Treatment of otitis media with effusion based on politzerization with an automated device

Daniel S. Arick, MD, FACS; Shlomo Silman, PhD

Abstract

This study evaluated the efficacy of politzerization with an automated, hand-held device that controls volume velocity (airflow) in the treatment of 20 children with otitis media with effusion. These patients underwent politzerization twice a week for up to 6 weeks. Another 20 children with otitis media with effusion who were not treated with politzerization served as controls. Following treatment, resolution of the average air-bone gap to within normal limits was achieved in 70% of the treated group and 20% of the controls, which eliminated the need for grommet insertion in these patients. Improvement in tympanometric peak pressure was also significantly greater in the treated group. Politzerization was efficiently and successfully performed in all patients. The automated device's ease of administration and its ability to control airflow suggests that it has the potential to be an effective home treatment that can be administered by the parents or guardians of children who have otitis media with effusion.

Introduction

Most preschool-aged children experience at least one episode of otitis media with effusion.[1-3] The most common complications of otitis media with effusion are an increase in the hearing threshold level and conductive hearing impairment.[3,4] Otitis media with effusion has been associated with eardrum changes,[5] and it predisposes patients to acute otitis media.[6] Other complications of otitis media with effusion are chronic suppurative otitis media, mastoiditis, cholesteatoma, and extension of the infection into the intracranial space.[1,7] Many investigators have suggested that otitis media with effusion can adversely affect speech, language, cognition, and academic performance, although these hypotheses are still subject to debate.[8-11]

The purpose of this investigation was to determine the efficacy of a nonsurgical treatment of otitis media with effusion. This treatment is based on a modified Politzer method, and it is administered with the help of an automated device of the authors' own invention. Unlike the standard devices, this portable, hand-held, easy-to-use device allows the physician to control the amount of air pressure and airflow. It also provides a continuous flow, and it enables the user to synchronize the air pressure stream with the act of swallowing.

In this article, we report the results of a 6-week study of the efficacy of this treatment in improving air-bone gaps and tympanometric peak pressure levels in 20 children with recurrent otitis media with effusion.

From the New York Eye and Ear Infirmary, New York City (Dr. Arick), and the City University of New York, New York City (Dr. Silman).
Reprint requests: Daniel S. Arick, MD, 755 Park Ave., New York, NY 10021. Phone: (212) 737-5511; fax: (212) 794-9630.

Materials and methods

Patients. Children were candidates for the treatment group if they met the criteria for grommet insertion for otitis media with effusion. Our criteria for grommet insertion were (1) age younger than 13 years, (2) persistence of otitis media with effusion based on microtoscopy for at least 2 months, and (3) persistence of substantial air-bone gaps (=15 dB) at 500, 1,000, and 2,000 Hz for at least 2 months. Informed consent was obtained for participation, with the stipulation that any grommet insertion would be deferred until the conclusion of treatment. Children whose parents or guardians refused their participation in the experimental treatment made up the control group.

Procedure. Our data were collected prospectively. At the initial treatment visit, each subject underwent a complete otolaryngologic evaluation, which was immediately followed by a complete audiologic evaluation (this sequence was followed for all retests as well). The otolaryngologic evaluation included microtoscopy. The audiologic evaluation included measurements of pure-tone air and bone conduction thresholds and the acoustic immittance pressure function.

Politzerization was performed with an automated device that was developed by the authors of this article and was administered by the senior author (DSA). Subjects were seated in the otolaryngologic examination chair for the procedure. The senior author inserted the pediatric probe tip, which was attached to the device, into one randomly

selected nostril while compressing the other nostril with his finger. The patient was asked to keep the mouth closed during the procedure. The device introduced airflow into the nostril at a constant rate. After approximately 5 seconds of airflow, the patient was asked to swallow water from a cup. Changes in air pressure in the nasal cavity during swallowing were indicated by a flashing light on the device. Politzerization was performed twice during each treatment session.

