Does otitis media affect later language ability? A prospective birth cohort study

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KEYWORDS

Otitis media; glue ear; epidemiology; Raine Study; language development

LIST OF ABBREVIATIONS

AOM: Acute otitis media

dB HL: Decibel (hearing level)

OM: Otitis media

OME: Otitis media with effusion

OR: Odds ratio

CI: 95% confidence interval

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ABSTRACT

PURPOSE: To examine whether otitis media (OM) in early childhood has an impact on language development in later childhood.

METHODS: We analysed data from 1,344 second generation (Generation 2) participants in the Raine Study, a longitudinal pregnancy cohort established in Perth, Western Australia, between 1989 and 1991. OM was assessed clinically at 6 years of age. Language development was measured using the Peabody Picture Vocabulary Test-Revised (PPVT-R) at 6 and 10 years of age and the Clinical Evaluation of Language Fundamentals-III (CELF-III) at 10 years of age. Logistic regression analysis accounted for a wide range of social and environmental co-variates.

RESULTS: There was no significant relationship between bilateral OM and language ability at 6 years of age (β = -0.56 [-3.78, 2.66]; p = .732). However, whilst scores were within the normal range for the outcome measures at both time points, there was a significant reduction in the rate of receptive vocabulary growth at 10 years of age (PPVT-R) for children with bilateral OM at 6 years of age (β = -3.17 [-6.04, -0.31]; p = .030), but not for the combined unilateral or bilateral OM group (β = -1.83 [-4.04, 0.39]; p = .106).

CONCLUSIONS: Children with OM detected at 6 years of age in this cohort had average language development scores within the normal range at 6 and 10 years of age. However, there was a small, but statistically significant reduction in the rate of receptive vocabulary growth at 10 years of age (on the PPVT-R measure only) in children who had bilateral OM at 6 years of age after adjusting for a range of socio-demographic factors.

INTRODUCTION

Otitis media (OM), a broad term referring to a spectrum of inflammatory conditions involving the middle ear, affects an estimated 80% of children before the age of three years (Teele et al., 1984). As one of the most common reasons for antibiotic prescription and surgery in children, OM has a high burden of disease in childhood (Williams & Jacobs, 2009). Children have a much higher prevalence of OM than adults, which is believed to be due to both immune system immaturity and development of the Eustachian tube resulting in poor drainage of fluid in the middle ear (Vergison et al., 2010). Although many children experience spontaneous resolution of symptoms with no lasting effects, some experience recurrent or persistent OM episodes and clinical complications (Rosenfeld & Kay, 2003).

Diagnosis of OM consists of two main sub-types: acute OM (AOM) and OM with effusion (OME), each of which can present at different stages on a spectrum (Rovers, 2008). AOM is characterized by a rapid onset of one or more signs or symptoms of inflammation in the middle ear, such as otalgia, fever, otorrhea, or irritability; it typically results in a temporary middle ear effusion, often with decreased hearing sensitivity for up to three months. OME refers to the presence of middle ear effusion without signs or symptoms of an acute ear infection. Typically, a child is considered to have chronic or recurrent OME if the middle ear effusion has been present for more than 3 months (Brennan-Jones et al., 2015). Diagnosis of either AOM or OME can be confirmed by the detection of an effusion of the middle ear. Middle ear effusion (MEE) can be reliably identified by tympanometry and pneumatic otoscopy (Kong & Coates, 2009; Rovers, Schilder, Zielhuis, & Rosenfeld, 2004; Takata, 2003). Evidence suggests pneumatic otoscopy is more accurate than tympanometry, although great variability exists between studies in terms of the reported sensitivity and specificity values (Lee, 2010; Rogers, Boseley, Adams, Makowski, &

Hohman, 2010; Takata, 2003). However, pneumatic otoscopy takes longer to perform, is more difficult to interpret, and thus requires a greater level of clinician training than tympanometry, which is the diagnostic method used in many large-scale epidemiological studies (Abbott, Rosenkranz, Hu, Gunasekera, & Reath, 2014; Takata et al., 2003).

