

# Conservative treatment of otitis media with effusion by autoinflation of the middle ear

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## Conservative treatment of otitis media with effusion by autoinflation of the middle ear

A total of 85 children on the waiting list for grommet insertion aged between 3 and 10 years with bilateral chronic otitis media with effusion (OME) were assigned at random to an observation or treatment group. Those in the treatment group were given the Otovent® device to use three times a day for the duration of the study and both groups were then seen at monthly intervals for 3 months for pneumatic otoscopy and tympanometry. Statistically significant improvement was seen in those using the treatment with a compliance of more than 70%. This was detected on the outcome measures of tympanometry and pneumatic otoscopy after 1, 2 and 3 months. No side effects were demonstrated.

We conclude that autoinflation is an effective short-term treatment for children with OME when used regularly under supervision.

Keywords *OME grommet insertion autoinflation non-surgical treatment*

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The advent of grommets placed surgically in the tympanic membrane revolutionized the treatment of otitis media with effusion (OME).<sup>1</sup> Some anxiety has been expressed recently about rare but possible complications of this procedure<sup>2,3</sup> and the increasing number of children treated by ventilation tube insertion, has both practical and cost implications to the health service. The search for an effective non-surgical treatment has yielded little success to date.

Manoeuvres described by Valsalva and Politzer in the eighteenth and nineteenth centuries rely on forcing air under pressure through the Eustachian tube into the middle ear to re-aerate it. In the former, the pressure is generated by forced expiration against a closed nose and mouth, the latter relies on a rubber bulb sealed into the nose which is then squeezed whilst the patient swallows to assist in tubal opening. Derivations of Politzer's techniques have been tried with some success in children<sup>4–6</sup> but have met with difficulties in compliance and in requiring external assistance. Valsalva's manoeuvre is difficult to teach children and to confirm correct execution. A modification by Hunt-Williams<sup>7</sup> uses a party blow out toy, inflated through the nose and by replac-

ing the furled paper with a balloon can be made more effective. Visual feedback similarly reinforces the manoeuvre when using a modified anaesthetic face mask attached to a high resistance flow-meter<sup>8</sup> but failed to show a significant benefit.

The Otovent® device consists of a rounded plastic nose piece to which a balloon is attached (Figure 1). Inflation of this requires pressure by Valsalva's manoeuvre equivalent to approximately 600 mm water and provides familiar visual feedback to the children. A significant benefit to children with OME has been demonstrated by Stangerup<sup>9</sup> but only over a 2-week-period. Our objective was to examine the effect of this treatment in children with OME when autoinflation was continued over a 3-month-period.

## Patients and methods

A power analysis was carried out using the results obtained by Stangerup<sup>9</sup> of an improvement in 64% of ears in the treatment group and 15% of ears in the control group. It was calculated for a power level of 90%, that 27 ears would be required in each group to detect an improvement at the 5% level of significance. In view of a greater expected failure of compliance over a longer study period and to allow for

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Figure 1. A demonstration of Otovent.

exclusions and drop-outs a target of 40 subjects in each group was set.

#### STUDY POPULATION

A consecutive series of children satisfying the entry criteria was selected from those on the waiting list for grommet insertion at the Bristol Children's Hospital. They were assumed to represent a target population of children with OME.

#### METHOD

Ethical committee approval was granted, informed consent was obtained and a questionnaire issued to those entering the study. The records of these children were scrutinized. The entry criteria were an age range of 3–10 years and confirmation of bilateral type B or C2 tympanograms on two occasions separated by at least 3 months (visits 1 and 2). Children treated previously by adenoidectomy or tonsillectomy and those with chromosomal and cranio-facial abnormalities were excluded. To control for a seasonal effect, entry into the

study was at weekly intervals from July to December 1991, the final follow-up was in March 1992.

