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Impact of ventilation tube insertion on long-term language outcomes at 6 and 10 years of age: A prospective pregnancy cohort study

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Abstract

Objective: Investigating the impact of early childhood ventilation tube insertion (VTI) on long-term language outcomes.

Design: Longitudinal cohort study.

Setting: A total of 2900 pregnant women participated in the Raine Study between 1989 and 1991 in Western Australia, and 2868 children have been followed up.

Participants: Based on parental reports, 314 children had a history of recurrent otitis media but did not undergo VTI (rOM group); another 94 received VTI (VTI group); while 1735 had no history of rOM (reference group) in the first 3 years of childhood. Children with data on outcomes and confounders were included in analyses of PPVT-R at ages 6 ($n = 1567$) and 10 years ($n = 1313$) and CELF-III at 10 years ($n = 1410$) (approximately 5% in the VTI group and 15% in the rOM group).

Main Outcome Measures: Peabody Picture Vocabulary Test-Revised edition and Clinical Evaluation of Language Fundamentals® Preschool-3.

Results: At 6 years, mean PPVT-R scores were significantly lower in the VTI group than the reference group ($\beta = -3.3$; 95% CI [−6.5 to −0.04], $p = .047$). At 10 years, while the difference between the VTI and reference groups was less pronounced for PPVT-R scores, there was a small but consistent trend of lower measures, on average, across CELF-III scores (expressive: $\beta = -3.4$ [−7.1 to 0.27], $p = .069$; receptive: $\beta = -4.1$ [−7.9 to −0.34], $p = .033$; total: $\beta = -3.9$ [−7.5 to −0.21], $p = .038$). There was no evidence to suggest that language outcomes in the rOM group differed from the reference group.

Conclusion: Lower scores of language outcomes in school-aged children who received VTI in early childhood may suggest a long-term risk which should be considered alongside the potential benefits of VTI.

KEYWORDS
grommets, language development, middle ear infections, otitis media, tympanostomy tubes, ventilation tubes insertion, VTI

1 | INTRODUCTION

Middle ear infection, known as otitis media (OM), is a common condition that is highly prevalent in the first 2 years of childhood.[1] This time of early childhood is considered to be critical for language development. Previous findings on the adverse impact of early childhood OM on language are inconsistent due to limitations and variations in the methodologies of the studies. Some have shown a short-term impact, with a tendency to resolve by school age,[2–5] whereas others have found a long-term impact of varying degrees.[6,7]

Due to concerns regarding adequate development, children with OM, unresponsive to other treatments (e.g., antibiotic use), often undergo ventilation tube insertion (VTI)[8] to remove the effusion, which is known to be the predominant cause of the subsequent hearing loss, and help ventilate the middle ear.[9] Indications for VTI usually include having persistent OM with effusion or recurrent acute OM.[10] Considering that children's language development can be adversely affected by OM-related hearing loss,[11] VTI may be carried out with the anticipation of preventing language delays.

A previous review showed that VTI can help reduce the duration of effusion in the middle ear and improve hearing in the short term.[12] However, VTI did not show an impact on language and other developmental outcomes. In a 7-month follow-up, Rach et al.[13] found that children with OM demonstrated improved performance in language measures, with no significant differences between those who had received VTI and those who had not. However, Maw et al.[14] found a marginal difference at a 9-month follow-up in expressive and receptive language outcomes between children undergoing prompt surgery and those who received VTI after a period of watchful waiting. Also, a 2-year follow-up study showed improvements in speech and language reported by parents, especially regarding children identified as being at higher risk of developmental delays.[15] Additional comparisons between outcomes of early and delayed VTI showed no significant differences between the two groups in terms of long-term language and other areas at the age of 4,[16] 6[17] and 9–11 years.[18] Evidence of VTI impact on long-term language outcomes needs further investigation as most studies have followed-up children in their early childhood, while long-term studies have mainly focused on insertion time, whereas most of the children initially assigned to delayed VTI had undergone the surgery within the first year of these studies.