Children suffering from either a single episode or recurrent episodes of OM may experience periods of temporary mild-to-moderate conductive hearing loss of between 15 to 40 dB (Fria, Cantekin, & Eichler, 1985; Hunter, Margolis, & Giebink, 1994). When OM occurs in early childhood there have been concerns that the hearing loss associated with the condition may lead to decreased performance in speech, language and developmental outcomes (Da Costa et al., 2018; Gravel, 2003). Northern and Downs (1978) originally suggested that OM in early childhood may have a negative impact on language development significant enough to reduce educational attainment and persist into later childhood. This hypothesis was based primarily on clinical observation and basic research findings. In particular, Lenneberg (1967) had proposed that mild forms of auditory deprivation during early brain development could lead to permanently underdeveloped auditory pathways and subsequent speech and language deficits. To begin examining this question, researchers used retrospective studies of OM and language development (Brandes & Ehinger, 1981; Sak & Ruben, 1981; Zinkus & Gottlieb, 1980). However, these studies suffered from a number of methodological limitations such as the exclusive use of parental report or questionnaires to identify OM and the inclusion of children with known learning disabilities in language outcome data. Subsequent prospective studies included objective identification of OM and hearing loss by otoscopy, tympanometry and audiometry, or a combination of these (Vernon Feagans et al., 2003). Despite these improvements, many studies lacked good diagnostic criteria for OM or used distal measures of language development, such as academic achievement at school. Whilst many of these studies tried to account for potential confounding variables at the time such as socioeconomic status, they neglected many other potential confounding environmental variables for both OM and language development such as prematurity, bilingualism, duration of breastfeeding, parental education level, exposure to passive smoking, presence of siblings or daycare attendance (Abraham et al., 1996; Armstrong et al., 2017; Brookhouser & Goldgar, 1987; Chaimay, Thinkhamrop, & Thinkhamrop, 2006; Clarkson, Eimas & Marean, 1989; Friel-Patti & Finitzo, 1990; Roberts et al., 1991; Silva et al., 1986; Teele et al., 1984, 1990; Wright et al., 1988). The ability to adjust for known or potential confounding variables enables a more direct comparison of the specific relationship between OM and language outcomes. In addition, small population samples made wider interpretation of these results difficult, although some studies, such as Silva et al. (1986) and Teele et al. (1990) used a population sample approach.

Following a number of prospective studies, two systematic reviews and meta-analyses of the potential impact of OM on language development have been conducted (Casby, 2001; Roberts et al., 2004). The review by Casby (2001) included 32 studies of variable quality and concluded that OM only accounts for a small population effect on children's language learning, with children who had OM scoring slightly lower on language outcomes (overall effect size for receptive language -0.16 [95%CI -0.10 to -0.23]; expressive language -0.23 [95%CI -0.30 to-0.16]). Roberts et al. (2004) included 38 studies in their meta-analysis and found either no effect or a very small negative association between OM and children's later speech and language development. They highlighted that most studies did not adjust for known confounding variables (such as socioeconomic status). They concluded that although some language differences were detectable due to OM, this may be due to increased statistical power, and the clinical relevance for otherwise healthy children was uncertain. Roberts et al. (2004) recommended that future studies should be prospective, well-powered and account for as many potential confounding variables as possible. Other recent prospective studies, such as Zumach et al. (2010), have provided important data since the 2004 meta-analysis, although they presented data only for relatively small sample sizes and limited environmental risk factors were able to be considered. The current study examines the impact of OM and language development at six years and later language development at 10 years of age in a prospective cohort of children followed children from 16 to 20 weeks gestation to 10 years of age. Importantly, this study is able to account for a range of co-variates for OM and language development that have not previously been examined in this context.

The hearing loss associated with OM, rather than the disease itself, is proposed to be responsible for any potential problems with language development. There is well-established literature reporting on the relationship between hearing loss and language development. However, the age at onset, degree and duration of hearing loss are likely to be important factors in determining the potential impact on language outcomes. For example, Tomblin et al. (2015) evaluated the language outcomes of 290 children with mild to severe hearing loss compared to 112 children without hearing loss in the preschool years. Children with hearing loss had lower levels of language, with the area of morphosyntax being the most delayed. Similarly, Wake et al. (2006) reported on 55 children of school-age children with slight to moderate bilateral sensorineural hearing loss (15 to 40 dB) compared to a cohort of over 6,000 children without hearing loss. They found that both groups had similar language scores (mean: 97.2 in hearing loss group vs 99.7 in group without hearing loss) but that phonologic short-term memory was significantly lower in the hearing loss group (mean: 91.0 in slight-to-moderate hearing loss group; 102.8 in group without hearing loss). Other studies have shown that, compared to children without hearing loss, children with hearing loss show slower rates of syntax growth in the early years (Geffner, 1987), as well as differences between groups in the application of morphosyntax as they approach preschool age (Friedman & Szterman, 2006). Children with hearing loss have also shown difficulties in word learning tasks (Cleary, 2009; Houston et al., 2005). Further, children with hearing loss have shown to have lower speech sound inventories than those without hearing loss (Cleary, 2009), which may affect literacy skills in children with hearing loss. Reading gaps reportedly widen between children with and without hearing loss from school age to adolescence (Harris & Moreno, 2004). In relation to OM, Casby (2001) highlighted that the specific effects of the disease, and the fluctuating mild to moderate hearing loss associated with the condition, are likely to be related to speech perception, including phonology and morphosyntax and suggest that school age children suspected of having OM must have more attention paid to their hearing abilities, and important aspects of quality of life.

