International Journal of Pediatric Otorhinolaryngology xxx (2013) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

A new device for treatment of persistent otitis media with effusion

Armin Bidarian-Moniri [a,b,*], Maria-João Ramos [b], Ilídio Gonçalves [b], Hasse Ejnell [a]

[a] Department of Otorhinolaryngology, Sahlgrenska University Hospital Gothenburg, Sweden
[b] Department of Otorhinolaryngology, Centro Hospitalar Barlavento Algarvio Portimão, Portugal

ARTICLE INFO

Article history:
Received 2 August 2013
Accepted 7 October 2013
Available online xxx

Keywords:
Otitis media with effusion
Serous otitis media
Autoinflation
Non-invasive conservative treatment
Valsalva
Politzer

ABSTRACT

Objectives: Most children suffer from otitis media with effusion (OME) before starting school. Insertion of grommets into the eardrum for treatment of OME is one of the most common operations performed in childhood. The efficiency and compliance of treatment with a new non-invasive device was evaluated in children with bilateral OME with disease duration of at least 3 months.
Methods: A device for autoinflation was developed to enable a combined modified Valsalva and Politzer maneuver. Ten children, aged 3–8 years (mean: 5 years and 2 months) with OME tested the device for estimation of its ability to ventilate the middle ear. Another thirty-one children, with persistent bilateral OME for at least three months, were divided into a treatment and a control group. Twenty-one children (42 ears), aged 2–7 year (mean: 4 years and 6 months), participated as the treatment group and ten patients (20 ears), aged 3–7 years (mean: 4 years and 5 months), were included as controls. Tympanometry and otomicroscopy were performed at inclusion and at the end of the study.
Results: In the treatment group the middle ear pressure was normalized in 52% and improved in 31% of the ears with 7 children (33%) achieving bilateral and 8 (38%) unilateral normalization. In the control group the middle ear pressure was normalized in 15%, improved in 15% and deteriorated in 10% of the ears with one child (10%) achieving bilateral and one child (10%) unilateral normalization. Statistically significant differences ($p < 0.001$) were observed in the pressure difference and the tympanometry type changes between the treatment and the control group. Otomicroscopic examination revealed that the number of ears judged as OME was reduced by 62% in the treatment group in comparison with 20% in the control group. All children managed to perform the maneuver and no side effects were neither reported nor detected.
Conclusions: The device was efficient in ventilation of the middle ear with normalization or improvement of the negative middle ear pressure and otomicroscopic findings in young children with persistent OME.

1. Introduction

Otitis media with effusion (OME) is an inflammation with fluid in the middle ear often combined with impaired hearing [1]. The lack of acute symptoms in children with OME makes it difficult to estimate the accurate incidence, but most children have at least one episode of OME before starting school [2].

The recommended technique for diagnosing OME is impedance audiometry (tympanometry) in combination with otomicroscopy or pneumatic otoscopy [1,3–7].

The Eustachian tube plays an important role in maintaining the middle ear healthy [8,9]. The tube plays a ventilatory function equilibrating the pressure between the middle ear and the ambient air [9,10]. The Eustachian tube in young children is short, floppy, more horizontal and therefore functions poorly [9]. These anatomical considerations are believed to cause the high prevalence of OME in young individuals [9]. Maturation of the tube is a gradual process, which explains the infrequency of OME after the age of 7 years [11,12].

The active opening ability of the Eustachian tube for equilibration of the middle ear pressure is reduced in children with middle ear disease [13,14]. Earlier studies have emphasized great variability of the Eustachian tube function in children with OME with a mean forced opening pressure of approximately 30 ± 15 cm H_2O [15,16].

The insertion of grommets into the eardrum is one of the most common operations performed under general anesthesia in childhood. The primary indication for the operation is restoration of normal hearing in children with long-standing bilateral OME [1,7,17]. The rationale for the procedure is to improve ventilation

* Corresponding author at: Department of Otorhinolaryngology, Sahlgrenska University Hospital Gothenburg, Sweden. Tel.: +46 760 747 970/+351 916 468 983.
E-mail addresses: armin.bidarian@vgregion.se, armin.bidarian@yahoo.com (A. Bidarian-Moniri).

