

Efficacy of a Modified Politzer Apparatus in Management of Eustachian Tube Dysfunction in Adults

Shlomo Silman*
Daniel Arick†

Abstract

This study evaluates the efficacy of politzeration on eustachian tube dysfunction following airplane travel using an automated, hand-held device that controls the volume velocity of air flow. Fourteen adults with eustachian tube dysfunction following airplane travel comprised the experimental group. They received politzeration over a period of 6 weeks on a twice-a-week basis. Fourteen adults with eustachian tube dysfunction following airplane travel comprised the control group. They were untreated. Complete audiologic and otolaryngologic evaluations were performed at the pretest and after politzeration treatment was completed. The results revealed a substantial, significant improvement in the mean tympanometric peak pressure from pretest to final post-treatment retest in the experimental, but not the control, subjects. The mean air-bone gap increased significantly from pretest to final post-treatment retest in the control, but not the experimental, subjects. Of the experimental subjects with abnormal tympanometric peak pressures at the pretest, resolution to within normal limits occurred in 71 percent of the experimental subjects versus 21 percent of the control subjects. These results suggest the potential feasibility of treatment of aerotitis media in adults with this modified Politzer method using the automated apparatus.

Key Words: Eustachian tube dysfunction, politzeration, Politzer maneuver, tympanometry, Valsalva maneuver.

Abbreviations: ABG = air-bone gap, TPP = tympanometric peak pressure

Eustachian tube dysfunction may be associated with airplane travel or descent. During these activities, rapid ambient-pressure changes occur that affect the middle ear. During airplane descent, the rapid increase in ambient air pressure results in a partial vacuum (i.e., negative pressure) in the middle ear. The negative middle-ear pressure can result in eustachian tube collapse in the absence of middle-ear ventilation by yawning, swallowing, Valsalva maneuver, etc. Symptoms of eustachian

tube dysfunction include otalgia and conductive hearing impairment.

Negative middle-ear pressure less than -100 daPa was found in 20 percent of the adults and 40 percent of the children who were evaluated after airplane descent (Stangerup, 1998). According to Stangerup (1998), the middle ears of 46 percent of adults and 33 percent of children with negative middle-ear pressure returned to normal following the use of the Valsalva maneuver; the remainder developed aerotitis.

Methods of management of eustachian tube dysfunction have included decongestants, antihistamines, corticosteroid therapy, antimicrobial agents, myringotomy with or without insertion of a tympanostomy tube, and insufflation of the eustachian tube/middle-ear system using the Valsalva or Politzer technique. The efficacy of treatment by drugs has been questioned. Cantekin et al (1983), for example, concluded that decongestant and antihistamine treatment was nonbeneficial in the management of middle-ear effusion.

*Department of Speech Communication Arts and Sciences, Brooklyn College City University of New York Brooklyn New York and Department of Speech and Hearing Sciences PhD Program Graduate School and University Center City University of New York New York New York;

†The New York Eye and Ear Infirmary New York New York
Reprint requests: Shlomo Silman Department of Speech Communication Arts and Sciences Brooklyn College City University of New York 2900 Bedford Avenue Brooklyn NY 11210

Also, Williams et al (1993), in a meta-analysis based on 33 studies, concluded that the beneficial effect of antimicrobial treatment of middle-ear effusion is slight and short term.

Effective nonsurgical treatment of otitis media with effusion remains elusive. Maneuvers that rely upon retrograde inflation of the middle ear by forcing air through the eustachian tube were described by Valsalva (1741) and Politzer (1909). The Valsalva maneuver, a self-inflation (autoinflation) method, involves forced nasal expiration with the nose and lips sealed. Politzer's method of inflation involves insertion of the tip of a rubber air bulb into one nostril and compression of the other nostril; then the rubber bulb is squeezed while the patient swallows to assist in tubal opening.

Cantekin et al (1976) evaluated the effect of the Valsalva maneuver on preschool-aged children with recurrent or chronic otitis media and functioning tympanostomy tubes. None of the children were successful in opening the eustachian tube with the Valsalva maneuver. Chan and Bluestone (1989) evaluated the efficacy of a modified Valsalva technique that permitted home use in a randomized clinical trial on children with chronic otitis media. Their results revealed that this procedure lacked demonstrable therapeutic efficiency after a 2-week clinical trial. Stangerup et al's (1992) modification of the Valsalva maneuver involved insertion of a nosepiece mounted with a balloon into one nostril and compression of the other nostril. The balloon was inflated when the maneuver was successful. The failure rate of the autoinflation treatment (two weeks, three times daily) in the 29 subjects with secretory otitis media was 48 percent. Blanshard et al (1993) evaluated Stangerup et al's modification on 85 children (3-10 years of age) with bilateral middle-ear effusion who were candidates for grommet insertion. Their results revealed the presence of a beneficial effect for the experimental group after 2 to 4 weeks of autoinflation treatment. The disadvantages of the Stangerup et al modification included difficulty in implementing the procedure. Because of the aforementioned limitations (Cantekin et al, 1976; Chan and Bluestone, 1989; Blanshard et al, 1993), the Valsalva maneuver infrequently has been employed for nonsurgical treatment of otitis media with effusion and related conditions.

