

Main Article

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Abstract

Objective. To determine the factors related to multiple ventilation tube insertions in children with otitis media with effusion.

Methods. A retrospective review was performed of 126 ears of 81 children aged less than 12 years who had undergone insertion of a Paparella type 1 ventilation tube for the first time between August 2012 and March 2018.

Results. Mean age at the first operation was 4.0 ± 2.2 years, and the mean duration of otitis media with effusion before the first ventilation tube insertion was 5.4 ± 4.5 months. Among 126 ears, 80 (63.5 per cent) had a single ventilation tube insertion and 46 (36.5 per cent) had multiple insertions. On multivariate logistic regression, tympanic membrane retraction, serous middle-ear discharge, and early recurrence of otitis media with effusion were independent predictive factors of multiple ventilation tube insertions.

Conclusion. Tympanic membrane retraction, serous middle-ear discharge, and early recurrence of otitis media with effusion after the first tube extrusion are associated with multiple ventilation tube insertions.

Introduction

Otitis media with effusion (OME) is a middle-ear disease involving fluid in the middle-ear cavity, with no acute symptoms such as otalgia or otorrhoea. Otitis media with effusion is a common disease, especially in children; two out of three patients aged less than three years suffer from OME at least once.¹

There are several hypotheses pertaining to the occurrence of OME, with the ex vacuo theory being accepted by many clinicians. Eustachian tube dysfunction causes negative pressure in the middle ear, which in turn causes vascular distension and mucosal oedema. The resulting increased capillary permeability causes effusion in the middle-ear cavity.

In order to determine candidates for surgical treatment, hearing status, associated symptoms, and the child's developmental risk and perceived likelihood of timely spontaneous resolution of the effusion should be considered. Clinicians should also offer ventilation tube insertion to children who have had bilateral OME for more than three months and who experience hearing difficulties.² Ventilation tube insertion offers the most reliable route to resolving hearing loss associated with OME.³ However, about 20–50 per cent of children with ventilation tube insertion have recurrence of OME and may need additional ventilation tube insertions.⁴

This study aimed to identify factors during the first tube insertion that can predict OME recurrence and the need for additional ventilation tube insertions. We expected that factors related to poor Eustachian tube function would cause OME recurrence.

Materials and methods

We performed a retrospective review of 126 ears of 81 children (57 males and 24 females) aged less than 12 years who had undergone insertion of a Paparella type 1 ventilation tube for the first time between August 2012 and March 2018 at our institution. Patients with congenital craniofacial anomalies, previous ventilation tube insertion history, insertion of a Paparella type 2 tube on the first occasion, or insufficient follow-up were excluded. In patients with ventilation tubes on both sides, the right and left ears were evaluated separately.

Patients were examined by the otologist one week after the first ventilation tube insertion. The patients were instructed to revisit the clinic for examination every month. The ears were followed up for at least three months after ventilation tube extrusion.

The cases were divided into groups on the basis of single or multiple tube insertions (the latter group comprised children who had been operated on at least twice). The pre-, intra- and post-operative characteristics of the two groups were compared.

The pre-operative features compared between groups included the duration of otitis media with effusion before the first operation, the presence of allergic disease, and the pure tone

audiometry results. In order to compare intra-operative features, we examined the character of middle-ear discharge (serous or mucoid) and the status of the tympanic membrane (normal or retracted position). Finally, for comparison of post-operative features, the presence of post-operative otorrhoea (early and late), the indwelling time of the ventilation tube, and early recurrence of otitis media (within the three months after ventilation tube extrusion) were investigated. The indwelling period of each ventilation tube was recorded in days from its insertion to the time when last observed to be extruded or when removed.

Statistical analysis

The chi-square test was used to compare categorical variables, and the independent *t*-test was applied for continuous variables. For all statistical analyses, we used SPSS software (version 20.0; SPSS, Chicago, Illinois, USA). *P*-values of less than 0.05 were considered statistically significant.