0165-5876/$ – see front matter © 2013 Elsevier Ireland Ltd. All rights reserved.
http://dx.doi.org/10.1016/j.ijporl.2013.10.009

and pressure regulation in the middle ear [17]. The procedure has been controversial for many years and opinions regarding the risks and benefits vary greatly [18–20].

Several non-invasive methods have been developed to improve the negative middle pressure in children with OME [13,21–25]. The aim of these procedures is to introduce air into the middle ear, through the Eustachian tube, in order to ventilate the middle ear and equilibrate the negative pressure [13,21–25]. The most common techniques involve modification of either the Valsalva maneuver or the Politzer method, i.e. autoinflation.

The Valsalva maneuver consists of performing forced nasal expiration with the nose and the lips sealed [26]. The Politzer method of inflation involves inserting the tip of a rubber air bulb into one nostril, while sealing the other nostril the rubber bulb is squeezed while the patient swallows causing tubal opening [23].

The results in previous studies using non-invasive methods are suggestive of improvement of disease in some patients [23–25,27]. Nevertheless the previous methods have experienced limited use in clinical practice mainly due to unsatisfactory compliance [25,27]. No studies on testing a combined Valsalva and Politzer maneuver treating children with OME have been published.

The aims of the present study were to develop a non-invasive device, which enables a combined modified Valsalva and Politzer maneuver in young children with persistent OME, to estimate its ability to ventilate the middle ear and to evaluate the treatment efficiency and compliance of the device in children with persistent OME.

2. Methods

2.1. The new device

A device (Fig. 1) for non-invasive treatment of children with persistent OME was developed. The device consisted of (1) an inflatable facemask, (2) a T-shaped junction tube connecting at one end to the facemask, (3) another to a balloon, and (4) the third end to a handheld pump. The pump was covered by (5) a teddy bear in order to improve compliance in young children.

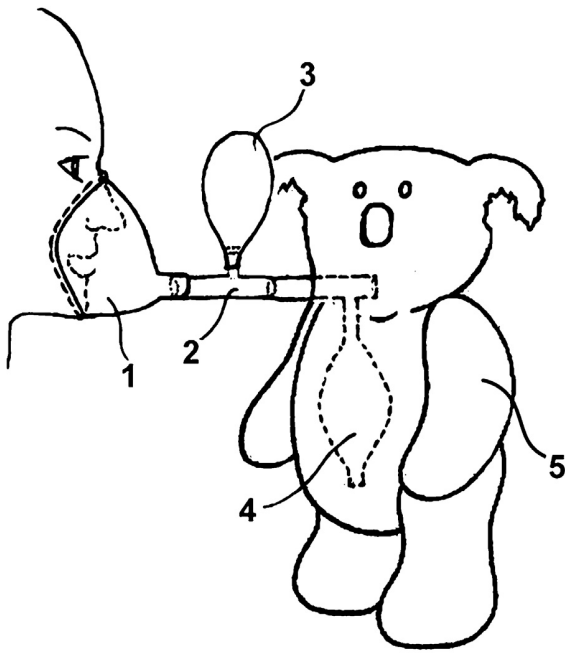

Fig. 1. The device for non-invasive treatment of OME in children consisting of (1) facemask, (2) T-shaped junction tube, (3) balloon, (4) pump and (5) teddy bear.

The inflatable facemask was used to cover the nose and the mouth of the child with individual adaptation in size. The parent helped the child to adapt the facemask in order to avoid air leakage during the maneuver.

The balloon was provided for regulation of the pressure and visual feed back of correct maneuver to the child and the parent. The balloon functioned also as an air reservoir producing a counter-pressure during a few seconds. Three different balloons with the respective opening pressures of 20 ± 3, 40 ± 2 and 60 ± 5 cm H_2O were used. The balloon opening pressure was verified by an anesthetic machine (Datex Ohmeda S5 ADU) with pressure monitoring and ventilation function used at the operating theater. To eliminate the initial high opening pressure of the balloon, 5 insufflations were done before the measurement of the opening pressure of each balloon. The quality of the balloons chosen for the purpose of the study provided a mean opening pressure that was substantially preserved during approximately 50 inflations.

