Does the EarPopper® device improve hearing outcomes in children with persistent otitis media with effusion? A randomised single-blinded controlled trial

Banigo, A., Hunt, A., Rourke, T., Whiteside, O. & Aldren, C.

Heatherwood and Wexham Park Hospital, Slough, SL2 4HL, UK

Objective: To provide an independent evaluation of the efficacy and safety of the EarPopper® in improving hearing outcomes in children with otitis media with effusion (OME) and reducing the ventilation tube insertion rate.

Study Design: Randomised single-blinded controlled trial.

Setting: The Ear Nose and Throat Department of a district general hospital (Heatherwood and Wexham Park).

Participants and Methods: Twenty-nine children aged between 4 and 11 years diagnosed with persistent OME lasting at least 3 months with an average hearing of 25 dBHL or worse in the better ear were randomised to a treatment or control group for 7 weeks using random computer-generated codes. Syndromic children, children with developmental delay, previous grommets and cleft palate were excluded. The audiologists were blinded at the final post-treatment audiogram.

Results: After the seven-week period, the mean improvement in air conduction across all frequencies was 10.9 dBHL in the treatment group ($P < 0.001$) and 3.6 dBHL in the control group ($P = 0.201$). At every frequency, the treatment group had larger improvements in air conduction, the largest being at 4 kHz where the mean air conduction in both ears improved by 14.8 dBHL. Compliance with the EarPopper® was over 90%, the only side-effect reported being discomfort in the ears immediately after use which resolved and did not affect compliance. The ventilation tube insertion rate was 53.3% in the treatment group and 78.6% in the control group. Median follow-up time for all patients is 47.7 months.

Conclusion: Our study shows that the EarPopper® is a safe, effective treatment option for children with hearing loss from persistent OME, and it reduces the rate of ventilation tube insertion. More studies with larger sample sizes are required to support our findings.

In the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) advises initial active observation for children under 12 years old with persistent OME.[1] During this period of observation, autoinflation can be considered for children likely to co-operate. Following 3 months of observation, there are only two management options for children with bilateral OME and an average air conduction of 25 dBHL or worse in the better ear: surgical with ventilation tube insertion or non-surgical with hearing aids. The guidance also states that non-surgical intervention should only be offered when surgical intervention is contraindicated or deemed not acceptable. Hearing aids unfortunately still have a certain level of negative stigmata attached to them so understandably some parents/guardians are not willing to trial them.[2]

The aetiology of OME is complex with several factors thought to play a role in its genesis, one being poor ability to equalise negative pressure via the Eustachian tube.[3] However, it is not clear whether this impaired Eustachian tube function is a cause or an effect of OME. Regardless, the idea of improving the Eustachian tube function in a non-invasive manner via Valsalva or Politzer manoeuvres offers another potential treatment modality for OME. It is important to note that the Valsalva and Politzer manoeuvres have a small but key difference; the Valsalva manoeuvre is performed by an uncontrolled forceful attempt at expiration against a closed airway, whereas the Politzer manoeuvre is a controlled delivery of air into the nostril against a closed airway. The standardised controlled delivery of air provided by the Politzer manoeuvre makes it much more reliable and reproducible, and a preferred method for non-surgical intervention.

The Otovent® balloon is an autoinflation Valsalva device, and a review showed no significant changes in pure

Correspondence: A. Banigo, ENT Department, Heatherwood and Wexham Park Hospitals, Slough, SL2 4HL, UK. Tel.: +01753 633811; Fax: +01753633075; e-mail: a.banigo@doctors.org.uk

