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ORIGINAL ARTICLE

Early onset of otitis media is a strong predictor of subsequent disease in urban Aboriginal infants: *Djaalinj Waakinj* cohort study

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Aim: Australian Aboriginal and/or Torres Strait Islander children in rural/remote areas suffer high rates of persistent otitis media (OM) from early infancy. We aimed to determine the proportion of Aboriginal infants living in an urban area who have OM and investigate associated risk factors.

Methods: Between 2017 and 2020, the *Djaalinj Waakinj* cohort study enrolled 125 Aboriginal infants at 0–12 weeks of age in the Perth South Metropolitan region, Western Australia. Proportion of children with OM based on tympanometry at ages 2, 6 and 12 months was evaluated, type B tympanogram indicating middle ear effusion. Potential risk factors were investigated by logistic regression with generalised estimating equations.

Results: The proportion of children with OM was 35% (29/83) at 2 months, 49% (34/70) at 6 months and 49% (33/68) at 12 months of age. About 70% (16/23) of those with OM at ages 2 and/or 6 months had OM at 12 months compared with 20% (3/15) if no prior OM (relative risk = 3.48, 95% confidence interval (CI): 1.22–40.1). On multivariate analysis, infants living in houses with ≥1 person/room were at increased risk of OM (odds ratio = 1.78, 95% CI: 0.96–3.32).

Conclusion: Approximately half of Aboriginal infants enrolled into the South Metropolitan Perth project have OM by the age of 6 months and early onset of disease strongly predicts subsequent OM. Early surveillance for OM in urban areas is needed for early detection and management to reduce the risk of long-term hearing loss which can have serious developmental, social, behavioural, educational and economic consequences.

Key words: Aboriginal infants; otitis media; risk factors; urban.

What is already known on this topic

1 Aboriginal and/or Torres Strait Islander children suffer high rates of otitis media (OM).
2 To date, most OM research has been conducted in rural and remote areas.
3 OM is frequently asymptomatic in early infancy until ear discharge is visible or hearing loss or language delay is noted.

What this paper adds

1 This study is the first in Australia to report the high proportion of children with OM in early infancy in an urban Aboriginal population.
2 Early onset of disease strongly predicts ongoing OM at age 12 months.
3 Surveillance for OM and prompt management are essential from early infancy in urban areas to avoid the long-term consequences of OM and associated hearing loss.

Otitis media (OM, middle ear infection) is a leading reason for medical consultations, antibiotic prescriptions and surgery among young children.[1] In 2009, the estimated annual cost for treatment of OM in Australia was $100–$400 million.[2] When OM and its suppurative complications are not treated adequately, the associated conductive hearing loss can result in delays in speech and language development which may affect school performance, socio-economic circumstances and quality of life in adulthood.[1,3–5] Australian Aboriginal and/or Torres Strait Islander children continue to experience severe, persistent and unacceptably high rates of OM from a young age.[4] OM in early life is frequently asymptomatic[6,7]; hence parents may not be aware that their child has the disease until hearing loss, delayed speech or poor balance are

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observed.[7] In the Kalgoorlie Otitis Media Research Project (KOMRP) conducted in the Goldfields of Western Australia (WA), the peak prevalence of OM in Aboriginal children in the early 2000s was 72% at 5–9 months of age, whereas the peak prevalence in non-Aboriginal children was 40% at 10–14 months of age.[8] A study in Perth, WA, found that 42% of primary school-aged Aboriginal children had middle ear disease.[9] The prevalence of OM is unknown in Aboriginal infants living in urban areas where 38% of Aboriginal families live.[3,10]

For Aboriginal and/or Torres Strait Islander children living in rural or remote areas of Australia, passive exposure to tobacco smoke, crowded living conditions, early onset of nasopharyngeal carriage and high bacterial load in the nasopharynx are associated with an increased risk of early OM.[4,11,12] The key risk factors for OM among infants living in urban areas are unknown and may differ to those in rural and remote areas given the differences in demographic, geographic, historical and social factors, culture, language and access to services.[13]

In 2017, the *Djaalinj Waakinj* (Listening Talking) cohort study was established to determine the prevalence of and risk factors for OM in Aboriginal infants living in an urban area to inform policy and ensure optimal and culturally appropriate services are available.[14] Here, we aim to (i) determine the proportion of children with OM in the first year of life, (ii) identify risk factors associated with OM in infancy and (iii) determine whether prior documented OM predicts subsequent risk of OM at 6 or 12 months of age among Aboriginal children in the Perth Metropolitan area, WA.