The handheld pump with a total volume of 250 ml was incorporated in the device. The pump was covered with a teddy bear and was used to produce a modified and controlled Politzer effect in order to facilitate the inflation of the balloon whenever necessary. To control the pressure produced by the handheld pump, a security valve of 40 cm H_2O was installed in the system. The child would be able to blow up balloons with different opening pressures ($\leq 60 \pm 5$ cm H_2O) via the facemask but any pressure exceeding 40 cm H_2O produced from the pump would activate the security valve.

2.2. Ventilation ability of the device

In order to estimate the ability of the device to ventilate the middle ear, ten children, aged 3–6 years from the outpatient clinic, followed up due to OME with tympanogram type C2 or B, were studied. Tympanometry and otomicroscopy were performed at inclusion. Three previously tested balloons with respective opening pressures of 20, 40 and 60 cm H_2O were used. Each child started with the balloon with the lowest opening pressure and changed gradually to a balloon with higher opening pressure until the child experienced a crackling sound in at least one ear. The child had then to specify in which ear the crackle was heard. Further confirmation of middle ear ventilation was achieved by otomicroscopy evaluating alterations in the position of the tympanic membrane (retracted or extended) and existence of gas bubbles and/or liquid in the middle ear before and after the maneuver. After 20 min of treatment the experiment was finalized and otomicroscopy and tympanometry were repeated.

2.3. Efficiency and compliance

For evaluation of the efficiency and compliance of the device for middle ear ventilation, a total of 45 families with children between the age of 2 and 7 years with persistent bilateral OME for at least 3 months, in waiting list for surgery with myringotomy and insertion of grommets, were invited.

Children with confirmed asthma, heart failure, craniofacial anomaly, active otologic disease such as otorrhea and deep retraction pockets, chronic perforation of the tympanic membrane or any other severe underlying systemic disease were not included in this study.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

In both groups, the entry into the study was from January 2009 to June 2010. Any case of upper airway disease during the study time was registered.

The parents and the children were instructed in how to use the device. The parents were equipped with the device, sufficient number of balloons with different opening pressures and a syringe to inflate the facemask whenever necessary. A written instruction manual and a diary (attachments 1 and 2) were provided for control of compliance, efficiency, side effects and other diseases during the course of treatment. Full compliance was defined as using the device two times a day to perform 20 insufflations at each session (approximately 5–10 min).

In order to eliminate the initial high opening pressure of each new balloon, the parents performed five inflations before starting the treatment. The balloon with the lowest pressure was initially used to help the child get familiar with the device. Within the first week of treatment the balloon was changed to another balloon with the opening pressure $\geq$40 cm H_2O. Middle ear ventilation was considered to have taken place if the child referred symptoms such as mild transient discomfort, sensation of air, water, alteration in hearing or a crackling sound in one or both ears. The final balloon type chosen for treatment was determined when the child referred one or several of the above mentioned symptoms. The children were followed up weekly by a doctor or nurse. If no normalization was observed after 2 weeks, the child continued the treatment for another 2 weeks but not longer than 4 weeks.

2.4. Measurements

Clinical ear, nose and throat examination including otomicroscopy was carried out by one examiner at inclusion and at the end of the study. With otomicroscopy the position of the tympanic membrane and presence of liquid or gas bubbles in the middle ear were compared before and after the treatment.

The tympanometric equipment used in the study was Grason-Stadler (GSI 33, Version 2 Middle-Ear Analyzer) with a probe frequency of 226 Hz. The tympanometry results with this equipment were considered pathologic, i.e. representing OME, in type B tympanograms with a flat curve with a relative gradient less than 0.1 or with middle ear pressure ≤ -400 daPa. In the present study type B tympanograms were registered as -400 daPa in middle ear pressure. In addition type C2 tympanograms with a middle ear pressure between -399 and -200 daPa were also considered pathologic [4,5]. Type A and C1 tympanograms with a middle ear pressure between -199 and +100 daPa were not considered to represent OME. Tympanometric measurements were achieved at inclusion and at the end of the study. Improvement (but not normalization) in the tympanometric findings was defined as the number of ears converting from type B to C2 tympanogram. Normalization was defined as conversion from type B or C2 to C1 or A tympanogram. Children with tympanometric normalization or improvement were defined as responders and children with no change or deterioration were defined as non-responders.