School-age children are an under-represented group in previous research examining the impact of OM on language outcomes with most studies focusing on children in their first three years of life. This is likely because the peak prevalence of OM is 60.99% in the one to four years old age group (Monasta et al., 2012), and this time period is also considered to be a sensitive period for language development (Newport et al., 2001). However, there is a spike in OM incidence around the time of school entry (Swanepoel et al., 2014) and the effect that this may have on language outcomes is unknown. Children over four years of age may already have a long-term chronic OM presentation due to biofilm formation (Bhutta et al., 2017), failed surgical interventions (estimated to be 11.2% of surgical cases, Kay et al., 2001); or they could be experiencing an acute OM presentation that resolves spontaneously, or an acute OM presentation that develops into persistent or recurrent OM during their early school years. Regardless of the cause of the OM in children in this age group, the potential for the condition to cause a hearing loss that may impact on language development is of concern as language development deficits in the early school years have been associated with poorer literacy, academic performance, negative behavioural outcomes and psychological problems (Aram & Nation, 1980; Clegg et al., 2005; Clegg, Hollis, Mawhood & Rutter, 2005; Cohen, 2001; Da Costa et al., 2018; Howlin et al., 2000; Mawhood et al., 2000; Silva et al., 1987; Snow, 1991; Snowling et al., 2001; Whitehouse, Line, Watt, & Bishop, 2009; Whitehouse, Watt, Line, & Bishop, 2009). The objective of this study was to examine whether the presence of OM in early childhood influenced language development in early and later childhood.

METHODS

Study design

This study examined the relationship between children experiencing OM during early childhood and language development at approximately six and 10 years of age whilst accounting for common co-variates. Data contained in the Raine Study, an established prospective pregnancy cohort was used for this study. The Raine Study data identified OM in early childhood (at six years of age) and measured language development outcomes in early childhood (six years of age) and later childhood (10 years of age).

The Raine Study cohort

The Raine Study enrolled pregnant women (first generation 'Generation 1' participants) at 16 to 20 weeks gestation from King Edward Memorial Hospital (KEMH), the major tertiary maternity hospital in Perth, Western Australia, along with nearby private medical centres. The Raine Study followed the 2868 live-born children (second generation 'Generation 2' participants) to these women between 1989 and 1992 as a longitudinal birth cohort (McKnight et al., 2012). Mothers were eligible to participate if they had sufficient proficiency in English to understand the implications of their participation in the cohort, the expectation that they would deliver at KEMH, and the intention to remain resident in Western Australia for purposes of child follow-up into adulthood (cf. Newnham et al., 1993).

Predictor variable

The main predictor variable was the presence of OM at six years of age. The identification of a broad diagnosis of OM (which could be either acute otitis media or otitis media with effusion) in the cohort was assessed by otoscopic examination with tympanometry at six years of age. Children were categorised into two OM groups. Children were categorised into the 'Bilateral OM' group if tympanometry showed 'Type B' low compliance tympanograms (no pressure or ≤ 0.1 mmho) in both ears at six years of age. A second 'Any OM' group included children in the Bilateral OM group and children who were experiencing to OM in one ear only (unilateral OM) at six years of age as determined by tympanometry.

Outcome variables

The outcome variable was language development measured using the Peabody Picture

Vocabulary Test-Revised (PPVT-R; Dunn & Dunn, 1981a) at six and 10 years of age and the Clinical Evaluation of Language Fundamentals-III (CELF-III; Semel, Wiig, & Secord, 1995) at 10 years of age.

Co-variates

A number of covariates in the study cohort that have previously been shown or hypothesised to influence either OM or language development were available in the Raine Study database and were included in the multivariate analysis (Brennan-Jones et al., 2017; Brennan-Jones et al., 2015; Da Costa et al., 2018). These included maternal education (completed high school), maternal language, maternal ethnicity, maternal alcohol consumption during pregnancy, below average household income (<$24k), sex of the child, parity, birth weight (low birth weight <2500g), prematurity (gestational age <37 weeks), exposure to passive smoking and day care attendance.

