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RESEARCH ARTICLE

Autoinflation compared to ventilation tubes for treating chronic otitis media with effusion

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ABSTRACT

Background: Otitis media with effusion (OME) is the most common cause of acquired hearing loss and surgery in children. Autoinflation has been suggested as an alternative treatment for OME.
Objectives: The aim of the study was to compare treatment outcome with a new autoinflation device versus ventilation tube (VT) surgery or watchful waiting in children with chronic bilateral OME from the waiting list for surgery.
Methods: Forty-five children performed autoinflation during four weeks, forty-five were submitted to VT surgery, and twenty-three were enrolled as control group. Tympanometry was performed in the autoinflation and the control groups and audiometry in all groups.
Results: An equivalent hearing improvement was achieved in the autoinflation and the VT group at one (p=.19), six (p=.23) and twelve (p=.31) months with no significant alteration in the control group. In the autoinflation group 80% of the children avoided surgery and no complications were reported compared to 34% complication rate in the VT group.
Conclusion: Autoinflation achieved an equivalent improvement in hearing thresholds compared to VT surgery for treating OME.
Significance: Autoinflation may be a reasonable first-line treatment for children with OME to potentially avoid surgery.

Article Summary: The Moniri autoinflation device is well tolerated and an effective alternative to ventilation tubes for treatment of chronic otitis media with effusion in young children.
What's known on this subject: Previous studies have shown that autoinflation may reduce effusion in children with otitis media with effusion; however limited compliance to treatment, lack of adequate hearing evaluation, short follow-up time and also lack of comparative data to ventilation tube surgery have been reported.
What this study adds: A new device was developed to allow for the performance of autoinflation in young children. The effect is compared to ventilation tube surgery and equivalent improvement in hearing is achieved in the short and the long-term follow-up.

Abbreviations: OME: Otitis media with effusion; VT: Ventilation tube

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Otitis media with effusion; ventilation tubes; autoinflation; hearing loss

Introduction

Otitis media with effusion (OME) is defined as accumulation of liquid in the middle ear, in the absence of signs or symptoms of an acute inflammation or infection [1]. OME is the most common cause of acquired hearing loss in childhood [2] with a cumulative incidence of approximately 80% to the age of four years and a decreasing incidence thereafter [3].

Inserting a ventilation tube (VT) into the eardrum under general anesthesia is the most common pediatric surgical procedure and is associated with a substantial health care burden [4]. The primary indication is restoration of normal hearing in children with long-standing middle-ear effusion [5]. Current clinical practice guidelines recommend watchful waiting for at least 3 months in otherwise healthy children prior to considering VT surgery [2,6] because of a favorable natural history in most children. In Sweden, for example, only about 10,000 VT surgeries are performed annually despite a yearly incidence of 400,000 OME cases in about 10 million inhabitants, suggesting that nearly 98% of cases improve without surgery [7].

The high prevalence of OME in children relates primarily to under-ventilation of the middle-ear space by the child's Eustachian tube, which is shorter, more floppy and

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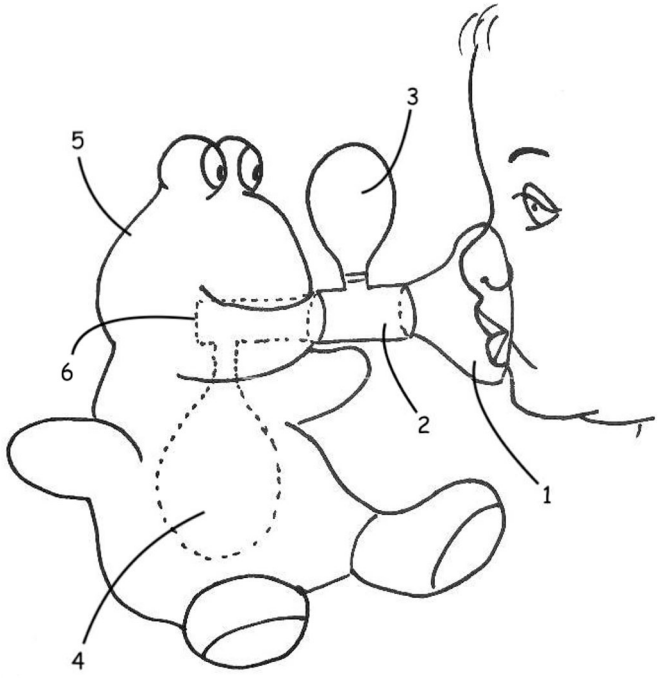