At visit 1, tympanometry was carried out over a pressure range  $-300$  mm H<sub>2</sub>O to  $+200$  mm H<sub>2</sub>O; a Grason Stadler GSI33 Middle-Ear analyser was used at the subsequent clinics to record over the range  $-600$  mm H<sub>2</sub>O to  $+400$  mm H<sub>2</sub>O. Classification of the tympanograms was by Fiellau-Nikolajsen's adaptation of Jerger's system.<sup>10</sup> Pure-tone audiometry was conducted on a Kamplex AC5 audiometer where age allowed. Pneumatic otoscopy was carried out by one observer (J.D.B.). A standardized lateral cephalogram was taken of all children entering the study from which the nasopharyngeal airway size was measured.

One hundred and ninety-six children were invited by post to the first review clinics (visit 2); 24 refused and 48 were not contactable, the remaining 124 attended the clinic for tympanometry, pneumatic otoscopy and pure-tone audiometry. Some 39 further exclusions were made of those found either to have had prior adenoidectomy or those in whom a type B or C2 tympanogram was not still present bilaterally.

A total of 85 children were entered into the study. They were allocated to either the treatment or to the control group by computer generated random numbers. Both groups were then seen at monthly intervals (visits 3, 4 and 5) for tympanometry, pneumatic otoscopy and questioning with regard to the number of attacks of upper respiratory infection, otalgia, tonsillitis and antibiotic courses. Pure-tone audiometry was repeated at the final visit when possible according to age (visit 5).

#### TREATMENT REGIME

A demonstration was given to those randomized to the treatment group. Instructions were issued to use the device once through each nostril three times a day stopping only for the first few days of an upper respiratory tract infection or an episode of otalgia. The balloon was changed every 3 days to maintain elasticity and a compliance sheet was issued to be filled in each time the device was used.

#### Results

Two exclusions were made from the analysis: one was discovered to have had prior adenoidectomy only after entry into the study, the other failed to attend any follow-up, leaving 42 children in the treatment group and 41 in the control group. One hundred and sixty-six ears were assessed at entry to the study (visit 2), 155 (93.4%) at visit 3, 154 (92.8%) at visit 4 and 159 (95.8%) at visit 5.

Compliance was measured as the number of times the device was actually used as a percentage of the maximum possible. Of the 42 children in the treatment group, 19 (45%) used it as prescribed ( $>70\%$ ), 18 (43%) used it irregularly and 5 (12%) were unable to use it at all. The treatment group

**Table 1.** Mean compliance

Visit no.		3	4	5
Mean (%)	HC	86 (SD 9.7)	86 (SD 11.7)	86 (SD 13.3)
Compliance	LC	45 (SD 37.4)	45 (SD 32.9)	29 (SD 26.8)

was divided into those with a high compliance (HC) of greater than 70% ( $n = 19$ ) and those with a low compliance (LC) of less than 70% ( $n = 23$ ). In this latter group the compliance deteriorated from 45% to 29% over the course of treatment (Table 1).

Statistical analysis of the variables and the otoscopy results was carried out using the Chi-square test with Yates' correction or Fisher's Exact test, where appropriate. The tympanometry results were analysed using the Mann-Whitney rank sum test. The outcome was assessed by tympanometry and by the clinical appearance of individual ears.

Analysis of the variables (Table 2) in the treatment and control groups yielded significance only in the age distribution and exposure to smoking. Those in the low compliance

group were younger than those in the control group ( $P = 0.04$ ) and younger than those in the high compliance group ( $P = 0.03$ ). There was no difference between the high compliance and control groups. More of both treatment groups were exposed to the effect of smoking which is believed to exacerbate OME so adding a negative bias to these groups.

**TYMPANOMETRY RESULTS**

Improvement in the tympanometric findings in ears was defined as the number of ears converting from a type B or C2 tympanogram to a type A or C1 tympanogram (Tables 3 and 4). A significant improvement was noted in the high compliance treatment group after 1, 2 and 3 months of treatment; no such response was seen in the low compliance group. At the start of treatment (visit 2) there were more type B tympanograms ( $P = 0.041$ ) in the low compliance group than in the high compliance group, an observation that persisted throughout the 3 months.