Cohort assessment and follow-up

The Raine Study used both medical records and parental self-report measures to collect detailed demographic and medical data prenatally and at birth. Parents were asked to keep detailed diaries of their child's medical history. During follow-up visits, parents completed questionnaires describing any illnesses and medical problems, which were coded by Raine Study research staff using International Classification of Diseases, 9th Revision (WHO, 1988).

Eligibility of participants for present study: Inclusion criteria

All women and their children who were eligible to participate in the Raine Study were eligible for inclusion in this study.

Eligibility of participants for present study: Exclusion criteria

Children in the cohort who were diagnosed with Down syndrome, cleft palate, autism or any other known cognitive, learning or developmental disability, children with missing OM, PPVT-R or CELF-III data were excluded from the study. Children with missing OM or language outcome data were excluded case-wise from the study.

Ethics declaration

Participant recruitment and follow-up for the Raine Study was approved by human ethics committees at King Edward Memorial Hospital and Princess Margaret Hospital, in Perth, Western Australia. Parents provided written informed consent for participation and at each follow-up. The Raine Study participants were re-consented at 18 years of age for the use of their stored data. Approval for the release of data for this project has been given by the Raine Study Executive Committee through approval of a project proposal.

Materials & procedures

Peabody Picture Vocabulary Test–Revised (PPVT-R)

The PPVT-R was used to assess receptive vocabulary development of children at age six and 10 years. The PPVT-R requires participants to choose which one of several pictures corresponds to a word they have heard (Dunn & Dunn, 1981a). The examiner says a word aloud and the child must choose the corresponding object from a group of four pictures, with items increasing in difficulty. The PPVT-R has been widely used for research purposes and as a clinical tool

(Choong & McMahon, 1983; Naglieri & Pfeiffer, 1983; Wake et al., 2005). The PPVT-R was current at the time of assessment but has since been superseded by other PPVT assessment tools.

Clinical Evaluation of Language Fundamentals-III (CELF-III)

Children in the Raine Study were assessed using the CELF-III at age 10 years. Assessment required the completion of three subtests of receptive language and three of expressive language (Semel et al., 1995). Receptive tests involve listening to statements and selecting from visually presented options (Sentence Structure), choosing pictures of geometric shapes in response to oral direction (Concepts & Following Directions), and choosing two out of three or four orally presented words that are associated (Word Classes). Expressive tests included generating a sentence given a word and picture stimulus (Formulated Sentences), composing intact sentences from visually and orally presented words (Sentence Assembly), and repeating orally presented sentences (Recalling Sentences). Raw scores are converted to standard scores for each subtest and added and converted to receptive language scores and expressive language scores, respectively. These scores are aggregated to yield a total language score. The CELF-III is a comprehensive diagnostic language tool for assessment of receptive and expressive language which has been widely utilised in both clinical and research environments (e.g. Boyle et al., 2007). Currently, the test is available in its fifth edition (Wiig, Semel, & Secord, 2013).

Statistical analysis methods

Analysis was conducted in three stages. Firstly, mean scores for language outcomes variables were calculated across both OM groups (bilateral OM and combined unilateral and bilateral OM (Table 1). Secondly, frequencies of predictor variables and association with presence of Any OM were examined using Pearson's chi-squared test ($\chi 2$) and summarised (Table 2). Thirdly, a multivariable regression analysis was conducted using a general linear model to examine the effect of the categorical predictor OM variables and covariates on continuous PPVT-R and CELF-III scores. All statistical analyses were undertaken using SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Effect of otitis media on language ability at age 6 years using the PPVT-R

A total of 1,343 participants completed the Raine study follow-up assessments at six years of age, of these n=1,333 had complete PPVT-R data at 6 years of age, n=1,015 had complete PPVT-R data at 10 years of age and n=1,132 had complete CELF-III data at 10 years of age. The frequency characteristics of the cohort who had OM data at six years of age and language data at six and 10 years of age are presented in Table 1. Table 1 shows that approximately 11.5% of children presented bilateral OM at six years of age and approximately 22.3% had unilateral or bilateral OM at six years. Table 2 presents the frequency characteristics for the range of co-variates and risk factors for OM included in the linear regression model. A multivariate linear regression model (Table 3) incorporating bilateral OM with a range of prenatal, perinatal and postnatal environmental covariates showed no association between presence of OM and language ability at six years of age for the bilateral OM group (β = -0.56 [-3.78, 2.66]; p = .732; r^2 (covariates only) = 0.02, r^2 (covariates and bilateral OM = 0.11); r^2 change = 0.10) or the combined unilateral or bilateral OM group (β = -1.60 [-4.03, 0.82]; p = .195; r^2 (covariates only) = 0.02, r^2 (covariates and unilateral or bilateral OM) = 0.09; r^2 change = 0.07). Other covariates with significant effects on language outcomes at six years of age were: having a mother who spoke a language other than English (β = -10.39 [-15.10, -5.67]; $p < .001$), having a mother who did not complete high school education (β = -3.63 [-5.73, -1.53; $p < .001$); presence of older siblings (β = -3.03 [-5.01, -1.04]; $p = .003$) and alcohol consumption during pregnancy (β = 2.14 [0.09, 4.18]; $p = .041$). Other potential confounders of maternal ethnicity, maternal smoking during pregnancy, household income, sex of the child, low birth weight, prematurity, exposure to passive smoking and attendance at day-care showed no association with language scores.