Figure 1. The device for autoinflation consisting of [1] a facemask [2], a T-shaped junction tube with one-way valve [3], a balloon [4] a handheld pump and [5] a stuffed animal [6] a safety valve.

horizontal than in adults and functions poorly [8]. These anatomical considerations make the middle-ear space more susceptible to pressure changes in the child's nasopharynx and also facilitate reflux of secretions up the Eustachian tube into the middle ear [2,8]. Maturation of the tube is a gradual process, which explains the decrease in OME after the age of 7 years [3,9].

Autoinflation refers to the opening of, and forcing of air through, the Eustachian tube by the raising of upper airway pressure, to ventilate the middle ear, relieve negative pressure, and clear effusion [5,10]. The Cochrane systematic review evaluated the effect of the existing autoinflation devices and concluded that the overall effect was heterogeneous but suggestive of clinical benefit in the short term [10]. The authors concluded that because of the low cost and absence of adverse effects it is reasonable to consider autoinflation while awaiting natural resolution of OME. Although based on eight randomized controlled trials, this recommendation was relatively weak because all studies were small, of limited treatment duration, and had only short-term follow-up.

Considering that autoinflation is the only non-surgical intervention with potential efficacy in treating chronic OME [5], availability of a child-friendly device suitable for treating even young children would be welcomed. A new autoinflation device (Moniri®) for home treatment of children with persistent OME was developed and tested during a PhD-thesis at the Sahlgrenska University Hospital in Gothenburg, Sweden. The new device was specifically designed to improve acceptability and adherence to therapy in young, preschool children [11,12], who are often unable to initiate or tolerate, autoinflation with existing nasal balloons or similar devices. The objective of this prospective cohort study was to evaluate the outcomes of autoinflation with this new device compared to VT surgery and watchful waiting.

Methods

Study design

In this study we compared children treated by autoinflation from our previous clinical trial [11] with cohorts treated with VT surgery and controls in order to evaluate treatment outcome and possible complications during short- and long-term follow-up. The children in the three groups were aged 2 (33 months) to 8 years (105 months) and were selected from the waiting list for VT surgery between May 2010 and June 2012 if they had chronic, bilateral OME for at least 3 months, with a type C2 or B tympanogram, and a history of hearing loss based on parental report and audiometry. Children were excluded if OME was not the primary indication for surgery, if at least one ear did not have effusion (type A or C1 tympanogram), if they were unable to perform a hearing test, or if they had a craniofacial anomaly, poorly controlled asthma, or active otologic disease, including otorrhea, tympanic membrane perforation, or a deep retraction pocket.

All children had otomicroscopy, tympanometry, and audiometry upon trial entry, along with a comprehensive ear, nose, and throat examination. The sampling was consecutive and to avoid disproportionate distribution in each group regarding age, gender and season of inclusion, allocation was done in blocks of six subjects. Due to the low parental motivation for participation in the control group, the sample size in this group was smaller and the follow-up time was limited to one month. The study was approved by the Medical Ethics Committees at Sahlgrenska University Hospital, Gothenburg, Sweden and Centro Hospitalar Universitário do Algarve, Portimão, Portugal. All parents gave their written informed consent.

