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Autoinflation for treatment of persistent otitis media with effusion in children: A cross-over study with a 12-month follow-up

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ABSTRACT

Objectives: The aims of the present study were to evaluate the efficacy of and compliance with a new device for autoinflation in the treatment of persistent otitis media with effusion (OME) in young children.
Methods: Forty-five children with persistent OME with a bilateral type B or C2 tympanogram for at least three months and history of subjective hearing loss, waiting for grommet surgery, were randomised to a treatment and a control group. Twenty-three children aged between three and eight years started as the treatment group with the new device for autoinflation. Another 22 children, aged between two and eight years were included as controls. After a period of four weeks, a cross-over was performed. Both groups underwent otomicroscopy, tympanometry and audiometry at inclusion and after one and two months for the evaluation of treatment efficiency. The primary outcome measurements were improvement in middle-ear pressure and hearing thresholds at eight weeks. Both groups were then followed up for another 10 months.
Results: In the treatment group, the mean middle-ear pressure for both ears and the mean hearing thresholds for the best ear improved by 166 daPa ($p < 0.0001$) and 6 dB ($p < 0.0001$), respectively after four weeks, while in the control group, non-significant alterations were observed. After the cross-over of the control group to treatment, equivalent improvements in the mean middle-ear pressure and the mean hearing thresholds of 187 daPa ($p < 0.0001$) and 7 dB ($p < 0.01$), respectively were achieved also in this group. After treatment in both groups at eight weeks, four of 45 children were submitted to grommet surgery. During the long-term follow-up another five children were submitted to surgery due to recurrence of disease. All the children managed to perform the manoeuvre and no side-effects were detected.
Conclusion: The device demonstrated efficiency in improving both middle-ear pressure and hearing thresholds in most children after four weeks of treatment. It might therefore be possible to consider this method of autoinflation in children with persistent OME during the watchful waiting period.

1. Introduction

Otitis media with effusion (OME) is an inflammation with fluid in the middle ear often combined with impaired hearing [1]. The insertion of grommets into the eardrum is one of the most common operations performed under general anaesthesia in childhood [2]. The primary indication for the operation is the restoration of normal hearing in children with long-standing bilateral OME by improving the ventilation and pressure regulation in the middle ear [1,3–5]. However, previous studies indicate that the benefits of grommets in children with OME are limited and that the effect on hearing diminishes during the first year [4,6,7]. Considering the potentially adverse effects on the tympanic membrane after grommet insertion, a period of watchful waiting is recommended for most children with OME [4].

Several non-invasive methods, i.e. autoinflation, have been developed to improve the negative middle-ear pressure in children with OME [8–12]. Autoinflation is a technique whereby the Eustachian tube is opened by increasing the intranasal pressure [2]. This can be achieved by forced exhalation with a closed mouth and nose or by blowing up a balloon through each nostril by active inflation [2]. A Cochrane review concluded that evidence for the

Abbreviations: OME, Otitis media with effusion; daPa, Decapascal; dB, Decibel hearing level.

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use of autoinflation in the short term is favourable, but, given the small number of studies and the lack of follow-up, the long-term effects cannot be determined [2].

The authors of the present study tested a new device for autoinflation, enabling a combined, modified Valsalva–Politzer manoeuvre. In a previous pilot study, 21 children, aged two to seven years, were able to perform the procedure and >80% of the children achieved improved middle-ear pressure [13]. However, due to the small number of subjects, lack of hearing evaluation and the short follow-up time, the long-term effects of this treatment could not be determined.

The aims of the present study were to: (I) evaluate the efficiency of and compliance with the new device in young children with persistent OME in a cross-over study with a follow-up period of eight weeks and (II) assess the long-term effects of the device with a follow-up period of one year.

2. Methods

2.1. Device for autoinflation

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

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

The balloon was provided for pressure regulation and visual feedback on a correct manoeuvre to the child and the parent. The balloon also functioned as an air reservoir producing a counter-pressure for 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 pressures were verified by an anaesthetic machine (Datex Ohmeda S5 ADU), with a pressure-monitoring and ventilation function, used at operating theatres. To eliminate the initial high opening pressure of the balloon, five inflations were performed before measuring 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.