Treatment was administered twice a week until the average air-bone gap resolved to within normal limits, or for 6 weeks for those patients whose impairment did not resolve. At the first treatment session, each patient underwent complete otolaryngologic and audiologic evaluations. At subsequent sessions, air and bone conduction thresholds were measured, and acoustic immittance testing was performed immediately before and after each politzerization. Complete audiologic and otolaryngologic evaluations were performed again 3 to 4 weeks after resolution or the discontinuation of treatment.

Resolution of conductive hearing impairment was defined as an average air-bone gap of less than 15 dB (based on 500, 1,000, and 2,000 Hz) prior to politzerization at a given treatment session. This criterion for resolution was chosen because closure of the average air-bone gap to less than 15 dB would have eliminated the need for grommet insertion. Tests to confirm resolution were administered 1 week later. When resolution was confirmed, politzerization was discontinued; otherwise, treatment continued for up to a maximum of 6 weeks.

For the purpose of data analysis, an absent tympanometric peak pressure was recorded as –401 daPa, because the air pressure sweep during tympanometry began at +200 and ended at –400 daPa.

Equipment. The apparatus for equalizing air pressure in the middle ear, which was developed by the authors (U.S. Patent No. 5,419,762 5/30/95 and No. 5,885,242 3/23/99), is a modified Politzer autoinsufflation device (figure 1). It is hand-held, portable, and battery-powered, and it is used for the nonsurgical management of otitis media with effusion and to treat eustachian tube dysfunction. The apparatus includes a compressor that provides a continuous flow of air at a predetermined pressure. A tapered nostril plug has a distal opening through which the continuous flow of air passes. The device can be set to deliver airflow in the range of approximately 1 to 4 L/min, which will provide an air pressure level between 0.5 psi and 3.0 psi.

Figure 1. Hand-held, portable modified Politzer autoinsufflation device developed by the authors.

Results

The treatment group consisted of 20 children, aged 3 to 12 years (mean: 7.8), and the control group was made up of 20 children, aged 4 to 11 years (mean: 8.1).

In pretest measurements, the average air-bone gap was slightly worse in the treatment group than in the controls. In the final test, the average air-bone gap was within normal limits in the treated group, and it exceeded normal limits in the control group (table 1). In both groups, the mean tympanometric peak pressure was better at the final retest than at the pretest. Also, there was more improvement in the treatment group than in the control group. Repeat-measures t tests were performed on the results of

Table 1. Average air-bone gap* (ABG) and tympanometric peak pressure (TPP) levels at the initial and the final tests

Group	Pretest ABG	Final ABG	Pretest TPP	Final TPP
Treated patients				
Mean	28.2	10.0	-388.4	-145.1
SD	9.4	12.8	39.6	113.7
Controls				
Mean	33.8	25.7	-343.1	-280.4
SD	8.7	10.6	181.3	151.9
151.9				

** Based on 500, 1,000, and 2,000 Hz.*

Table 2. Summary statistics for pretest-minus-final-retest differences in average air-bone gap* and tympanometric peak pressure level

Measure	Treated group	Control group	*t* statistic	*p* value
Average air-bone gap				
Mean	18.1	8.1	2.0938	0.043
SD	16.8	13.2		
Tympanometric peak pressure				
Mean	−245.8	−102.8	−3.1817	0.003
SD	112.5	166.6		

** Based on 500, 1,000, and 2,000 Hz.*

the pretest-minus-final-retest average air-bone gap and the pretest-minus-final-retest tympanometric peak pressure level in both groups (table 2). Statistical analysis revealed significant differences between the two groups. Although both groups showed improvement in both measures from pretest to final test, the improvement was significantly greater in the treatment group.

All of the treatment and control subjects had abnormal average air-bone gaps (=15 dB) at the pretest. Resolution of the average air-bone gap to within normal limits occurred in 70% of the treated subjects, compared with only 20% of the control subjects. In the 70% of treated patients who improved, politzerization eliminated the need for grommet insertion. All subjects also had abnormal tympanometric peak pressure levels (<–100 daPa) at the pretest. At the final retest, improvement of tympanometric peak pressure to within normal limits (~100 daPa) was seen in 55% of the treated patients and 25% of the controls.