All children were followed for 12 months, during which time all examinations, except tympanometry in the VT group, were repeated at 1, 6 and 12 months. The children in the control group returned to the waiting list for VT surgery after one month of follow-up and were submitted to surgery. The children in the VT group were submitted to surgery under general anesthesia with insertion of Shepard ventilation tubes combined with adenoid and/or tonsil surgery if indicated. No surgical re-interventions were performed in the VT group during the follow-up period. In the autoinflation group if a new episode of OME was detected, a new four-week period of treatment was initiated.

Device for autoinflation

The autoinflation device (Figure 1) consisted of [1] a facemask [2], a T-shaped junction tube with a one-way valve connecting at one end to the facemask, another end to a balloon [3] and the third end to [4] a handheld pump. The

Figure 2. Parent assisting in the performance of autoinflation.

pump was covered by [5] a stuffed animal to improve adherence to therapy in young children.

The facemask was used to cover the nose and mouth of the child enabling performance of autoinflation by nose and/or mouth. The balloon was provided for pressure regulation, pressure reservoir and visual feedback on a correct maneuver to the child and the parent. Three different colored balloons with the respective opening pressures of approximately 20 (green), 40 (blue) and 60 (red) cm H2O were used. The balloon opening pressures were verified by an anesthetic machine (Datex Ohmeda S5 ADU), with a pressure monitoring and ventilation function, used at operating theatres.

The handheld pump was incorporated to create external pressure within the device. A safety valve [6] set on 40 cm H2O was installed to avoid hazardously high pressures created by the pump. The child would be able to inflate balloons with different opening pressures autonomously *via* the facemask without the activation of the pump; however, any pressure exceeding 40 cm H2O produced by the pump would activate the safety valve.

The treatment started by the parent performing five inflations into the mask to demonstrate the treatment to the child and also to eliminate the initial high opening pressure in the new balloon. The parent assisted in holding the mask to cover the nose and mouth of the child to create a hermetic seal (Figure 2).

During inspiration the air entered without any resistance, and during expiration the air was captured within the device by a one-way valve. The captured air inflated the balloon and increased the pressure in the device, which was transmitted to the upper airways of the child to open the Eustachian tube for middle ear ventilation.

With the mask hermetically adapted, autoinflation could be achieved by several maneuvers:

1. Inflating the balloon by nose (autonomous maneuver)
2. Inflating the balloon by mouth (autonomous maneuver)
3. Laughing, coughing, or screaming "mommy" or "daddy" (autonomous maneuver)
4. In children with no active collaboration or small lung capacity, to autonomously inflate the balloon, the parent squeezed the pump in the belly of the stuffed animal (assisted maneuver)

The three different balloon colors and pressures provided a didactic method for gradual pressure increase and created new challenges in the treatment that was presented as a game to the child. Subjective signs of middle-ear ventilation included sensation of air, water, alterations in hearing, crackling sound or mild transient discomfort in one or both ears.

Otomicroscopy

Clinical ear, nose and throat examination, including otomicroscopy, was performed at entry and during follow-up visits. The position and morphology of the tympanic membrane and the presence of liquid, gas bubbles in the middle ear, presence and position of VTs and any signs of infection of the middle ear and/or the ear canal were registered during the follow-up period. A duration of VT in the tympanic membrane within 3 months of insertion was defined as early tube extrusion.

Tympanometry

The tympanometry equipment used in the study was a Grason Stadler GSI 33, Version 2 Middle-Ear Analyzer, 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 (middle-ear pressure $<$ -400 daPa) or type C2 tympanograms (middle-ear pressure <-200 daPa). Type A and C1 tympanograms (middle-ear pressure of between -199 and $+100$ daPa) were not considered to represent OME [13,14]. Tympanogram type changes from B to C2/C1/A or from C2 to C1/A were considered as improvements and the children considered as responders to treatment.

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 better ear. All the presented values for PTA and SFA are for the better ear and are in decibel hearing level but are abbreviated to dB.