Methods

Study design and setting

Djaalinj Waakinj was a cohort study of 125 Aboriginal infants enrolled soon after birth between 8 June 2017 and 18 February 2020 and followed for 12–18 months in the Perth South Metropolitan region on Noongar *Whadjuk Boodja* (the Country of the *Whadjuk* people). The study design and population characteristics have been described elsewhere.[14] An Aboriginal Community Advisory Group provided cultural governance throughout the project.[14]

Enrolment, follow-up and ear health assessment

Inclusion criteria for the study were: Aboriginal children living in the South Metropolitan Perth region, intending to remain in the area for 18 months and enrolment before 12 weeks of age. Briefly, mothers were assented antenatally or soon after birth by the Aboriginal Research Assistant (ARA) and/or Project Coordinator. Following written informed consent by parents/guardians at a subsequent home visit, demographic, obstetric, birth, social and environmental data were collected. Feeding practices and pacifier use were recorded at age 2- and 6-month routine visits, and pacifier use at a 12-month routine visit. The number of people in the household at enrolment divided by the total number of rooms was used as a measure of household density. Information about fathers was only obtained if living with the enrolled child.

At 2 and 6 months of age, the research nurse and/or ARA performed a general health check and ear health screening in participants' homes. A further health check and ear health screening were conducted at 12 months of age either in the home or when attending our audiology clinic for a full audiology assessment.[15] The ear health screening included otoscopic inspection of the ear canal and eardrum followed by tympanometry unless contraindicated due to the presence of ear discharge through a perforated membrane. Tympanometry detects middle ear effusion, which is indicative of OM. A Titan Middle Ear Analyser (Interacoustics) or GSI 39 or MI 44 tympanometers (Maico) was used; 1000 Hz probe tone was used to assess infants aged <4 months and 226 Hz probe tone thereafter. An audiologist reviewed the

Table 1 Demographic, socio-economic and environmental characteristics at enrolment of 103 urban Aboriginal infants who had tympanometry performed at least once in the first year of life, Perth, Australia, 2017–2020

Characteristic		Frequency (%)
Child		
Sex	Male	57 (55.3)
	Female	46 (44.7)
Gestational age (weeks)	<37	15 (14.6)
Birthweight (g)	<2500	9 (8.7)
Pacifier use	Yes	60 (58.3)
Breastfeeding	Breast only	33 (32.0)
	Breast and bottle	25 (24.3)
	Bottle only	45 (43.7)
Parental		
Maternal age (years)	<20	13 (12.6)
	20–24	30 (29.1)
	25–29	30 (29.1)
	>29	30 (29.1)
Aboriginal mother	Yes	79 (76.7)
Aboriginal father†	Yes	75 (81.5)
Mother non-smoker	Yes	61 (59.8)
Household		
Total number of people living in household	2–3	13 (12.6)
	4	20 (19.4)
	5	23 (22.3)
	6	12 (11.7)
	7	13 (12.6)
	8–16	22 (21.4)
Number of people per room of household	<1.0	39 (37. 9)
	1.0–1.9	56 (54.4)
	2.0–2.9	7 (6.8)
	≥3.0	1 (1.0)
Number of households with children attending day-care or school	Day-care or school	69 (67.0)
	Neither	13 (12.7)
	No other children	20 (19.6)

† Data only collected from fathers who are part of the household. Denominators vary due to missing data.

tympanometry results and confirmed the final classification. Study participants were referred to an audiologist or ENT specialist for clinical management as required.

Diagnostic criteria

Tympanometry using 1000 Hz probe tone was classified in accordance with the presence of a positive peak, indicative of normal middle ear function, and a negative or no peak, indicative of middle ear dysfunction (indicative of OM). Tympanometry results using 226 Hz probe tone were classified according to the ear canal volume, static compliance and tympanometric peak pressure values as described in Table S1 (Supporting information).[15]

The final tympanometry result was based on the child's worst ear. Overall type A (normal) tympanogram included bilateral or unilateral type A when the contralateral ear tympanogram result was unknown (generally when a valid tympanogram could not be obtained). An overall type B tympanogram included unilateral or bilateral type B results as well as high-volume B (indicative of tympanic membrane perforation or grommet in situ); in this category, we also included those with middle ear discharge (indicative of tympanic membrane perforation). Overall type C tympanogram included bilateral type C or unilateral type C with a type A or unknown result in the contralateral ear.