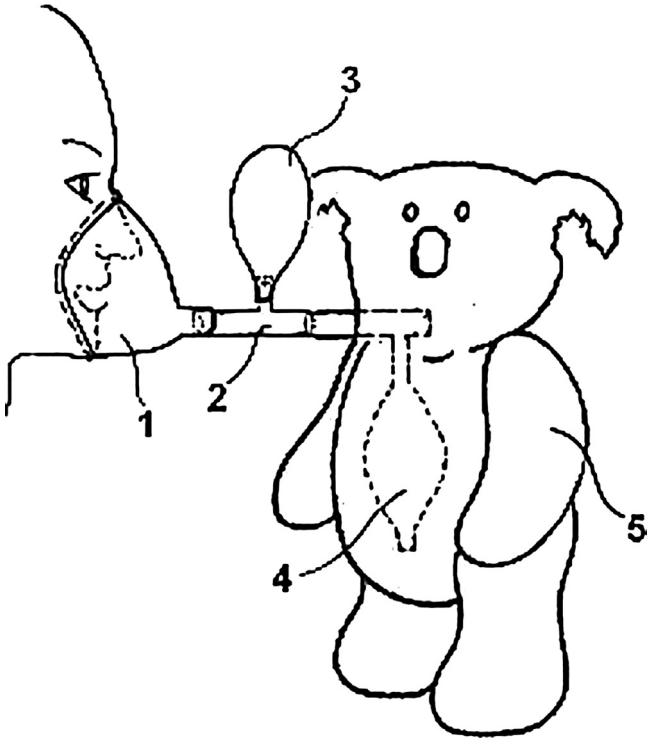

Fig. 1. The device for autoinflation consisting of (1) a facemask, (2) a T-shaped junction tube, (3) a balloon, (4) a handheld pump and (5) a teddy bear.

The handheld pump with a total volume of 250 ml was incorporated into the device. The pump, covered by a teddy bear, was used to produce a modified, controlled Politzer effect in order to facilitate the inflation of the balloon whenever necessary. To control the pressure produced by the handheld pump, a safety 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 by the pump would activate the safety valve.

The parents performed five inflations before starting treatment on the child in order to eliminate the initial high opening pressure of each new balloon. The balloon with the lowest pressure was initially used to help the child become familiar with the device. Within the first day of treatment, the balloon type was changed to another one with opening pressure of $\geq$40 cm H_2O. The parents were advised to replace the balloons each day in order to maintain the desired pressure during the treatment. Middle-ear ventilation was considered to have taken place if the child mentioned 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 mentioned one or several of the above-mentioned symptoms. A doctor or a nurse followed up the children every week.

Audiometry, tympanometry and clinical ear, nose and throat examinations including otomicroscopy were performed at inclusion and after one, two, six and 12 months. During the 10 months follow-up period, when a new episode of OME was detected, a control was scheduled within eight weeks and, if the OME was persistent, a new four-week period of treatment was initiated.

2.2. Otomicroscopy

A clinical ear, nose and throat examination including otomicroscopy was carried out by one examiner (ABM). By otomicroscopy, the position and morphology of the tympanic membrane and the presence of liquid or gas bubbles in the middle ear were compared before and after the treatment. A neutrally positioned eardrum, with gas in the middle ear and no signs of effusion, gas bubbles or retractions, was regarded as normal. A retracted or neutrally positioned eardrum with middle-ear effusion with or without gas bubbles was judged as pathological. The otomicroscopy findings were primarily used to evaluate the correct performance of the manoeuvre by the child and to help the parents choose the right balloon pressure at the follow-ups. These results were not used in the statistical analyses due to possible subjective bias.

2.3. Tympanometry

The tympanometric equipment used in the study was a Grason–Stadler GSI 33, Version 2 Middle-Ear Analyser, with a probe frequency of 226 Hz. The tympanometry results produced by this equipment were regarded as pathological, i.e. representing OME, in type B tympanograms with a flat curve with a relative gradient of less than 0.1 or with middle-ear pressure of ≤ -400 daPa. In the present study, type B tympanograms were systematically

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registered as −400 daPa in middle-ear pressure. In addition, type C2 tympanograms with middle-ear pressure of between −399 and −200 daPa were also regarded as pathological. Type A and C1 tympanograms with middle-ear pressure of between −199 and +100 daPa were not considered to represent OME [14,15]. An improvement (but not normalisation) in the tympanometric findings was defined as the number of ears converting from a type B to a type C2 tympanogram. Normalisation was defined as conversion from a type B or C2 to a type C1 or A tympanogram. Children with tympanometric normalisation or improvement were defined as responders and children with no change or a deterioration were defined as non-responders.