Manual and diary

Diaries were provided to check compliance, efficiency, side effects, infections and other diseases during the study. The parents of the children in the autoinflation group received written, verbal and visual (video) instructions on how to use the device for autoinflation. To perform the treatment at home, the parents were equipped with the device, sufficient number of balloons with different opening pressures. Full compliance was defined as using the autoinflation device twice a day to perform 20 inflations at each session (approximately 5–10 min.) during a period of four weeks.

Statistical analyses

A power analysis was conducted to estimate the appropriate sample size. In order to achieve the observed tympanometry improvement of 160 daPa in the pilot study, at a confidence level of 95% and a power level of 90%, assuming a standard deviation (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 >20 children was set in each group. Since the distribution in some of the variables seemed to deviate from normality, non-parametric tests were applied in the present study. Kruskal–Wallis for independent samples was used for comparison of the characteristics of the groups at inclusion. In case of significant difference Bonferroni post-hoc test was performed. The treatment and the control effect 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 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 audiometry from inclusion as the main covariate, and other variables with statistically significant difference between the groups at entry, as the adjustment variables. The differences between the treated groups were 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[1] computer software v 9.2 (Cary, NC) by an independent statistician.

Results

Cohort recruitment

All children were included from the waiting list for VT surgery. A total of 142 families accepted to participate in the present study. Of the 61 children who accepted to participate in the autoinflation group, 16 were excluded due to normal tympanometric and otomicroscopic findings in at least one ear upon trial entry. The remaining 45 children, aged between two and eight years (mean 60 months, min 33, max 105), with bilateral OME with a type C2 or B tympanogram at inclusion comprised the autoinflation group.

Thirteen of the 81 children who accepted to participate in the VT and the control groups were excluded due to normal tympanometric and otoscopic findings in at least one ear upon trial entry. Forty-five children aged between three and eight years (mean 66 months, min 38, max 99) were enrolled as the VT group and 23 children aged between three and seven years (mean 53 months min 37, max 87) comprised the control group.

Characteristics of the groups

At inclusion no significant differences were observed between the tympanogram type and the mean hearing threshold in the better ear between the three groups. The characteristics of the groups at entry are summarized in Table 1.

Short-term follow-up

In the autoinflation group one child was lost to follow-up. After four weeks of autoinflation, 41 (93%) of 44 children could avoid grommet surgery based on audiometric and/or tympanometric improvement in at least one ear. One child in the control group had improvement in one ear at four weeks of follow-up. The children in the VT group were all submitted to surgery.

Tympanometry

After four weeks of autoinflation tympanometric type change in at least one ear was achieved in 38 (86%) children. There was an increase in type C1/A tympanogram from 0% to 70% ($p<.0001$) with a reduction in type B tympanogram from 84% to 9% in the better ear. In the control group all but one child had type B/C2 tympanogram after four weeks of follow-up (Table 2).

Hearing thresholds

In the autoinflation group after four weeks of treatment, the mean hearing thresholds for the better ear changed from 22 to 16 dB ($p<.0001$), compared to 24 to 15 dB ($p<.0001$) in the VT group with no significant difference between the groups ($p=.19$). In the autoinflation group the number of ears with hearing thresholds of ≥20 dB was reduced from 60 (77%) to 16 (22%) compared to 82 (91%) to 15 (18%) in the VT group. No significant alteration in hearing thresholds was observed in the control group ($p=.65$) (figure 3).

Otomicroscopy

In the autoinflation group, otomicroscopy indicated normal findings in 50 ears (57%) after four weeks of treatment. In

Table 1. Characteristics at entry of the 113 evaluable subjects.

