Autoinflation as a Treatment of Secretory Otitis Media

A Randomized Controlled Study

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• This study was undertaken to evaluate the effect of a new method of autoinflation as an alternative treatment of secretory otitis media. Up to 80% of all children experience one or more episodes of eustachian tube dysfunction and secretory otitis media before school age. Common treatment of this condition is insertion of a ventilation tube in the tympanic membrane. Because of the very high incidence of secretory otitis media in childhood, insertion of ventilation tubes is the most frequently performed operation under general anesthesia in children. In addition to possible anesthetic complications, insertion of ventilation tubes may be associated with purulent suppuration, pathologic findings in the eardrum, and hearing impairment. One hundred children were consecutively randomized to undergo either autoinflation, using a new device, or placed in a control group. The children were between 3 and 10 years of age and were entered into the study after having had secretory otitis media for at least 3 months, as verified by tympanometric findings. Tympanometry was repeated at 2 weeks and at 1, 2, and 3 months after the children were entered into the study. After 2 weeks of autoinflation, the tympanometric conditions were improved in 64% of ears, unchanged in 34%, and deteriorated in the remaining 2%. In the control group, tympanometric findings were improved in 15% of ears, unchanged in 71%, and deteriorated in the remaining 14%.

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Epidemiologic studies have shown that up to 80% of all children have episodes of eustachian tube dysfunction and secretory otitis media of varying duration before attaining school age.[1] In addition to causing reduced hearing and various eardrum changes,[2] secretory otitis media predisposes to acute middle ear infection.[3] Some investigators even claim that all chronic middle ear diseases occurring later in life, such as chronic otitis media and cholesteatoma, are directly attributable to secretory otitis media in childhood.[4] Owing to the great variability of the spontaneous course of secretory otitis media, it has been common policy to observe the child and postpone treatment until the condition has persisted for at least 3 months. The following forms of treatment are available: sustained antibiotic treatment[5]; adenoidectomy; paracentesis; politerization; and, finally, the most common and, perhaps, most effective, insertion of a ventilation tube in the eardrum.[6] The latter procedure is usually performed under general anesthesia and is, in fact, the most frequent reason for general anesthesia in children. Because of the high extrusion rate of the ventilation tubes, many children undergo the procedure several times. In addition to the possible complications of anesthesia, insertion of ventilation tubes may have the following adverse effects: purulent discharge of varying duration[7]; development of eardrum changes, such as myringosclerosis[8]; and permanent eardrum perforation.[9] Throughout the ages, various methods have been used for inflation of the middle ear,[10] but, since the pioneering work of Politzer in 1869,[11] the Valsalva maneuver and passive inflation (the Politzer test) have been the prevailing methods.

The present study was undertaken to determine whether it was possible to teach children a new method of autoinflation using a specially designed tube designed to improve their middle ear ventilation and, thereby, reducing the need for insertion of ventilation tubes.

SUBJECTS AND METHODS

From June to December 1988, 100 children were included in the study. The inclusion criteria included unilateral or bilateral secretory otitis media for at least 3 months as verified by tympanometry (performed at visits 1 and 2), and the child's age needed to be between 3 and 10 years. The age limits had been established in a pilot study showing that some children younger than 3 years of age had difficulties performing autoinflation, whereas all children at or older than 3 years of age were able to perform the task.

The patients were randomized to either a group performing autoinflation for 2 weeks or to a group being observed without treatment for 2 weeks. Otomicroscopy and tympanometry were performed after 2 weeks (at visit 3), after 1 month (visit 4), after 2 months (visit 5), and after 3 months (visit 6). The children's medical history for the year preceding the study was recorded and special emphasis was placed on the following conditions: place of nursing, acute otitis media, adenoidectomy, paracentesis, grommet insertion, and antibiotic treatment. At each visit, the anamnesis for the preceding period was recorded, especially with regard to acute otitis media and antibiotic treatment.