The changes in the average air-bone gap and the tympanometric peak pressure in a typical treated patient (a 7-year-old boy) are illustrated in figures 2 and 3. Note that the complete resolution of the average air-bone gap preceded that of the tympanometric peak pressure. A comparison of pre- and post-test results at any given treatment session reveals that politzerization brought about improvement in both measures, although both might become abnormal over time. This suggests that the criteria for declaring success in resolving otitis media after politzerization should be based on the findings of at least one retest. In this 7-year-old boy, resolution was achieved after continued politzerization over a 2-week period, as evidenced by the normal average air-bone gap at the pretests performed during weeks 2 and 3.

Discussion

Effective nonsurgical treatment of children with otitis media with effusion remains elusive. Maneuvers that cause retrograde inflation of the middle ear by forcing air through the eustachian tube were described by Valsalva[12] and Politzer.[13] Valsalva's maneuver, a self-inflation (autoinflation) method, involves forced nasal expiration while the nose and lips are sealed. The Politzer method of inflation involves inserting the tip of a rubber air bulb into one nostril while compressing the other nostril; the rubber bulb is squeezed while the patient swallows, which causes tubal opening.

Cantekin et al evaluated the effect of Valsalva's maneuver on preschool-aged children who had recurrent or chronic otitis media and functioning tympanostomy tubes.[14] None of these children was successful in opening the eustachian tube with Valsalva's maneuver. In a randomized clinical trial of children with chronic otitis media, Chan and Bluestone evaluated the efficacy of a modified Valsalva's technique that could be performed at home.[15] Their results

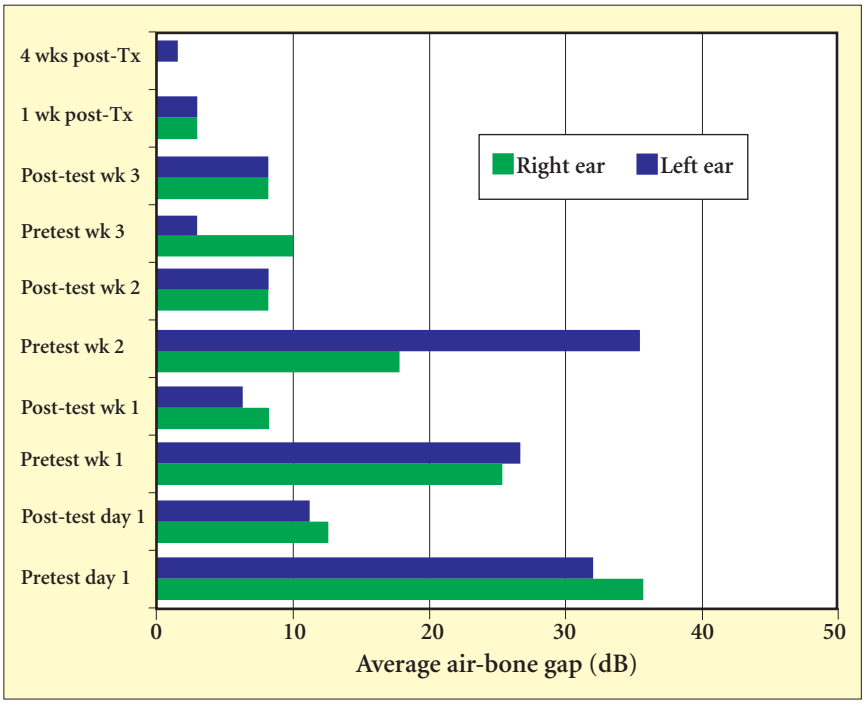

Figure 2. Average air-bone gap (based on 500, 1,000, and 2,000 Hz) over 4 weeks in a 7-year-old boy treated with politzerization.

revealed that this procedure lacked demonstrable therapeutic efficacy after a 2-week trial. Stangerup et al's modification of Valsalva's maneuver involved inserting a nosepiece attached to a balloon into one nostril and compressing the other nostril.[16] The balloon inflated when the maneuver was successful. This autoinflation method was performed three times daily for 2 weeks by 29 patients who had secretory otitis media. The failure rate was 48%.