2.5. Statistical analysis

All the analyses were performed according to the intention to treat principle. Differences in the mean pressure difference before and after treatment or follow-up in each group, were tested with the Student *t*-test for independent groups. The tympanometry type change in the groups from B to C2, C1 or A and from C2 to C1 or A was tested with the Wilcoxon rank sum test.

Table 1
Estimation of ventilation of the middle ear with the new device using three different balloons with respective opening pressures of 20, 40 and 60 cm H_2O. The child' reaction, otomicroscopic alterations and tympanometry type change (B to C2/C1/A or C2 to C1/A) in at least one ear was registered at different pressures.

Child nr.	Child' reaction at pressure (cm H_2O)	Otomicroscopy change at pressure (cm H_2O)	Tympanometry change at pressure (cm H_2O)
1	40	40	40
2	40	-	40
3	40	-	-
4	40	40	-
5	-	60	60
6	60	60	60
7	60	60	60
8	40	40	40
9	20	20	20
10	-	-	-

"-" Stands for no observed changes in otomicroscopy, tympanometry or lack of reaction from the child.

2.6. Ethics

The study was approved by the Medical Ethics Committee at the Sahlgrenska University Hospital, Gothenburg, Sweden. All parents gave their written informed consent.

3. Results

3.1. Ventilation ability of the device

A reaction was noticed in 8 of 10 children; 6 with balloons with the opening pressures $\leq$40 cm H_2O and 2 with balloons with opening pressure = 60 cm H_2O. In 7 of 10 children otomicroscopic findings suggested middle ear ventilation in at least one of the ears; 4 with balloons with the opening pressures $\leq$40 cm H_2O and in 3 with balloons with opening pressure = 60 cm H_2O. Tympanometric type change (B to C2/C1/A or C2 to C1/A) was observed in 7 of 10 children; 4 with balloons with opening pressure $\leq$40 cm H_2O and 3 with the balloons with opening pressure = 60 cm H_2O. In one child neither crackle nor changes in otomicroscopy nor tympanometry were observed. Thus in 9 of 10 patients at least one of the observed parameters indicated middle ear ventilation with the new device using a balloon with the opening pressure $\leq$60 cm H_2O. The results are summarized in Table 1.

3.2. Efficiency and compliance of the device

Eight of the 45 included children were excluded due to normalization in at least one of the ears. Twenty-three children were included as the treatment group and 14 children as the control group. Within the first week after inclusion 3 children from the treatment group and 4 children from the control group were excluded due to surgery with grommets. The inclusion procedure is summarized in Fig. 2.

The efficiency of treatment with the device was evaluated by tympanometry and otomicroscopy. The treatment group consisted of 21 children (42 ears) with tympanogram type C2 (7 ears, 17%) and B (35 ears, 83%), aged between 2 and 7 years (mean 54 months, min. 20, max. 89). The control group consisted of 10 children (20 ears) aged between 3 and 7 years (mean 53 months, min. 35, max. 87) with bilateral OME with tympanogram type C2 (3 ears, 15%) or B (17 ears, 85%).

In the treatment group the tympanometric results indicated normalization in 22 ears (52%) and improvement in 13 ears (31%). Seven ears (17%) remained unchanged and no deterioration was

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

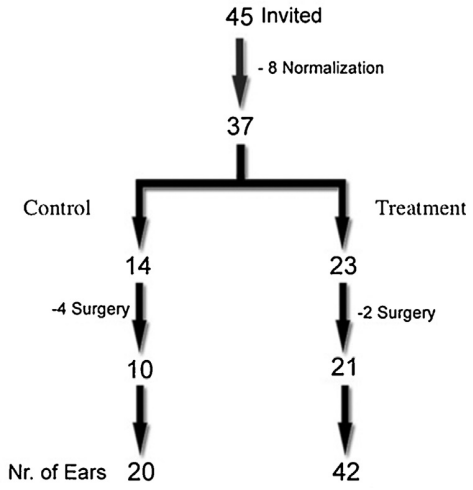

Fig. 2. Inclusion procedure.