	Control ($n = 23$)	Autoinflation ($n = 45$)	VT ($n = 45$)	p Value
Age in months (SD)	57*(15)	60 (18)	66*(18)	.005
Mean Hearing Threshold in better ear in dB HL (SD)	24 (8)	22 (6)	24 (7)	.061
Gender (%)				
Male	13 (57)	25 (56)	23 (51)	.39
Female	10 (43)	20 (44)	22 (49)	
Tympanometry				
Type in better ear (%)				
B	20 (87)	38 (84)	34 (76)	.42
C2	3 (13)	7(16)	11 (24)	
Season of inclusion (%)				
Spring	8 (35)	16 (36)	12 (27)	.52
Summer	4 (17)	10 (22)	5 (11)	
Autumn	4 (17)	4 (8)	9 (20)	
Winter	7 (30)	15 (33)	19 (42)	
Previous surgery (%)				
VT	3 (13)	9 (2)	11 (24)	.96
Adenoid surgery	4 (17)	11 (24)	8 (18)	
Tonsil surgery	3 (13)	7 (16)	5 (11)	

Mean hearing threshold for the better ear was based on PTA or SFA dependent on the collaboration of the child. The values in parenthesis represent SD or % for each category.
*Significant difference between the control and the VT groups.

Table 2. Tympanometry findings at inclusion and four weeks.

	Autoinflation		Control		
Tympanogram better ear	Inclusion	4w	Inclusion	4w	p-value between the groups at 4w
C1/A (%)	0	30 (70)*	0	1 (4)	<.001
C2 (%)	7 (16)	10 (23)	3 (13)	3 (13)	<.05
B (%)	38 (84)	4 (9)*	20 (87)	19 (83)	<.0001

The figures represent the tympanometry results at inclusion and after four weeks in the better ear. The values in parenthesis represent %.
*p<.0001 as compared to baseline.

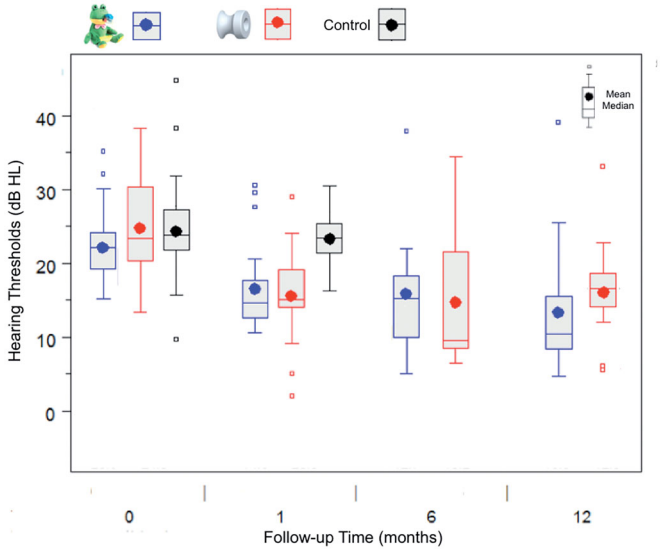

Figure 3. Mean hearing thresholds at 0, 1, 6 and 12 months in the Autoinflation (blue), Grommet (red) and the Control (black) groups.

the VT group, four weeks after the surgery two tube-extrusions were observed due to postoperative infections. In the control group after four weeks of follow-up the number of ears with normal findings increased by one.

Long-term follow-up

One child was lost to follow-up and four children were submitted to grommet surgery in the autoinflation group after four weeks. The remaining forty children were followed up by otomicroscopy, tympanometry and audiometry. Individual fluctuations in tympanometry and hearing thresholds were observed in the autoinflation group, mainly as a result of respiratory tract infections. When deterioration was observed, treatment with the device was reinitiated during another 4-week period. During the long-term follow-up another five children (11%) were submitted to grommet surgery. The children in the VT group were followed up by otomicroscopy and audiometry. Complications related to VT tubes were documented during the follow-up period (Table 3). No re-interventions were performed during the follow-up time in the VT group (Figure 4).

Tympanometry

At six months 23 children (64%) had normal tympanometric findings in the better ear (p<.0001). At 12 month 28 children (80%) had normal tympanometric finding in the better ear (p<.0001). The number of Type B tympanograms in the better ear changed from 38 (84%) at inclusion to 4 (9%) at 1 month (p<.0001), 9 (25%) at 6 months (p<.0001) and 4 (11%) at 12 months (p<.0001). These results are summarized in Table 3.