Effect of otitis media on language ability at age 10 years using the PPVT-R

Table 4 presents a multivariate linear regression model incorporating OM with a range of prenatal, perinatal and postnatal environmental covariates showed a modest, but significant association between bilateral OM group at six years and receptive vocabulary growth at 10 years of age (β = -3.17 [-6.04, -0.31]; $p = .030$; r^2 (covariates only) = 0.02, r^2 (covariates and bilateral OM = 0.17); r^2 change = 0.16), but not for the combined unilateral or bilateral OM group (β = -1.83 [-4.04, 0.39]; $p = .106$; r^2 (covariates only) = 0.02, r^2 (covariates and unilateral or bilateral OM) = 0.06; r^2 change = 0.05).

Other covariates with significant effects on language outcomes at 10 years of age were: household income below the poverty line (β = -2.69 [-4.67, -0.70]; $p = .008$); having a mother who did not complete high school education (β = -3.21 [-5.16, -1.25]; $p < .001$); passive smoking (β = -3.44 [-5.58, -1.31]; $p = .002$) and asthma (β = -4.01 [-6.59, -1.42]; $p = .002$). There was a strong positive association between PPVT-R scores at six and 10 years of age for the 1,276 children who presented with data at both time points [$r = 0.58$; $p < .001$].

Effect of otitis media on language ability at age 10 years using the CELF-III

A multivariate linear regression model (Table 5) incorporating bilateral OM with a range of prenatal, perinatal and postnatal environmental covariates showed no significant association between OM and language ability at 10 years of age using the CELF-III (β = -0.20 [-3.87, 3.48]; p = .916; r^2 (covariates only) = 0.02, r^2 (covariates and bilateral OM = 0.04; r^2 change = 0.03). The only covariate with significant effects on language outcomes at ten years of age was breastfeeding duration (β = 3.09 [0.18, 5.99]; p = .037).

DISCUSSION

The current study shows that children with OM at six years of age scored, on average, within the normal range for the language outcome measures available in this study at six and 10 years of age. However, there was a small but statistically significant reduction in rate of receptive vocabulary growth at 10 years of age, using the PPVT-R, for children in this cohort who had bilateral OM present at six years of age. Although the effect size is very small, the association between OM and receptive vocabulary development at 10 years of age remained once adjusted for a range of prenatal, perinatal, postnatal and environmental variables, suggesting that the association was not merely reflective of socio-demographic advantage or disadvantage. Children with OM had slightly lower average scores using the PPVT-R measure (103.00 (SD: 11.76) compared to 104.78 (SD: 11.86) in the group of children without OM. There was no association between OM diagnosis at six years and an effect on language development using the CELF-III diagnostic language assessment at 10 years of age. The sensitivity and specificity values for the CELF-III are reported as 71.3% and 92.6%, respectively (Semel et al., 1995). A sensitivity value below 80% would be considered unacceptable based on recommendations from Plante and Vance

(1994). It is therefore possible the CELF-III overestimated the language abilities of children in the sample and may explain why predicted associations were not found using this tool.

Several caveats must be addressed when interpreting the information provided by the PPVT-R in isolation. Firstly, the tool is not diagnostic, in that it uses single word recognition to provide information of a child's ability to retrieve information regarding a lexical item using dichotomous scoring, and neglects other critical aspects of language functioning, such as phonological processing (Pennington & Bishop, 2009), morphosyntax (Tomblin et al., 2003), pragmatics (Hart et al., 2004) and word learning capacity. Therefore, a child's receptive vocabulary alone is not a clinical marker of language difficulty. Further, Crais (1990) has indicated that using dichotomous scoring systems to assess vocabulary are constrained, as there are many levels of understanding required for lexical acquisition, especially at the advanced stages of language learning (above 7 years old) (Paul & Norbury, 2012). Finally, the test had not been normed on Australian populations (Dunn & Dunn, 1981b). Considering the experience dependence and cultural implications inherent to vocabulary acquisition, it may be reasoned that the PPVT-R stimulus items, that were validated in 1979, could have had some degree of unfamiliarity for Australian children when tested at the age of 10 years in this study. Although recognised as a valuable tool, the PPVT-R has clear limitations in its capacity to identify clinically significant language difficulties when used in isolation.