Table 2
Tympanometry results of ears and children in the treatment and the control group at inclusion and end of the study.

		Treatment	Control	
Inclusion	Nr. of ears (%)	B	35 (83)	17 (85)
		C2	7 (17)	3 (15)
		C1/A	0	0
	Nr. of children (%)	Bilat. B	15 (71)	7 (70)
		Unilat. B	5 (24)	3 (30)
		Bilat. C2	1(5)	0
		Unilat. C2	5 (24)	3 (30)
		Bilat. C1/A	0	0
		Unilat. C1/A	0	0
End	Nr. of ears (%)	B	5 (12)	14 (70)
		C2	15 (36)	3 (15)
		C1/A	22 (52)	3 (15)
	Nr. of children (%)	Bilat. B	1 (5)	7 (70)
		Unilat. B	3 (14)	0
		Bilat. C2	3 (14)	1 (10)
		Unilat. C2	8 (38)	1 (10)
		Bilat. C1/A	7 (33)	1 (10)
		Unilat. C1/A	8 (38)	1 (10)

observed. In the control group, normalization was seen in 3 ears (15%) and improvement in another 3 ears (15%). 12 ears (60%) remained unchanged and 2 ears (10%) deteriorated during the follow-up time (Fig. 3).

In the treatment group 7 children (33%) achieved bilateral and 8 children (38%) unilateral normalization of the tympanogram type (C1/A) in comparison with one child (10%) with bilateral and another child (10%) with unilateral normalization in the control group. In the treatment group, the number of children with bilateral type B tympanogram was reduced from 15 (71%) to 1 (5%) in comparison with an unchanged result of 7 (70%) in the control group, due to normalization in two ears and deterioration in another two. The registered tympanogram types at inclusion and at the end of the study are presented in Table 2.

In the treatment group the tympanometry results indicated a reduction of the mean middle ear pressure from −385 to −179 cm daPa. In the control group mean middle ear pressure was altered from −376 to −337 daPa. Student paired *t*-test revealed a significant change in the pressure difference between treatment versus control group ($p < 0.001$).

83% of the ears in the treatment group were considered to be responders whilst 30% in the control group achieved spontaneous regression and 15% deterioration during the follow-up time. Statistical analysis with the Wilcoxon rank sum test showed significant improvement in the treatment group compared with the control group ($p < 0.001$).

In the treatment group the number of ears judged as OME by otomicroscopy was reduced from 42 (100%) at inclusion to 16 (38%) after treatment. In the control group the number of ears with OME were reduced from 20 (100%) at inclusion to 16 (80%) at end of the study.

All children from the age of 2 years were able to use the device after instruction. Two children (10%) in the treatment group did not fulfill complete compliance, which was defined by using the device two times per day performing 20 insufflations each time during 2–4 weeks. The parents reported "lack of time" to perform the treatment in the morning as the principal reason for reduction in compliance. In general the children considered the device an amusing toy and in fact many were not willing to return the device after completed treatment. No complications were reported during the study. No new upper airway disease was reported during the study time in neither the treatment nor the control group.

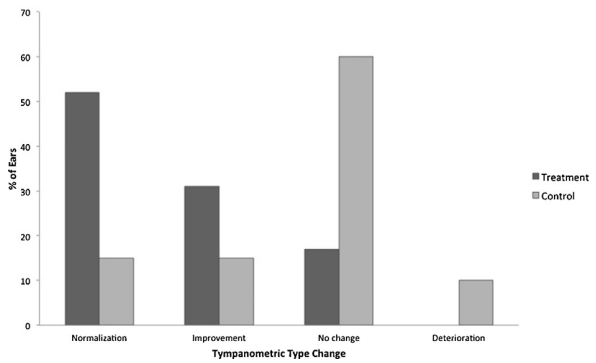

Fig. 3. Tympanometric type change in the treatment and the control group at the end of the study. Normalization stands for alteration from B/C2 to C1/A and improvement alteration from B to C2.