tone audiometry.[4] Furthermore, it is heavily user dependent and certainly we have found in our practice that younger children struggle to use it. On the other hand, Perera *et al.*'s[4] review showed a statistically significant effect of using a Politzer device for under 1 month (RRI 7.07, 95% CI 3.70–13.51) and over 1 month (RRI 2.25, 95% CI 1.67–3.04). One of the Politzer devices they looked at was the modified Politzer device, an older version of the EarPopper® designed by the same creators. We chose the EarPopper® (see Fig. 1) as it had been tested in a randomised controlled trial by its manufacturers, it was the only automated Politzer device available in the United Kingdom at the time of this trial and it appears to still be the only one available (based on a Web search 03 May 2014). It is an automated hand-held Politzer device that works by delivering a pulsed stream of air and on swallowing (with the other nostril closed) the stream of air is directed into the Eustachian tubes. There are two airflow settings (levels I and II) which represent a lower and higher airflow level, respectively. Sucking on a boiled sweet or drinking via a straw is sometimes needed to encourage young children to swallow whilst using the EarPopper®. One can normally tell a dose has been delivered from the reaction on the child's face with the sudden rush of air through the Eustachian tube, or the child may remark that their ear suddenly feels unblocked. Although some children may describe an uncomfortable feeling in the ears, this sensation usually eases within minutes. From our experience, most children report an immediate unblocked feeling and improvement in their hearing. The device is used twice a day, and on each occasion is used twice in each nostril. A

Fig. 1. EarPopper® device EP2100 version used in our trial.

seven-week treatment period is recommended by its manufacturers. It should not be used in the presence of an upper respiratory tract infection.

The EarPopper® device has been shown by its manufacturers to successfully treat OME, but with very short follow-up of 4 weeks and in one study, the device was administered by the author.[5,6] The aim of our study was to provide the first independent assessment of the EarPopper® in improving hearing outcomes in children with persistent OME.

Materials and methods

Study design

A single-centre randomised controlled trial was carried out in our institution between September 2008 and March 2013. Children were referred to the ENT department from their general practitioner with suspected OME. OME was diagnosed following history, otoscopic examination, pure tone audiogram and tympanometric assessments. After a 3-month period of observation, children with persistent OME were placed on the waiting list for ventilation tube insertion by an independent waiting list co-ordinator. Only children who had been listed for a date more than 7 weeks away (during busy operative times of the year) were entered into the trial following informed consent of their parents/guardians. This is to comply with the Declaration of Helsinki that the health of our patients is our first consideration, and we considered it unethical to delay the gold standard treatment for purposes of the trial.

At the point of entry into the trial, children were allocated to treatment or control groups using a randomly allocated computer-generated code. No other treatments were permitted in either group. The audiologists performing the final audiogram at 7 weeks were blinded to which group each child belonged to. The primary outcome measured is the difference between the baseline and seven-week air conduction thresholds for each group, and the data were analysed by an independent researcher using SPSS® software SPSS Inc. PASW Statistics for Windows, Chicago, Illinois, USA. Secondary outcomes include side-effects of the device, compliance with the device and rate of ventilation tube insertion in each group. Patients who still had hearing loss with audiograms meeting the NICE criteria after the seven-week period went ahead with planned ventilation tubes insertion. Patients who regained normal hearing were followed up in a three-month clinic and then discharged if their hearing remained normal. Longer follow-up of up to 4.8 years was carried out via telephone consultation and checking medical records to ascertain whether there was any further deterioration in hearing or consultations regarding this.
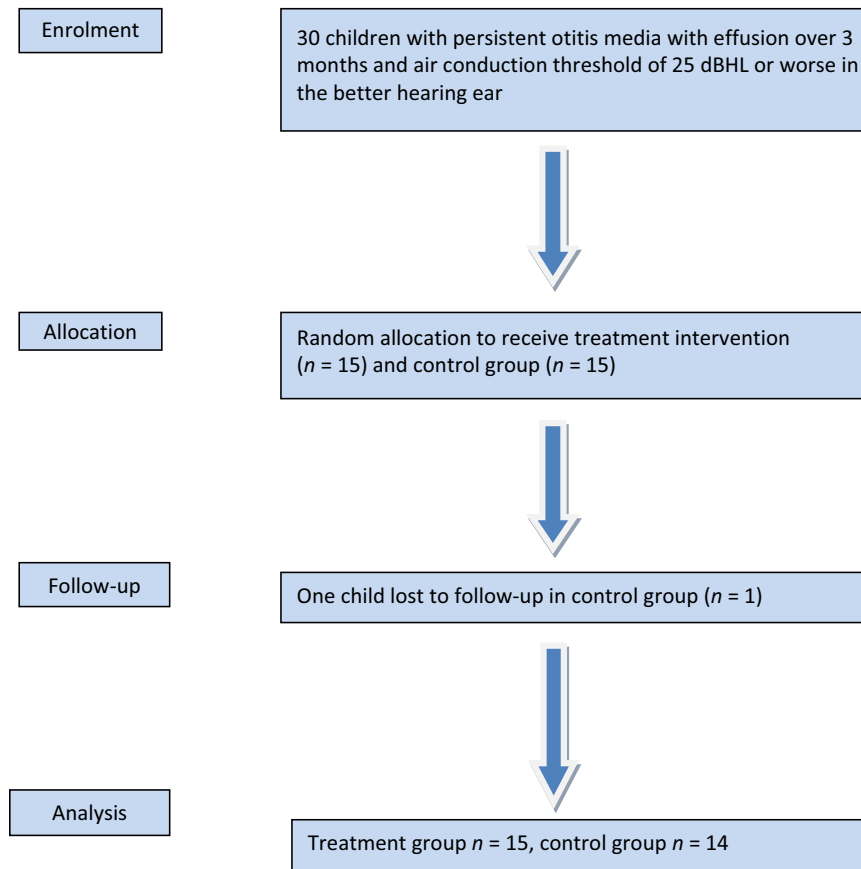
Enrolment	30 children with persistent otitis media with effusion over 3 months and air conduction threshold of 25 dBHL or worse in the better hearing ear
Allocation	Random allocation to receive treatment intervention (n = 15) and control group (n = 15)
Follow-up	One child lost to follow-up in control group (n = 1)
Analysis	Treatment group n = 15, control group n = 14