1.1 | Objective

This study aimed to investigate the long-term impact on expressive and receptive language outcomes of recurrent OM (rOM) and VTI in the first 3 years of life, which is hypothesised to be a critical period for children's development.

Key points

- Undergoing ventilation tube insertion (VTI) in the first 3 years of life was associated with a small but consistent negative impact on long-term language outcomes at around the age of 6 and 10 years in this study.
- Children who received VTI had the lowest mean language scores, compared to children who did not undergo the surgery or those who had no history of recurrent otitis media (OM).
- A history of recurrent OM in the first 3 years of life without undergoing VTI did not have a significant impact on long-term language outcomes.
- In general, mean language outcome scores for most children were within the population-average range.
- The adverse impact of VTI on long-term language outcomes found in this study highlights the importance of weighing the benefits against the risks of VTI prior to performing the surgery on children.

2 | METHODS

2.1 | The Raine Study cohort and follow-up

Between May 1989 and November 1991, 2900 pregnant women (Gen 1) in gestational week 16–20 participated in the Raine Study.[19] Eligibility criteria included that the pregnant women must have the intention to deliver at a tertiary maternal hospital in Western Australia, to live in the state for follow-up purposes and to have sufficient English proficiency to understand the implications of participation. A total of 2868 liveborn children (Gen 2) in the cohort were prospectively followed up at different stages in their lives to assess different areas related to their health and development, including middle ear health and language.

To obtain demographic and medical information about children, the Raine Study used information from medical examinations, developmental measures, and parental reports. Parents were asked to keep a detailed diary to record information regarding their child's medical history and to complete a questionnaire noting any medical concerns or procedures performed prior to each follow-up, which were coded using the World Health Organization's ninth revision of the International Classification of Disease (ICD-9). The present study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines.

2.2 | Ethical considerations

Participation and follow-up of participants were approved by the human ethics committees at King Edward Memorial Hospital and

TABLE 1 Characteristics of the study population.

Characteristic	Overall, $N = 1703$[a]	Reference, $N = 1373$[a]	rOM, $N = 255$[a]	VTI, $N = 75$[a]	p-Value[b]
Sex					.2
Male	882 (52%)	707 (51%)	129 (51%)	46 (61%)	
Female	821 (48%)	666 (49%)	126 (49%)	29 (39%)	
Mostly English often spoken at home					.083
No	88 (5.2%)	79 (5.8%)	8 (3.1%)	1 (1.3%)	
Yes	1615 (95%)	1294 (94%)	247 (97%)	74 (99%)	
Mother Caucasian					<.001
No	170 (10.0%)	159 (12%)	9 (3.5%)	2 (2.7%)	
Yes	1533 (90%)	1214 (88%)	246 (96%)	73 (97%)	
Family income below $27, 000[c]					.2
No	990 (60%)	796 (60%)	159 (64%)	35 (52%)	
Yes	648 (40%)	526 (40%)	90 (36%)	32 (48%)	
Mother completion on high school					.7
No	949 (56%)	770 (56%)	140 (55%)	39 (52%)	
Yes	748 (44%)	597 (44%)	115 (45%)	36 (48%)	
Passive smoke exposure in the first 3 years					.7
No	964 (57%)	780 (57%)	145 (57%)	39 (52%)	
Yes	736 (43%)	591 (43%)	109 (43%)	36 (48%)	
Other siblings					.001
No	800 (47%)	671 (49%)	93 (36%)	36 (48%)	
Yes	903 (53%)	702 (51%)	162 (64%)	39 (52%)	
Pre-term birth (<37 weeks)					.8
No	1589 (93%)	1280 (93%)	240 (94%)	69 (92%)	
Yes	114 (6.7%)	93 (6.8%)	15 (5.9%)	6 (8.0%)	
Breastfeeding stopped <1 year					.7
No	364 (21%)	296 (22%)	50 (20%)	18 (24%)	
Yes	1339 (79%)	1077 (78%)	205 (80%)	57 (76%)	
Low birth weight (<2500 g)					.2
No	1590 (93%)	1281 (93%)	242 (95%)	67 (89%)	
Yes	113 (6.6%)	92 (6.7%)	13 (5.1%)	8 (11%)	
Prenatal alcohol consumption					.12
No	948 (60%)	782 (61%)	129 (54%)	37 (54%)	
Yes	642 (40%)	503 (39%)	108 (46%)	31 (46%)	
Day care attendance in the first 3 years					<.001
No	823 (48%)	702 (51%)	96 (38%)	25 (33%)	
Yes	875 (52%)	666 (49%)	159 (62%)	50 (67%)	
Smoking during pregnancy					.8
No	1321 (78%)	1065 (78%)	200 (78%)	56 (75%)	
Yes	382 (22%)	308 (22%)	55 (22%)	19 (25%)	
Hearing loss at age 6 years[d]					.5
No	1340 (97%)	1070 (97%)	213 (98%)	57 (95%)	
Yes	46 (3.3%)	38 (3.4%)	5 (2.3%)	3 (5.0%)	
Peabody standard score (age 6 years)	106 (14)	106 (14)	106 (13)	103 (14)	.2
Peabody standard score (age 10 years)	105 (12)	105 (12)	104 (12)	103 (13)	.8
CELF expressive language score (age 10 years)	91 (15)	91 (15)	93 (15)	88 (18)	.10