2.4. Audiometry

The audiometric equipment used in the present study was a Grason–Stadler GSI 16 Audiometer. Pure tone air conduction thresholds for each ear or sound field audiometry for both ears were performed by an experienced audiologist who was blinded to the group allocation of the child. The examination was performed in an approved audiometric test booth, provided by CA Tegnér AB, Sweden. Pure tone audiometry was performed in all children, except for those that would not collaborate in the performance of this examination. These children performed sound field audiometry instead. The pure tone average (PTA) of the frequencies 500, 1000 and 2000 Hz were measured for the left and right ear in each child. When sound field audiometry (SFA) was performed, the achieved values were assumed to represent the best hearing ear. All the presented values for PTA and SFA are for the best hearing ear and are in decibel hearing level but are abbreviated to dB.

2.5. Manual and diary

The parents and the children received written, verbal and visual (video) instructions on how to use the device. In order to perform the treatment at home, the parents were equipped with the device, a sufficient number of balloons with different opening pressures and a syringe to inflate the facemask when necessary. A written instruction manual and a diary (Appendices I and II) were provided to check compliance, efficiency, side-effects and other diseases during the course of treatment. Based on the results from the previous study, full compliance was defined as using the device twice a day to perform 20 inflations at each session (approximately 5–10 min.) during a period of four weeks.

2.6. Statistical analyses

A power analysis was conducted to estimate the appropriate sample size, using the result of the previous pilot study [13]. In order to achieve the observed tympanometry improvement of 160 Da Pa in the pilot study, at a confidence level of 95% and a power level of 90%, assuming an SD of 130, in a two-sided test with Wilcoxon signed-rank test, the sample size in both groups would be 12. In view of a higher expected failure rate at follow-up and to allow for exclusions and drop-outs, as well as obtaining more exact estimates, a target sample of approximately 30 children was set in each group.

Conventional cross-over analysis was not performed due to expected carry-over effect after the treatment period. Since the distribution in some of the variables seemed to deviate from normality, non-parametric tests were applied in the present study. The mean of tympanometry measurements for the right and left ear and the hearing thresholds for the best hearing ear, i.e. the minimum observed value, were analyzed to avoid within-patient correlation effects. The carry-over effect was confirmed by testing the differences between the groups with respect to the measurements at four and eight weeks. The main analysis was defined as treatment effect adjusted by the control effect. The adjustment was done by subtracting each child's control effect from the treatment effect.

The treatment effect, the control effect and the treatment minus the control effect within the groups were tested by Wilcoxon signed-rank test for continuous variables and sign test for the categorized tympanometry and audiometry variables. Mann–Whitney *U*-test was applied for comparison between the groups with respect to tympanometry and audiometry variables. Additional statistical analyses were performed applying the last observation carried forward (LOCF) method in order to replace the missing values at six and 12 months.

Logistic regression was applied for corresponding adjusted analysis with the group variable as dependent variable, change in tympanometry and audiometry from inclusion to four weeks as the main covariate, and other variables with statistically significant difference between the two groups at entry, as the adjustment variables.

The difference between the treated groups was tested by Mann–Whitney *U*-test for continuous variables, Mantel–Haenszel Chi-squared test for ordered categorical variables and Fisher's exact test for dichotomous variables. All statistical tests were two-tailed and conducted at 5% significance level. All analyses were conducted with SAS® computer software v 9.2 (Cary, NC) by an independent statistician.

2.7. Ethical considerations

The study was approved by the Medical Ethics Committee at Sahlgrenska University Hospital, Gothenburg, Sweden and Centro Hospitalar do Algarve, Portimão, Portugal. All parents gave their written informed consent.

2.8. Inclusion procedure

Sixty-one children, aged between two and eight years (mean 60 months, min 33, max 105), with history of persistent bilateral OME with a duration of disease of at least three months and history of subjective hearing loss, waiting for grommet surgery, were invited to participate in the present study. The indication for grommet surgery was primarily based on the tympanometry and otomicroscopy findings indicating OME [16], combined with the clinical history of subjective hearing loss. Children with uncontrolled asthma, craniofacial anomaly, active otological disease such as otorrhea, deep retraction pockets or perforations of the tympanic membrane were not included in this study. The children with medication for allergic conditions continued with their previous prescription during the study period. The inclusion procedure is summarised in Fig. 2.

