



## RESEARCH

# LONG TERM EFFECT OF AUTOINFLATION IN THE TREATMENT OF OTITIS MEDIA WITH EFFUSION

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### SUMMARY

**Objective:** The aim of the study was to evaluate the long-term effect of autoinflation on reducing the need for insertion of ventilation tube in chronic otitis media with effusion (COME). **Material and methods:** Ninety three ears of 60 children diagnosed as COME were randomly divided into 2 groups: Group 1 (autoinflation); treated with autoinflation three times a day for 6 weeks (Otovent®) with nasal saline irrigation, and group 2 (control); treated with only nasal saline irrigation for 6 weeks. Before the COME diagnosis all the patients medicated with antibiotic (amoxicillin for 3 weeks), antihistamines (in case with allergy), and nasal saline irrigation. Both groups were followed for 9 months with respect to need for insertion of ventilation tube, free of effusion, and recurrence of effusion. **Results:** During the 9 months follow-up, in autoinflation group; 20 out of 48 ears (42%) required the ventilation tube insertion, 22 ears (46 %) were free of effusion, and 6 ears (12%) were lost in follow-up and in control group; 30 out of 45 ears (67%) required the insertion of ventilation tube, 8 ears (17.7 %) were free of effusion, 5 ears (11%) were lost in follow-up, and 2 ears of 1 patient who regretted the insertion of ventilation tube had still COME. **Conclusion:** Autoinflation reduce the need for insertion of ventilation tube not only in short term but also in long term as well. The children should be followed as long as they are at risk of recurrence.

**Keywords:** autoinflation, Eustachian tube dysfunction, Otovent®, grommets, otitis media with effusion

### EFÜZYONLU OTİTİS MEDİA TEDAVİSİNDE OTOİNFLASYONUN UZUN DÖNEM ETKİSİ

#### ÖZET

**Amaç:** Bu çalışmanın amacı, efüzyonlu kronik otitis mediada (EKOM) otoinflasyonun ventilasyon tüpü takılması gerekliliğini azaltma üzerine uzun dönem etkisinin değerlendirilmesidir. **Yöntem ve gereçler:** EKOM tanısı almış 60 çocuğun 93 kulağı iki gruba ayrılmıştır: Grup 1 (otoinflasyon) 6 hafta boyunca günde 3 kez otoinflasyonla (Otovent®) ve burun salin lavajı yapılarak tedavi edilmiş, grup 2 (kontrol) 6 hafta boyunca sadece burun salin lavajı yapılarak tedavi edilmiştir. EKOM tanısından önce tüm hastalar antibiotik (amoksisilin 3 hafta boyunca), antihistaminik (alerjisi olan hastalarda) ve burun salin lavajı reçetelendi. Her iki grup 9 ay boyunca ventilasyon tüpü takılması gerekliliği, efüzyonun düzelmesi ve efüzyonun tekrarlama bakımından takip edilmiştir. **Bulgular:** Dokuz aylık takip boyunca, otoinflasyon grubunda 48 kulaktan 20 kulağa (%42) ventilasyon tüpü takılması gerekti, 22 kulak (%46) tamamen iyileşti ve 6 kulak (%12) ise takipten çıktı. Kontrol grubunda ise 45 kulaktan 30 kulağa (%67) ventilasyon tüpü takılması gerekti, 8 kulak (%17.7) tamamen iyileşti, 6 kulak (%12) takipten çıktı ve tüp takılmasını kabul etmeyen hastanın 2 kulağında ise halen efüzyonlu kronik otitis media mevcuttu. **Sonuç:** Otoinflasyon kısa dönemde olduğu gibi uzun dönemde de ventilasyon tüpü takılması gerekliliğini azaltmaktadır. Çocuklar, hastalığın tekrarlama riskinin devam ettiği dönem boyunca takip edilmelidir.

**Anahtar Kelimeler:** otoinflasyon, östaki tüp disfonksiyonu, Otovent®, grommet, efüzyonlu otitis media

## INTRODUCTION

It is well established that impaired middle ear ventilation plays an important role in the pathogenesis of COME, where the persistent negative pressure induces metaplasia of the middle ear mucosa with goblet cell formation and subsequently effusion in the tympanic cavity<sup>1</sup>. It is also seen clinically that if middle ear ventilation is restored the mucosa becomes normal and the effusion clears.