Autoinflation was performed using a tube designed by one of the authors (S.E.S.) (Fig 1). One end of the tube is sealed tightly

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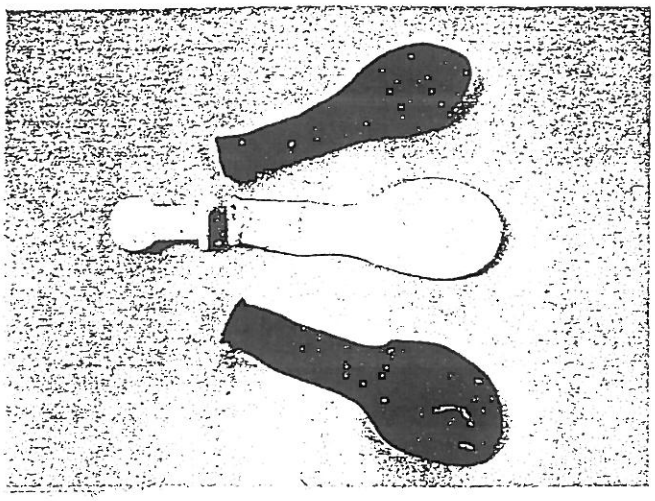

Fig 1.—*Nose tube and balloons for mounting.*

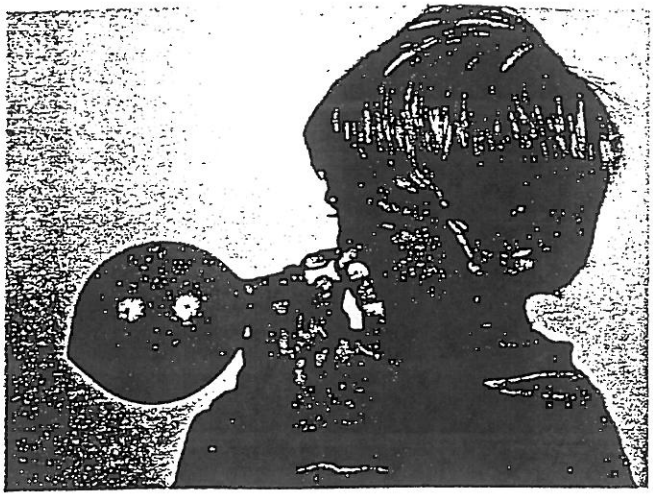

Fig 2.—*Autoinflation using the nose tube.*

Table 1.—Tympanometry at Entry and After 2 Weeks Related to the Degree of Autoinflation*

	Degree of Autoinflation					
	None (N=6)		Only a Few Times (N=16)		3 Times/d (N=51)	
Tympanogram Type	Entry	After	Entry	After	Entry	After
A	. . .	. . .	. . .	6.3	. . .	27.5
C1	. . .	. . .	. . .	6.3	. . .	19.6
C2	33.3	50.0	43.8	37.5	43.1	23.5
B	66.7	50.0	56.3	50.0	56.9	29.4
P	NS		NS		<.01	

*Children were randomized to the autoinflation group.

to the nostril and a balloon is fitted at the other end (Fig 2). When the other nostril is squeezed hard and the child is performing the Valsalva maneuver, the balloon is blown up, thereby causing the positive pressure in the nasopharynx to be transmitted through the eustachian tube to the middle ear where the negative pressure is equalized. The children were asked to perform autoinflation three times daily for 2 weeks, between visits 2 and 3, and to cease if they acquired a common cold or purulent rhinitis. At the second visit after the start of the trial, the use of the nose balloon was scored in the following way: 0, not used; 1, used a few times; and 2, used as prescribed. If a type C2 or a type B tympanogram still persisted after 2 weeks of autoinflation, the children were instructed to continue with the test for 2 more weeks.

Of the 50 children randomized to the autoinflation group, 20 girls and 26 boys (median age, 5.3 years) attended, as a minimum, the first three trials, including the first visit after 14 days with autoinflation. Of the 50 children in the control group, 19 girls and 28 boys (median age, 5.3 years) attended at least the three first trials.

Statistical analysis was performed using the Mann-Whitney rank sum test. The chosen level of significance was $P<.05$.

RESULTS

Statistical Results

No statistically significant differences were computed between the treated group and the control group with regard to nursing conditions, occurrence of acute otitis media, adenoidectomy, grommet insertion, or the use of antibiotics in the year preceding the study period. At the 2-week visit, three children had not performed autoinflation, 10 children had done it only once, and 33 children had followed the instructions. In this group, the best tympanometric conditions after the first period of treatment were found in those children who had performed the procedure as prescribed, whereas the poorest conditions were demonstrated in children who had not performed the procedure (Table 1). In the autoinflation group, at entry into the study, a type C2 tympanogram was demonstrated in 42.5% of ears, and a type B tympanogram was recorded in 57.5% of ears, for a total of 73 ears. Comparison of the two groups included only those children who had performed autoinflation as prescribed. In the control group, a type C2 tympanogram was demonstrated in 57.5% of ears, and a type B tympanogram was recorded in 42.5% of ears, constituting a total of 73 ears.