The children underwent otomicroscopy, tympanometry and audiometry. Sixteen children were excluded from the study due to normal tympanometric and otoscopic findings in at least one ear. The remaining 45 children with bilateral OME with a type C2 or B tympanogram at inclusion were randomised to Groups A and B. Computer-generated, independent allocation sequences were used for randomisation. To avoid disproportionate numbers of patients in each group, randomisation was performed in blocks of six subjects (three allocated to the treatment and three to the control group). The children were enrolled by a secretary and assigned to group A or B by one of the authors (ABM). The characteristics of each group are summarised in Table 1.

The children in Group A started as the treatment group and the children in Group B as the control group. After a period of four weeks, a cross-over was performed. After completing the eight weeks of the cross-over study, both groups were followed up at the

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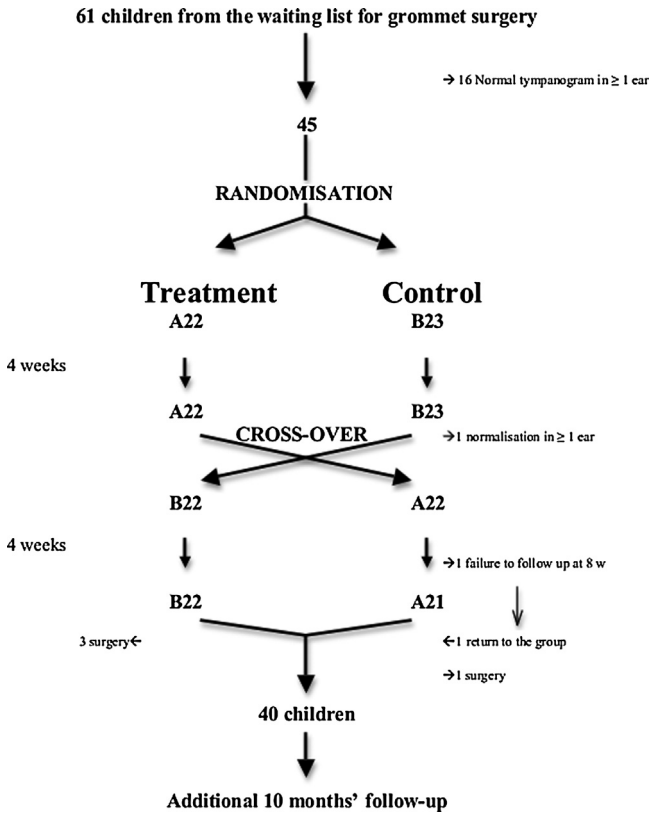

Fig. 2. Inclusion procedure.

out-patient clinic with otomicroscopy, tympanometry and audiometry for another 10 months. Entry into the study took place from May 2010 to June 2012.

3. Results

3.1. Cross-over study

3.1.1. Tympanometry

In Group A, the mean middle-ear pressure improved by 166 daPa (median 156, min 0, max 365, $p < 0.0001$) after four weeks of treatment in comparison with 19 daPa (median 0, min −50, max 376, $p = 0.31$) in Group B after four weeks of follow-up (Fig. 5).

In Group A, after four weeks of treatment, 36 ears (82%) were judged as responders, of which 19 (43%) achieved normalised (C1/A) and 17 (39%) improved (C2) middle-ear pressures, while eight ears (18%) remained unchanged and no deterioration was observed. In Group B, after four weeks of follow-up, three ears (7%) had normalised and one ear was improved (2%), 41 ears (89%) remained unchanged and one ear (2%) had deteriorated.

In Group A, at the end of the cross-over study at eight weeks, a total of 35 ears (83%) were regarded as responders, of which 26 ears (62%) had normalised and nine (21%) had improved. Seven ears (17%) remained unchanged and no deterioration was observed.

At eight weeks after treatment in Group B, the mean middle-ear pressure had improved by 187 daPa (median 189, min 0, max 530, $p < 0.0001$). Thirty-three ears (77%) were judged as responders, of which 23 ears (53%) had normalised. Ten ears (23%) remained unchanged and no deterioration was observed (Fig. 3).