Most adults can easily ventilate the middle ear by performing Valsalva maneuver but for the children this maneuver is difficult to learn and it is almost impossible to control that the maneuver is made effectively. Since Politzer in 1863<sup>2</sup> devised his own method for active inflation of the middle ear, several studies have been published showing beneficial effect of autoinflation in the treatment of secretory otitis media<sup>3-9</sup>. Hunt-Williams<sup>4</sup> in 1968 introduced a method for middle ear ventilation for children.

The children inflate carnival-blower through the nose with or without a balloon. Stangerup et al.<sup>7</sup> in 1992 published a randomized controlled study of children aged 3 to 10 years suffering from Eustachian tube dysfunction or secretory otitis media. One group was randomized to autoinflation, using a nose-piece mounted with a balloon, the other group was

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observed without treatment for two weeks. The nasal balloon inflation could improve or normalize the middle ear pressure in 82% of the ears with negative middle ear pressure and in 52% of the ears with effusion. In 1993 Blanshard et al.<sup>8</sup> evaluated the same autoinflation technique in children recruited from the waiting list for grommet insertion. Sixty-eight percent of children with high compliance autoinflation had no effusion after 2 weeks and 42% after 3 months.

All studies examined the short term effect of the autoinflation. The aim of the study was to evaluate the long-term effect of autoinflation on reducing the need for insertion of ventilation tube in COME.

### **MATERIAL and METHODS**

During the two years period (between January 2002 and April 2004), 60 patients (93 ears) who were diagnosed as COME were included in the study. Thirty-two were male and 28 were female. The mean age was 6.2 years (range 4 to 10 years).

Patients who were admitted to our clinic with middle ear effusion (MEE) and free of sign of otitis media at least 4 weeks period (earach, ear discharge etc) were selected as pre-study group. Children were excluded from entry when they had any of the following conditions: hypersensitivity or significant adverse reactions to penicillins; previous tonsillectomy and/or adenoidectomy; previous ear surgery other than tympanocentesis or myringotomy with or without tube insertion; history of seizure disorder, diabetes mellitus, asthma requiring daily medication, or any health condition that could make entry potentially dangerous; medical conditions with a predisposition for MEE, such as cleft palate, Down syndrome, congenital malformations of the ear, cholesteatoma, or chronic mastoiditis; severe retraction pockets; acute or chronic diffuse external otitis; perforation of the tympanic membrane; intracranial or intratemporal complications of MEE; upper respiratory obstruction attributable to tonsil or adenoid enlargement or both with cor pulmonale, sleep apnea, or severe dysphagia; history of varicella exposure within the previous 30 days (if never had clinical varicella or varicella vaccine) or clinical varicella in the previous 3 weeks; history of measles exposure in the previous 30 days; or immunization in the previous 30 days. This group was followed 3 months and the patients who had new otitis media attack in this period were excluded from the study group. In this 3 months period all the patients were medicated with antibiotic (amoxicillin for 3 weeks),

antihistamines (in case with allergy), and nasal saline irrigation.

Diagnosis of COME was established by the typical appearance (fluid level or air bubbles in middle ear, white opacification in the tympanic membrane, vascularization of the tympanic membrane without erythema, lack of mobility of the tympanic membrane in ventilation of the external ear canal, etc) of the tympanic membrane at the pneumatic otoscopic examination and type B tympanogram at the end of the 3 months follow-up. The details of the study were described to the child's parent(s) and informed consent for the child to participate in the study was obtained.

The patients were randomly divided into two groups: Group 1 (autoinflation); treated with autoinflation three times a day for 6 weeks (Otovent®), with nasal saline irrigation 3 times a day for 6 weeks, and group 2 (control); treated with only nasal saline irrigation 3 times a day for 6 weeks.

The autoinflation group consisted of 30 patients (48 ears, 12 unilateral and 18 bilateral) who could inflate the nasal balloon. The children were instructed to perform autoinflation three times a day for 6 weeks. In case of upper respiratory tract infection the patient was advised not to autoinflate.

The control group consisted of 30 patients (45 ears, 15 unilateral and 15 bilateral). The children were treated with only nasal saline irrigation for 6 weeks.

The patients in both groups were examined with pneumatic otoscopy and tympanogram once every two weeks for the first two months and then once a month for 7 months. Examinations were recorded at 6<sup>th</sup> week, 3<sup>rd</sup>, 6<sup>th</sup>, and 9<sup>th</sup> month. Distributions of age and sex of these groups were similar. Chi-square test was used for the statistical analysis.