4. Discussion

In the present study a device was developed to enable a combination of the Politzer and the Valsalva maneuvers. The pump produced a modified Politzer maneuver in order to improve middle ear ventilation. However, within the first day of treatment most children were able to use the device to inflate balloons without the pump, i.e. modified Valsalva. The balloon functioned as pressure regulator, reservoir to maintain the high pressure and provided visual feedback. The installed security valve was activated when hazardously high pressures were produced by the pump. Covering the pump with a teddy bear most probably improved compliance.

The Eustachian tube in young children has reduced ventilatory function compared to older children [11,12,28]. Earlier studies have shown a mean forced opening pressure of 30 ± 15 cm H_2O in children with OME [15,16]. In the present study, some children achieved middle ear ventilation at higher opening pressure of the balloons. This observation might be explained by the fact that the children included were younger and the method used to measure the opening pressure was less accurate. The primary purpose of this part of the study was to find balloons with different opening pressures suitable for the device and not to measure the exact opening pressure of the Eustachian tube.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

Evidence for the use of autoinflation in the treatment of OME in children is conflicting [22]. One of the most recognized methods for autoinflation is with the Otovent device [25]. Compliance has been a problem with this device in young children [27]. In the present study, satisfactory compliance and bilateral normalization in tympanometry was achieved in 7 children (33%) with a mean age of 49 months (min: 20, max: 89) and unilateral normalization in 8 children (38%) with a mean age of 54 months (min: 35, max: 79). No complication was reported during the study time.

Using the Otovent device, Stangerup et al. showed a higher efficiency in children with type C2 tympanogram compared with B tympanogram [25]. In the present study 35 of 42 ears (83%) had tympanogram type B and 7 ears (17%) type C2 at inclusion. Of the 35 ears with tympanogram type B, 17 ears (49%) were normalized (C1/A) and 13 (37%) were improved (C2). Five of the 7 ears with tympanogram type C2 at inclusion were normalized. In the treatment group seven of the ears remained unchanged; five ears with B tympanogram and 2 ears with C2 tympanogram at inclusion. Thus 86% of the children with type B tympanogram at inclusion achieved either improvement or normalization of the middle ear pressure with the new device.

In the present study the tympanometric results were used as the main objective out-come of the study and otomicroscopy as supplementary diagnostic method. The observed discrepancy between the tympanometric and otomicroscopic findings may reflect the acknowledged difference in sensitivity and specificity of these methods [6].

5. Conclusions

Treatment with the present device is suggestive of clinical effect and satisfactory compliance in young children with persistent OME with no report of complications. Considering the high spontaneous resolution of OME [1,5] and the numerous contributing factors to the development of this disease [29], it is imperative to follow a larger number of children over a longer time in future studies.

Conflict of interest

The corresponding author of the present article (ABM) is the patent holder of *Device for equalization of the pressure in the middle ear*.

Acknowledgements

This work was financially supported by grants from the Rune and Ulla Amlöv Foundation for Neurological, Rheumatology, and Audiological Research. The sponsor had no role what so ever in the study design, in the collection, analysis and interpretation of data, neither in the writing of the manuscript nor in the decision to submit the manuscript for publication.

Appendix A

See Figs. A1 and A2.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

Manual

Your child has been diagnosed with otitis media with effusion. This device might help your child improve her/his condition reducing the hearing disability. For successful treatment please pay attention to the following instructions.

To get started

1. **Inflate** each **balloon 5 times before** starting the **treatment** on your child

2. **Adapt the facemask** to your **child's face covering both nose and mouth.**

3. Your **child inflates the balloon** while you help holding the **facemask tight**.

4. Whenever needed, **assist** your child by squeezing the teddy's belly to **pump air.**

5. When the procedure is done correctly the **balloon** will **inflate**.

Important aspects

Avoid air leakage around the **facemask**.