At the end of the cross-over study, the number of children with bilateral or unilateral tympanometric normalisation were 12 (57%) and two (10%) respectively in Group A and seven (32%) and nine (41%) respectively in Group B. Seven children (33%) in Group A and six children (27%) in Group B had bilateral OME (type B/C2). The tympanometric types in each group at inclusion and at follow-up or treatment after four and eight weeks are summarised in Fig. 3.

3.1.2. Hearing level

In Group A after four weeks of treatment, the mean hearing thresholds for the best ear had improved by −6 dB (median −7, min −17, max 4, $p < 0.0001$), in comparison with −1 dB (median 0, min −21, max 22, $p = 0.65$) in Group B after follow-up. After the cross-over, the mean remained unchanged in Group A and improved in Group B by −7 dB (median −9, min −17, max 17, $p < 0.01$) after treatment (Fig. 6).

In Group A, 25 ears (66%) had hearing thresholds of ≥20 dB at inclusion, in comparison with 35 ears (88%) in Group B. After four weeks of treatment, the number of ears with hearing thresholds of ≥20 dB was reduced to seven (18%) in Group A, while no change was seen in Group B. After the cross-over at eight weeks, the number of ears with hearing thresholds of ≥20 was six (17%) in Group A and was reduced to 11 (28%) in Group B after treatment. The results are summarised in Fig. 4.

Table 1
Characteristics at entry of the 45 evaluable subjects.

		Group A (%)	Group B (%)
Number of children		22	23
Age (months)		68	53
Mean middle ear pressure (daPa) both ears		−388	−391
Mean hearing thresholds (dB) best hearing ear		20	25
Gender	Male	13 (59)	12 (52)
	Female	9 (41)	11 (48)
Tympanogram (ears)	Type B	40 (91)	42 (91)
	Type C2	4 (9)	4 (9)
	Type A/C1	0	0
Season of inclusion	Spring	8 (36)	8 (35)
	Summer	5 (23)	5 (22)
	Autumn	1 (5)	3 (13)
	Winter	8 (36)	7 (30)
Previous surgery	Grommet surgery	5 (23)	4 (17)
	Adenoidectomy	6 (27)	5 (22)
Awaiting surgery	Grommet surgery	All	All
	Adenoidectomy or adenotonsillectomy	3 (14)	8 (35)

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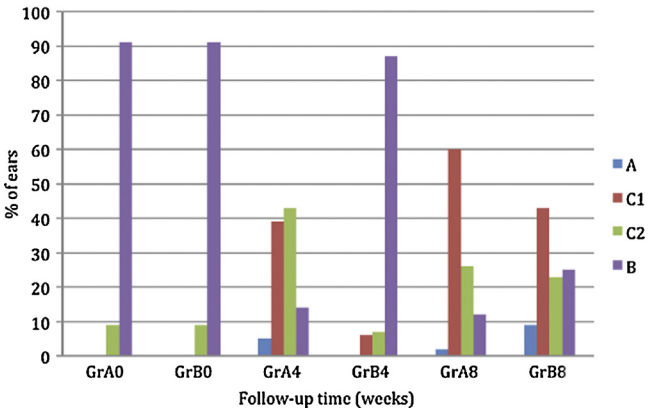

Fig. 3. Percentage of ears with type A, C1, C2 and B tympanogram at inclusion (0) and after four and eight weeks. Group A (GrA): treatment to control, Group B (GrB): control to treatment.

3.1.3. Otomicroscopy

In Group A, otomicroscopic examination indicated normal findings in 25 ears (57%) after four weeks of treatment and 31 ears (74%) at eight weeks. In Group B, two ears (4%) were judged as normal after four weeks of follow-up and 25 ears (58%) after cross-over to treatment at eight weeks.

3.1.4. Surgery

At eight weeks after treatment in both groups, based on the tympanometric, audiometric and otomicroscopic findings four of 45 children were submitted to grommet surgery (Fig. 2).

3.2. Long-term follow-up

A total of 40 children from Groups A and B were followed up for an additional 10 months, with otomicroscopy, tympanometry and audiometry at six and 12 months after inclusion. Fluctuations in middle-ear pressure and hearing thresholds were observed, mainly as a result of respiratory tract infections. When a bilateral deterioration was observed in tympanometry, the child was checked by repeating the examination after four to eight weeks. If the status was unchanged, treatment with the device was re-initiated. During the 10 month follow-up period, 12 children (30%) were treated at least once with the device, of which seven (16%) were subjected to further follow-up at the end of the study and five were submitted to grommet surgery.

