

Middle ear effusion: rate and risk factors in Australian children attending day care

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SUMMARY

There have been no previous longitudinal studies of otitis media conducted in non-Aboriginal Australian children. This paper describes the rate and risk factors for middle ear effusion (MEE) in children attending day care in Darwin, Australia. A prospective cohort study of 252 children under 4 years was conducted in 9 day care centres over 12 fortnights between 24 March and 15 September 1997. Tympanometry was conducted fortnightly and multivariate analysis used to determine risk factors predicting MEE. The outcome of interest was the rate of type B tympanograms per child detected in either ear at fortnightly examinations. After adjusting for clustering by child, MEE was detected on average 4.4 times in 12 fortnights (37% of all examinations conducted). Risk factors associated with presence of effusion were younger age, a family history of ear infection, previous grommets (tympanostomy tubes), ethnicity and the day care centre attended. A history of wheeze appeared protective. These effects were modest (RR 0.57–1.70). Middle ear effusion is very common in children attending day care in Darwin. This has clinical importance, since MEE during early childhood may affect optimal hearing, learning and speech development. There is little scope for modification for many of the risk factors for MEE predicted by this model. Further study of the day care environment is warranted.

INTRODUCTION

There have been no longitudinal studies of otitis media (OM) conducted in non-Aboriginal children in Australia. Given that *Streptococcus pneumoniae* is the most common bacterial cause of OM in young children [1, 2] and the introduction of conjugate vaccine is likely in the near future, it is opportune to measure to baseline incidence of OM. This information will be helpful in predicting the impact of

vaccination upon the incidence of these infections. We describe the presence of middle ear effusion (MEE) and examine risk factors predicting MEE in Darwin children attending day care over a 6-month period.

METHODS

Setting

The Northern Territory (NT) has a population of 170000 and covers an area of 1.4 million square

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kilometres. Darwin is the capital and is situated in the tropical north of the territory. It has a population of approximately 80 000.

Study design

A prospective cohort study was conducted in Darwin day care centres between 24 March and 15 September 1997. Approval for the study was granted by the Joint Institutional Ethics Committee of Royal Darwin Hospital and the Menzies School of Health Research and informed consent provided by parents. The 10 largest day care centres which also cared for children under 2 years were approached. All centres cared for children in large groups. Eligible children were those under 4 years at study commencement who attended their centre on the morning of our visit. Parents completed a voluntary questionnaire on their child's attendance at day care, past medical history and risk factors for ear infection. Limited, de-identified information was collected about non-participating children. Participating parents were telephoned fortnightly to enquire about infections in their child over the preceding 2 weeks.

Examinations

Research personnel examined enrolled children at each centre on the same morning each fortnight. Tympanometry (Earscan Acoustic Impedance, model ES-2.1; Micro Audiometrics Corp., Port Orange, Fla.) was conducted by trained research personnel (2 audiologists for 8 centres and a research nurse for 1 centre) following confirmation of an intact tympanic membrane via otoscopy. Tympanograms were interpreted at the time of examination and defined as follows: Type B = peak compliance of less than 0.2 mmho; Type A = peak compliance \geq 0.2 mmho, peak pressure +50 to -100 mmH₂O; Type C: peak compliance \geq 2 mmho, peak pressure < -100 mmH₂O.

Statistical analysis

The target sample size was estimated based upon a conservative assumption that 50% of children attending day care would be affected by acute OM (AOM) in 12 fortnights [3–7]. Surveillance of 200 children would therefore allow estimation of the proportion of children affected by AOM with a precision of 7%.

EpiInfo was used to conduct *t* tests for comparison of means and χ^2 statistics for 2 by *n* tables [8]. STATA was used to conduct univariate and multivariate backward, stepwise Poisson regression analyses of risk factors predicting MEE detection rates. Poisson regression was used to allow for the different number of observations for each child. A generalized estimating equations approach was used to adjust for clustering by day care centre and by child (across time) [9]. A *P* value of < 0.05 was accepted as statistically significant and used for the stepwise criterion.

