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ORIGINAL ARTICLE

Non-Surgical Treatment of Otitis Media with Effusion in Children: Efficacy of Middle Ear Inflation with a Politzerization Device*

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Objective: To evaluate the efficacy of politzerization in the treatment of otitis media with effusion (OME) and to investigate the continuity of this efficacy.

Materials and Methods: Children who met the criteria for grommet ventilation tube insertion for OME were evaluated in this study. Politzerization was performed once a week for four weeks with a handheld device. Audiological evaluations were done before and after all treatment sessions and one week and two months after the completion of treatment.

Results: There were 30 children in either of the study and control groups. Tympanometric peak pressure levels were improved in 57% of the study group and resolution of the averages of air-bone gaps to near-normal limits was noted in the half of these patients one week after four-week treatment. Two months later, overall improvement rate dropped to 32% in both of the outcome measures.

Conclusions: Once a week middle ear inflation over a 4-week period was efficacious in the treatment of OME in the short-term but it did not provide satisfactory long-term benefits. Autoinflation may avoid the need for drugs or surgery for middle ear effusion and it may be considered as an alternative to the other choices of treatment of OME. However, further efficacy studies investigating the ideal frequency of application of Politzerization and optimal duration of this conservative treatment are required.

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Otitis media with effusion (OME) is an inflammatory middle ear disease with unpredictable course and prognosis.[1,2] The efficacy of medical and surgical treatments for OME has still been questioned.[3] In the clinical practice guideline of OME that was published in 2004, it has been noticed that medication for OME does not provide long-term benefits.[4] This guideline recommends surgical insertion of ventilation tube (VT) for the children who have OME for four months or longer. However, there are also several arguments against VT's in the treatment of children with OME because of the complications following VT placement.[3]

Inflation of the eustachian tube-middle ear system by Valsalva maneuvar or Politzer method are the alternatives in the conservative treatment of OME.[3,5-7] Politzerization has been demonstrated to be highly efficacious in the treatment of children with OME.[3,5,7]

The purpose of this study was to evaluate the effectivity of middle ear inflation with a Politzerization device in the treatment of children with OME who were waiting for VT insertion and to investigate the permanence of this effectivity in selected children.

Materials and Methods

Study group: Patients with bilateral OME who were between 6-12 years of age were selected from the waiting list for VT insertion. Our criteria for VT insertion were 1) persistence of OME at least three months, 2) persistence of tympanometric peak pressure

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levels smaller than -250 daPa, 3) persistence of air-bone gaps of 15 db or more at three frequencies: 500, 1,000 and 2,000 Hz. Children who had significant deformity or retraction of the tympanic membrane and those for whom adenoidectomy was also indicated were not included in this study.

All of the patients and their parents were informed about the procedure itself and its purpose, in keeping with the mandate of the Declaration of Helsinki. In our practice in the university hospital, we can schedule surgery for children with OME at least 4-6 weeks later. Middle ear inflation was performed during this waiting period for VT insertion. Hence, surgical treatment for a patient who had no response to middle ear inflation was not delayed anyhow.

Control group: The first thirty children whose parents refused Politzerization procedure during the same period were included in the control group.

Middle ear inflation procedure: A handheld, battery-operated Politzerization device (EarPopperTM) was used. Politzerization was done once a week, the same day of each week, for four consecutive weeks. All of the politzeration procedures and audiological examinations were performed by the same investigators (AIT, OBO).

During each session, the child was instructed to be in a sitting position and to held a small amount of water in the mouth without swallowing it. Next, the investigator inserted the probe tip of the device into one nostril while compressing the other nostril by his finger. The investigator, then, turned on the device and thereby introduced airflow into the nostril. After a few seconds, he instructed the child to swallow the water in the mouth. The same procedure was repeated for the other nostril. The children were asked to note pain if they felt. Immediately after politzerization every child was evaluated by tympanometry. If there was no improvement in tympanometry, politzeration was repeated immediately and after 30 minutes rest. If there was still no improvement, politzerization was repeated one week later. After the politzerization in the following week, if no response was noted for this child, no more politzerizations were performed for these patients. Subsequently, these patients were undergone surgery: VT insertion.

Audiological and Otomicroscopic Examinations: Pure tone audiometry and tympanometry was performed and averages of air-bone gaps at 500, 1,000 and 2,000 Hz were calculated for all patients. Audiological examinations were done before and after each politzerization procedure every week. Otomicroscopy was done before and after 4-week politzerization. It was just used to detect deformity or retraction of tympanic membrane before the treatment and to confirm the resolution of middle ear effusion after 4-week treatment. As it would have been subjective, no special otomicroscopic parameter was taken into account to evaluate or grade the severity of effusion before and after weekly treatment sessions.