Table 2.—Tympanometry Types After 2 Weeks of Autoinflation or Observation*

Tympanogram Type After 2-wk Period	Control Group (n=42), No. (%)	Autoinflation Group (n=22), No. (%)
A	2 (4.8)	12 (54.5)
C1	4 (9.5)	6 (27.3)
C2	26 (61.9)	3 (13.6)
B	10 (23.8)	1 (4.5)

*These ears had a type C2 tympanogram at entry. $P<.001$.

Type C2 Tympanogram at Entry

In the control group, middle ear pressure improved spontaneously after 2 weeks of observation in 14.3% of

Table 3.—Tympanometry Types After 2 Weeks of Autoinflation or Observation*

Tympanogram Type After 2-wk Period	Control Group (n=31), No. (%)	Autoinflation Group (n=29), No. (%)
A	. . .	2 (6.9)
C1	2 (6.5)	4 (13.8)
C2	3 (9.7)	9 (31.0)
B	26 (83.9)	14 (48.3)

*These ears had a type B tympanogram at entry. $P<.01$.

Table 4.—Tympanometry Types After Additional 2 Weeks of Autoinflation or Observation After Initial Treatment*

Tympanogram Type After 2-wk Period	Control Group (n=24), No. (%)	Autoinflation Group (n=12), No. (%)
A	. . .	2 (16.7)
C1	4 (16.7)	1 (8.3)
C2	12 (50.0)	9 (75.0)
B	8 (33.3)	. . .

*These ears had a type C2 tympanogram at entry.

Table 5.—Tympanometry Types After Additional 2 Weeks of Autoinflation or Observation After Initial Treatment*

Tympanogram Type After 2-wk Period	Control Group (n=31), No. (%)	Autoinflated Group (n=15), No. (%)
A	2 (6.5)	. . .
C1	2 (6.5)	. . .
C2	6 (19.4)	4 (26.7)
B	21 (67.7)	11 (73.3)

*These ears had a type B tympanogram at entry.

ears. In 61.9% of ears, the pressure was unchanged; in 23.8% of ears, it had deteriorated. In the autoinflation group, the tympanometric conditions were improved in 81.8% of the ears, unchanged in 13.6%, and deteriorated in 4.5%. (Table 2). The difference between the two groups is statistically significant ($P<.001$).

Type B Tympanogram at Entry

In the control group, 83.9% of ears still showed a flat curve after 14 days. In the autoinflation group, 48.3% of ears still had a type B tympanogram after 2 weeks of autoinflation; 31% had type C2; 13.8%, type C1, and 6.9%, type A. The difference between the two groups is statistically significant ($P<.01$) (Table 3). The children in the autoinflation group who still had a type C2 or type B tympanogram after 14 days of treatment were asked to continue the test for 2 more weeks. Among ears with a type C2 tympanogram after 2 weeks of treatment, findings from tympanometry showed improved conditions in 25% of ears and unchanged conditions in the other 75%. In the control group, the tympanogram type was improved in 16.7% of ears, unchanged in 50%, and deteriorated in the remaining 33.3% (Table 4). In ears with a type B tympanogram after 2 weeks of treatment, conditions had improved in 26.7% of ears and were unchanged in the other 73.3%. In the control group, the conditions were improved in 32.3% of ears and unchanged in the other 67.7% (Table 5). Overall, the tympanometric conditions were better in the treated group than in the control group 14 days after cessation of autoinflation; no statistically significant differences could be demonstrated after 2 or 3 months (Table 6).

Need for Further Therapy

One of the main arguments against autoinflation has been the theoretical risk of blowing bacteria from the nasopharynx into the middle ear cavity. To determine the risk of developing acute otitis media in connection with performing the autoinflation test, both groups of children

Table 6.—Tympanometry at Entry and After Four Visits in Control Group and Autoinflation Group

	Entry, %		Day 14, %		Day 30, %		Day 60, %		Day 90, %	
	Control	Autoinflation	Control	Autoinflation	Control	Autoinflation	Control	Autoinflation	Control	Autoinflation
A	. . .	. . .	2.7	27.5	3.3	17.4	7.0	9.3	12.2	9.8
C1	. . .	. . .	8.2	19.6	9.8	6.5	8.8	11.6	2.0	7.3
C2	57.5	43.1	39.7	23.5	36.1	50.0	33.3	39.5	28.6	31.7
B	42.5	56.9	49.3	29.4	50.8	26.1	50.9	39.5	57.1	51.2
N	73	51	73	51	61	47	57	44	49	42
P	NS		<.001		<.05		NS		NS	