Fig. 2. CONSORT flow diagram.

Ethical considerations

Ethical approval was obtained from Berkshire Local Research Ethics Committee.

Inclusion and exclusion criteria

Children aged from 4 to 11 years with hearing loss from persistent OME over a three-month period and an average air conduction of 25 dBHL or worse in the better ear across 0.5, 1.0, 2.0 and 4.0 kHz were considered eligible for the trial. Children with developmental delay, previous grommets, cleft palate and congenital syndromes were excluded. All four frequencies were tested (if the child was compliant) by our blinded audiologists 7 weeks after treatment and recorded as the primary outcome.

Sample size

Based on the results of the New York study,[6] which reported 73.9% resolution in children with glue ear who had been allocated to 7 weeks of Politzer device usage compared with 26.7% of those in the control group, the study has been conservatively powered to detect a slightly smaller difference of 35% (70% *versus* 35%). A sample size of 30 patients per group would give 80% power at two-sided $P < 0.05$ to detect a difference of this magnitude, with a 95% confidence interval of 11–59%. To allow for loss to follow-up, 35 patients will be recruited per group.

Statistical analysis

Paired samples t-test was used to analyse the difference between the air conduction thresholds at week 0 and week 7. Significance level was considered achieved at $P < 0.05$.

Results

Thirty children satisfied the inclusion criteria and were recruited prospectively. Fifteen children were randomly allocated to the treatment group, and the remaining fifteen to the control group. One patient from the control group was lost to follow-up (see Fig 2). Audiometry results were available in all cases. Baseline characteristics for these children are shown in Table 1. Mean age in treatment and control groups is 5.94 years (range 4.36–8.19) and

Table 1. Mean baseline air conduction thresholds (dBHL)

	0.5 kHz	1.0 kHz	2.0 kHz	4.0 kHz
Control	38.6	36.5	32.1	37.3
Treatment	40.5	37.5	35.0	38.6

5.55 years (range 3.96–7.79), respectively. Male: female ratio was 8 : 7 in the treatment group and 8 : 6 in the control group. The treatment group received the device and were instructed to use it twice a day, and on each occasion to be used twice in each nostril as described from the manufacturers' manual. A diary card was kept to monitor compliance. We set the device to the lower air pressure setting (level I) as previous trials had shown some patients complaining of discomfort at the higher level II setting.[6]

Primary and secondary outcomes

Hearing outcomes. Children in the treatment group have statistically significant improvements in air conduction thresholds at all four tested frequencies, compared to the control group who had improvements in air conduction thresholds but not statistically significant (see Table 2, Fig. 3–6). The improvement in the treatment group was greatest at 4.0 kHz where the mean air conduction for both ears improved by 14.82 dBHL (95% CI 9.40–20.24 $P < 0.001$) compared to a 4.6 dBHL improvement in the control group (95% CI -0.71 to 9.94 $P = 0.086$). When each ear was analysed separately, again there were statistically significant improvements in the treatment group across all frequencies. None of the control group ears had a statistically significant improvement.