#### **Technique of otovent use:**

1. The balloon is attached to the nose-piece.
2. The ball-shaped end of the tube is held airtight to one nostril, the opposite nostril is compressed with a finger and with the mouth closed the balloon is inflated through the nose to the size of an orange (Figure 1).

### **RESULTS**

Follow-up of the progress of the autoinflation and of the control group over the period of 6 weeks, 3 months, 6 months and 9 months were shown in table 1 and 2. Tympanic membrane perforation due to autoinflation was not observed. The compliance of

the children to the autoinflation was satisfactory and the autoinflation was somehow amusing for the children.



Figure 1: Application of otovent® to the nose.

Eleven children who had upper respiratory tract infection ceased the autoinflation for 5 days but autoinflation treatment was completed to 6 weeks. In this period patients did not have acute otitis media.

Recovery rates of effusions in both groups in the 6th week, 3rd month, 6th month, and 9th month follow-up were shown in table 3. Except for the 3rd month autoinflation group has statistically significant (prd month there was no statistically significant difference ( $p > 0.05$ )). Insertion of ventilation tube in both groups in the 3rd month, 6th month, and 9th month follow-up was shown in Table 4.

In control group there was a statistically significant need for insertion of ventilation tube according to autoinflation group ( $p < 0.05$ ).

**Autoinflation group:**

In the 6th week of treatment, effusion had cleared in 27 out of 48 ears (56%). At the last control (in the 9th month) 4 ears were lost at follow-up and 22 out of 42 ears (52%) were effusion free. A total of 20 (in 18 ears after 3 months and in 2 ears after 6 months) out of 48 ears (42%) required ventilation tubes due to lack of improvement (Table 1 and 3).

**Control group:**

In the 6th week of treatment, effusion had cleared in 14 out of 45 ears (31%). At the last control (in the 9th month); 3 ears were lost at follow-up, 8 of 40 ears (20%) were effusion free, and 2 ears of 1 patient who regretted the insertion of ventilation tube had still COME. A total of 30 (in 28 ears after 3 months and in 2 ears after 9 months) out of 45 ears (67%) required ventilation tubes due to lack of improvement (Table 2 and 3)