At six months, tympanometric evaluation demonstrated a mean middle-ear pressure of −196 dB (median −185, min −400, max 77) for the whole group, with bilateral normalisation in 15 children (42%) and unilateral normalisation in eight children (22%). The mean hearing thresholds were 16 dB (median 13, min 5, max 38).

At 12 months the 35 children that were not submitted to grommet surgery, had a mean middle-ear pressure of −151 dB (median −123, min −400, max 18) and mean hearing thresholds of 14 dB (median 12, min 5, max 40). Bilateral tympanometric normalisation was observed in 22 children (63%) and unilateral normalisation was seen in six children (17%), with fifty-one ears (78%) achieving hearing thresholds of <20 dB. A comparative analysis of the tympanometric and audiometric findings for the whole group is presented in Figs. 5, 6 and Table 2.

Otomicroscopy findings at six and 12 months were similar to the tympanometric findings for the detection of middle-ear effusion and no otological complications were detected.

3.3. Compliance

All children from two years and nine months of age were able to use the device after demonstration by a doctor or nurse. No adverse effects were observed. In one case, the compliance was not satisfactory to complete the four-week treatment. In general, the children regarded the device as an amusing toy and many were in fact unwilling to return it after the completion of treatment. Some parents reported partial compliance failure described as “lack of time” to perform the exercise, especially in the mornings. The child's enthusiasm about playing with the new “toy” was reduced in some cases after two weeks of treatment. The overall compliance for the total treatment time was satisfactory.

4. Discussion

The effect of autoinflation on hearing thresholds in children with OME has not been established due to the lack of studies with sufficient scientific evidence [1]. In the present study, after treatment in both groups at eight weeks, the mean hearing level improved from 22 to 16 dB and the number of ears with hearing thresholds of ≥20 dB was reduced from 61 (78%) to 17 (23%).

Previous studies report conflicting evidence in favour of the use of autoinflation in the treatment of OME in young children [9]. One of the most recognised methods for autoinflation is the Otovent device [12]. Using the Otovent device, Stangerup et al. showed greater efficiency in children with a type C2 tympanogram compared with a type B tympanogram [12]. Despite the clinical effect on OME, this method has experienced problems with compliance, especially in young children [12,17]. Treatment with the present device showed satisfactory compliance. Autoinflation via both mouth and nose, the combination of the Valsalva and Politzer manoeuvres and also and the incorporation of a teddy bear

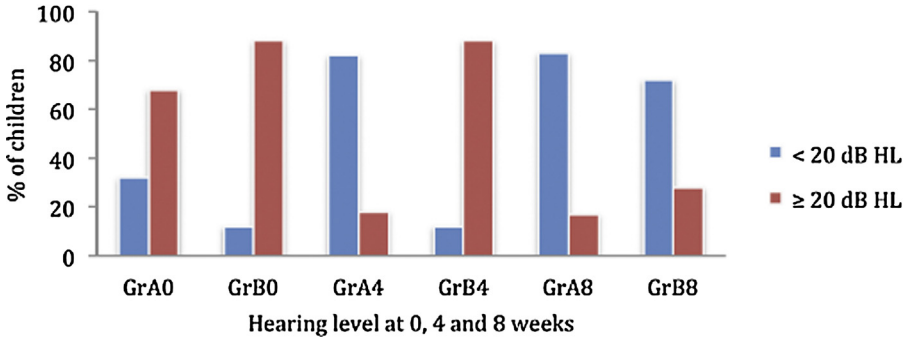

Fig. 4. Hearing thresholds with a cut-off at 20 dB measured at inclusion (0) and after four and eight weeks in both groups. Group A (GrA): treatment to control, Group B (GrB): control to treatment.