In this study, OM was diagnosed cross-sectionally at six years of age and the PPVT-R was used to monitor progress in receptive vocabulary development, and statistically significant differences were found between time-points. OM status at six years of age is an important time point as this corresponds with the approximate age of primary school entry in Australia and a peak in the incidence of OM in this population (Swanepoel et al., 2014). This study also used the CELF-III to assess language at 10 years of age. The CELF-III was designed to measure language knowledge and proficiency necessary for children to acquire literate language and functionally communicate in a classroom environment (Coret & McCrimmon, 2015; Paslawski, 2005; Semel et al., 1995). If language difficulties were associated with OM, scores on the CELF-III would be expected to reflect impairment as well as the PPVT-R. This, however, was not the case and there was no significant association with bilateral OM at six years and CELF-III scores at 10 years. Although the PPVT-R captured a slightly slower or stagnated development in receptive vocabulary at 10 years in children diagnosed with OM at six years old, drawing causative conclusions must be approached discerningly.

It has been proposed that children raised in safe, stimulating environments would recover any language development deficit sustained due to OM in early childhood as a result of a reduction in OM episodes and increasing exposure to linguistic cues as children grow older (Vernon-Feagans et al., 1999). Of two previous meta-analyses, both have shown a negative effect of OM on language development at the population level, although, as in this study, the effect sizes are small, the specific language domains impacted are not consistent between studies and the findings unlikely to be of clinical significance (Casby, 2001; Roberts et al., 2004). There are also inconsistencies in which covariates are accounted for in the statistical analysis of previous reports, the age of children at assessment for OM and language outcomes and the types of language outcomes used, often making direct comparison between studies difficult (Roberts et al., 2000; Rovers et al., 2000; Shriberg et al., 2000). This study is one of the few studies to include a large range of potential covariates.

Not all children with OM suffer a significant hearing loss. (Hunter et al., 1994). This heterogeneity in the hearing profile of children makes the impact of OM difficult to assess, both in this study population and in previous meta-analyses (e.g. Casby, 2001; Roberts et al., 2004). The cross-sectional nature of this study also makes it difficult to assess whether cases of OM were acute or chronic in nature. Considering this, from our findings it appears that, at the population level, the presence of OM at six years of age is not a strong predictor of later language difficulties in this population, although it may account for a slightly slower rate of receptive language vocabulary development, the effect it is likely to have is negligible and not clinically significant. It must also be remembered that OM and the hearing loss associated with the condition, present with a diverse range of severity and language development is similarly multi-faceted. The risk that OM poses to a child's development therefore be considered in the context of the child and their exposure to or experience of other risk or protective factors.

This study does not specifically examine of the potential risks to language development when OM becomes persistent and hearing levels are significantly reduced for long periods of time, and further evidence is still needed addressing the specific impacts of the fluctuating nature of hearing loss associated on development. The disparity between language outcome measures suggests that much of the research variation in this field is methodological. This study too, despite its limitations, provides a comparison of the effect that different language outcome measures can have on study results. More naturalistic assessment procedures, such as language sample analysis, would provide a better indicator of the functional impact of OM on language development.

Strengths and limitations

This study has numerous strengths including a large sample of children, prospectively recruited and followed-up, a large array of covariates examined and a robust diagnosis of OM at the six-year follow-up. Limitations of this study include a lack of OM diagnostic data at the 10-year follow-up, inability to adjust for the impact of OM on hearing threshold levels in the analysis and the use of the PPVT-R which is limited in its examination of receptive vocabulary development only. Children who received ventilation tubes (grommets), a common treatment for OM, were not identified in the cohort and therefore could not be accounted for in this analysis. Potential multicollinearity was not formally assessed in the regression analyses, although the significance of the association favoured the more severe OM presentation (bilateral OM) which is consistent with what would be expected if the relationship between receptive language ability and OM was independent of other potential variables. We therefore cannot speculate what effect this intervention had on their language scores. Further, the only data indicating language difficulties that may be correlated with OM was attained through a non-diagnostic, receptive vocabulary measure.