Schwartz et al's (1978) modification of the Politzer maneuver was patterned after that described by Shea (1971). Schwartz et al's procedure was performed by forcing air through

the nostril using a 1-oz infant nasal syringe with a plastic tip, which is inserted into a nostril. The effectiveness of politzeration was examined using tympanometry at 5 and 10 minutes post politzeration in 24 experimental subjects with negative middle-ear effusion and associated tympanic-membrane retraction and in 12 control subjects (children and adults). The mean improvement in tympanometric peak pressure (TPP) for the total group of subjects following politzeration was only 9 mm H₂O. Limitations of the study included the one-time use of the procedure, measurement only of short-term benefit minutes after employing the procedure, and failure to analyze the results for the control versus experimental subjects.

Kaneko et al (1997) evaluated the efficacy of politzeration over a 3-month period in 227 patients with secretory otitis media. The treatment results were beneficial in 49 percent at the end of this period.

The potential advantage of the Politzer method over the Valsalva maneuver is that forced air flow is initiated by an external source in the former procedure, whereas it is initiated by the subject, who often is noncompliant, in the latter case. Very few studies have investigated the efficacy of the Politzer method in treatment of otitis media with effusion and eustachian tube dysfunction. Factors accounting for this paucity of research on the Politzer method include the following: (a) the cumbersome nature of existing devices, (b) noncontinuous and fluctuant air-pressure flow with existing device, (c) difficulty in time-locking the air-pressure stream with swallows, and (d) air-pressure and air-flow volume cannot be controlled with existing devices, so harmful or ineffective air pressures may be introduced. These limitations also have precluded investigation of the efficacy of long-term treatment with the Politzer maneuver on otitis media with effusion and eustachian tube dysfunction.

Therefore, the purpose of this investigation was to determine the efficacy of a 6-week treatment of eustachian tube dysfunction in adults following airplane travel. The treatment is based on the use of a modified Politzer method with an automated device that overcomes the previously mentioned limitations. This automated, easy-to-use device allows control of air-pressure and air-flow volume, provides a continuous air-pressure flow, and enables the air-pressure stream to be time-locked with swallowing. The preliminary findings on the efficacy of this device for treatment of middle-ear effusion in children

Table 1 Mean Pretest and Final Post-Treatment Retest Air-Bone Gap (ABG) and Tympanometric Peak Pressure (TPP) in the Experimental and Control Groups

Group	Pretest ABG	Final ABG	Pretest TPP	Final TPP
Experimental (N = 14)				
Mean	9.7	10.4	-282.4	-99.4
SD	6.3	6.6	91.0	148.8
Control (N = 14)				
Mean	7.6	21.1	-257.6	-275.8
SD	5.2	14.9	95.8	150.8

revealed that the average air-bone gap (ABG) recovered to within normal limits in 70 percent of the experimental group versus 20 percent of the control group (Arick and Silman, in press)

METHOD

Subjects

Adults who were evaluated over a 6-month period at a private otologic practice were candidates for the experimental group if eustachian tube dysfunction following airplane travel was present. The criteria for study inclusion were as follows: (a) age greater than or equal to 18 years; (b) presenting complaint of middle-ear pain, fullness, or clogged sensation following airplane travel or descent; and (c) TPP less than -100 daPa. Informed consent was obtained for participation in the experimental treatment. Adult subjects who refused participation in the experimental treatment comprised the adult control group.

Procedure

The data were collected prospectively. Each subject was scheduled for a complete otolaryngologic evaluation immediately prior to a com-

plete audiologic evaluation at the same session (initial test and all retests). The otolaryngologic evaluation included microscopy. The audiologic evaluation included the pure-tone air- and bone-conduction thresholds, speech-recognition threshold, suprathreshold speech-recognition score for monosyllabic words, and tympanometry. Tympanometry was performed using the Madsen ZO-73 acoustic-immittance device. The air-pressure sweep during tympanometry began at +200 daPa and ended at -400 daPa, with a 50 daPa/sec rate of air-pressure change.