(Continues)

TABLE 1 (Continued)

Characteristic	Overall, $N = 1703$[a]	Reference, $N = 1373$[a]	rOM, $N = 255$[a]	VTI, $N = 75$[a]	p-Value[b]
CELF receptive language score (age 10 years)	102 (16)	102 (16)	103 (15)	97 (18)	.3
CELF total language score (age 10 years)	96 (15)	96 (15)	98 (16)	92 (18)	.2

Note: Some percentages do not add up to 100% due to missing data.
Abbreviation: rOM, recurrent otitis media; VTI, ventilation tube insertion.
[a]*n*(%); or mean (standard deviation).
[b]Dichotomous outcomes: Pearson's Chi-squared test; Fisher's exact test if small numbers; Language scores: Kruskal–Wallis rank sum test.
[c]Australian Dollar.
[d]Hearing loss defined as four frequency average of 500, 1000, 2000 and 4000 Hz >25 dB in the better ear.

Princess Margaret Hospital in Perth, Western Australia. Parents provided written informed consent prior to participating in the study and each of the follow-ups when children were less than 18 years of age. Past this age, children provided written informed consent. The Raine Study Executive Committee has approved the release of the data by accepting the research proposal of this study.

2.3 | Variables and outcome measures

Outcome variables of the present analysis were long-term language outcomes as assessed using the Peabody Picture Vocabulary Test–Revised edition (PPVT-R), which evaluates the receptive vocabulary,[20] and the Clinical Evaluation of Language Fundamentals® Preschool-3 (CELF-III), which assesses receptive and expressive language skills in relation to a normative sample.[21] The PPVT-R was administered at Gen2–5-year follow-up, when children were approximately 6 years old,[7] and Gen2–10-year follow-up, when children were approximately 10 years old, while the CELF-III was administered at Gen2–10-year follow-up. Bias was reduced as the assessors (i.e., research assistants) were not aware of the objectives of this study.

Undergoing VTI in the first 3 years of life and having rOM without undergoing the surgery were the predictor variables in the current analysis. Children were classified into three groups. The first group included children with rOM (rOM group), which is defined in this study as having at least three episodes of any type of OM in the first 3 years of life. This information was obtained from parents' responses to the question, 'Has your child had ever had (in his/her) life OM (middle ear infection)? If yes, how many times?'. The second group included those with rOM who received VTI in the first 3 years of childhood (VTI group), as identified using the ICD-9. These groups were compared to a reference group, which included children from the same cohort with no early history of rOM. Previous work on the Raine Study has suggested several confounding variables that may have an impact on rOM and language outcomes[7,22] (Table 1).