CONCLUSION

Bilateral otitis media with effusion (OM) in early childhood (six years of age) does not appear to be a strong predictor of later language ability (at 10 years of age). However, there was a detectable reduction in the rate of receptive vocabulary growth at 10 years of age in children with bilateral OM that was not accounted for by socio-demographic factors. Although statistically significant, the effect size was small and not clinically significant as children with OM remained within the normal range for the language outcomes measures and there was not consistency across language outcome measures. Whilst the presence of OM at six years of age is not a strong predictor of later language development, it could still be considered a modifiable risk factor that has potential to impact receptive vocabulary development. The potential impact of OM on language outcomes may be minimal at the population level but needs to be considered in the context of a child's OM severity, level of hearing loss and the potential impact of offer risk and protective sociodemographic and environmental factors. Parents, teachers, clinicians and therapists involved in a child's care should still be encouraged to actively monitor children for OM and refer for audiological assessment and medical management if OM is detected. Future research should examine the long-term effects of hearing loss associated with OM using more robust measures of receptive and expressive language functioning.

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The authors have no conflicts of interest to declare.

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Table 1: Outcomes for children with and without bilateral OM at Year 6 and combined unilateral and bilateral OM at Year 6

	PPVT-R at Year 6		
Bilateral OM at Year 6	n (%)	Mean	SD
Yes	153 (11.5)	105.78	13.60
No	1180 (88.5)	106.29	13.84
	PPVT-R at Year 10		
Bilateral OM at Year 6	n (%)	Mean	SD
Yes	114 (11.2)	103.00	11.76
No	901 (88.8)	104.78	11.86
	CELF-III at Year 10		
Bilateral OM at Year 6	n (%)	Mean	SD
Yes	126 (11.1)	102.49	12.67
No	1006 (88.9)	102.02	13.46
	PPVT-R at Year 6		
Any OM at Year 6	n (%)	Mean	SD
Yes	296 (22.3)	106.12	13.53
No	1033 (77.7)	106.39	13.89
	PPVT-R at Year 10		
Any OM at Year 6	n (%)	Mean	SD
Yes	233 (23.1)	104.55	11.64
No	778 (76.9)	104.75	11.97
	CELF-III at Year 10		
Any OM at Year 6	n (%)	Mean	SD
Yes	253 (22.4)	102.45	12.17
No	875 (77.6)	102.12	13.73

Table 2: Frequency distribution of co-variates in the study population at 6 years for all children experiencing OM ('Any OM'), whether unilateral or bilateral. (* indicates significant at $p < 0.05$)

Risk Factors	**Any OM at 6 years (*n*=299)**		**No OM (*n*=1044)**		*p*-value
	n	**%**	***n***	**%**	
Sex					
Female	163	54.5	570	54.6	.005*
Male	136	45.5	471	45.1	
Mother Spoke Only English					
Yes	273	91.3	994	95.5	.005*
No	26	8.7	47	4.5	
Maternal Ethnicity					
Caucasian	257	86.0	957	91.9	.002*
Other	42	14.0	84	8.1	
Household Income Below Poverty Line					
< 24 K	114	38.1	370	35.5	.388
> 24 K	171	57.2	625	64.5	
Low Maternal Education					
< Year 12	159	53.2	574	55.1	.639
> Year 12	133	44.5	451	44.9	
Passive Smoking					
Yes	103	34.4	315	30.3	.106
No	148	49.5	573	69.7	
Parity					
No older siblings	142	47.5	455	43.7	.227
One or more older siblings	156	52.2	586	56.3	
Prematurity (< 37 weeks gestation)					
Yes	19	6.4	72	6.9	.743
No	273	91.3	948	93.1	
Breastfeeding Stopped < 6 months					
Yes	156	52.2	439	42.2	.882
No	125	41.8	559	57.8	
Low birth weight (< 2500 g)					
Yes	21	7.0	75	7.2	.905
No	278	93.0	963	92.8	
Alcohol in Pregnancy (at 34 weeks)					
Once a week or more	105	35.1	399	38.3	.302
Zero Alcohol	173	57.9	569	61.7	

Daycare Attendance					
Yes	132	44.1	510	49.0	.042*
No	77	25.8	213	51.0	
Introduction of Other Milk					
< 6 months	190	63.5	798	76.7	.214
> 6 months	91	30.4	283	23.3	
Asthma					
Yes	37	12.4	137	13.2	.839
No	262	87.6	904	86.8	
Allergies					
Yes	73	24.4	252	24.2	.722
No	168	56.2	599	75.8	

Table 3: Output of linear regression analyses comparing the effect of bilateral OM at Year 6 upon PPVT-R score at Year 6 (* indicates significant at $p < 0.05$)