Risk factors for MEE included in the regression model were based upon evidence provided by previous studies and biological plausibility. Some variables were considered in both continuous and categorical forms. The impact of each variable on presence of MEE was tested individually in a simple univariate model and the variable from each related group (categorical and continuous) which had the lowest *P* value was included in the initial stepwise model. Twenty-two variables were included. Goodness of fit of the model was tested by examining dispersion and deviance.

Definitions for analysis

Presence of ear effusion: A type B tympanogram in either ear determined at the time of the fortnightly examination.

Outcome of interest: The standardised rate of MEE detection per child during the study period. This was calculated as the sum of examinations with effusion present divided by the total number of examinations for each child, multiplied by the 12 fortnights of the study period.

RESULTS

Study cohort

All ten centres agreed to participate. One centre which had allocated itself to a day we were subsequently unable to staff was left out of the study. Parents enrolled 296 children of which 252 were included in the final analysis: 35 children did not meet eligibility criteria, 6 left day care centres before the first visit and 3 did not return questionnaires.

At commencement of the study, enrolments represented 71% (236/331) of eligible children (range 46–89% in different centres). Participants were of a

Table 1. Comparison of participants and non-participants at study onset, Darwin day care centres, March 1997

	Participants (252)	Non-participants (95)	<i>P</i>
Mean age (months)	34	33	0.49*
Female sex	114 (45%)	55 (58%)	0.03†
History of past ear infection	181 (72%)	36 (38%)	< 0.001†
Mean days attending day care per week	4.6	3.9	< 0.001*
Mean hours attending day care per week	37.2	33.6	0.03*
Mean age of first infection (months)	10.9	12.9	0.04*

* *P* value for comparison of means (*t* test).

† *P* value for Yates-corrected χ^2 statistic for a 2×2 table.

Table 2. Child characteristics which varied significantly between day care centres, Darwin, March–September 1997

	Centre									<i>P</i>
	1	2	3	4	5	6	7	8	9	
Number of children enrolled per centre	16	30	23	29	18	34	26	44	32	—
Number of children previously breast fed	9	26	22	28	18	32	21	40	29	< 0.001*
Number of children with past grommets	4	2	0	0	4	0	1	1	0	< 0.001*
Mean months at current centre	10	8	7	14	19	12	10	14	9	< 0.001†
Mean age (months) first ear infection	9	12	14	13	9	12	8	11	8	< 0.01†

* *P* value for comparison of proportions.

† *P* value for comparison of means (*t* test).

similar age to non-participants ($n = 95$). However, they were more likely to have a past history of ear infection, younger mean age of ear infection and attend day care for more separate days and hours per week (Table 1).

The size of the cohort fluctuated throughout the study, with a net outward movement. The dropout rate was 30% (75/252). Of the 75 children who did not complete the study, most left because they left their day care centre (55/75, 73%). Staff or parents withdrew a further 12 children and 8 children changed their day of attendance. Ongoing recruitment was irregular and dependent upon day care centre directors remembering to ask parents of new children. Twenty-two children joined the study after commencement.

During the study period of 12 fortnights, 102 of 107 scheduled visits to centres were made (94%). Visits were missed due to public holidays (5) and staff absences (1). During the study, attendance of enrolled

children on examination days was 83%, allowing 2012 of 2431 potential examinations (range 72–89% between centres). Tympanometry was completed for 1966 of 2012 examinations (98%). The average number of completed examinations per child was 7.8 during the study period (median 9, range 0–12). There were 4 children with no tympanometry results recorded. Of parents who sought health advice and treatment for their children, 2% of such visits were due to information provided by study staff.

