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Research Article

Long-term Outcomes for Children with Middle Ear Disease in Western Australia

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Abstract

Objectives: This study aimed to examine the rates and outcomes of myringotomy plus ventilation tube insertion (MVTI) for middle ear disease in Western Australia, both alone and in combination with pharyngeal surgery, and to assess the long-term effect of MVTI on the development of cholesteatoma.

Methods: A retrospective, population-based study was performed using hospital administrative data collected using a validated public health database for children who underwent MVTI in both public and private hospitals in Western Australia between 1981 and 2004.

Results: Over 50,000 children underwent MVTI during the period specified. Adenoidectomy with or without tonsillectomy at the time of first or subsequent MVTI was associated with a lower rate of reinsertion. Longitudinal data demonstrated that children with refractory middle ear disease who required multiple MVTI procedures were at increased risk of developing cholesteatoma. In contrast, lower rates of cholesteatoma were observed in those children who underwent MVTI at a younger age, who had subsequent procedures in quick succession, and who underwent adenoidectomy or adenotonsillectomy at the same time as MVTI.

Conclusions: In Western Australia, 8.4% of children have at least one MVTI before the age of 15 years. This compares favourably with other health systems internationally. Active management of middle ear disease in children through MVTI in combination with pharyngeal surgery resulted in reduced incidence of cholesteatoma development over time. Conversely, delayed management of eustachian tube dysfunction was associated with increased risk of cholesteatoma.

Keywords: Ventilation tube; Grommet; Adenoidectomy; Adenotonsillectomy; Cholesteatoma

Introduction

Otitis media with effusion (OME) and acute otitis media (AOM) are major causes of childhood morbidity and developmental delay [1,2]. Otitis media (OM) is the most common reason for children to undergo surgery [3] and is the fourth most prevalent illness in Australia, accounting for 10% of all antibiotics prescribed [4].

Much work has been conducted investigating the benefits of myringotomy with ventilation tube insertion (MVTI) for OME and AOM. Current Australian guidelines recommend MVTI for OME with hearing loss (present for 3 months or more), recurrent AOM, or acute complications of AOM such as retraction pockets, mastoiditis, facial nerve palsy or intracranial abscess [5]. The value of pharyngeal surgery at the time of MVTI in children is controversial. However, a number of well-designed studies have shown that adenoidectomy or adenotonsillectomy in conjunction with MVTI can be beneficial in selected patients [6]. Current paediatric otolaryngology textbooks recommend adenoidectomy but not tonsillectomy at the time of MVTI, both in children with severe ear disease and in those undergoing placement of a second set of ventilation tubes [7]. The resolution of OME following removal of large adenoids suggests that mechanical obstruction is one factor involved in the pathogenesis of the condition [8]. However, adenoidal involvement in recurrent AOM and rhinosinusitis indicates that smaller adenoids may also act as a reservoir for pathogenic bacteria that contribute to oedema and malfunction of the eustachian tube [9].

Short-term complications of MVTI include otorrhoea, tube blockage, granulation, premature extrusion and tube displacement into the middle ear [10]. Longer-term issues related to the procedure include tympanosclerosis, persistent perforation and cholesteatoma [10-12].

Development of secondary cholesteatoma is reported in approximately 1% of children who undergo MVTI [13]. Its incidence is associated with long-term use of ventilation tubes [11] and is most likely due to the development of retraction pockets that result from negative middle ear pressure secondary to chronic OME.

Using data collected in a validated health database for the state of WA we aim to examine the rates of MVTI, both alone and in combination with pharyngeal surgery, and to investigate the relationship between the procedure and the long-term development of secondary cholesteatoma.

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Methods

Data was acquired from the Western Australian Data Linkage System (WADLS) through the WA Safety & Quality of Surgical Care Project following ethical approval from the HumanResearch Ethics Committees of the Western Australian Department of Health and Curtin University [14]. The WADLS is an on-going, validated database system that systematically links state-based administrative data from six core data sets dating back to 1980. Data includes all in-patient hospital morbidity data (including day surgery admissions), birth and death registrations, midwives' notifications, mental health services data and all cancer registrations [15]. A de-identified extraction of hospital morbidity of all persons who underwent MVTI in a WA hospital from 1981 to 2004 was performed. International Classification of Disease (ICD) coding was used to identify procedures and associated diagnoses.

All children who underwent MVTI after 1980 and who were residing in WA at the time of surgery were included in the study. Pharyngeal surgery was defined as having the ICD procedure codes for adenoidectomy, adenotonsillectomy or tonsillectomy during the admission for MVTI. If the diagnosis codes ICD-9-CM 474 or ICD-10 J35 were associated with the MVTI admission, the child was defined as having adenotonsillar disease. Haemorrhage and readmission within 30 days of the procedure were recorded. Cholesteatoma was defined as acquired if diagnosis was made more than six months after the first MVTI. Children with cleft palate, chromosomal abnormalities or any other congenital anomaly of the ear, nose or face were also isolated.