The experimental treatment consisted of politzeration with an automated device, which was developed by the present authors. Politzeration was administered twice a week by the coauthor (DA). Subjects were seated in the otolaryngologic examination chair for the politzeration. The pediatric probe tip, which was attached to the device, was inserted into one randomly selected nostril while the other nostril was compressed with a finger. The patient was instructed to keep the mouth closed during the politzeration. The device introduced air flow into the nostril with a constant volume velocity. After approximately 5 seconds of air flow from the device, the patient was asked to swallow water from a cup. Change in air pressure in the nasal cavity, during swallowing, was indicated

Table 2 Summary Statistics for the Differences* in Air-Bone Gap (ABG) and Tympanometric Peak Pressure (TPP) for the Experimental and Control Groups

	Experimental (N = 14)	Control (N = 14)	t	p
TPP				
Mean	-182.9	18.1	-3.1599	.004
SD	153.0	182.4		
ABG				
Mean	-0.6	-13.5	2.5107	.019
SD	8.7	17.1		

*Pretest minus final post-treatment retest score

Table 3 Distribution of Normal and Abnormal Tympanometric Peak Pressures (TPPs) at the Pretest and Final Post-Treatment Retest in the Experimental and Control Groups

Group	<i>N to N*</i>	<i>N to ABN[†]</i>	<i>ABN to N[‡]</i>	<i>ABN to ABN[#]</i>
Experimental	0%	0%	71%	29%
Control	0%	0%	21%	79%

*Normal TPP (≥ -100 daPa) at pretest and final post-test.

[†]Normal TPP at pretest and abnormal TPP (< -100 daPa) at final post-test

[‡]Abnormal TPP at pretest and normal TPP at final post-test

[#]Abnormal TPP at pretest and final post-test

by the flashing of a light indicator on the device. The politzeration was repeated twice during each treatment session.

The experimental treatment was provided twice a week over a 6-week period. At the first treatment session, complete otolaryngologic and audiologic evaluations were performed. At subsequent treatment sessions, air- and bone-conduction thresholds and tympanometry were performed immediately prior to and after the politzeration. Complete audiologic and otolaryngologic evaluations also were performed at 3 to 4 weeks post-treatment.

Resolution of eustachian tube dysfunction was defined as a TPP > -100 daPa upon repeat testing. For the purpose of data analysis, an absent TPP was designated as a TPP equivalent to -401 daPa as the air pressure sweep during tympanometric tympanometry terminated at -400 daPa.

Apparatus for Equalizing the Air Pressure in the Middle Ear

The apparatus for equalizing air pressure in the middle ear, developed by Arick and Silman (U.S. Patent Number 5,419,762 5/30/95), is a modified Politzer autoinsufflation device. The Food and Drug Administration has granted Section 510(k) marketing of the apparatus. It is a portable, hand-held, battery-powered, auto-

ated autoinsufflation device for nonsurgical management of middle-ear effusion and eustachian tube dysfunction. The apparatus includes a compressor, activating means coupled to a compressor, the activating means having a closed state and an open state. The open state provides a continuous flow of air from the compressor at a predetermined pressure and a tapered nostril plug in communication with the compressor. The nostril plug has a distal opening for delivering the continuous flow of air. The predetermined pressure is in the range of approximately 0.5 psi to approximately 3.0 psi. The predetermined rate of the air flow is in the range of approximately 1.0 liter/minute to approximately 4.0 liters/minute. Further details about the apparatus are provided in Appendix 1.

For all subjects, an intermediate psi setting (approximately 1.75 psi) and intermediate air-flow rate (approximately 2.5 liters/minute) were employed. The psi and air flow were adjusted by turning the attenuator to the midpoint of the range.

RESULTS AND DISCUSSION

The mean age was 34.6 years (range = 18–76 years) for the experimental group and 35.1 years (range = 16–64 years) for the control group. Politzeration was successfully performed in all of the experimental subjects.

Table 4 Distribution of Nonsignificant and Significant Air–Bone Gaps (ABG) at the Pretest and Final Post-Treatment Retest in the Experimental and Control Groups

Group	<i>NS to NS*</i>	<i>NS to S[†]</i>	<i>S to NS[‡]</i>	<i>S to S[#]</i>
Experimental	65%	7%	14%	14%
Control	43%	43%	7%	7%

*Nonsignificant average ABG (≤ 10 dB) at pretest and final post-test.

[†]Nonsignificant average ABG at pretest and significant average ABG (> 10 dB) at final post-test

[‡]Significant average ABG at pretest and nonsignificant average ABG at final post-test

[#]Significant: average ABG at pretest and final post-test

Table 1 shows the mean pretest and final (last session) retest average TPPs and ABGs, based on 500, 1000, and 2000 Hz, in both groups

Inspection of this table reveals that the pretest average TPP was significantly negative in both groups, although the pretest average ABG did not exceed 10 dB in either group, consistent with a diagnosis of eustachian tube dysfunction. The mean TPP at the final post-treatment session was within normal limits in the experimental but not the control group. In fact, the mean TPP at the final post-test was worse than the mean pretest TPP in the control group.