Questionnaire responses indicated participants were likely to have lived in Darwin all their lives (192/247, 78%) and to have been breast-fed (224/251, 89%, mean duration 9 months). A past medical history of wheeze was reported in 39% (97/249), allergy in 18% (44/250) and pneumonia in 6% (16/250). Mean household size was 3.8 persons; 61% (153/251) of participants had siblings and 44% (109/250) slept with others in the same room. A family history of ear infection was noted in 49% (123/249), allergy in 48%

Table 3. *Crude standardized rate of detection of effusion for all children stratified by sex, ethnicity and age group, Darwin day care centres, March–September 1997*

Variable	<i>n</i> (%/range)	<i>n</i> *	Effusion present at examination	Number of examinations	Crude standardized rate of effusion /child year†	Crude RR‡ (95% CI)	Adjusted RR (95% CI)
Total	252	—	739	2012	9.6	—	—
Females	113 (45)	252	300	867	9.0	Referent	—
Males	139 (55)	252	439	1145	10.0	1.1 (1.0, 1.2)	1.1 (1.0, 1.2)
Ethnicity – non-Aboriginal	195 (77)	252	522	1537	8.8	Referent	—
Ethnicity – Aboriginal	16 (6)	252	42	107	10.2	1.2 (0.9, 1.5)	—
Ethnicity – unknown	41 (16)	252	175	368	12.4	1.4 (1.2, 1.6)	1.3 (1.2, 1.5)
Mean age (months)	33 (5–53)	252	—	—	—	—	—
Age 0–12 months	9	252	38	72	13.8	Referent	—
Age 13–24 months	56	252	232	483	12.5	0.9 (0.7, 0.9)	—
Age 25–36 months	76	252	228	583	10.2	0.7 (0.6, 0.9)	—
Age > 36 months	110	252	240	864	7.3	0.5 (0.4, 0.7)	0.7 (0.6, 0.8)

* *n*, number completing question in questionnaire.

† Extrapolated from 12 fortnights of data.

‡ Relative risk.

(119/250) and pneumonia in 10% (24/249). The majority of fathers (212/222, 95%) and mothers (215/247, 87%) worked. Smoking inside the house was reported by 22% (54/244) of families.

There was a statistically significant difference between children in different centres with regard to history of breast feeding, previous grommets, previous months at the current centre and age of first ear infection (Table 2). There were no significant differences for any of the following variables: age at end of study, sex, hours of attendance at day care, ethnicity, siblings, sleeping with others in the same room, ear infection, wheeze, allergy, pneumonia, family history of ear infection or allergy, parental working status or smoking habits.

Crude rate of presence of effusion

MEE was present in 739 of the 2012 (37%) examinations. The mean crude standardized rate of detection of effusion for all children was 4.5 in 12 fortnights (range 0–12; 95% CI 4.2, 4.9). This estimate and 95% CI becomes 4.4 (3.9, 5.0) after adjusting for clustering by child (for repeated measurements). Of children examined 6 or more times, 64/201 (32%) had MEE detected in 50% or more of examinations. There was no significant difference in the rate of presence of effusion by sex (Table 3). However, young children were significantly more likely to have a higher rate of presence of effusion, as were Aboriginal children and children of unknown ethnicity.

Multivariate analysis

Adjusting for clustering by day care centre, the backward stepwise procedure resulted in a final Poisson regression model with 9 risk factors from an initial model of 22 variables. The intracluster correlation coefficient was estimated to be 0.07, indicating some degree of correlation between children attending the same centre. However, there was considerable overdispersion (dispersion factor 2.0 compared with the ideal, unity) presumably due to the fact that individual children were contributing more than one examination with effusion during the study period. This was addressed by repeating the backward stepwise procedure with adjustment for clustering by child instead of centre and including centre as a categorical variable (23 variables in initial model), thus allowing the centres to be modelled with different baseline rates of effusion. As expected this resulted in a more conservative final model with a smaller subset of statistically significant variables (Table 4) and a higher intracluster correlation (0.18), indicating that examinations with effusion in individual children were not independent.

