



SUMMARY OF OTOVENT PUBLICATION

Blanshard, J.D., Maw, A.R., and Bawden, R. *Conservative treatment of otitis media with effusion by autoinflation of the middle ear.* Clin. Otolaryngol. Vol 18, 1993, 188-192.

The aim of the study was to evaluate the effect of autoinflation versus observation for a study group awaiting surgical intervention.

A total of 85 children on the waiting list for grommet insertion (tubes) 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 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.

In addition to reinforcing the results found by Stangerup,¹ the study aimed to evaluate the effect of treatment when continued over a three month period. The entry criteria included 3-10 years of age, bilateral type B or C2 tympanograms on two occasions separated by at least 3 months. Pure tone audiometry, pneumatic otoscopy and a standardized lateral cephalogram were conducted, the later to measure the nasopharyngeal airway size.

Compliance was measured as the number of times the device was actually used. Of the 42 children in the treatment group 19 (45%) used it as prescribed (greater than 70%), 18 (43 % used it irregularly and 5 (12%) were unable to use it at all. The treatment group was divided into high compliance (19) and low compliance (23) groups. A significant improvement was noted in the high compliance group after 1,2 and 3 months of treatment; no such response was seen in the low compliance group.

The results indicated that compliance was fundamental to achieving any benefit from 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 maximum effect after 1 month with subsequent deterioration. Lack of enthusiasm was perceived as the study progressed.

Analysis of the results by intention to treat were less conclusive with the large number of low compliance subjects generated. The effect of the treatment was subsequently diluted. The study concluded that autoinflation provides an effective short-term alternative to surgery and may avoid the need for surgery altogether.

Any questions or points of clarification can be directed to the undersigned.

Document prepared by:

J.P. CURTIN

ABIGO Medical AB

Contact ABIGO Medical AB

Tabish Waseem

Global Business Unit Manager

tabish.waseem@abigo.se

+46 7010 888 63

1. Stangerup, S.E., Sederberg-Olsen, J., Balle, V. *Autoinflation as a treatment of Secretary Otitis Media.* Archives of Otolaryngology – Head and Neck Surgery, Vol 118, Feb 1992, 149-152.