Variables		Treatment		Control $n = 41$
		HC $n = 19$	LC $n = 23$	
Age (months)	Mean	62.7	52.8 <sup>+</sup>	59.9
	SD	17.5	8.9	18.3
Smoke exposure	Smokers	12 <sup>+</sup>	16 <sup>+</sup>	13
	Non-smokers	7	7	28
Sex	M	13	12	27
	F	6	11	14
Duration of reported HL (months)	Mean	32.2	24.2	27.2
	SD	17.8	14.2	15.2
Prior G insertion	Number (%)	1 (5.3)	5 (21.7)	6 (14.6)
NP X-ray airway size	Mean (mm)	4.9	3.4	4.2
	SD	2.9	1.9	2.3
Month of entry	Jul/Aug/Sep	14	11	26
	Oct/Nov/Dec	5	12	15

**Table 2.** Analysis of the variables between the high compliance and low compliance treatment groups and the control group

Numbers of subjects. <sup>+</sup> $P = < 0.05$  vs. control group.

%	Visit number									
	1		2		3		4		5	
	CON	HC	CON	HC	CON	HC	CON	HC	CON	HC
A	—	—	—	—	3.8	13.5	5.4	15.8	0.0	13.2
C1	—	—	—	—	5.1	18.9	8.1	13.2	5.2	13.2
C2	1.2	5.3	29.3	34.2	14.1	35.1	13.5	26.3	16.9	15.8
B	98.8	94.7	70.7	65.8	76.9	32.4	73.0	44.7	77.9	57.9
$n =$	82	38	82	38	78	37	74	38	77	38
$P$	ns		ns		$P < 0.001$		$P < 0.05$		$P < 0.05$	

**Table 3.** Tympanometry results for the high compliance group vs. Control

**Table 4.** Tympanometry results for the low compliance group vs. Control

	Visit number									
	1		2		3		4		5	
%	CON	LC	CON	LC	CON	LC	CON	LC	CON	LC
A	—	—	—	—	3.8	5.0	5.4	0.0	0.0	0.0
C1	—	—	—	—	5.1	7.5	8.1	0.0	5.2	2.3
C2	1.2	0.0	29.3	13.0	14.1	15.0	13.5	14.3	16.9	2.3
B	98.8	100	70.7	87.0	76.9	72.5	73.0	85.7	77.9	95.4
n =	82	46	82	46	78	40	74	42	77	44
P	ns		ns		ns		ns		ns	

**OTOSCOPY RESULTS**

The observed clearance of fluid on pneumatic otoscopy is summarized in Table 5. Only complete clearance of fluid was accepted so the presence of bubbles or a fluid level was interpreted as fluid being present. Significant clearance of fluid was seen in the high compliance treatment group throughout treatment but not in the low compliance group. The differences between the tympanometric and otoscopic findings reflect the recognized sensitivity and specificity of these investigations.

**AUDIOLOGICAL RESULTS**

Pure-tone audiometry was available on less than half the children due to age limitations. The difference between the means of the thresholds at 250 Hz, 500 Hz, 1 kHz, 2 kHz and 4 kHz at entry and exit was taken for individual ears for analysis. A deterioration was recorded of 0.52 dB in the control group (n = 34 ears), 4.08 dB in the low compliance group (n = 19) and an improvement of 2.13 dB in the high compliance group (n = 19). A significant difference was detected only between the high compliance group and the low compliance group (P = 0.026).

**RADIOLOGICAL NASOPHARYNGEAL AIRWAY SIZE**

A direct association existed between airway size and age (P = 0.046) which may have accounted for the difference in mean airway size between the low and high compliance groups (Table 1). It was noted that those with larger airways tended to develop a greater proportion of the peaks, though age may have been a confounding factor.

**COMPLICATING FACTORS TO TREATMENT**

There was a tendency for more of the control group (44%) to have had attacks of otitis media compared with the high compliance (36%) and low compliance group (30%). Sixty-one per cent of the low compliance group had more than one URTI over the 3 months, compared with 32% of the high compliance and 23% of the control group (overall P = 0.01). There was a tendency for more (22%) of the low compliance group to have had an episode of tonsillitis compared with the high compliance group (5%) and the control group (13%) and a tendency for more (43%) of the low compliance group to have had a course of antibiotics compared with the high compliance group (21%) and the control group (33%).