Blanshard et al evaluated Stangerup et al's modification in 85 children (age range: 3 to 10 yr) who had bilateral middle ear effusion and were candidates for grommet insertion.[17] Their study demonstrated that this autoinflation technique had a beneficial effect after 2 to 4 weeks of treatment. The disadvantages of the Stangerup et al modification included difficulty in performing the procedure. Because of its aforementioned limitations,[14,15,17] Valsalva's maneuver is not often employed as a nonsurgical treatment of otitis media with effusion and related conditions.

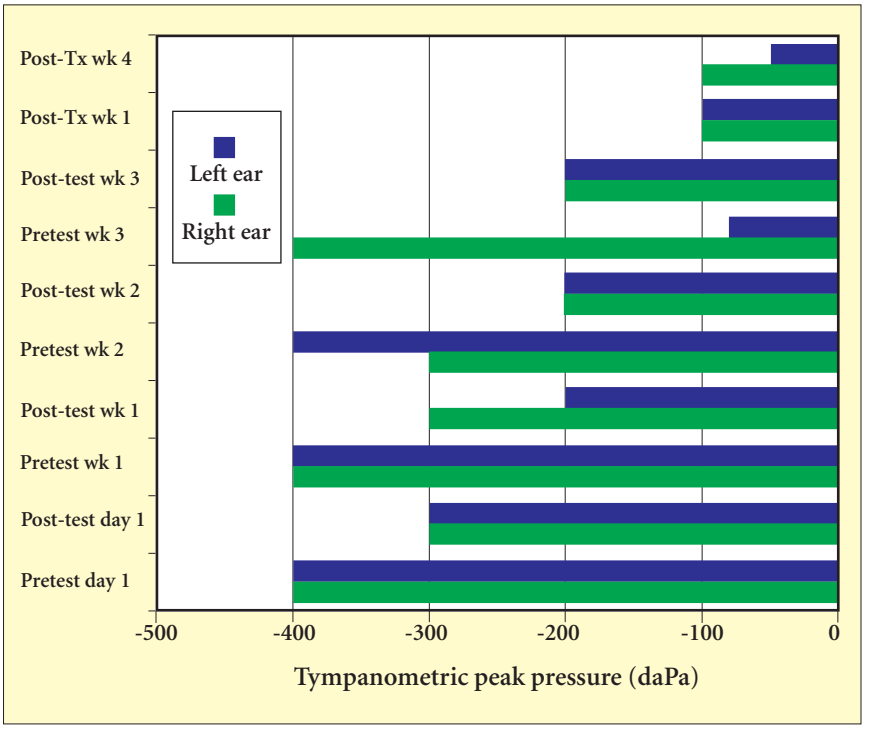

Figure 3. Tympanometric peak pressure levels over 4 weeks in the same 7-year-old boy.

Schwartz et al's[18] modification of the Politzer maneuver was patterned after that described by Shea.[19] Schwartz et al's procedure was performed by forcing air through the nostril with a 1-oz infant nasal syringe outfitted with a plastic tip that was inserted into a nostril. They studied 24 children who had negative middle-ear pressure and associated tympanic membrane retraction and 12 untreated controls (children and adults). The effectiveness of the technique was evaluated by tympanometry at 5 and 10 minutes post-politzerization. The mean improvement in tympanometric peak pressure levels following politzerization in the group as a whole was only 9 mm H_2O. Three limitations of this study were that (1) the procedure was performed only once on each patient, (2) only the short-term benefit was measured, and (3) no comparison was made between the treated patients and the controls. Kaneko et al evaluated the efficacy of politzerization over a 3-month period in 227 patients with secretory otitis media.[20] Treatment was beneficial in 49% of these patients.

The potential advantage of the Politzer method over Valsalva's maneuver is that forced airflow is initiated by an external source in the former procedure, whereas in the latter case, airflow is initiated by the subject, who often is noncompliant. Very few studies have investigated the efficacy of the Politzer method in the treatment of otitis media with effusion and related conditions. Four factors that account for this paucity of research are (1) the cumbersome nature of the standard devices, (2) the intermittent and fluctuating airflow seen with standard devices, (3) the difficulty in coordinating the air pressure stream with swallowing, and (4) the fact that because air pressure and volume cannot be controlled with standard devices, they might introduce harmful or ineffective air pressure levels. These limitations have also precluded investigation of the efficacy of long-term treatment.