Ethics statement

The study protocol was reviewed and approved by the Catholic University Hospital Institutional Review Board (number: DC18RESI0074). The requirement for informed consent was waived by the board.

Results

The mean age at the first operation was 4.0 ± 2.2 years, and the mean duration of otitis media with effusion (OME) before the first ventilation tube insertion was 5.4 ± 4.5 months. The mean ventilation tube indwelling time was 303.5 ± 151.1 days (Table 1).

Among 126 ears, 80 (63.5 per cent) had a single ventilation tube insertion and 46 (36.5 per cent) underwent multiple insertions. In the multiple operation group, tubes were inserted twice in 34 ears, 3 times in 6 ears, 4 times in 2 ears, 5 times in 1 ear, and 6 times in 3 ears. The comparison between the single and multiple operation groups revealed significant differences in terms of the presence of tympanic membrane retraction (16.3 per cent vs 67.4 per cent, respectively) and the character of middle-ear discharge (mucoid discharge proportion, 6.5 per cent vs 24.3 per cent, respectively) (Table 2). The mean ventilation tube indwelling time was significantly shorter in the multiple versus single operation group (325.7 ± 155.9 days vs 265.1 ± 135.4 days). Early recurrence after ventilation tube extrusion showed the most significant difference between groups (32.5 per cent vs 87.5 per cent) (Table 2). Other factors, including sex, age, presence of allergic diseases, average duration of OME and post-operative otorrhoea, showed no significant group differences (Table 2).

A multivariate logistic regression was performed to determine which factors increase the probability of multiple ventilation tube insertions. The presence of tympanic membrane retraction (odds ratio = 4.368, 95 per cent confidence interval (CI) = 1.132–16.851, $p < 0.05$), serous middle-ear discharge (odds ratio = 5.582, 95 per cent CI = 1.258–24.770, $p < 0.05$) and early recurrence of OME (odds ratio = 13.627, 95 per cent CI = 3.997–46.453, $p < 0.0001$) were independent predictors of multiple ventilation tube insertions, but ventilation tube indwelling time was not (Table 3).

Discussion

Ventilation tube insertion is the most reliable treatment for otitis media with effusion (OME) in children, but about 20–

Table 1. Patient characteristics

Characteristic	Value
Age (mean \pm SD; years)	4.0 \pm 2.2
Gender ratio (males: females)	57:24
Duration of OME before first ventilation tube insertion (mean \pm SD; months)	5.4 \pm 4.5
Tympanic membrane retraction ratio (normal: retraction)*	98:28
Hearing loss ratio (no hearing loss: hearing loss) [†]	16:46
Middle-ear discharge ratio (serous: mucoid) [‡]	13:85
Ventilation tube indwelling time (mean \pm SD; days)	303.5 \pm 151.1
Post-operative otorrhoea ratio (none: early: late)*	115:4:7
Total ventilation tube insertions ratio (single: multiple)*	80:46
Early recurrence of OME ratio (none: present)*	65:61

*Values represent numbers of ears (not patients). [†]Hearing loss was assessed in 62 patients using pure tone audiometry; hearing thresholds greater than 25 dB HL were regarded as hearing loss. [‡]Middle-ear discharge assessed in 98 patients. SD = standard deviation; OME = otitis media with effusion

50 per cent of children undergo an additional operation because of recurrence after surgery.⁴ Previous studies have investigated factors affecting OME recurrence and multiple ventilation tube insertions, but their results are diverse.

Our study showed that serous middle-ear discharge significantly increased the likelihood of multiple ventilation tube insertions. Serous middle-ear effusion is reportedly associated with allergic disease. Kwon *et al.*⁵ reported that serous discharge was seen more often in patients with allergic diseases than in those without allergic diseases. Furthermore, many studies indicate that allergic diseases such as allergic rhinitis, atopy and asthma, and even food allergies, have significant relationships with OME.^{6–11} Although a past history of allergic disease in the multiple ventilation tube insertions group was not common, we believe that serous middle-ear effusion may have been related to OME recurrence caused by the allergic condition of the children.