2.4 | Inclusion and exclusion criteria for the current analysis

All Gen 2 participants except those who had not completed language assessments or had missing information on OM and VTI were included. Those with missing information related to key confounding variables were excluded from the multivariable regression analysis.

2.5 | Statistical analysis

Descriptive statistics were used to summarise the characteristics of the study population and the main outcome measures. For language outcomes, any standard score within one standard deviation (15) of the population mean (100) was considered within the population-average range (i.e., scores between 85 and 115). Associations between the confounding variables and study group membership were examined using Pearson's Chi-squared test and Fisher's exact test. Multivariable linear regression was conducted to study associations of OM recurrence and VTI treatment with language outcome scores. Comparative regression analyses were adjusted for predictors of language outcome scores, with the adjustment sets chosen by backwards step-wise selection in the analysis of each outcome restricted to the reference group only. Only variables with minimal missingness were considered potential adjustors, with missingness addressed by imputation. Analyses were undertaken using SPSS (version 28.0) and R (version 4.02).

3 | RESULTS

3.1 | Participants and demographics

Data from the follow-ups in the first 3 years showed that 314 children had a history of rOM but did not undergo VTI surgery (rOM group), whereas 1735 children had no history of rOM (reference group). Another 94 children were in the VTI group. A small number of children received VTI more than once during the same period ($n = 11$). As such, the VTI group included all children who received VTI, regardless of the number of insertions.

A total of 1567, 1313 and 1410 children, who also had data on the confounding variables, completed the PPVT-R at Gen2–5 and 10-year follow -ups, and CELF-III at Gen2–10-year follow-up, respectively, and were therefore included in the regression analyses (Table 2). Approximately 5% of those children were in the VTI group, 15% in the rOM group, and 80% in the reference group.

TABLE 2 Multivariable linear regression analyses comparing long-term language outcomes in VTI and rOM groups against the reference group at age 6 and 10 years.

	Model coefficient (β)[a]	95% CI	*p*-value	Cohen's *d*[b]
PPVT-R at Gen2–5 year follow-up[c] (*N* = 1567)				
Standard score: rOM	−0.49	−2.3 to 1.3	.6	−.04
Standard score: VTI	−3.3	−6.5 to −0.04	.047*	−.24
PPVT-R Gen2–10 year follow-up[d] (*N* = 1313)				
Standard score: rOM	−0.68	−2.4 to 1.1	.5	−.06
Standard score: VTI	−1.5	−4.5 to 1.4	.3	−.13
CELF-III at Gen2–10 year follow-up[e] (*N* = 1410)				
Expressive language score: rOM	1.6	−0.55 to 3.8	.14	.11
Expressive language score: VTI	−3.4	−7.1 to 0.27	.069	−0.22
Receptive language score: rOM	1.0	−1.2 to 3.3	.4	.06
Receptive language score: VTI	−4.1	−7.9 to −0.34	.033*	−.26
Total language score: rOM	2.0	−0.15 to 4.2	.068	.13
Total language score: VTI	−3.9	−7.5 to −0.21	.038*	−.25

Abbreviations: CELF-III, Clinical Evaluation of Language Fundamentals® Preschool-3; CI, confidence interval; PPVT-R, Peabody Picture Vocabulary Test–revised edition; rOM, recurrent otitis media; VTI, ventilation tube insertion.

[a]Mean difference from the reference group in language scores, adjusted for model covariates.

[b]Standardised difference from reference group, calculated from adjusted regression model.

[c]Model adjusted for language, family income below $27 000, mother's completion of high school, other siblings, breastfeeding stopped <1 year and low birth weight (<2500 g).

[d]Model adjusted for sex, family income below $27 000, mother's completion of high school, pre-term birth (<37 weeks), breastfeeding stopped <1year and low birth weight (<2500 g).

[e]Model adjusted for sex, language, family income below $27 000, mother's completion of high school, other siblings, breastfeeding stopped <1 year and smoking during pregnancy.

*Statistically significant.

