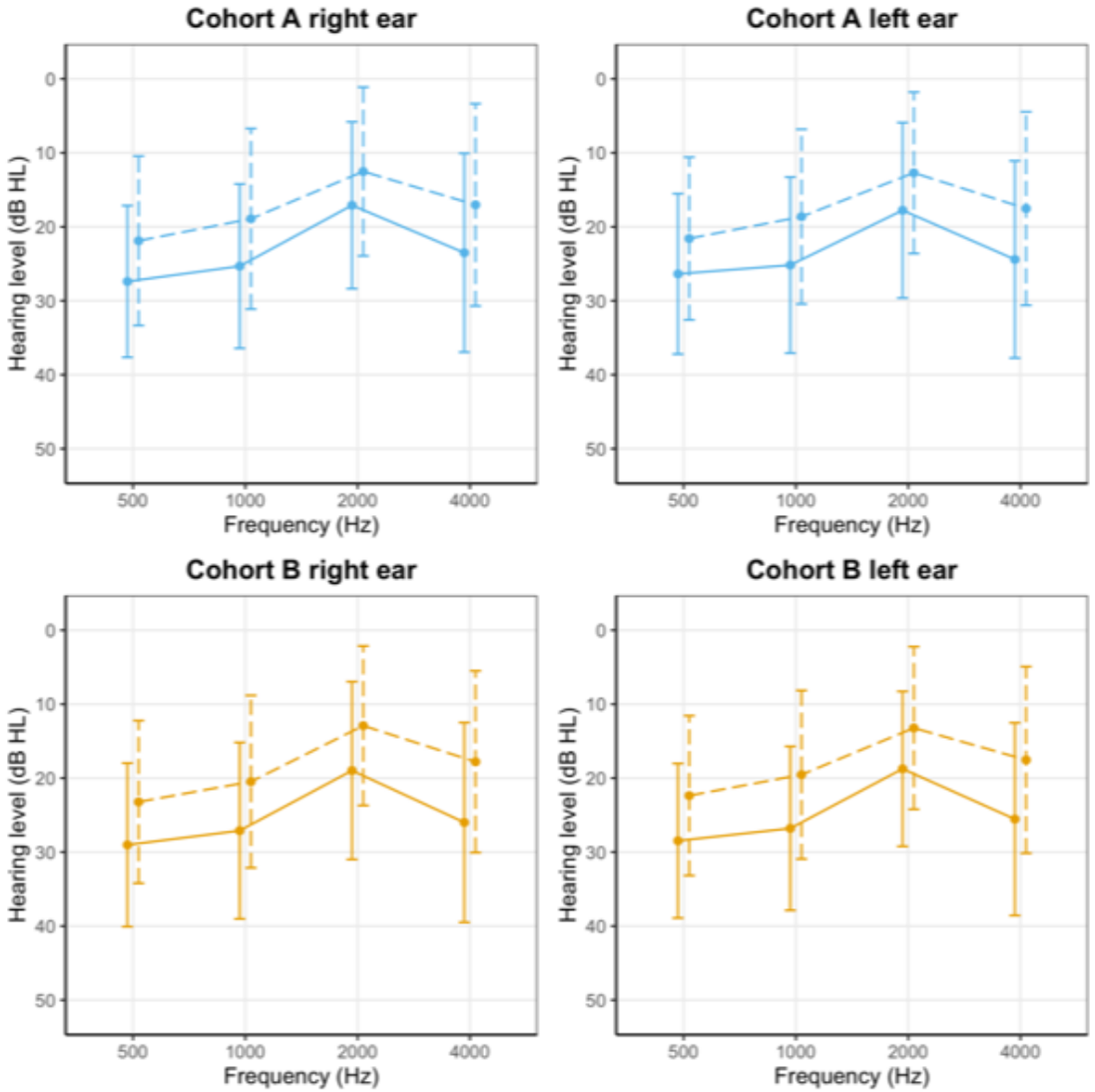
Group comparisons were done using chi-square tests (one-sided). Significant comparisons ($p < .05$) are shown in boldface.

Supplementary table B Regression modelling for pure tone audiometry improvements over time for Cohort B consistent use group

	Cohort A (n=513)	Cohort B consistent users (n=156)		
	Reduction in threshold over time (dB HL)	Reduction in threshold over time (dB HL)	Beta (SE)	*p*
Right ear pure tone thresholds				
500 Hz	5.18	5.48	-0.6 (1.1)	.574
1000 Hz	5.67	6.33	-0.6 (1.1)	.572
2000 Hz	4.28	5.28	-1.2 (1.3)	.356
4000 Hz	6.05	8.20	-2.7 (1.4)	**.045**
Pure tone average	5.29	6.77	-0.7 (1.1)	.521
Left ear pure tone thresholds				
500 Hz	4.72	6.03	-1.6 (0.9)	.069
1000 Hz	5.60	7.86	-2.1 (1.1)	.070
2000 Hz	4.99	6.19	-1.7 (1.2)	.174
4000 Hz	6.36	7.87	-1.8 (1.3)	.166
Pure tone average	5.42	7.30	-1.7 (1.1)	.124

SE = standard error. Significant comparisons ($p < .05$) are shown in boldface.


COHORT A
Total patients 2017-18 (n=693)
Patients who did not have follow up recorded:
• DNA (n=31)
• CBP (n=2)
• Ref to ENT (n=45)
• Discharged (n=0)
• No information (n=26)
Patients with no PTA results:
• At first appt (n=11)
• At second appt (n=8)
Patients with soundfield results only:
• At first appt (n=36)
• At second appt (n=9)
Other exclusions
• Perforation at second appt (n=2)
• Occluding wax at second appt (n=7)
• Ear infection at second appt (n= 0)
• Grommets at second appt (n=3)
Patients in analysis (n=513)
COHORT B
Total patients 2018-19 (n=588)
Patients who did not have follow up recorded:
• DNA (n=10)
• CBP (n=1)
• Ref to ENT (n=6)
• Discharged (n=1)
• No information (n=59)
Patients with no PTA results:
• At first appt (n=11)
• At second appt (n=8)
Patients with soundfield results only:
• At first appt (n=13)
• At second appt (n=10)
Other exclusions
• Perforation at second appt (n=2)
• Occluding wax at second appt (n=1)
• Ear infection at second appt (n= 2)
• Grommets at second appt (n=1)
Patients in analysis (n=463)


Cohort A right ear
Cohort A left ear
Cohort B right ear
Cohort B left ear
Hearing level (dB HL)
Frequency (Hz)
0
10
20
30
40
50
500
1000
2000
4000