Analysis and statistical methods

Statistical analyses were performed using STATA 17 Software.[16] The primary outcome was defined as the proportion of type B tympanograms (indicative of OM) among children with successfully completed tympanometry on at least one ear. For categorical variables, Pearson's X^2 test was used to determine differences between groups of interest, including comparisons of demographic, socio-economic and environmental characteristics between those who had tympanometry at least once and those who did not attend for tympanometry. Relative risk (RR) of subsequent OM based on presence or absence of prior OM was calculated. We examined the influence of risk factors for OM at all ages using logistic regression incorporating generalised estimating equations (GEEs) to account for within-person dependencies. The presence or absence of OM was the dependent variable in the regression models and the following were considered as potential predictors: infant sex, gestational age (weeks), birthweight (g), pacifier use at 2, 6 or 12 months of age, breastfeeding at 2 or 6 months of age, maternal age, maternal smoking at enrolment, number of people per room of household and household with other children attending day-care or school. All models were adjusted for age. For multivariate models, variables were included if $P \leq 0.10$ on univariate analysis. P value <0.05 was considered statistically significant in multivariate analyses.

Sample size

Sample size and power calculations for the *Djaalinj Waakinj* study have been described previously.[14] While it was intended that 252 Aboriginal infants would be enrolled, only 125 children were enrolled due to cessation of home-visiting during the COVID-19 pandemic and grant completion.

Results

Population characteristics, enrolment and follow-up

A total of 125 infants were enrolled in the *Djaalinj Waakinj* study. There were Fifty-five participants who did not complete all three routine assessments: 22 were enrolled but did not attend the first ear health assessment at 2 months of age; 44 could not be located for one or more of the assessments despite numerous attempts to contact them, 7 were known to have moved away, 3 withdrew from the study and 1 could not be seen due to COVID restrictions. Of the 103 infants who had tympanometry performed at least once, there was a preponderance of males and 15% of infants were preterm (Table 1). Most infants were breastfed, and most mothers were non-smokers. Almost half the children lived in households of 6 or more people (range 2–16 people). There were no significant differences in socio-demographic characteristics between infants who had tympanometry performed at least once and those who never had tympanometry, except day-care/school attendance of older siblings was more common among those who had tympanometry (X^2 (2) = 10.2, P = 0.006) (Table S2, Supporting Information).

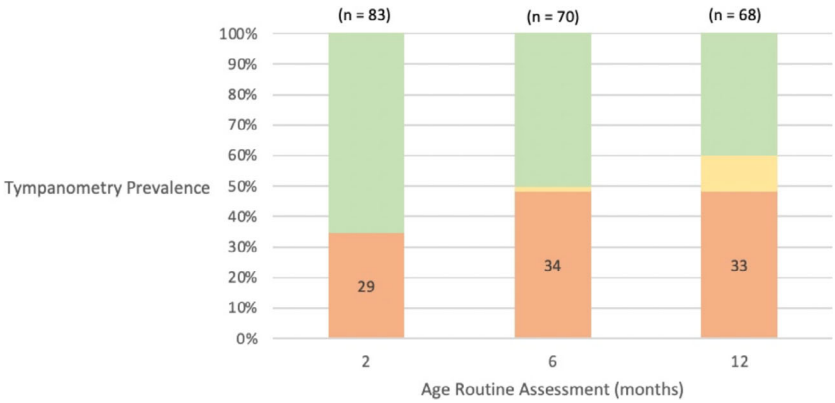

Fig. 1 Tympanometry results at 2, 6 and 12 months of age in urban Aboriginal infants, Perth, Australia, 2017–2021 (n = total number of valid tympanometry results in relevant age group). OM, otitis media. (■) A (no OM) aerated middle ear; (■) C (ETD) eustachian tube dysfunction; (■) B (OM) middle ear effusion.