Age at the time of first MVTI was measured in years. Residential location was defined as metropolitan, rural or remote and was based on post-code at the time of admission for first MVTI. Hospitals were grouped into Health Service Districts according to their location. Indigenous status was defined as Aboriginal, Torres Strait Islander or non-Indigenous. History of ventilation tube insertion was categorised as having had one, two, three, or four or more MVTI procedures during the follow-up period.

Loss to follow up was not directly measured in this study.

Multivariate logistical regression was performed to identify procedural, demographic, social and hospital factors associated with: 1) pharyngeal surgery at the time of first or second MVTI; 2) subsequent second MVTI procedure; 3) haemorrhage during pharyngeal surgery; and 4) readmission within 30 days of MVTI for haemorrhage. Analysis was adjusted for age, time of the year, residential location, socioeconomic status, indigenous status, health service district, chromosomal abnormality, cleft palate and other congenital anomalies of the ear, nose or face that would predispose towards middle ear dysfunction. A multi-state modelling structure using Cox (proportional hazards) models under an extended Markov assumption was used to examine the association between potential risk factors and the development of cholesteatoma. This was used to minimize bias and misinterpretation of hazard values, given that internal time-dependent variables (such as pharyngeal surgery and VT history) may act as confounding factors, mediating variables, or both. All statistical analysis was performed using Stata 9 (College Station, TX).

Table 1: Relative Rate of MVTI in Children Younger Than 15 Years at Time of First Procedure.

	RR	95%CI
Age group		
0-4 years	2.10	2.07-2.14
5-9 years (referent)	1.0	-
10-14 years	0.09	0.08-0.10
Female	0.73	0.71-0.74
Indigenous status	0.63	0.60-0.66
Residential location		
Metropolitan Perth	1.0	-
Rural	0.91	0.89-0.93
Remote	0.67	0.64-0.68

Abbreviations: CI, confidence interval; IRR, incidence rate ratio; MVTI, myringotomy with ventilation tube insertion.
*Multivariate Poisson regression Wald test P values associated with individual rate ratios were all less than .001.

Results

There were 53,673 children born after 1980 who underwent at least one MVTI before the age of 15 years in a WA hospital between 1981 and 2004.64% of first MVTI procedures had otitis media-related diagnosis codes associated with them. Of the 23% of children with no record of OME, 18% had an unspecified ear disorder, 4.5% had adenoid or tonsil disorders and the remaining 0.5% had sleep apnea and other respiratory conditions. The age-standardized rate of first MVTI peaked in 1997 at 6.7 per 1000 person years after which time there was an average decrease of 1.6% each year (95% CI, 1.1%-2.1%). Children aged 0-4 had the highest rates of MVTI. Other factors associated with high rates of MVTI included male sex, living in metropolitan areas and being non-Indigenous (Table 1).

When we examined the rates of pharyngeal surgery in patients who underwent MVTI, we found that 51,373 children under the age of 10 years had at least one MVTI performed in a WA hospital during the same period. 29% (14,841) of children had their first MVTI performed at the same time as adenoid or tonsil surgery. 7.4% of these children (1,096) had no record of adenoid or tonsil disease. Rates of pharyngeal surgery at the time of first MVTI fluctuated from 40% in the 1980s down to 21% in 1995 and then began to slowly increase again. The proportion of patients undergoing adjuvant pharyngeal surgery at the time of second MVTI (in the absence of documented adenotonsillar disease) increased steadily from 2% in 1994 to 9% in 2004. Adenoidectomy was the most common pharyngeal procedure performed at the time of first or second MVTI. Adenoidectomy with first MVTI has undergone a variable trend with its most significant decline in the mid 1990s. Since then it increased to a peak of 5%, but by 2004 was again beginning to decline. Conversely, adenoidectomy at the time of second MVTI has gradually increased from 1993 onwards (Figure 1).

Multivariate logistic regression was performed to account for potential confounding factors related to first MVTI procedure and whether subsequent MVTI surgery was performed.

Children who underwent adenoidectomy at the time of first MVTI were 39% less likely, those who had adenotonsillectomy were 42% less

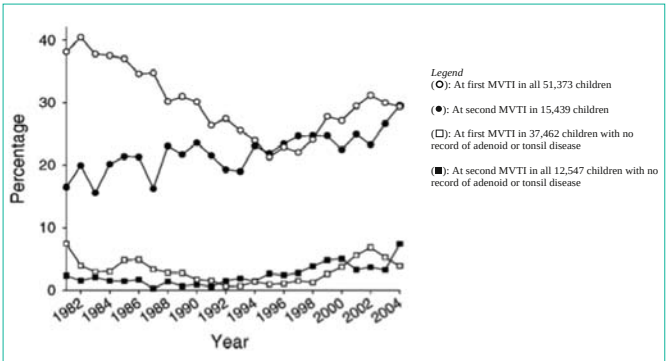

Figure 1: Percentage of myringotomy plus ventilation tube insertion (MVTI) procedures performed with additional pharyngeal surgery in children from 1981-2004 *(see Legend)*. The trends of surgery over time pertaining to children who had MVTI with tonsillectomy are not shown because of small numbers.