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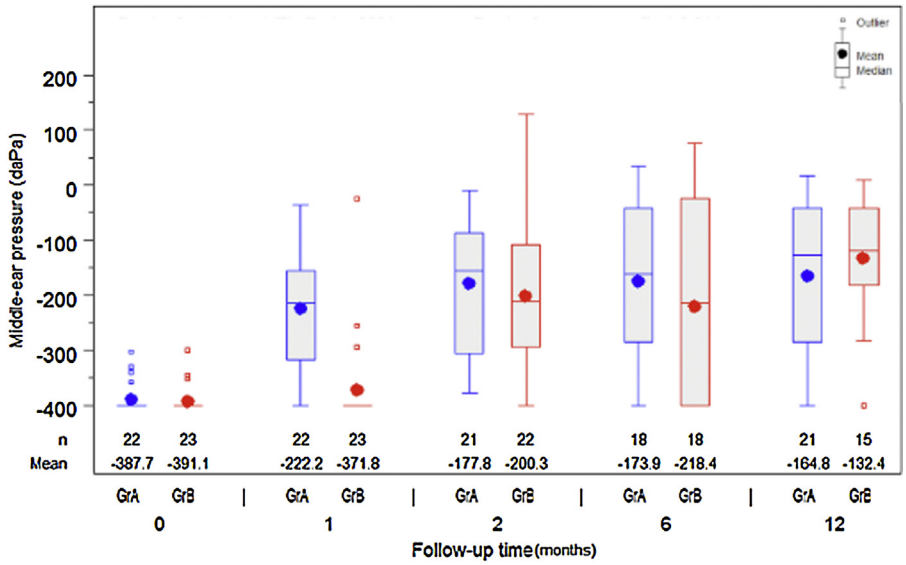

Fig. 5. Mean middle-ear pressure for both ears at inclusion (0), one, two, six and 12 months. Group A (GrA): treatment to control, Group B (GrB): control to treatment, *n*: number of children. Treatment-control effect ($p < 0.0001$), carry-over effect ($p = 0.014$).

in the device most probably improved the compliance even in young children.

During the first eight weeks a cross-over setting was implemented. This model permitted a comparison of the treatment effect in both groups with reduction of the confounders. A disadvantage of this model was that the control group was lost for long-term follow-up and evaluation of spontaneous remission of disease.

Two Cochrane reports confirm the evidence of short-term efficiency using autoinflation methods, however, the long-term effects have not been determined [2,16]. In the present study, at 12 months, nine (20%) of the initial 45 children underwent grommet surgery, whilst 36 children (80%) had not been operated upon.

Potential confounders at entry were age, gender, middle ear pressure, hearing thresholds, allergic disease, season of inclusion, adeno-tonsillary hypertrophy, previous grommet surgery and previous adeno-tonsillary surgery. There was a difference between the groups regarding age ($p = 0.004$) and hearing thresholds for the best hearing ear ($p = 0.016$) at entry. Logistic regression analysis of the first four weeks with adjustment for possible confounders, revealed significant difference between the treatment and the control group with respect to mean middle ear pressure and mean hearing thresholds for the best ear ($p = 0.002$). Additional statistical analyses with the application of the last observation carried forward method regarding tympanometry and audiometry changes at six and 12 months revealed significant improvements ($p < 0.05$) in both groups.

OME may be associated with a conductive hearing level that varies between 0 and 50 dB [18]. Although at inclusion the mean hearing level was 20 and 25 dB in the groups A and B respectively, after treatment significant improvements of respectively 6 and 7 dB were achieved. This correlates well with previous findings regarding observed audiometric improvement of 6 dB after grommet surgery in children with OME [19]. In the present study,