Ventilation tube insertion rate. Despite improvements in their hearing, 8 of the 15 (53.3%) treatment group children
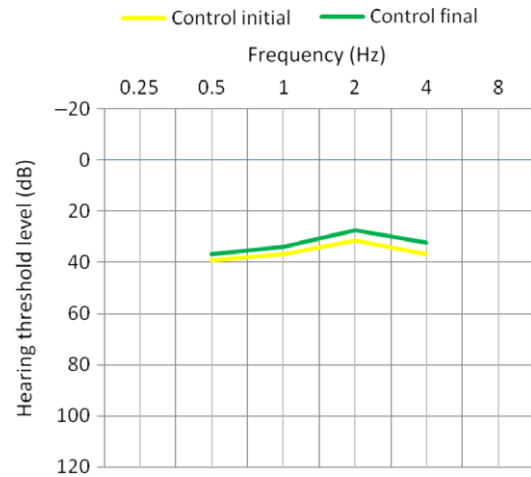
Fig. 3. Mean air conduction thresholds in Control group before and after treatment period.

still had hearing loss and met the criteria set by NICE (including history, otoscopic examination, tympanometry and audiometry findings) so they had ventilation tubes inserted. In the control group, 11 of 14 had ventilation tubes (78.6%, difference between groups P value $= 0.2451$ Fisher's exact test).

Side-effects and compliance. The most common complaint from the children in treatment group was ear discomfort and a blocked sensation in the ears immediately following its use, which was short-lived and did not affect compliance (94% on average). There was no report of an acute otitis media during EarPopper® use.

Long-term outcome. None of the successfully treated EarPopper® patients at 7 weeks subsequently required

Table 2. Results: Air conduction thresholds in both groups

| Freq kHz	Mean pre-treatment dBHL	Mean post-treatment dBHL	Difference	Standard deviation	95% Confidence interval	P-value
Controls						
0.5	39.0741	36.8519	2.22222	10.2219	−1.82143 to 6.26587	0.269
1.0	36.7857	33.7500	3.03571	14.80361	−2.70453 to 8.77595	0.287
2.0	31.6000	27.2000	4.40000	15.365	−1.94236 to 10.74236	0.165
4.0	36.7308	32.1154	4.61538	13.18507	−0.71018 to 9.94095	0.086
EarPopper®						
0.5	40.5172	32.2414	8.27586	13.11187	3.28837–13.26335	0.002
1.0	37.5000	28.5000	9.00000	9.68468	5.38368–12.61632	<0.001
2.0	34.6429	23.0357	11.60714	10.7198	7.45044–15.76385	<0.001
4.0	38.5714	23.7500	14.82143	13.97631	9.40198–20.24088	<0.001
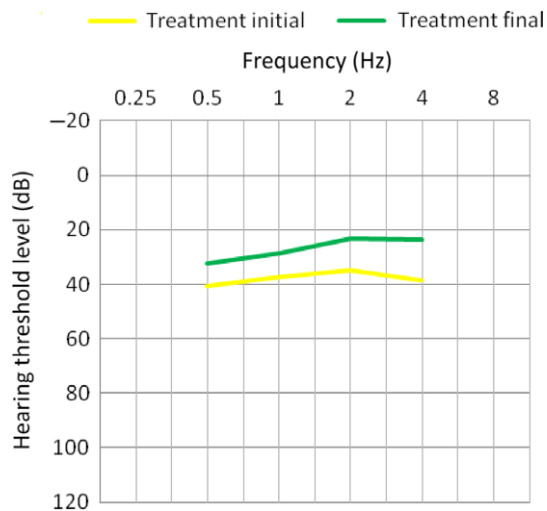
Fig. 4. Mean air conduction thresholds in EarPopper® group before and after treatment period.
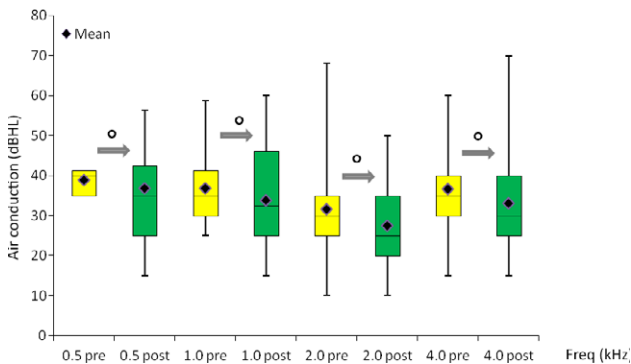