Table 2: Crude and Adjusted Odds Ratio (OR) for needing further MVTI procedures when combined with adjuvant pharyngeal surgery.

	Crude			Adjusted*		
	OR	**95% CI**	**p value**	**OR**	**95% CI**	**p value**
MVTI alone	1.0	-	-	1.0	-	-
MVTI + adenoidectomy	0.48	0.45-0.51	<0.001	0.61	0.53-0.71	<0.001
MVTI + adenotonsillectomy	0.43	0.41-0.46	<0.001	0.59	0.50-0.69	<0.001
MVTI + tonsillectomy	0.50	0.4-0.63	<0.001	0.72	0.54-0.95	0.022

*Adjusted for age, year, SES, indigenous status, gender, hospital, residential location, presence of adenoid/tonsil disease and congenital abnormalities

likely and those who had tonsillectomy were 28% less likely to have further MVTI procedures, compared with children who had MVTI alone. Other factors associated with lower rates of additional MVTI procedures included older age at first MVTI, indigenous status, living in an area of higher socioeconomic status, undergoing first MVTI in later years of the study, and having adenotonsillar disease at the time of surgery (Table 2).

In 2004 the mean length of stay for MVTI alone was 0.17 days versus 0.15 days for MVTI and adenoidectomy. Adenotonsillectomy and tonsillectomy had a mean length of stay of 1.0 days, being significantly longer than MVTI alone. There were no recorded cases of haemorrhage associated with MVTI alone. The odds ratio for readmission within 30 days compared to MVTI plus adenoidectomy was 12.5 (95% CI, 6.3-24.8) for MVTI with adenotonsillectomy, and 7.2 (95% CI, 2.2-23.4) for MVTI with tonsillectomy.

460 (1%) patients were admitted to hospital with a diagnosis of cholesteatoma following MVTI. The median follow-up period was 9.1 years. The median age of children undergoing MVTI was 3 years (Interquartile range (IQR), 1-5 years), while the median age at admission for cholesteatoma was 8 years (IQR, 6-12 years). The average time in years from the most recent MVTI to the development of cholesteatoma was 3.8 years.

Univariate survival analysis showed that having a higher number of MVTIs was associated with an increased incidence of cholesteatoma. The percentage of children who had one MVTI and went on to develop cholesteatoma within 15 years was 0.9% (95% CI, 0.8-1.0), compared with 2.1% (95% CI, 1.6-2.3) of children who had two MVTIs, 3.8% (95% CI, 2.9-4.8) who had three MVTIs and 5.2% (95% CI, 4.0-6.7) of children who underwent four or more MVTIs. In children with cleft palate the relative risk of developing cholesteatoma for those who had undergone their fourth MVTI was no different from those who only had one MVTI (Hazard ratio, 1.2 95% CI, 0.3-4.5). Increasing age at first MVTI and increasing time in years since last MVTI was associated with an increased risk of cholesteatoma. Adenoidectomy was shown to be protective against cholesteatoma development with the rate dropping by 27% in all children who underwent adenoidectomy. Living in a rural area was associated with a 43% increased risk of cholesteatoma development (Table 3).

Discussion

The main pitfall of this study is that our results were collated from hospital administrative data that was not collected specifically for the purpose of the study. Certain clinical details were absent which may lead to over- or underestimation of results. That being said, the fact that the study is large, longitudinal and population-based allows it the statistical power to identify small changes in clinical outcomes as well as the reducing the bias that is often observed in single-centre analyses.

The rate of MVTI in WA has declined since 1995. This is likely due to the introduction of management guidelines for middle ear disease in 1993 [5] and introduction of the pneumococcal vaccination for infants in 2001 (Figure 2). The latter is likely to account for the reduction in rates of MVTI in children under 5 in particular. Our figures compare favourably with international reported rates from both Canada and the Nordic countries [16-18] and are equivalent to other states within Australia [19]. The mild climate in Australia may account for lower rates of AOM and consequently OME in comparison to other countries that experience harsher weather conditions, particularly during winter. Higher rates of MVTI were observed in higher socioeconomic groups suggesting easier access to services. All Australians are entitled to free health care in the public system but higher income families tend to have improved access to private health services and hence avoid longer waiting times that are associated with public hospitals [20]. Higher income families are also more likely to employ the use of day care facilities, which is thought to increase the prevalence of OM [21]. Lower rates of MVTI in

Table 3: Haemorrhage following MVTI surgery.