In conclusion, politzerization with the device used in this study was successful in all subjects. The authors are currently conducting a study funded by the National Institute on Deafness and Other Communication Disorders to evaluate the feasibility of using this procedure as a daily autoinsufflation treatment administered at home (figure 4). The parents or guardians of children who have otitis media with effusion will be trained in operating the device. We also plan to conduct large clinical trials of the apparatus at several centers throughout the United States.

References

1. Bluestone CD, Klein JO. Otitis Media in Infants and Children. 2nd ed. Philadelphia: W.B. Saunders, 1995.
2. Fiellau-Nikolajsen M. Tympanometry and secretory otitis media: Observations on diagnosis, epidemiology, treatment, and prevention in prospective cohort studies of three-year-old children. Acta Otolaryngol Suppl (Stockh) 1983;394:1-73.
3. Tos M. Epidemiology and natural history of secretory otitis. Am J Otol 1984;5:459-62.
4. Fria TJ, Cantekin EI, Eichler JA. Hearing acuity of children with otitis media with effusion. Arch Otolaryngol 1985;111:10-6.

Figure 4. An ongoing study is examining the usefulness of the autoinsufflation device for daily treatment at home, as demonstrated here.

5. Tos M, Stangerup SE, Holm-Jensen S, Sorensen CH. Spontaneous course of secretory otitis and changes of the eardrum. Arch Otolaryngol 1984;110:281-9.
6. Stangerup SE, Tos M. The etiologic role of acute suppurative otitis media in chronic secretory otitis. Am J Otol 1985;6:126-31.
7. Tos M. Upon the relationship between secretory otitis in childhood and chronic otitis and its sequelae in adults. J Laryngol Otol 1981; 95:1011-22.
8. Friel-Patti S, Finitzo T. Language learning in a prospective study of otitis media with effusion in the first two years of life. J Speech Hear Res 1990;33:188-94.
9. Gravel JS, Wallace IF, Ruben RJ. Early otitis media and later educational risk. Acta Otolaryngol 1995;115:279-81.
10. Grievink EH, Peters SA, van Bon WH, Schilder AG. The effects of early bilateral otitis media with effusion on language ability: A prospective cohort study. J Speech Hear Res 1993;36:1004-12.
11. Schilder AG, Van Manen JG, Zielhuis GA, et al. Long-term effects of otitis media with effusion on language, reading and spelling. Clin Otolaryngol 1993;18:234-41.
12. Valsalva AM (1666-1723). De aura humane tractatus, 1741.
13. Politzer A. Diseases of the Ear. Philadelphia: Lea & Febiger, 1909.
14. Cantekin EI, Bluestone CD, Parkin LP. Eustachian tube ventilatory function in children. Ann Otol Rhinol Laryngol 1976;85(Suppl 25):171-7.
15. Chan KH, Bluestone CD. Lack of efficacy of middle-ear inflation: Treatment of otitis media with effusion in children. Otolaryngol Head Neck Surg 1989;100:317-23.
16. Stangerup SE, Sederberg-Olsen J, Balle V. Autoinflation as a treatment of secretory otitis media: A randomized controlled study. Arch Otolaryngol Head Neck Surg 1992;118:149-52.
17. Blanshard JD, Maw AR, Bawden R. Conservative treatment of otitis media with effusion by autoinflation of the middle ear. Clin Otolaryngol 1993;18:188-92.
18. Schwartz DM, Schwartz RH, Redfield NP. Treatment of negative middle ear pressure and serous otitis media with Politzer's technique: An old procedure revisited. Arch Otolaryngol 1978;104:487-90.
19. Shea JJ. Autoinflation treatment of serous otitis media in children. J Laryngol Otol 1971;85:1254-8.
20. Kaneko Y, Takasaka T, Sakuma M, et al. Middle ear inflation as a treatment for secretory otitis media in children. Acta Otolaryngol 1997; 117:564-8.