Table 2 shows the results of repeated-measures t-tests on the difference between the pretest and final post-treatment test TPP and ABG scores for the experimental and control groups. A negative difference in TPP indicates improvement from pretest to final post-treatment retest, whereas a positive difference indicates decline from pretest to final post-treatment retest. A positive difference in ABG indicates improvement from pretest to final post-treatment retest, whereas a negative difference indicates decline from pretest to final post-treatment retest. The results of statistical analysis on the mean pretest minus final post-treatment retest average ABGs and TPPs in the experimental versus control groups revealed significant differences between these groups. The mean TPP improved significantly from pretest to final post-treatment retest in the experimental but not the control group and the mean ABG increased significantly from pretest to final post-treatment retest in the control but not the experimental group.

Table 3 shows the distribution of normal (≥ -100 daPa) and abnormal (< -100 daPa) TPPs at the pretest and final post-treatment retest in the experimental and control groups. None of the experimental or control subjects had normal TPPs at the pretest. At the final post-treatment retest, 71 percent of the experimental subjects versus 21 percent of the control subjects demonstrated resolution of the TPP to within normal limits

Table 4 shows the distribution of non-significant (≤ 10 dB) and significant (> 10 dB) average ABGs at the pretest and final post-treatment retest in the experimental and control groups. Inspection of Table 4 reveals that 72 percent of the experimental subjects and 86 percent of the control subjects had nonsignificant ABGs at the pretest. Only half of the control subjects and half of the experimental subjects with

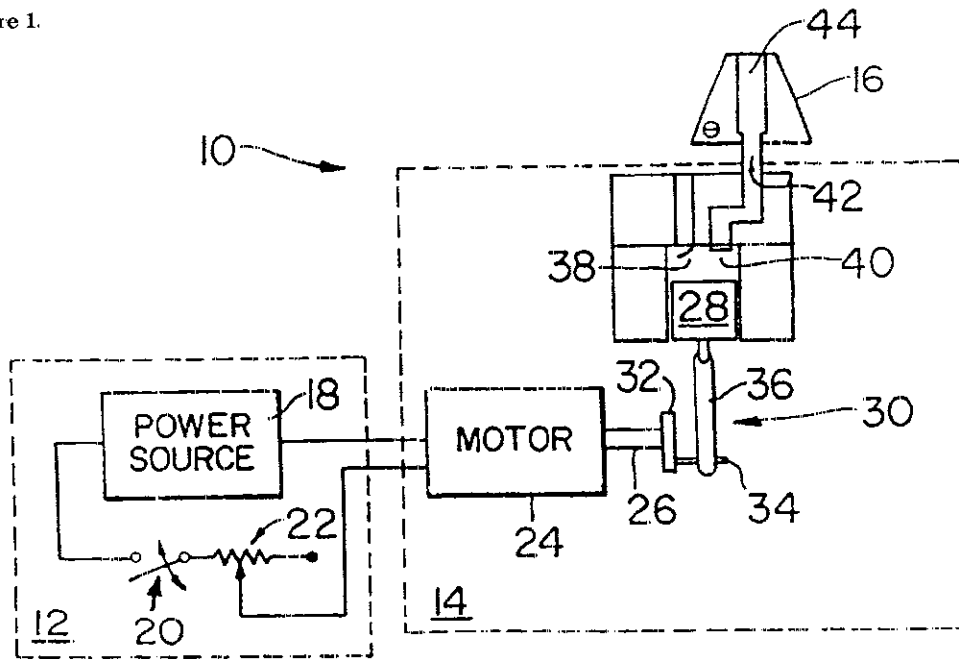
significant average ABGs at the pretest had recovery in the average ABG to within 10 dB at the final post-treatment session

These findings suggest the potential efficacy of a 6-week period of treatment of eustachian tube dysfunction in adults using a modified Politzer method with an automated device. Large-scale studies are needed to corroborate these findings. Studies also are needed to determine whether the success rate can be improved with either a longer period of treatment or the same period of treatment using daily politzerizations.

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Figure 1.



APPENDIX

Description of the Apparatus and Method for Equalizing Pressure in the Middle Ear

Figure 1 is a schematic/cross-sectional view of a first embodiment of the apparatus.

Detailed Description of the Invention

Referring to Figure 1, activation means 12 includes power source 18, switch 20 and power variation means 22. Compressor 14 is activated

by activation means 12. More specifically, compressor 14 includes motor 24 having motor shaft 26. Motor shaft 26 is connected to piston 28 through pivoting linkage 30. Pivoting linkage 30 includes rotating disk 32 having pin 34 extending transversely therefrom, and arm 36. Pin 34 pivotally engages arm 36. Arm 36 pivotally drives piston 28 upon rotary motion of shaft 26 and disk 32. Oscillation of piston 28 affects operation of flutter valves 38 and 40. Deflection of flutter valves 38 and 40 operate to create air flow through exit port 42. Exit port 42 communicates with channel 44 in nostril plug 16.