However, the results of previous studies on the relationship between middle-ear effusion characteristics and repetitive insertion of ventilation tubes showed conflicting results. Some reported that the characteristics of middle-ear effusion were not related to recurrence,^{12,13} while others reported that mucoid discharge was associated with recurrence.¹⁴ Therefore, the relationship between the nature of middle-ear effusion and recurrence needs to be confirmed in a larger, well-planned study.

Early recurrence of OME and tympanic membrane retraction at the time of surgery were also significantly associated with repeated ventilation tube insertion in this study. Tympanic membrane retraction is a common sequela of recurrent OME.¹⁵ Canali *et al.*¹⁶ reported that type C tympanograms were more frequent in a moderate to severe retraction group than in normal and mild retraction groups. This suggests that patients with a retracted tympanic membrane would likely have poor Eustachian tube function, which can result in recurrent OME. Early recurrence of otitis media after ventilation tube extrusion is also closely related to poor function of the Eustachian tube.

Ventilation tubes are usually extruded from the tympanic membrane about 6 to 24 months after tube insertion. If the tubes are extruded early, patients might require an additional

Table 2. Comparison between groups of single and multiple ventilation tube insertions

Characteristic	Single ventilation tube insertion	Multiple ventilation tube insertions	P-value
Age (mean \pm SD; years)	4.0 \pm 2.0	4.2 \pm 2.4	0.508
Gender ratio (males: females)	56:24	34:12	0.687
Duration of OME before first ventilation tube insertion (mean \pm SD; months)	4.9 \pm 3.5	6.4 \pm 6.1	0.217
Allergy ratio (no: yes)	67:12	33:10	0.194
Tympanic membrane retraction ratio (normal: retraction)	67:13	31:15	0.045*
Middle-ear discharge ratio (serous: mucoid)	4:57	9:28	0.028*
Ventilation tube indwelling time (mean \pm SD; days)	325.7 \pm 155.9	265.1 \pm 135.4	0.030*
Post-operative otorrhoea ratio (none: early: late)	74:2:4	39:2:3	0.748
Early recurrence of OME ratio (none: present)	53:26	9:35	<0.001*

* $P < 0.05$, t -test and chi-square test. SD = standard deviation; OME = otitis media with effusion

Table 3. Predictive factors for multiple ventilation tube insertions

Variable	Odds ratio (95% CI)	P-value
Tympanic membrane retraction	4.368 (1.132–16.851)	0.032*
Serous middle-ear discharge	5.582 (1.258–24.770)	0.024*
Early recurrence of OME	13.627 (3.997–46.453)	<0.001*

* $P < 0.05$, multiple logistic regression. CI = confidence interval; OME = otitis media with effusion

operation given the likely insufficient effects of treatment.^{17,18} However, in our multivariate logistic regression analysis, the indwelling time was not independently associated with an increased likelihood of multiple ventilation tube insertions. Our findings also differ from previous studies in that no association between age and multiple ventilation tube insertions was seen. It is well known that the use of ventilation tubes in young patients is associated with otitis media recurrence or multiple ventilation tube insertions.^{13,19} However, the number of patients in the multiple ventilation tube insertions group was relatively small, which may have affected the results; thus, further studies that include larger populations are needed.

- About 20–50 per cent of children who undergo ventilation tube insertion have recurrence of otitis media with effusion (OME) and may need additional ventilation tube insertions
- Tympanic membrane retraction, serous middle-ear discharge, and early recurrence of OME after the first tube extrusion can predict recurrent OME and additional ventilation tube insertions
- Clinicians should pay particular attention to patients with the above factors

This study has some limitations. Its retrospective nature yielded incomplete patient data, and the total number of patients included in this study is slightly smaller than in previous studies. In addition, we did not have pure tone audiometry results for all patients because of compliance issues. If play audiometry was possible, we could further analyse the hearing of many children aged less than five years. These limitations might have been responsible for the differences between the results of our study and those of previous studies. Further investigations comparing the hearing level between single and multiple operation groups are needed.

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