	β	SE (β)	*p*	95% CI (β)	
Sex: Female	0.28	1.00	.777	-1.684	2.252
Mother Spoke English Only	-10.39	2.40	**< .001***	-15.100	-5.670
Maternal Ethnicity (Caucasian)	0.47	1.92	.805	-3.291	4.240
Household Income Below Poverty Line	-1.80	1.08	.097	-3.929	0.327
Low Maternal Education	-3.63	1.07	**.001***	-5.727	-1.535
Passive Smoking	-1.77	1.16	.128	-4.041	0.510
Parity	-3.03	1.01	**.003***	-5.007	-1.047
Prematurity (< 37 week gestation)	-0.34	3.19	.915	-6.606	5.923
Breastfeeding Stopped < 6 months	-2.18	1.23	.076	-4.598	0.229
Low birth weight (< 2500 g)	-1.31	2.71	.630	-6.635	4.021
Alcohol in Pregnancy (34 weeks)	2.14	1.04	**.041***	0.092	4.185
Day-care Attendance	0.55	1.09	.612	-1.579	2.680
Introduction of Other Milk	-1.29	1.30	.320	-3.832	1.254
Asthma	-2.35	1.42	.097	-5.133	0.427
Allergies	1.55	1.14	.176	-0.695	3.791
Any OM at Year 6	-1.60	1.24	.195	-4.026	0.824
Bilateral OM at Year 6	-0.56	1.64	.732	-3.784	2.659

Table 4: Output of linear regression analyses comparing the effect of bilateral OM at Year 6 upon PPVT-R score at Year 10 (* indicates significant at $p < 0.05$)

	β	SE (β)	*p*	95% CI (β)	
Sex: Female	1.61	0.93	.084	-0.216	3.441
Mother Spoke English Only	-1.30	2.08	.532	-5.384	2.785
Maternal Ethnicity (Caucasian)	2.02	1.79	.260	-1.499	5.547
Household Income Below Poverty Line	-2.69	1.02	**.008***	-4.667	-0.705
Low Maternal Education	-3.21	1.00	**.001***	-5.165	-1.250
Passive Smoking	-3.44	1.09	**.002***	-5.579	-1.308
Parity	-1.04	0.94	.267	-2.884	0.801
Prematurity (< 37 week gestation)	-0.71	2.94	.810	-6.474	5.064
Breastfeeding Stopped < 6 months	-1.43	1.15	.215	-3.692	0.832
Low birth weight (< 2500 g)	-0.12	2.51	.962	-5.041	4.801
Alcohol in Pregnancy (34 weeks)	1.52	0.99	.123	-0.412	3.459
Day-care Attendance	1.12	1.00	.262	-0.838	3.072
Introduction of Other Milk	-0.66	1.20	.584	-3.020	1.702
Asthma	-4.01	1.31	**.002***	-6.595	-1.416
Allergies	1.35	1.08	.211	-0.769	3.473
Any OM at Year 6	-1.83	1.13	.106	-4.042	0.389
Bilateral OM at Year 6	-3.17	1.46	**.030***	-6.037	-0.311

Table 5: Output of linear regression analyses comparing the effect of bilateral OM at Year 6 upon CELF-III score at Year 10 (* indicates significant at $p < 0.05$)

	β	SE (β)	*p*	95% CI (β)	
Sex: Female	1.26	1.19	.291	-1.078	3.589
Mother Spoke English Only	-2.76	2.74	.314	-8.136	2.615
Maternal Ethnicity (Caucasian)	-1.54	2.22	.487	-5.909	2.818
Household Income Below Poverty Line	0.60	1.31	.646	-1.964	3.166
Low Maternal Education	-2.48	1.27	.050	-4.968	0.003
Passive Smoking	-1.84	1.41	.191	-4.604	0.922
Parity	-1.59	1.20	.185	-3.937	0.760
Prematurity (<37 weeks gestation)	0.42	3.75	.910	-6.935	7.779
Breastfeeding Stopped < 6 months	3.09	1.48	**.037***	0.185	5.987
Low birth weight (< 2500 g)	-0.29	3.24	.928	-6.659	6.075
Alcohol in Pregnancy (34 weeks)	1.20	1.25	.340	-1.263	3.653
Daycare Attendance	2.17	1.29	.091	-0.351	4.695
Introduction of Other Milk	-1.58	1.53	.301	-4.575	1.416
Asthma	0.36	1.68	.832	-2.943	3.656
Allergies	1.34	1.36	.325	-1.331	4.008
Any OM at Year 6	-0.28	1.44	.844	-3.119	2.552
Bilateral OM at Year 6	-0.20	1.87	.916	-3.870	3.477