To adjust the **air** in the **facemask** use the **syringe** provided.

Start with the **balloon** marked **20.** Within the **first week** of treatment **change to** a more resistant **balloon**.

Confirm the **effect** by asking your child, whether he/she hears a **crackling sound** when blowing the balloon and in **which ear**.

It is necessary to blow at least **20 balloons** in each session and **two times a day** for **2-4 weeks**.

In the **beginning** when the air enters into the ears the child might experience some **discomfort**.

In the case of **infections or any other discomfort,** stop the treatment and restart it again after **consulting** your **doctor.**

In case of **allergy or nasal blockage, consult** your **doctor** for treatment of these conditions first.

Fig. A1. Manual to ensure correct performance of maneuver.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

Diary

NAME: **DATE:**

A. How many times did your child use the device?

B. How many times did your child inflate the balloon(s)?

C. Do you notice any difference in your child´s hearing? **B**etter/**S**ame/**W**orse

D. Has your child experienced any discomfort? If so please specify.

E. Has your child suffered from any diseases during this treatment? If so please specify the disease and the eventual treatment.

If you need any more space please use the backside of this sheet.

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day10	Day 11	Day 12	Day 13	Day 14
A														
B														
C														
D														
E														

	Day 5	Day16	Day 17	Day18	Day19	Day20	Day21	Day22	Day23	Day 24	Day 25	Day 26	Day 27	Day 28
A														
B														
C														
D														
E														

Thank you for your collaboration!

Fig. A2. Diary for control of compliance, complications and other disease during the course of treatment.

Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijporl.2013.10.009.

References

[1] S. Hellstrom, A. Pettersson, Tympanostomy tube treatment in otitis media. A systematic literature review. SBU summary and conclusions, Lakartidningen 105 (July–August (30–31)) (2008) 2104–2106.
[2] G.A. Zielhuis, G.H. Rach, P. Van den Broek, The occurrence of otitis media with effusion in Dutch pre-school children, Clin. Otolaryngol. Allied Sci. 15 (April (2)) (1990) 147–153.
[3] C.D. Bluestone, Otitis Media in Infants and Children, WB Saunders Company, Philadelphia, 1988.
[4] J. Jerger, Clinical experience with impedance audiometry, Arch. Otolaryngol. 92 (October (4)) (1970) 311–324.
[5] G.A. Zielhuis, G.H. Rach, P. van den Broek, Screening for otitis media with effusion in preschool children, Lancet 1 (February (8633)) (1989) 311–314.
[6] D.J. Rogers, M.E. Boseley, M.T. Adams, R.L. Makowski, M.H. Hohman, Prospective comparison of handheld pneumatic otoscopy, binocular microscopy, and tympanometry in identifying middle ear effusions in children, Int. J. Pediatr. Otorhinolaryngol. 74 (October (10)) (2010) 1140–1143.
[7] Otitis media with effusion, Pediatrics 113 (May (5)) (2004) 1412–1429.
[8] D.J. Lim, Y.M. Chun, H.Y. Lee, S.K. Moon, K.H. Chang, J.D. Li, et al., Cell biology of tubotympanum in relation to pathogenesis of otitis media – a review, Vaccine 19 (December (Suppl. 1)) (2000) S17–S25.
[9] C.D. Bluestone, Eustachian tube function and dysfunction, in: R.M. Rosenfeld, C.D. Bluestone (Eds.), Evidence-Based Otitis Media, B C Decker, Hamilton, ON/London, 1999, pp. 137–156.
[10] C.D. Bluestone, Evidence-Based Otitis Media, BC Decker, Hamilton, ON, 1999.
[11] T. Chonmaitree, Viral and bacterial interaction in acute otitis media, Pediatr. Infect. Dis. J. 19 (May (Suppl. 5)) (2000) S24–S30.
[12] B. Winther, F.G. Hayden, E. Arruda, R. Dutkowski, P. Ward, J.O. Hendley, Viral respiratory infection in schoolchildren: effects on middle ear pressure, Pediatrics 109 (May (5)) (2002) 826–832.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009