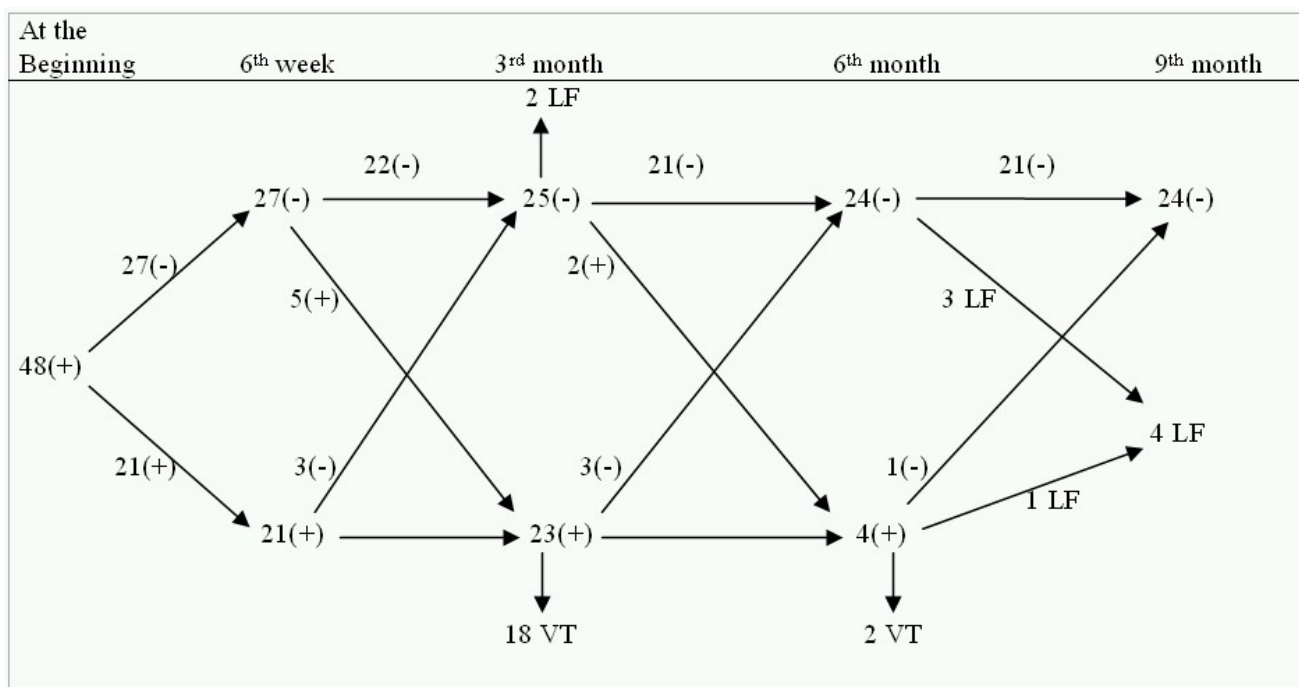
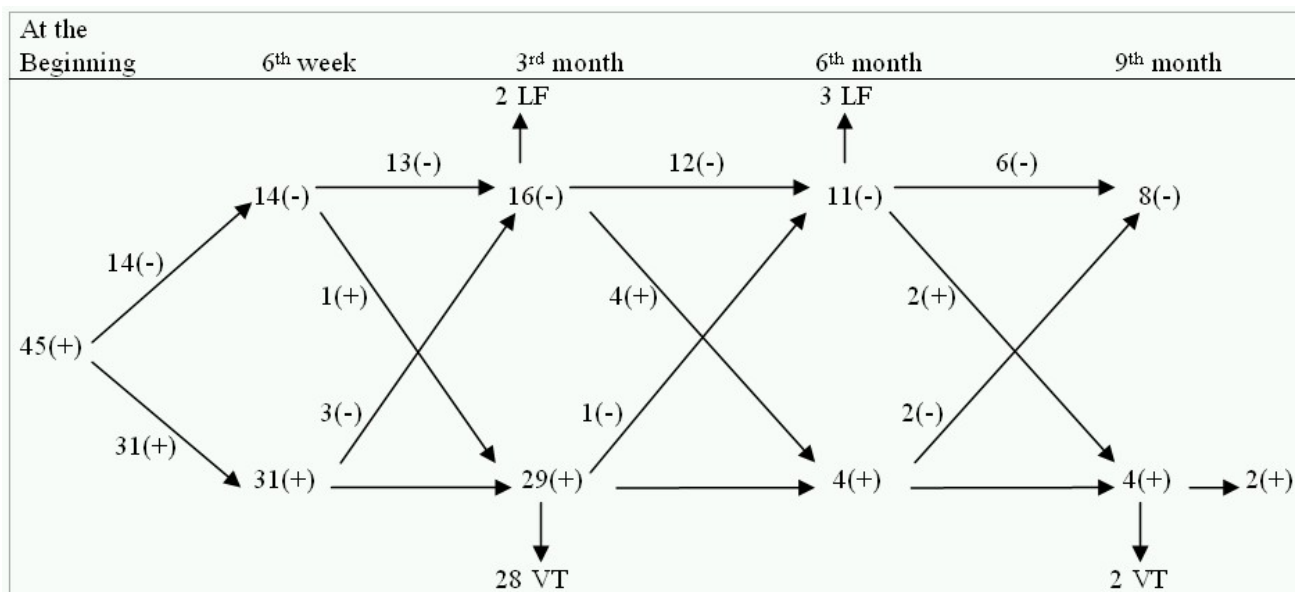


Table 1: Progress of effusion in autoinflation group at the 6th week, 3rd month, 6th month, and 9th month.



**Table 2:** Progress of effusion in patients in control group at the 6th week, 3rd month, 6th month, and 9th month.

	Autoinflation group		Control group		$\chi^2$	P
	No	%	No	%		
6 <sup>th</sup> week	27/48	56	14/45	31	5,95	0,014
3 <sup>rd</sup> month	25/48	52	16/45	35,5	2,57	0,108
6 <sup>th</sup> month	24/46	52,1	11/43	25,5	6,59	0,010
9 <sup>th</sup> month	22/42	75	8/40	20	9,26	0,002