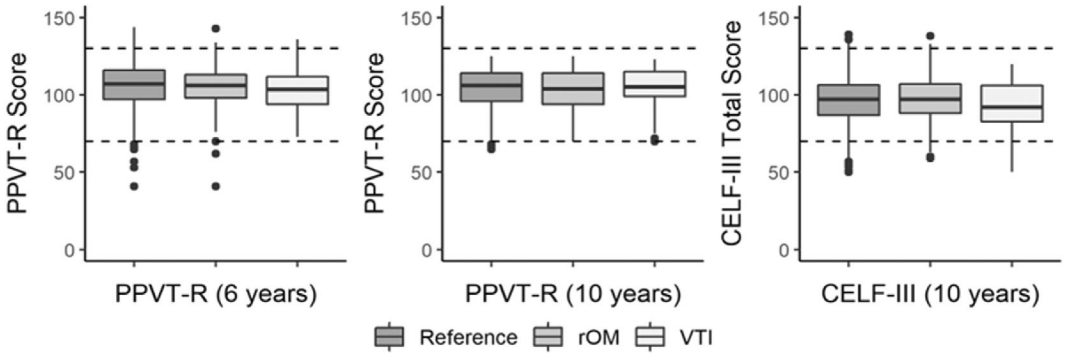

FIGURE 1 Mean and standard deviations of PPVT-R and CELF-III scores at the age of 6 and 10 years. CELF-III, Clinical Evaluation of Language Fundamentals® Preschool-3; PPVT-R, Peabody Picture Vocabulary Test–revised edition.

3.2 | PPVT-R: at Gen2–5 and 10-year follow-ups

The mean standard score and standard deviation of children in the VTI, rOM and reference groups were within the population-average range (Table 1), with more than 95% of all children falling within the average range (Figure 1). Table 2 shows results from the multivariable linear regression analysis that investigated the long-term receptive vocabulary outcomes as assessed using the PPVT-R at approximately the age of 6 years with adjustment for key confounding variables listed in Table 1. Those who underwent VTI surgery had significantly lower scores than those in the reference group (β = −3.3; 95% CI [−6.5 to −0.04]; $p = .047$), but this difference was not apparent in the rOM group ($p > .6$). By 10 years of age, the difference between the mean PPVT-R scores of VTI and reference groups had diminished to nearly half of that observed at 6 years (Cohen's *d* reduced from −.24 to −.13) (Table 2).

3.3 | CELF-III: at Gen2–10-year follow-up

CELF-III scores were consistently lower in the VTI group with a standardised effect size similar to that observed in the analysis of PPVT-R at 6 years of age (Cohen's *d* ranging from .22 to .26) and reaching

statistical significance for receptive ($\beta = -4.1$; 95% CI [−7.9 to −0.34]; $p = .034$), and total language ($\beta = -3.9$, 95% CI [−7.5 to −0.21]; $p = .038$) scores (Table 2). Approximately 10% of CELF-III scores from the VTI group fell below the lower limit of the population-average reference range, compared to approximately 5% of those from the other two groups. In general, scores for the CELF-III outcome measure were similar in the rOM and reference groups ($p > .14$).

4 | DISCUSSION

The results of this study showed that undergoing VTI in the first 3 years of life was consistently associated with lower scores on language outcomes at around the ages of 6 and 10 years. This finding differs from those reported previously. A previous review showed no impact of VTI on speech, and language, or other developmental outcomes, although VTI was shown to reduce the time of effusion in the middle ear cavity and improve hearing in the first year post-insertion.[12] The improvement in hearing, however, was found to be temporary, lasting nearly 12 months. Absence of an impact on language post-VTI was reported in a randomised controlled trial (RCT) by Rach et al.,[13] who did not find a significant difference in language outcomes between pre-schoolers who received VTI and those who did not at a 6-month follow-up, whereas Rovers et al.[23] did not find a difference in a 12-month follow-up of 1- to 2-year-old children. However, both groups scored below the age-appropriate level in terms of expressive language. It is possible that the follow-up time in these studies may have been too short to observe a significant change in language outcomes. However, a marginal improvement in language for the VTI group compared to non-surgically managed children was found in a 9-month follow-up in an RCT.[14] In a 2-year follow-up, parents reported improvements in speech, language, and academic performance post-VTI, particularly in those at high risk for developmental delays.[15]