Four of the risk factors for presence of effusion were the same as the model with clustering by centre: number of previous grommets, family history of ear infection, ethnicity and previous history of wheeze (protective). Age and the day care centre attended were also statistically significant. The dispersion factor for this model was now 0.66, suggesting under-

Table 4. Risk factors for presence of effusion, final model, Darwin day centres, March–September 1997

Variable	RR	95% Confidence	Intervals	P
Day care centre* 1	Referent	—	—	—
Day care centre* 2	1.33	0.84	2.13	0.2
Day care centre* 3	1.30	0.79	2.12	0.3
Day care centre* 4	0.96	0.61	1.51	0.9
Day care centre* 5	1.60	1.03	2.48	0.04
Day care centre* 6	1.42	0.92	2.20	0.11
Day care centre* 7	0.89	0.52	1.54	0.7
Day care centre* 8	0.69	0.42	1.12	0.14
Day care centre* 9	1.56	0.97	2.51	0.07
History of wheeze	0.82	0.68	0.98	0.03
Ethnicity†: non-Aboriginal	Referent	—	—	—
Ethnicity†: Aboriginal	1.23	0.89	1.70	0.2
Ethnicity†: unknown	1.31	1.09	1.59	0.004
Age at study end‡ (0–12 months)	Referent	—	—	—
Age at study end‡ (13–24 months)	1.03	0.70	1.53	0.9
Age at study end‡ (25–36 months)	0.79	0.51	1.20	0.3
Age at study end‡ (> 36 months)	0.57	0.38	0.87	0.009
Family history ear infection	1.26	1.04	1.51	0.02
Number of previous grommets	1.70	1.40	2.06	< 0.001

* Combined *P* value for day care centre categories = < 0.001.

† Combined *P* value for ethnicity categories = 0.01.

‡ Combined *P* value for age at study end categories < 0.001.

§ Other variables considered in this model were: sex, months at current day care centre, usual days or hours per week attending day care, months in Darwin prior to study entry, household number, number of siblings, number of others slept with in the same room, months of breast feeding, number of past ear infections, previous wheeze or pneumonia, family history of allergy or pneumonia, maternal and paternal working status and number of household members who smoke inside.

dispersion [final deviance (1299) and Pearson χ^2 (1238) were less than the D.F. (1972)]. However, further modelling of the correlation structure across time was precluded by the number of gaps in the sequence of observations for each child.

DISCUSSION

Rate of presence of effusion

After adjusting for clustering by child, the average rate of presence of effusion was 4.4 for the 12 fortnight period (9.6 per child year). Although these do not represent discrete episodes of effusion, fortnightly examinations with effusion present provide an estimate of the total time during which children in this population experienced fluid in the middle ear space. This is clinically important, since MEE during early

childhood may affect optimal hearing, learning and speech development [10–13].

There are few studies with a prospective surveillance design with assessments at sufficiently short intervals and criteria for MEE episodes which enable a comparison of the rate of presence of effusion observed in our study. The largest longitudinal study of MEE conducted to date found the mean cumulative days with effusion to be 20% in the first year of life and 16% in the second year of life [14]. Another study using a comparable design and definition for MEE prospectively surveyed 102 black infants in 9 day care centres for OME [15]. In this study, the proportion of examinations observed with unilateral or bilateral OME (defined by pneumatic otoscopy \pm tympanometry) was 69%. Given that the authors confirmed this as the highest rate of OME reported to 1995, our

observation of MEE in 37% of examinations is also high, particularly in light of the age differences between the children in each study. Zeisel and colleagues examined only children under 2 years of age (mean age at the time of the first examination 8 months). By comparison, only a quarter of the children in our study were under 2 years (mean age at study completion 34 months). We have commenced further work to confirm these findings based on physician diagnosis of videotaped otoscopy views and computer-stored tympanograms.