Improvement after middle ear inflation was based on the criteria modified from the study of Arick and Silman.[5] Average air-bone gap of less than 15 dB at 500, 1,000 and 2,000 Hz and typamometric peak pressure greater than -100 daPa were used as the indicators of resolution of OME. If resolution was noted after 4-week trial period and if this could be confirmed by otomicroscopy one week later, no treatment was recommended for these patients and they were reevaluated two months later. Persistence of improvement in that visit eliminated the need for ventilation tube insertion and all of the parents were advised to call us immediately in case of any change in in hearing status of their children thereafter.

The patients whose conditions did not improve during or at the end of 4-week trial and those who presented significant air-bone gaps and high negative tympanometric peak pressure at post-trial two months were scheduled for early VT insertion.

Statistical Analysis: The post-trial audiometric and tympanometric results were based on the evaluation that was done one week after the four-week trial period. These post-trial results were compared with those of the last pre-trial evaluations and with those of the late post-trial evaluations that was done two

months after the four-week trial. For the control group, the last audiological examinations at the time of surgey scheduling and the ones that were done at the day before surgery were taken into consideration as pre-trial and post-trial examinations, respectively. Friedman multiple comparision test was used for these comparisons. Pre-trial audiological measures of patients were compared with those of controls by using Mann-Whitney test.

Results

Thirty consecutive children who met the criteria for patient selection during one-year study period (Jan. to Dec. 2007) were included in the study group. One child was lost to follow-up, and pure tone averages of another one were not available due to non-cooperative behaviour during audiological examinations. Thus, results of 28 children were handled.

In the study group, there were 15 boys and 13 girls, and the mean age was 8.7 years. The control group consisted of 12 boys and 18 girls with a mean age of 9.8 years. The majority of our patients had had multiple medical treatments before they were referred to our tertiary care center.

No pain was noted during middle ear inflation procedure of any patient. At the end of 4-week trial, 16 (57 %) of 28 children were completely improved in terms of tympanometric peak pressure levels and average air-bone gaps within near-normal limits were noted in 14 of them. There was no doubt for middle ear effusion on the otomicroscopic examination. Statistical results of pre- and post-trial audiological results of them were given in Tables 1 and 2. These 16 children were advised for reevaluation two months later with no further treatment. The remaining 12 children who had no response to this conservative treatment underwent surgery for VT insertion.

There was no difference between pre-trial tympanometric peak pressure levels and average air-bone gaps of patient and control groups ($p>0.05$). No significant audiological improvement was noted in any of the children in the control group during the waiting period before surgery (Tables 1, 2).

Even though none of the parents called us during 2-months post-trial period, we found that 9 of the 16 children whose conditions were previously improved had high negative tympanometric pressure levels (levels smaller than -250 daPa) and high average air-bone gaps more than 15 dB at late visit. Interesting enough, there was also no statistically significant difference between the post-trial and late post-trial audiological results of patient group. All of these 9 patients in whom OME recurred at last visit underwent surgery for insertion of VT's, except one patient. The parents of a girl refused surgical treatment and offered us to follow their daughter by the same conservative treatment. We recommended third times a week treatment and followed her once a month. Her tympanometric peak pressure levels, air conduction tresholds and microotoscopic examination were all within normal limits at the end of third month and she was still under follow-up.

Discussion

First-line treatment for OME in children usually includes decongestants, antihistamines, antibiotics and corticosteroids.[3,8] It has been noticed that decongestants and antihistamines were not beneficial in the treatment of OME.[9] Moreover, the beneficial effect of antibiotics for OME has been reported to be minor and short-term.[10] These results have also been confirmed in the clinical practice guideline for OME.[4] When medical treatment fails, the majority of the otolaryngologists tend to insert VT's, as recommended in the guideline.[3,8]

Even though insertion of VT is not a complicated surgical intervention, there are some issues against the surgical treatment of OME with VT's: 1) OME may resolve spontaneously, 2) VT may fall out prematurely and replacement of it may be required, 3) VT may allow microorganisms or allergens to migrate into the middle ear.[3] Furthermore, there are some reported complications of VT insertion including persistant tympanic membrane perforation or retraction; localized foreign-body reaction; granulation; tympanosclerosis; VT blockage; displacement of VT into the middle ear cavity; hearing impairment: either

Table 1. Pre-& post-trial tympanometric peak pressure levels(daPa) of patients & controls

	Pre-trial		Post-trial		Late post-trial	
Patients						
	L	R	L	R	L	R
Median	392	328	50	68	86	70
Min-Max	254-400	252-400	16-148	0-144	0-400	0-400
p		< 0.001		> 0.05		
	Pre-trial		**Post-trial**			
Controls						
	L	R	L	R		
Median	333	351	369	390		
Min-Max	256-400	254-400	272-400	276-400		
p		> 0.05				

P: P value from Friedman Multiple Comparison Test, L: Left ear, R: Right ear.