Hearing thresholds

At 6 months the autoinflation group had a mean hearing threshold of 16 dB (min 5, max 38) compared to 15 dB (min 6, max 35) in the VT group (p=.23). At 12 months the mean hearing thresholds were 14 dB (min 5, max 40) in the

Table 3. Tympanometry findings in the autoinflation group at inclusion and follow-up.

Tympanogram type in better ear	Inclusion	1 mo	6 mo	12 mo
C1/A (%)	0	30 (70)*	22 (64)*	28 (80)*
C2 (%)	7 (16)	10 (23)	5 (14)	3 (9)
B (%)	38 (84)	4 (9)*	9 (25)*	4 (11)*

Tympanogram types at inclusion and 1, 6 and 12 months in the better ear. The values in parenthesis represent %.
*$p<.0001$ as compared to baseline.

autoinflation group compared to 16 dB (min 5, max 33) in the VT group ($p=.31$). At 12 months fifty-one ears (78%) achieved hearing thresholds of <20 dB in the autoinflation group as compared to 49 ears (72%) in the VT group ($p=.11$) (Figure 3).

Otomicroscopy

In the autoinflation group 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.

At six months 12 (34%) children in autoinflation group and 12 (27%) in the grommet group were diagnosed as having bilateral OME. At 12 months the number of children with bilateral OME was 7 (20%) in the autoinflation group and 14 (31%) in the VT group (Figure 4).

Compliance and complications

In the autoinflation group all children from two years of age were able to use the device. In this study younger children were not included due to difficulties in performing hearing evaluation. After instruction most children from 4 years of age managed to perform autoinflation autonomously. Younger children performed assisted maneuvers, after activation of the pump by a parent. No adverse effects were observed. In one case, the compliance was not