Risk factors for presence of effusion

Using the most conservative backward stepwise regression model for this study population, we found that risk factors associated with presence of effusion were: age, a family history of ear infection, a history of previous insertion of grommets, ethnicity and the day care centre attended; while a past history of wheeze appeared protective.

Children less than 12 months of age were at greatest risk of effusion. This risk progressively decreased with age. With every year of age, the risk of subsequent effusion decreased by around 22%. Older age has previously been shown to be related to a lower incidence of OM. This is thought to be related to maturation of both the immune system and eustachian tube function [16].

Familial factors have also been shown to be important in the aetiology of OM [5, 17, 18]. We confirmed that a family history of ear infection was a predictor of effusion in this population.

The reliability of information from questionnaires asking about grommet surgery in children is high [17]. We found a strong association between previous grommets and subsequent rate of presence of effusion. The long-term effects of grommet insertion on speech, language and learning are unknown. The extent of short-term benefits are also unclear [12]. The association found in this study between past grommets and subsequent effusion suggests that benefits following surgery are short-lived and that the risk for further disease persists.

Ethnicity has previously been shown to be related to the incidence of OM. Indigenous populations of North America have more infections than Caucasian Americans [19, 20]. We found a higher rate of presence of effusion for Aboriginal children in day care than non-Aboriginal children. This was not statistically significant due to the low numbers of children (6%)

identified as Aboriginal (RR = 1.23, 95% CI 0.89, 1.7). While this risk is increased, rates of disease are considerably less than those described in rural NT Aboriginal children [21, 22]. Children whose parents did not complete the question about ethnicity (16%) had the greatest risk of effusion (RR 1.31, 95% CI 1.09, 1.59). It is plausible that those who did not declare their ethnicity were also Aboriginal. However, there are currently no published data on the ethnicity of non-responders for Aboriginality to either contest or support this hypothesis.

It is difficult to explain why a previous history of wheeze might protect against subsequent presence of effusion in this population, particularly since no such relationship was found for breast feeding, parental smoking habits or history of allergy. Recent studies have suggested that exposure to frequent bacterial infection early in life may promote the T helper cell type 1 immune response and protect against atopy. Conversely those with few bacterial infections early in life may have a stronger T helper cell type 2 response, predisposing to atopy [23, 24]. Since 39% of children had a history of wheeze, it is possible that such children existed in our study population in sufficient numbers to demonstrate this effect. Other researchers have found no association [25] or a moderate positive association between MEE and allergy [26, 27]. Further work in this area is indicated.

The rates of MEE varied substantially across the different day care centres attended. Consideration must be given to characteristics of either the centre environment or the children attending each centre which were not adequately adjusted for by the model. For example, only a very crude measure of socioeconomic status was included: parental working status. Levels of crowding, staffing and sanitation may have differed between centres. Staff experience, education and hygiene practice may have also varied. Given that the centre attended was the only risk factor for presence of MEE predicted by this model that might be amenable to intervention, further studies examining the role of the day care centre environment are indicated.

Critique of study design and methodology

Our estimate for rates of presence of effusion may be elevated by the higher numbers of children with histories of past ear infection among participants compared with non-participants. It is also acknowledged that in conducting our study in a high risk

group we may have found rates that are higher than might be expected for the general Australian population under 4 years. However, we believe the study population here is important given that over one third of all Australian children attend formal day care [28].

In conclusion, this study has demonstrated the success of a community based approach in measuring middle ear infection in young children attending day care. Middle ear effusions were frequently detected. Risk factors for MEE predicted by a Poisson regression model confirm the important role of young age, familial factors, a history of grommet insertion, ethnicity and day care centres. A history of wheeze appeared protective. There is little scope for the modification of many of these risk factors. Further study of the day care environment is warranted. The development and introduction of a vaccine against *Streptococcus pneumoniae* that is effective in young children remains an important avenue to pursue in the management of these common infections.

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