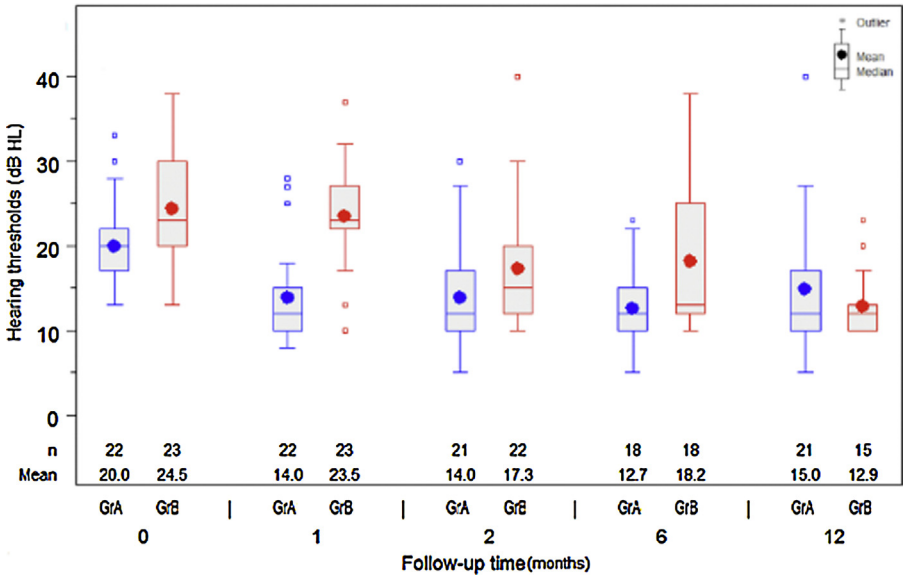

Fig. 6. Mean hearing thresholds for the best hearing ear at inclusion (0), one, two, six and 12 months. Group A (GrA): treatment to control, Group B (GrB): control to treatment, *n*: number of children. Treatment-control effect ($p < 0.0001$), carry-over effect ($p = 0.0001$).

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Table 2
Comparative analysis of the tympanometric and audiometric findings for the groups, children and ears at inclusion and after two, six and 12 months.

	Groups A + B		Number of children with tympanogram (%)				Hearing thresholds ≥20 dB HL (%)	
	Mean and median middle-ear pressure for both ears in daPa (min; max)	Mean and median hearing level for best ear in dB HL (min; max)	Bilat. type C1/A	Unilat. type C1/A	Bilat. type B/C2	Bilat. type B	All evaluable ears	Best ear
Inclusion	−389 −400 (−400; −300)	22 22 (13; 38)	0	0	45 (100)	38 (84)	60 (77)	31(69)
2 months	−189* −182 (−400; 130)	16* 13 (4; 40)	19(44)	11(26)	13 (30)	4 (9)	17 (23)	9 (21)*
6 months	−196* −185 (−400; 77)	16* 13 (5; 38)	15 (42)	8 (22)	13 (36)	5 (14)	14 (22)	8 (22)*
12 months	−151* −123(−400; 18)	14* 12 (5; 40)	22 (61)	6 (17)	7 (19)	4 (11)	14 (22)	6 (17)*

* $p < 0.0001$.

at inclusion 60 ears (77%) had hearing thresholds of ≥20 dB and this was reduced to 16 ears (22%) after treatment in both groups at eight weeks.

The performance at audiologic testing may improve as a function of the age in children [20,21]. At six and 12 months the children's audiometric results may have improved to some extent due to age and also spontaneous regression. Due to the lack of a control group for the long-term follow-up, it is not possible to correct for such bias.

The authors of the present study have not found any previous papers that have been published on treatment with autoinflation in children below the age of three years. The youngest child, who performed the treatment with the present device and completed the 12 month follow-up, thereby avoiding surgery, was two years and nine months old. Another child, aged three years and one month, with persistent OME and chronic cardiac failure was included in the study in order to avoid grommet surgery under general anaesthesia due to possible cardiac complication risks. She was included in the study with bilateral type B tympanogram with a disease duration >12 months. After four weeks of treatment the PTA was improved from 28 to 18 dB and she achieved bilateral type C1 tympanogram with no recurrence during the long-term follow-up.

Due to the limited number of prototypes, the parents were asked to return their device after each treatment period. Some children might have benefited from prolonged treatment to achieve a further improvement in middle-ear pressures and hearing thresholds. The insufficient number of devices caused a delay in treatment after upper airway tract infections in some cases.

There are no obvious data supporting medical treatment such as antihistamine-decongestant combinations and steroids in the long-term treatment of OME [6,22,23]. In the present study possible effect of medical treatment was not studied.

Judging from the reaction of the child, some parents reported a reinforced effect of the manoeuvre when the child swallowed. These parents were encouraged to instruct their children to swallow saliva or water when performing the manoeuvre. In the clinical evaluation of these children, no signs or symptoms of aspiration or any other complication could be detected. However, in the present study, this modification of the method was not applied to all the children.

5. Conclusions

The new device for autoinflation provides promising results in treatment of persistent OME in children. The device demonstrated efficiency in improving both middle-ear pressure and hearing thresholds in most children after four weeks of treatment in a randomised controlled cross-over study. The device was well tolerated, even in young children, with no complications reported. It might therefore be possible to consider this method of autoinflation in children with persistent OME during the watchful waiting period. Future larger studies should compare the efficiency of and compliance with this novel method of autoinflation with grommets and watchful waiting.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijporl.2014.05.015.

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