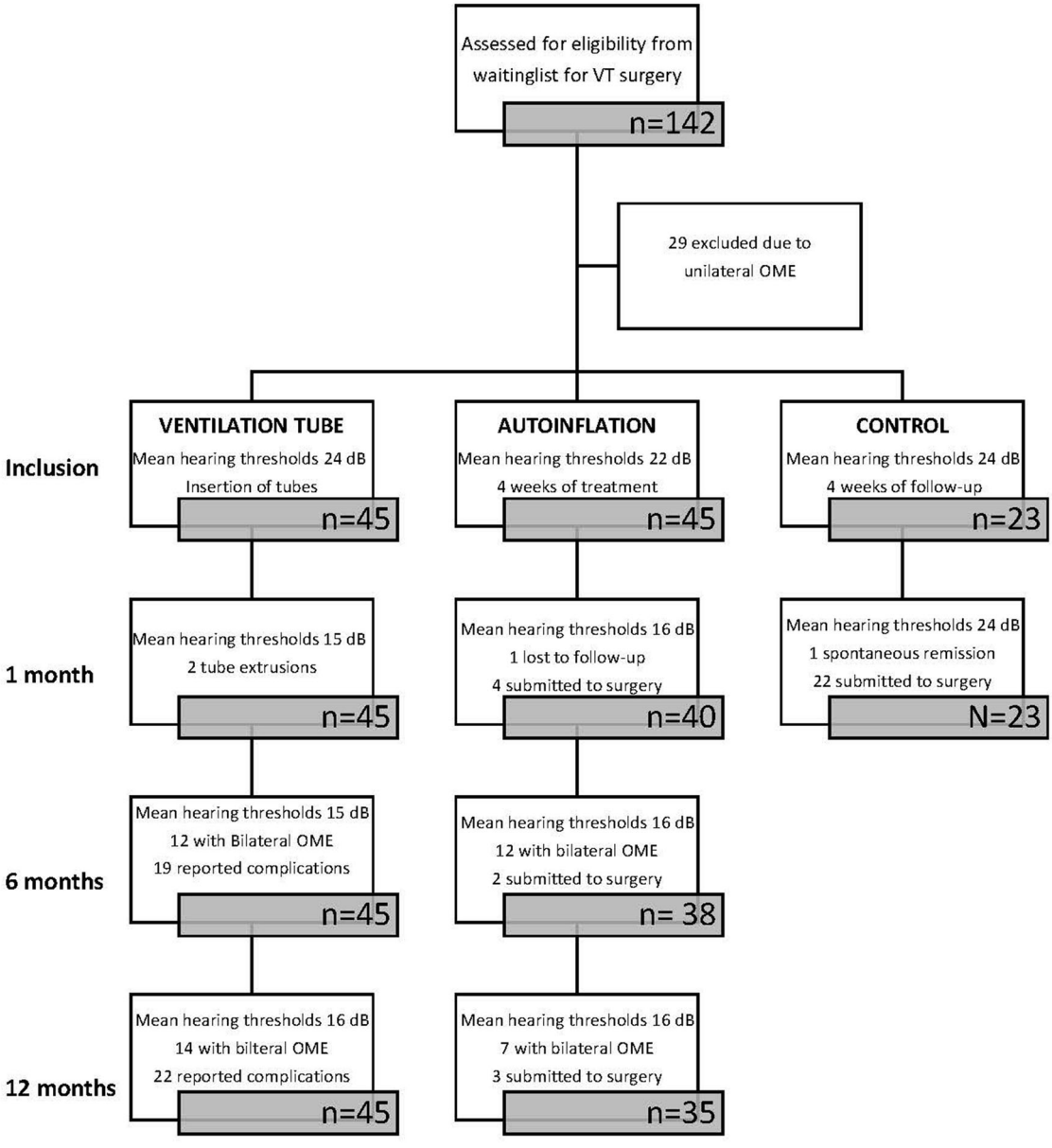

Figure 4. Summary of the main findings.

Table 4. Ventilation tube related complications. Number of ears with grommet related adverse effect. The figures in the parenthesis represent %.

Pain (%)	7 (8)
Otorrhea (%)	13 (14)
Obstruction (%)	4 (4)
Early extrusion (%)	6 (7)
Chronic Perforation (%)	1 (1)
Total (%)	31 (34)

satisfactory to complete the four-week treatment. Some parents reported partial compliance failure described as "lack of time" to perform the exercise, especially in the mornings but compensated with treatment in the afternoon. The child's enthusiasm was reduced in some cases after two weeks of treatment. The overall compliance for the total treatment time was satisfactory. During the follow-up period, 12 children (27%) were treated at least twice with the device due to recurrence of OME, of which seven (16%) were subjected to further follow-up. At the end of the study nine children (20%) were submitted to grommet surgery.

In the VT group during the follow-up period of 12 months, 31 (34%) grommets related adverse effects were reported (Table 4), i.e. pain (8%), otorrhea (13%), obstruction (4%), early extrusion (7%) and chronic perforation (1%). 12 children (27%) had recurrence of OME during the long-term follow-up.

VT related complications are summarized in Table 4.

Discussion

Our prospective, cohort study, using a novel and well-tolerated autoinflation device, found comparable short-term improvements in hearing and effusion resolution with VT surgery, with 80% of children treated with autoinflation avoiding the need for VT insertion during the 12 month follow-up period. In addition, tympanometric outcomes were substantially better at 1 month for autoinflation compared to controls, with 86% showing tympanometric type change and 68% achieving resolution in the better ear (type A or C1 curve) with autoinflation compared with only 4% of controls ($p<.001$). The acceptability of this new autoinflation device to children as young as 2 years of age is important, given the high prevalence of OME and VT surgery in this age group and the inability to successfully use a traditional nasal balloon in many preschool children [10,15]. Moreover, given the cost and potential complications of VT surgery, our research suggests that autoinflation may eliminate the need for surgery in most children.