Table 7.—Occurrence of Acute Otitis Media*

	No. of Visit, %					
	1	2	3	4	5	6
Control (C)	19.2	5.5	5.5	6.6	5.3	4.1
Autoinflation (A)	35.3	5.9	2.0	. . .	9.1	9.1
No. C/A	73/51	73/51	73/51	61/47	57/44	49/42

*Children in the control group and the autoinflation group were asked to relate any ear complaint before each of six visits.

were specifically asked to inform us about any ear complaint they might have had in the period preceding each visit. In the first period, acute otitis media occurred in 2% of ears in the autoinflation group and in 5.5% in the control group. In the second period, none of the children in the autoinflation group had acute otitis media, compared with 6.6% in the control group (Table 7).

In the period between the second and third visit, none of the children in the autoinflation group had been prescribed antibiotics, compared with 4.3% of the children in the control group. Between the third and fourth visit, 2.6% of the children in the autoinflation group received antibiotics, compared with none in the control group. No statistically significant differences could be demonstrated in the tympanometric conditions among ears treated with ventilation tubes in the year preceding entry into the study and ears that had not been treated with ventilation tubes.

COMMENT

The results of the present trial show that from the age of 3 years many children with tubal dysfunction may benefit from performing autoinflation using the nasal tube. Because of its short-lasting effect, however, repeated use of the tube is necessary. By carrying out this test, many children learn to perform the Valsalva maneuver in a more effective way, thereby making the nasal tube superfluous. It is important that the child is carefully instructed in the use of the nasal balloon. According to today's common treatment strategy, a child with negative middle ear pressure verified by tympanometric examination is usually observed for 3 months, whereupon a ventilation tube in inserted into the eardrum. Our inflator is well accepted by children, who often find it amusing to use; also, autoinflation can be carried out by the child and is apparently without adverse effects. We have not observed an increased incidence of middle ear infection or eardrum performation in connection with autoinflation. Thus, it is our opinion that as soon as negative pressure has been demonstrated autoinflation should be carried out during the observation period. If the child then continues to have severe negative pressure and a hearing impairment that requires treatment, ventilation tubes can be inserted. It should be stressed, however, that children who have positive results from using the autoinflation balloon should be checked regularly by an otologist.

References

1. Tos M. Epidemiology and natural history of secretory otitis. *Am J Otol.* 1984;5:459-462.
2. Tos M, Stangerup SE, Holm-Jensen S, Sorensen CH. Spontaneous course of secretory otitis and changes of the eardrum. *Arch Otolaryngol.* 1984;110:281-289.
3. Stangerup SE, Tos M. The etiological role of acute suppurative otitis media in chronic secretory otitis. *Am J Otolaryngol.* 1985;6:126-131.
4. Tos M. Relationship between secretory otitis in childhood and chronic otitis and its sequelae in adults. *J Laryngol Otol.* 1981;95:1011-1022.
5. Thomsen J, Sederberg-Olsen J, Balle V, Vejlsagård R, Stangerup SE, Bondesson G. Antibiotic treatment of children with secretory otitis media. *Arch Otolaryngol Head Neck Surg.* 1989;115:447-451.
6. Armstrong BW. A new treatment for chronic secretory otitis media. *Arch Otolaryngol.* 1954;59:653-654.
7. Brockbank MJ, Jonathan DA, Grant HR, Wright A. Goode T-tubes: do the benefits of their use outweigh their complications? *Clin Otolaryngol.* 1988;13:351-356.
8. Tos M, Bonding P, Poulsen G. Tympanosclerosis of the drum in secretory otitis after insertion of grommets: a prospective comparative study. *J Laryngol Otol.* 1983;97:489-496.
9. Lildholt T. Ventilation tubes in secretory otitis media: a randomized, controlled study of the course, the complications, and the sequelae of ventilation tubes. *Acta Otolaryngol.* 1983;398(suppl):1-28.
10. Black NA. Fashion, science and technical change: the history of the treatment of glue ear. *Clin Otolaryngol.* 1985;10:31-41.
11. Politzer A. *A Textbook of the Diseases of the Ear for Students and Practitioners.* 5th ed. London, England: Ballière Tindall & Co; 1909;145-155, 282-302.

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