	MVTI Alone N=36,268		MVTI +A N=7648		Grommets +AT N=6984		MVTI + T N=479		All N=51,379**	
Haemorrhage	n	%	n	%	n	%	n	%	n	%
Index admission	0	0	21	0.27	47	0.67	2	0.42	70	0.14
30 Day Readmissions	1	0.01	9	0.12	101	1.45	4	0.84	115	0.22

A = adenoidectomy; AT = Adenotonsillectomy; T = Tonsillectomy

**Children with congenital facial abnormalities or Down's syndrome were excluded (n=454)

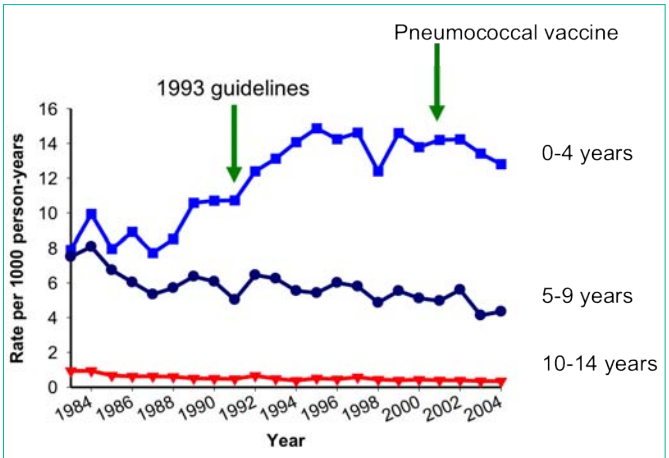

Figure 2: WA MVTI rate per 1000 person-years over time according to age group. Highest rates were seen in the 0-4 age bracket. Introduction of formal management guidelines in 1993 and Pneumococcal conjugate vaccination in 2001 are shown.

Indigenous children despite the fact that prevalence of OME is known to be high in this population may reflect poor access to services.

Our results have also demonstrated that adenoidectomy at the time of MVTI, with or without tonsillectomy, was associated with reduced risk of further MVTI surgery. In the 1980s pharyngeal surgery at first MVTI was performed with relative frequency. This practice declined throughout the 1990s, and towards the end of the study we noted that it is beginning to increase once more. This is likely due to increasing evidence that pharyngeal surgery can reduce OME, particularly where adenoid hypertrophy is contributing to eustachian tube dysfunction [22]. Adenoidectomy at initial MVTI is not recommended unless there is evidence of adenoidal disease [23], but it is indicated if OME recurs following extrusion of the first set of ventilation tubes. We found that a significant proportion of patients underwent adenoidectomy or adenotonsillectomy at the time of MVTI for OME in the absence of documented adenotonsillar disease. This suggests a growing awareness among otolaryngologists of the implications of pharyngeal disease in the aetiology of OME. The fact that adenoidectomy is performed as a same-day procedure and has minimal associated morbidity (e.g. post-operative haemorrhage) makes it an acceptable adjuvant surgery at the time of MVTI. In contrast, tonsillectomy is associated with a more significant risk of haemorrhage and is of little or no benefit in OME, making it a less justifiable adjuvant procedure.

Cholesteatoma was observed in 1% of children included in our study. Cholesteatoma risk was 5.6 times higher after four or more MVTIs in children without cleft palate. In particular, children who were older at the time of first MVTI as well as those who had longer intervals between MVTIs had increased risk of cholesteatoma development. These observations highlight the significant impact that refractory middle ear disease, chronic eustachian tube dysfunction and negative middle ear pressure have in the development of cholesteatoma, rather than suggesting that cholesteatoma is iatrogenic in children who have had multiple MVTIs [11,12]. In children with cleft palate, lack of association between the number of MVTIs and cholesteatoma development further supports this theory. Indigenous children were not found to be at increased risk of cholesteatoma in this study despite the prevalence of middle ear disease in this group. However, it should be noted that our study was only sufficiently powered to note large differences in outcome.

Adenoidectomy was protective in the development of cholesteatoma, which is again thought to be attributable to its effect on eustachian tube function and middle ear pressure [24]. Further work is required to determine if the reduced risk of cholesteatoma is facilitated by reducing the need for tube placement, or if adenoidectomy itself has a direct effect on cholesteatoma development.

The fact that we were unable to identify the severity of middle ear disease, the type of tympanostomy tubes used and the laterality of disease and tube placement are major limitations of this portion of the study. Despite these limitations, our results further support the theory that refractory and/or untreated middle ear disease are major contributing factors in the pathogenesis of cholesteatoma.

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