Tympanometry and proportion of children with OM

Eighty-three of the 103 (81%) infants assessed at 2 months of age had a valid tympanometry result in at least one ear; equivalent figures at 6 and 12 months of age were 70/76 (92%) and 68/70 (97%) participants, respectively. It was more difficult to obtain a valid tympanogram in children aged 2 months than in older children (X^2 (2) = 12.68, P = 0.002). The proportion of children with type B tympanogram (indicative of OM) was 35%

Table 2 Proportion of children with OM (type B tympanogram) at 6 or 12 months of age among infants who had documented prior OM or no prior OM

Age early OM	Early OM	*N* (%)	Subsequent OM *n*/*N*† (%)	Relative risk (95% CI)	*P* value
			At 6 months		
2 months	Yes	18 (34.6)	8/18 (44.4)	1.26 (0.63–2.51)	0.52
	No	34 (65.4)	12/34 (35.3)		
			At 12 months		
2 months	Yes	20 (37.0)	12/20 (60.0)	1.36 (0.81–2.29)	0.26
	No	34 (63.0)	15/34 (44.1)		
6 months	Yes	25 (51.0)	18/25 (72.0)	2.88 (1.38–6.00)	0.001
	No	24 (49.0)	6/24 (25.0)		
2 and/or 6 months	Yes	23 (60.5)	16/23 (69.6)	3.48 (1.22–40.1)	0.005
	No prior OM	15 (39.5)	3/15 (20.0)		

† *n*/*N*: Subsequent OM/Early OM. CI, confidence interval; OM, otitis media.

Table 3 Generalised estimating equations for birth, socio-demographic and environmental risk factors for OM (type B tympanogram) at 2, 6 and 12 months of age in urban Aboriginal infants with valid tympanometry, Perth, Australia, 2017–2021

Variable		Univariate OR (95% CI)	Univariate *P* value	Multivariate OR (95% CI)	Multivariate *P* value
Age (months)	2	Ref		Ref	
	6	1.67 (0.89–3.13)		1.76 (0.92–3.40)	0.09
	12	1.63 (0.88–3.03)		1.79 (0.93–3.44)	0.08
Sex	Male	1.20 (0.65–2.23)	0.56		
	Female	Ref			
Gestational age (weeks)	<37	1.20 (0.41–3.49)	0.74		
	≥37	Ref			
Birthweight (g)	<2500	2.32 (0.62–8.72)	0.21		
	≥2500	Ref			
Pacifier use	Yes	0.63 (0.35–1.13)	0.12		
	No	Ref			
Breastfeeding	Breast and bottle	1.14 (0.57–2.28)	0.71		
	Bottle only	Ref			
Maternal age	<20 years	1.46 (0.67–3.18)	0.34		
	≥ 20 years	Ref			
Mother smoking at enrolment	Yes	1.79 (0.95–3.37)	0.07	1.60 (0.85–3.01)	0.15
	No	Ref			
Number of people per room of household	≥1	2.02 (1.08–3.76)	**0.03**	1.78 (0.96–3.32)	0.07
	<1	Ref			
Households with other children attending day-care or school	Yes	1.54 (0.81–2.92)	0.19		
	No	Ref			

All models adjusted for age. Covariates were included in multivariate models if the univariate effect was significant ($P \leq 0.10$). Bold type indicates a statistically significant result ($P < 0.05$). Valid tympanometry: 2 months (n = 83), 6 months (n = 70) and 12 months of age (n = 68). CI, confidence interval; OM, otitis media; OR, odds ratio.

(29/83, including 1 child with a dry perforation) at a median age of 2.56 months (range 1.77–4.11), 49% (34/70) at a median age of 6.93 months (range 5.06–9.95) and 49% (33/68, including 1 child with suppurative discharge through a grommet, and one with patent grommets) at a median age 12.75 months (range 10.18–17.84) (Fig. 1). Bilateral type B was more common than unilateral type B tympanograms when readings were valid in both ears (16/27 at 2, 23/30 at 6 and 24/30 at 12 months of age).

We investigated the association between early detection of OM at routine ear screens and subsequent OM at 6 or 12 months of age (Table 2). Among infants who had OM at 2 months of age, 44% (8/18) had OM at 6 months of age compared with 35% (12/34) with no OM at 2 months (RR = 1.26, 95% confidence interval (CI): 0.63–2.51; $P = 0.52$). If OM was detected at 2 months, the RR of OM at 12 months was 1.36 (95% CI: 0.81–2.29; $P = 0.26$). Infants with OM at 6 months were at increased risk of OM at 12 months, with 72% (18/25) having OM detected at both routine visits compared with 25% (6/24) having OM detected at 12 months but no OM detected at 6 months (RR = 2.88, 95% CI: 1.38–6.00; $P = 0.001$). Thirty-eight infants had valid results at all three routine ear screens. Of those with OM recorded at ages 2 and/or 6 months, 16/23 (70%) had OM detected at 12 months compared with 3/15 (20%) with no prior OM (RR = 3.48, 95% CI: 1.22–40.1; $P = 0.005$). Of the 15 infants with no OM present (healthy ears) at 2 and 6 months, 12 had no OM present at the 12-month visit.