Table 2. Pre- & post-trial average air bone gaps (dB) of patients & controls

	Pre-trial		Post-trial		Late post-trial	
Patients						
	L	R	L	R	L	R
Median	28	27	7	8	12	14
Min-Max	20-34	18-36	4-12	4-14	5-22	0-30
p		< 0.001		> 0.05		
	Pre-trial		**Post-trial**			
Controls						
	L	R	L	R		
Median	28	26	27	25		
Min-Max	21-33	19-35	18-36	16-33		
p		> 0.05				

P: P value from Friedman Multiple Comparison Test, L: Left ear, R: Right ear.

temporary or permanent; and cholesteatoma.[3,11] It is possible to add some other complications due to VT's and also, some arguments against VT insertion.

Inflation of the eustachian tube/middle ear system involves retrogradely forcing air from the nostrils into the middle ear cavity via eustachian tube and it is assumed that repetetion of this procedure will normalize the middle ear pressure and help the resolution of the effusion in the middle ear cavity.[3,5,6,8]

Valsalva maneuvar and Politzer method have been used for the inflation of eustachian tube-middle ear system.[3,5-7,12] Successful outcomes of middle ear inflation in the conservative treatment of OME have been reported in several studies.[2,3,5,7,8,12] However, middle ear inflation technique and treatment period vary from study to study. Hence, ideal number of middle ear inflation per day, appropriate frequency of application per week and optimal duration of this treatment are still investigated. Recently, after using a automated Politzerization device, Arick and Silman have concluded that twice daily home treatment over a period of 7-weeks was highly efficacious in the treatment of children with OME.[3] In their validation study, Silman et al. have also concluded that patients for whom initial treatment was not successful may benefit from extended treatment.[7]

In this study, we used a Politzerization device to force pressured air from the nose. This was an handheld, battery operated home device. No pain was noted in any patient during politzerization and no additional problem was encountered while using the device. Since we have selected bigger children to have optimal cooperation during politzerization, there were no cooperation problem. In our hands, middle ear inflation with a Politzerization device was efficacious in 57% of children with OME, in terms of audiological examinations. However, two months after the completion of 4-week trial, our efficacy rate dropped to 32 %. Respecting the comments of Silman et al.[7] about extended treatment, we considered that once a week application and 4- week trial period were not sufficient to achieve satisfactory results from middle ear inflation. Unfortunately, we had limited number of device and therefore, patients should come to the hospital with their parents more than once a week for a long time. This would not be cost-effective. Furthermore, in our country, it would not be feasible to instruct parents to buy Politzerization devices. These parents were also thinking that this conservative treatment had no long term benefits. They were forcing us to change the treatment of choice, as they were informed at the beginning that if this treatment fails, our alternative will be VT insertion. Because of all these reasons, we recommended surgical insertion of VT for these children.

Our results do not imply that middle ear inflation by a Politzerization device is an ineffective method in the treatment of children who had OME. We selected bigger children for the study and the majority of our patients had had multiple medical treatments before they were referred to our tertiary care center. Thus, our patients have recurrent or chronic OME. Nevertheless, in our study, once a week inflation over a 4-week period was 57% efficacious in the short-term. However, this treatment did not provide satisfactory long-term benefits for selected patients. At least, these results confirmed the need for periodical reevaluation of these patients. Even though their conditions are improved after the initial treatment, these patients may need extended or further treatment during the follow up. In the light of our results and our clinical observations, we considered that extended treatment would provide long-term benefit particularly for our patients whose audiological measures were deteriorated two months after they responded initial treatment. Although we had only one patient who underwent extended treatment, we believe that home treatment with a hand-held Politzerization device is more effective, because it allows more frequent repetition of Politzerization for a long time. However, long-term studies with much number of patients are required in order to figure out the ideal frequency of repetition of Politzerization procedure and optimal duration of this conservative treatment for the children who had OME. Autoinflation may avoid the need for surgery for middle ear effusion but, further efficacy investigations are needed before serving Politzerization devices as alternatives to surgical insertion of ventilation tubes.

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