Fig. 5. Data above are for the control group patients pre-observation (yellow boxes) and post-observation (green boxes) using box and whisker plots. Symbol above arrow denotes significance level in the mean differences $*P < 0.05$ $^{\bigcirc}P > 0.05$.
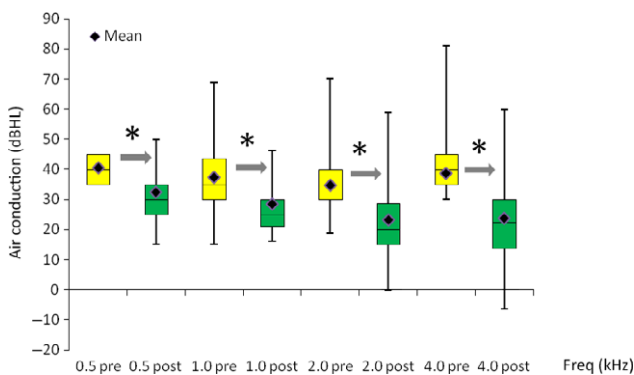

Fig 6. Data above are for the treatment group patients pre-treatment (yellow boxes) and post-treatment (green boxes) using box and whisker plots. Symbol above arrow denotes significance levels in mean differences $*P < 0.05$ $^{\bigcirc}P > 0.05$.

ventilation tubes; median follow-up time is 47.7 months (mean 34.2 months).

Discussion

Strengths of the study

The randomised blinded controlled trial design of this study reduces potential bias which may have been present in previous non-blinded studies using the EarPopper®. This study is the first of its kind using a Politzer device. The statistically significant results in the treatment group and the long follow-up period (median 47.7 months) add to the strength of this study.

Comparison with other studies

A review on ventilation tube insertion showed in one trial the hearing improvement was 12 dBHL, but its meta-analysis showed a benefit of only 4 dBHL;[7] this figure is 10.9 dBHL in our EarPopper® group of children.

Clinical applicability of the study

It is well known that some children with OME will undergo spontaneous resolution following a period of active observation.[8] This study is not aimed at comparing whether the EarPopper® is better than active observation and we do not at all suggest that active observation should be replaced. In fact, we completely agree with NICE guidelines on active observation for 3 months. Our study included a control group as part of a controlled trial design to support the evidence that the changes observed in the treatment group are unlikely to have occurred by chance. NICE guidelines state that autoinflation devices (e.g. Otovent®) can be used during this period of active observation, which suggests these devices are seen as adjuncts rather than definitive treatment. As discussed earlier, a review article has shown non-significant changes in hearing thresholds with the Otovent® balloon. Effective non-surgical interventions may be considered a suitable alternative to ventilation tubes after the period of observation, even when surgery is not contraindicated.

Whilst our study numbers are not large enough to necessarily advocate that every child with persistent OME be given an EarPopper® device, nonetheless with an overall mean improvement (across all four frequencies) of 10.9 dBHL the EarPopper® may be particularly suitable for children with an average hearing level of 30 dBHL in the better ear. We also accept that a small sample size increases the chances of detecting random differences between groups and we are cautious to reach any overarching

conclusions; however, the strength of our *P* values in the treatment group (0.002 and less) makes it very unlikely that the differences we detected were random. Furthermore, some parents/guardians may prefer to trial a non-surgical intervention, eliminating the anxiety some have towards a general anaesthetic.[2] It is noted that some of the treatment group patients still had hearing loss at the end of their treatment. The aim of our study was to independently assess whether the EarPopper® improves hearing outcomes, not the restoration to normal hearing. This study shows the level of improvement in air conduction thresholds that can be achieved with the EarPopper®, it is up to the clinician to decide whether this improvement is significant enough to restore normal or near-normal hearing and obviate the need for ventilation tube surgery.