Risk factors for OM

On univariate analysis, infants living in households with ≥1 person/room had an increased likelihood of OM being detected ($P = 0.027$). In addition, infants of mothers who smoked at time of enrolment had somewhat increased risk of OM (odds ratio (OR) = 1.79, 95% CI: 0.95–3.37; P value = 0.070; Table 3). On multivariate analysis, after adjusting for covariates, those living in houses with ≥1 person/room were at some increased risk of OM (OR = 1.78, 95% CI: 0.96–3.32; Table 3).

Discussion and Conclusions

To our knowledge, this is the first study to document the high proportion of OM in Australian Aboriginal and/or Torres Strait Islander infants living in an urban area. Approximately one-third of infants had OM at 2 months of age increasing to ~50% from age 6 months onwards. Furthermore, those with evidence of OM at 2 and/or 6 months of age were 3.5 times more likely to have OM at 12 months of age than those with no prior OM. We recently reported that one in three of these infants had moderate hearing loss at 12 months of age.[15] The association between early onset OM and persistent disease at 12 months is consistent with previous studies in remote communities.[17] This may relate to the persistence of middle ear infection in bacterial biofilm,[18] which is resistant to antibiotics, and host immune responses resulting in chronic and recurrent disease due to ongoing inflammation.[19] While larger longitudinal studies are needed, our results highlight the feasibility of and need for early ear health assessments in infants living in urban areas, given the generally asymptomatic nature of OM in infancy. Prompt management is then needed to reduce the likelihood of long-term hearing loss and potential developmental, social, behavioural, educational outcomes and economic consequences.[4–6,15] Twenty of the 125 study participants are known to have had grommets inserted before 3 years of age, a further indication of the disease burden and need for services. The proportion of infants with OM in our urban Aboriginal cohort is somewhat lower than in the Goldfields 20 years ago (35% at 2 months in this study vs. 44% in the KOMRP)[8] and lower than that reported recently in remote Northern Territory communities, where only 20% had normal ears bilaterally at 4 months of age.[17]

Larger studies are also needed to confirm that those infants living in crowded conditions or are exposed to maternal smoking are at increased risk of OM; however, findings from this urban study are consistent with the KOMRP.[8] Housing issues were evident in our urban study: at enrolment, one-quarter of participants were living with relatives and planning to move, impacting on our ability to follow up some families.[14] Crowding has previously been reported as the strongest predictor for the carriage of bacteria causing OM.[20] Given the limited availability of subsidised housing and cultural family obligations in the Aboriginal community, we need to continue to advocate for improved housing conditions in the metropolitan area for Aboriginal families.

The main limitation of the study is the sample size and number of infants seen at all three routine assessments. The proportion of children who did not complete the study was similar to that in the KOMRP.[8] While interested to be in the study, many families face complex social issues, transport issues and conflicting priorities which preclude ongoing participation and attendance for routine health checks.[14] The COVID-19 pandemic restrictions impacted recruitment and follow-up as staff were unable to conduct home visits and audiology clinics ceased to operate. Nevertheless, we have documented the high proportion of children with OM in early infancy, emphasising the need for surveillance and prompt management of OM for urban Aboriginal infants. The most recent national guidelines recommend examining 'Every ear of every child at every opportunity'[3] and the accompanying OMapp (https://www.earandhearinghealth.org.au/projects/om-tag-app) is a useful tool for health professionals. The *Pina Karnbi* program in the Goldfields now offers ear health screening when children attend routine immunisations and could be a model for an urban program for general practitioners and child health/community nurses.[21]

The findings of the *Djaalinj Waakinj* study have informed the development of the WA Government state-wide ear health program in young children and led to an expanded program aimed at evaluating new models of care co-designed with the Aboriginal community.[14,22] This clinical research program aims to diagnose and prioritise the treatment of children with OM near people's homes in an Aboriginal-friendly environment.

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Ethics Statement

The project received ethical approval from the Western Australian Aboriginal Health Ethics Committee (Reference: #759), and the Child and Adolescent Health Services Human Research Ethics Committee (Reference: #RGS000012).

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Table S1. Tympanometry result classification used in *Djaalinj Waakinj* study
Table S2. Demographic, socio-economic and environmental characteristics at enrolment of 103 urban Aboriginal infants who had tympanometry performed at least once for routine screen and 22 who never attended for routine tympanometry, Perth, Australia, 2017–2021