[13] E.I. Cantekin, C.D. Bluestone, L.P. Parkin, Eustachian tube ventilatory function in children, Ann. Otol. Rhinol. Laryngol. 85 (March–April (2 Suppl. 25 Pt 2)) (1976) 171–177.
[14] G. Poulsen, M. Tos, Tubal function in chronic secretory otitis media in children, ORL J. Otorhinolaryngol. Relat. Spec. 39 (2) (1977) 57–67.
[15] E.M. Mandel, J.D. Swarts, M.L. Casselbrant, K.K. Tekely, B.C. Richert, J.T. Seroky, et al., Eustachian tube function as a predictor of the recurrence of middle ear effusion in children, Laryngoscope (April) (2013) 2285–2290.
[16] M. Bunne, B. Falk, S. Hellstrom, B. Magnuson, Variability of Eustachian tube function in children with secretory otitis media. Evaluations at tube insertion and at follow-up, Int. J. Pediatr. Otorhinolaryngol. 52 (April (2)) (2000) 131–141.
[17] J. Lous, M.J. Burton, J.U. Felding, T. Ovesen, M.M. Rovers, I. Williamson, Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children, Cochrane Database Syst. Rev. 1 (2005) CD001801.
[18] C.D. Bluestone, J.O. Klein, G.A. Gates, 'Appropriateness' of tympanostomy tubes. Setting the record straight, Arch. Otolaryngol. Head Neck Surg. 120 (October (10)) (1994) 1051–1053.
[19] C.D. Bluestone, G.A. Gates, J.L. Paradise, S.E. Stool, Controversy over tubes and adenoidectomy, Pediatr. Infect. Dis. J. 7 (November (Suppl. 11)) (1988) S146–S149.
[20] G.G. Browning, M.M. Rovers, I. Williamson, J. Lous, M.J. Burton, Grommets (ventilation tubes) for hearing loss associated with otitis media with effusion in children, Cochrane Database Syst. Rev. (10) (2010) CD001801.
[21] R. Hunt-Williams, A method for maintaining middle-ear ventilation in children, J. Laryngol. Otol. 82 (October (10)) (1968) 921–926.
[22] D.D. Reidpath, P.P. Glasziou, C. Del Mar, Systematic review of autoinflation for treatment of glue ear in children, Br. Med. J. 318 (May (7192)) (1999) 1177.
[23] D.M. Schwartz, R.H. Schwartz, N.P. Redfield, Treatment of negative middle ear pressure and serous otitis media with Politzer's technique. An old procedure revisited, Arch. Otolaryngol. 104 (September (9)) (1978) 487–490.
[24] J.J. Shea, Autoinflation treatment of serous otitis media in children, J. Laryngol. Otol. 85 (December (12)) (1971) 1254–1258.
[25] S.E. Stangerup, J. Sederberg-Olsen, V. Balle, Autoinflation as a treatment of secretory otitis media. A randomized controlled study, Arch. Otolaryngol. Head Neck Surg. 118 (February (2)) (1992) 149–152.
[26] R. Perera, J. Haynes, P. Glasziou, C.J. Heneghan, Autoinflation for hearing loss associated with otitis media with effusion, Cochrane Database Syst. Rev. (4) (2006) CD006285.
[27] J.D. Blanshard, A.R. Maw, R. Bawden, Conservative treatment of otitis media with effusion by autoinflation of the middle ear, Clin. Otolaryngol. Allied Sci. 18 (June (3)) (1993) 188–192.
[28] A. Tasker, P.W. Dettmar, M. Panetti, J.A. Koufman, J.P. Birchall, J.P. Pearson, Reflux of gastric juice and glue ear in children, Lancet 359 (February (9305)) (2002) 493.
[29] M.M. Rovers, A.G. Schilder, G.A. Zielhuis, R.M. Rosenfeld, Otitis media, Lancet 363 (February (9407)) (2004) 465–473.

Please cite this article in press as: A. Bidarian-Moniri, et al., A new device for treatment of persistent otitis media with effusion, Int. J. Pediatr. Otorhinolaryngol. (2013), http://dx.doi.org/10.1016/j.ijporl.2013.10.009