The current retail price of the EarPopper® in the United Kingdom is £99.00 ($160.00).[9] Ventilation tube insertion costs on average £1358.00 in the United Kingdom ($2100);[10] 32 777 ventilation tubes were inserted in England between 2010 and 2011 which is a typical annual figure.[11] We would like to avoid drawing any conclusions about potential cost savings, but it is clear to see that if our results were maintained at a population level, then there is room for a sizeable reduction in the cost of managing OME, which is welcome news in the current climate of massive cost challenges faced by the NHS. Furthermore, we would not advocate that every child who has been placed on a waiting list for ventilation tubes should be given an EarPopper®. Instead, a select group of children with a 10–15 dbHL conductive loss are more likely to gain benefit from this device and they would be the appropriate target group.

Trial limitations

Even though our results are statistically significant, it would have been ideal to reach our calculated larger sample size. We had envisaged having larger numbers as the waiting lists for ventilation tube insertion in our department was longer when we registered the trial. As mentioned before, it would have been unethical to delay ventilation tube insertion for the purposes of this trial. When we commenced the trial, our waiting lists had dropped significantly which is certainly welcome news for patient care, but made patient recruitment difficult. In hindsight, a multicentre trial would have been a better study design. We looked into changing our single-centre status to multicentre, but unfortunately we were unable to secure approval for a single centre to be the sponsor for multiple centres. For these reasons, we would like our study to be considered as a pilot study and we hope that our study can lead on to a similar larger study including a younger population of children from a wider range of demographic backgrounds.

We could have checked regularly with parents/guardians of children in the treatment group during the seven-week study period to confirm the proper technique of use of the device was being adhered to. However, a daily log of compliance was documented by parents/guardians which showed high compliance rates. Furthermore, it was important that the device was used with minimal interference from the research co-ordinators, so the results would be applicable in non-test conditions.

Potential criticism could be directed towards our follow-up design. We did not perform repeat audiograms in the follow-up consultations after the seven-week post-treatment audiogram if there was no concern regarding the child's hearing. This is the case for both the treatment and control groups. The argument could be that there is no objective evidence to show that children in the treatment group who were successfully treated and did not require ventilation tube insertion (7 of 15) did not suffer a subsequent relapse in their hearing. However, it is our practice to only perform audiograms when clinically indicated. Tympanometry was performed on all patients at all visits, but we did not choose this as part of our secondary outcomes and did not analyse measurements pre- and post-treatment. We felt that although this is a useful outcome measure for the diagnosis of OME at the initial and 3 month visit, our aim in this pilot study was centred on hearing outcomes. However, this can be incorporated in future trials.

We concede that it would be ideal to trial the EarPopper® in children younger than 4 years of age and indeed in our experience this age group are less likely to be able to use self-ventilation devices like the Otovent® balloon so the EarPopper® would be particularly beneficial. In addition, grommet insertion in this age group can be more complex logistically as the protocol in some ENT units dictates that these patients have to be anaesthetised in a specialised paediatric unit, which may be farther away from the patient's home and involve more travelling and disruption to the parents/guardians. However, the EarPopper® is only licensed for use in children aged four and above and has only been used in this age group in experimental studies. There may be an ongoing study in children aged 2–4 years, and a modified device is being developed for children aged 6 months to 2 years.[12]

Conclusion

Our independent study demonstrates that the non-surgical EarPopper® is effective in improving hearing outcomes in children with otitis media with effusion and reducing the rate of ventilation tube insertion. More studies with larger sample sizes are required to support our findings.

Keypoints

- At every frequency, the treatment group had larger statistically significant improvements in air conduction thresholds.
- Compliance with the EarPopper® is 94%.
- The ventilation tube insertion rate is 53.3% in the treatment group compared to 78.6% in the control group.
- None of the successfully treated patients in the treatment group at 7 weeks subsequently required ventilation tubes.

Conflict of interest

None to declare.

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