In terms of longer follow-ups, an RCT that mainly focused on the timing of the surgery (i.e., early vs. delayed surgery) revealed no significant differences in language and other developmental outcomes at the ages of 4,[16] 6[17] and 9–11 years.[18] Other long-term follow-ups, not related to language outcomes, suggested that VTI can be associated with adverse impact on TM structure and hearing. According to de Beer et al.,[24] children who had a history of rOM had a slight conductive hearing loss that persisted for some time in early childhood through adulthood. This loss was greater (up to 10 dB HL) for those who received VTI, which was believed to be related to the subsequent TM abnormalities. In this study, hearing loss might have contributed to lower scores, especially in the VTI group. Lower scores may also be attributed to a more severe history of OM and its sequelae (e.g., hearing loss and developmental delays), which might have been an indication for the need for VTI in those children.

Another finding of this study was that having a history of rOM did not appear to have a significant impact on long-term language outcomes. Findings in this area varied widely due to the different methodologies and limitations of some studies. However, with little difference between the rOM and reference group means for any of the outcomes, our findings are consistent with several studies, which indicated that the impact of OM in early childhood on language tends to resolve with time. For example, a history of rOM and hearing loss experienced in the first 2 years of the children's lives was associated with short-term impairment in expressive language.[2,4] However, this relationship no longer existed when retesting those children at the age of 7 years. Contrarily, long-term consequences of OM on language development were found by Teele et al.[6] The outcomes of their study showed poorer expressive and receptive language outcomes in 7-year-old children with an early history of rOM. Definitive conclusions, however, could not be drawn due to the study's design and limitations.

5 | STRENGTHS AND LIMITATIONS

A key strength of this study was the large sample size of children who have been prospectively and comprehensively followed up. Another strength was the ability to control for a wide range of confounding variables, including pre-, ante- and postnatal variables, which can allow for a more direct evaluation of VTI impact on long-term language outcomes, although it is acknowledged that this is an observational study and control for confounding variables may not be complete.

One limitation of this study was the lack of sufficient audiometric data, which led to an inability to control for hearing loss. Furthermore, the recurrency of OM was determined based on parental reports, which may not be as accurate as other sources (e.g., clinical records) in documenting OM episodes. Information regarding specific OM types was not available, so the rOM group might include children with different OM types. Information on language disorders unrelated to OM was not available and was therefore not controlled for. Finally, only a small number of children who underwent VTI in early childhood completed language assessments and had information related to the confounding variables available.

6 | CONCLUSION

To our knowledge, this was the first prospective pregnancy cohort study that investigated the impact of early childhood VTI on language outcomes at around the age of 6 and 10 years. In this sample, long-term language outcomes did not significantly differ between children with no history of rOM in early childhood and those with rOM who did not receive VTI. For those with rOM who underwent VTI in early childhood, there was a consistent trend of lower scores on language outcomes at 6 and 10 years of age, but mean language scores did remain in the population-average range for the majority of children. Our findings support the previous recommendations in the literature and the current clinical guidelines. That is, VTI should be recommended for children who meet strict criteria, and that the risks of surgery (e.g., general anaesthesia) and potential adverse impacts of VTI (e.g., TM abnormalities) should also be weighed against the benefits of VTI prior to surgery.

AUTHOR CONTRIBUTIONS

This study was conceptualised and developed by E. M. A. A. and C. G. B.-J., with critical input from R. H. E. and P. C. R. Data analysis and manuscript drafting were primarily done by E. M. A. A. M. R. assisted with gaining approvals for the release of the data. E. J. M. assisted with the statistical analysis of data. All the authors critically reviewed the manuscript and analyses and provided detailed feedback on the interpretation of the findings. The submission of this manuscript for publication has been approved by all the authors.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/coa.14121.

DATA AVAILABILITY STATEMENT

Data can be available by submitting an application to the Raine Study committee.

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