Previous method for autoinflation target children above the age of four years [15,16], whilst OME principally affects children below the age of four [3]. Recent studies using a nasal balloon and plastic cannula (Otovent®), which is a commonly used method of autoinflation for OME in children aged 4 years and older, show a promising effect on improving middle-ear pressure in primary care settings [15]. Unfortunately, the impact of the device on hearing levels is unknown, only short-term results are available, and the adherence to therapy is limited in young children [10,15]. In the present study the possibility of performance of maneuvers also by mouth, thanks to the facemask, and the possibility of squeezing the pump, allowing for autoinflation without the active collaboration of the child, most probably increased both efficiency and adherence to therapy. The pump function in the device was similar to the Politzer maneuver however the pressure was transplanted through an elastic media (the balloon) and was well tolerated. The gradual increase in pressure by replacement of the balloons, lead to improved tolerance and adaptation to the treatment. In fact, most children considered the device an amusing toy rather than a medical treatment, which also facilitated the repetition of treatment during the follow-up in case of recurrence of OME after a new upper airway infection.

VT surgery in children may be associated with complications and recurrence of disease [6]. In the present study no complications were observed in the autoinflation group. In the grommet group only, surgical complications were taken into account and the follow-up period was limited to 12 months, nevertheless adverse effects were reported in approximately 1/3 of the operated children. These children were subjected to further follow-up, and some must undergo new surgeries. Nine (20%) children in the autoinflation group were submitted to grommet surgery due to treatment failure or recurrence of OME during the follow-up time of 12 months. Eleven (25%) children in the autoinflation group were in the waiting list for adjuvant adenotonsillar surgery. Although most children in the waiting list for surgery undergo treatment with nasal corticosteroids for adenoid hypertrophy [17], our clinical impression indicate that symptomatic adenoid and/or tonsil hypertrophy may influence treatment success in autoinflation.

OME may be associated with a conductive hearing loss that varies between 0 and 50 dB [18]. This large variation is partially explained by the heterogeneity in the audiometric testing technique. In the present study all audiometric testing was performed in an approved test booth. Although bilateral B tympanogram was detected in more than >90% of children at trial entry, most children had a mild hearing loss. However, the observed change in dB hearing improvement in the present study corresponds well to previous studies of OME children undergoing VT surgery [19].

Strong points of this study include an a priori protocol, planned data collection, and a consecutive sample of children with well-documented bilateral OME and hearing loss. Follow-up assessments were performed at 1, 6, and 12 months using specific outcome criteria for the autoinflation and VT surgery groups, but were limited to only 1 month for the control group. A novel device for autoinflation was developed and used, with excellent adherence to therapy, even in children as young as age 2 years. There were no complications or problems related to using the device reported by parents.

The primary limitation of the study was related to the control (watchful waiting) group, which because of reduced interest by parents was smaller than the other groups and limited to 1 month of follow-up. However, comparative data were obtained at 1 month and our primary interest was in comparative outcomes for autoinflation vs. VT surgery, for

which data were available at 12 months. Although no obvious data supports the use of medical therapy for the long-term treatment of OME [6], possible effect of medical treatment was not documented in the present study.

Only a handful of children with OME are detected and a minority undergoes VT surgery leaving a great majority with no active treatment [7], motivating for a non-surgical approach in treatment of OME in most children. To our knowledge there is no other method of autoinflation for treatment of children under age 4 years that suggests hearing thresholds comparable to VT surgery.

Conclusion

Autoinflation by the Moniri® device is well tolerated and an effective alternative to VT surgery. This device may be initiated directly after diagnosis in order to improve the hearing and the quality of life in children with OME and reduce the need for VT surgery.

Author contributions

Armin B Moniri conceived the study hypothesis, carried out the experiments and took the lead in writing the manuscript. Richard M. Rosenfeld contributed to the writing of the manuscript. Luaay Aziz and João Lino adapted and submitted the manuscript to the journal. All authors contributed to the interpretation of the results, provided critical feedback and contributed to the final manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Disclosure statement

Armin B Moniri is the patent holder of the autoinflation device. The other authors have no conflicts of interest to disclose.

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