**Table 3:** Recovery rates of effusion in both groups in the 6th week, 3rd month, 6th month, and 9th month follow-up

	Autoinflation group		Control group		$\chi^2$	P
	No	%	No	%		
3 <sup>rd</sup> month	18/48	37	28/45	62	5,68	0,017
6 <sup>th</sup> month	20/46	43	28/43	65	4,19	0,040
9 <sup>th</sup> month	20/41	43	30/40	75	5,89	0,015

**Table 4:** Required ventilation tube in both groups in the 3rd month, 6th month, and 9th month

## DISCUSSION

COME is one of the most common medical problems during childhood<sup>10</sup>. It is reported that more than 3.5 Billion dollars are spent annually for treatment of COME in the U.S.A<sup>11</sup>. Untreated, it may predispose acute otitis media<sup>12</sup>, chronic otitis media and cholesteatoma<sup>10</sup>. Although the mechanical obstruction of the Eustachian tube is suggested to play a role in the etiology of COME, Bluestone and Beery<sup>13</sup> reported that the functional dysfunction of Eustachian tube as being the most common cause of Eustachian tube dysfunction in children. The inability of opening of the Eustachian tube results in negative middle ear pressure. Persistent tubal obstruction causes middle ear effusion in some children.

According to suction-insufflation theory, positive nasopharynx pressure, which acts synergistically to negative middle ear pressure,

provides an opening of the Eustachian tube to balance the changes of negative pressure in the middle ear<sup>11</sup>. Increasing positive pressure in the nasopharynx, which is obtained when inflating Otovent, may help a passive opening of the Eustachian tube. Schwartz et al.<sup>6</sup> reported that COME could be treated, and middle ear pressure could return to normal, with home politizerization. Stangerup et al.<sup>7</sup> showed the efficacy of autoinflation treatment of COME, where 52% was cleared of the effusion after two weeks of autoinflation.

In our study, with respect to the need for ventilation tubes during the follow up for 3, 6, and 9 months, it is apparent that the autoinflation group required significantly ( $p < 0.05$ ) fewer ventilation tubes than the control group (Table 4).

There are 3 studies in the literature<sup>14-16</sup> indicating the bad effect or the lack of effect of autoinflation. Reidpath et al.<sup>17</sup> analyzed the studies on autoinflation and reported that the major drawback was the short term follow-up period. They also commented that although the use of autoinflation in the case of glue ear is conflicting, some benefits may be acknowledged. However, they also reported that larger and long term trials are needed for autoinflation to be considered for clinical practise.

There is also an argument that COME recurs even after a successful autoinflation treatment<sup>7,13</sup>. However in our study the long term follow-up of spontaneous recoveries and spontaneous deteriorations were observed to be similar in both groups. In 9 months follow-up 7 ears (26%) which are healed after 6 weeks autoinflation treatment deteriorated to COME whereas 7 ears (33.3%) with



no improvement at the end of the 6 weeks autoinflation treatment spontaneously healed in group 1. On the other hand, in group 2, in 9 months follow-up 7 ears (50%) which are spontaneously healed after 6 weeks nasal saline irrigation deteriorated to COME whereas 6 ears (19.3%) with no improvement at the end of the 6 weeks spontaneously healed. Thus, we concluded that in long term follow-up there is no increased recurrence risk of COME after the autoinflation treatment. The risk involved is as much as it is found to be in the control group.

The role of elasticity of the tympanic membrane and gas exchange on the balance of middle ear pressure is known<sup>18</sup>. It is apparent that the mechanical opening of the Eustachian tube with Otovent cannot solve the problem in all patients with COME. If the Eustachian tube pathology is the major problem, autoinflation seems beneficial. It is suggested that a middle ear pressure of -200 mm H<sub>2</sub>O can not remain for a long time without development of transudation. Chronic Eustachian tube dysfunction, without the development of COME, causing a long lasting negative middle ear pressure, can cause loss of elastic fibers of the tympanic membrane, and as a result, can lead to the development of retraction, atelectasis and cholesteatoma.

Otovent<sup>®</sup> makes home politzerization fun for the child and contributes to the therapy. With more common use of Otovent on patients with COME and Eustachian tube dysfunction, we will have more information about the optimal number and duration of applications during the disease period. To our best of the knowledge this is the first study evaluating the long term effect of autoinflation. We conclude that autoinflation could be added to medical treatment of serous otitis media and reduce the need for insertion of ventilation tube not only in short term but also in long term as well. The children should be followed as long as they are at risk of recurrence.

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