**ANALYSIS BY INTENTION TO TREAT**

The results of the low and high compliance groups were combined and compared with the control group. A significant improvement was detectable at 1 month on tympanometry (P < 0.01) and at 1 and 2 months on otoscopy (P < 0.05).

**Discussion**

The results indicate that compliance is fundamental to achieving any benefit from the treatment. A significant improvement was seen only in those who used the treatment with a high compliance for the duration of the study. There was a trend showing a maximum effect after 1 month with subsequent deterioration. Some lack of enthusiasm was perceived on questioning the children towards the end of the

**Table 5.** Number of ears clear of fluid on pneumatic otoscopy

Visit no.	1	2	3	4	5
HC n = 38 (%)	—	2 (5.3)	18 (47.4)* <sub>0</sub>	17 (44.7)* <sub>0</sub>	14 (36.8)† <sub>0</sub>
LC n = 46 (%)	—	0 <sup>+</sup>	5 (12.5) <sub>6</sub>	3 (7.1) <sub>4</sub>	2 (4.6) <sub>2</sub>
CON n = 82 (%)	—	7 (8.6)	11 (14.3) <sub>5</sub>	8 (10.8) <sub>8</sub>	8 (10.5) <sub>6</sub>

n = missing ears, P-values for HC or LC vs. CON, +P = < 0.05, †P = < 0.01, \*P = < 0.001.

treatment, indicating that compliance may be a problem if used continuously over long periods. Our findings support those of Stangerup<sup>9</sup> who demonstrated a beneficial effect after 2–4 weeks of regular use, which was reversed on stopping the treatment.

It was difficult to determine any one reason for low compliance. The mean age of this group was lower than that of the control group; more upper respiratory tract infections were encountered in this group, hindering the use of the treatment; a tendency for a smaller radiographic nasopharyngeal airway size in the low compliance group compared with the high compliance group may have been an effect of the age difference between the groups, it may also have accounted for some of the difficulty in compliance. Some children with severe OME find performing the Valsalva manoeuvre painful and may therefore refuse; the low compliance group started off with more type B tympanograms, possibly reflecting a worse status at the outset. The fact that all the children were already on the waiting list for surgery may have lessened the enthusiasm of some of the parents from trying an alternative.

Analysis of the results on an 'intention to treat basis' is less conclusive. The effect of the treatment is diluted by the low compliance group such that it is significant at 1 month on both outcome measures, at 2 months only on otoscopy and at 3 months no significant difference is seen. The five children who showed zero compliance were unable to inflate the balloon on the first visit and might therefore have been excluded in clinical practice at the start. The remainder of the low compliance group were able to inflate the balloon on the first attendance but compliance diminished over the study period. If autoinflation had been used for shorter periods the long-term compliance might have been improved in this group and the initial beneficial effect maintained.

There is a theoretical risk associated with Valsalva's manoeuvre of causing a pneumocele or air embolism or of forcing infected nasopharyngeal secretions into the middle ear to cause acute otitis media. The only reported cases in the literature<sup>11,12</sup> of a pneumocele are after myringotomy and inflation of the external ear canal with a Politzer balloon; in this technique there is no simultaneous increase in the intracranial pressure, as seen in Valsalva's manoeuvre, possibly making the risk greater. No complications were shown to arise from using the treatment in this study and there are no

reports in the literature of adverse effects using treatments of a similar principle.

The population studied were all on the waiting list for grommet insertion with a mean reported duration of hearing loss of 27.5 months. Many of these children wait a further 6 months to a year for surgical treatment of their hearing impairment. Although in actual figures only a small number were improved, in the absence of any other effective conservative measures, autoinflation provides a short-term alternative to surgery and may avoid the need for surgery altogether in some.

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