DOCUMENT RESUME

ED 406 006 PS 025 221

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| AUTHOR | Johnson, Dale L.; And Others |
| TITLE | The Effects of Early Otitis Media with Effusion on Child Cognitive and Language Development at Ages Three and Five. |
| PUB DATE | Apr 97 |
| NOTE | 18p.; Paper presented at the Biennial Meeting of the Society for Research in Child Development (62nd, Washington, DC, April 3-6, 1997). |
| PUB TYPE | Speeches/Conference Papers (150) -- Reports - Research/Technical (143) |
| EDRS PRICE | MF01/PC01 Plus Postage. |
| DESCRIPTORS | At Risk Persons; *Cognitive Development; *Developmental Delays; *Language Acquisition; *Language Impairments; Longitudinal Studies; *Otitis Media; Symptoms (Individual Disorders) |

ABSTRACT

This study examined the hypothesis that children with persistent otitis media with effusion (OME) during the first 3 years of life are at risk for cognitive and language delays. The prospective study enrolled 698 children and controlled for 8 demographic and environmental factors. Subjects were recruited at birth, and frequently monitored at home for ear status; 379 children were assessed at age 3, and 294 at age 5. Findings revealed a significant direct relation between duration of bilateral OME and scores on the Stanford-Binet Fourth Edition (SBIV) Composite and Nonverbal/Reasoning Visualization factor at age 3, but not at age 5, and scores on the Carrow Elicited Language Inventory and Goldman-Fristoe Articulation at age 5. There were several moderated effects for the SBIV, the Carrow Auditory Visual Test and Test of Auditory Comprehension of Language--Revised also at age 5. No significant relations were obtained at age 3 for the Sequenced Inventory of Communication Development. Results suggest that prolonged OME, especially between 6 and 12 months, may put children at risk for language delays at age 5. Persistent OME also places children at risk for cognitive delays at age 3 but delays were not apparent at age 5. (Contains 29 references.) (Author/KDFB)

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Poster Session: SRCD, April, 1997, Washington, DC.

# The Effects of Early Otitis Media with Effusion on Child Cognitive and Language Development at Ages Three and Five

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Abstract

This research tested the hypothesis that children with persistent otitis media with effusion (OME) during the first 3 years of life are at risk for cognitive and language delays. A prospective study enrolled 698 children and controlled for 8 demographic and environmental factors. Subjects were recruited at birth, amd monitored for ear status frequently in the home; 379 children were assessed at age 3, and 294 were assessed at age 5. Using the SAS General Linear Models procedure, we found a significant direct relation between duration of bilateral OME and the Stanford-Binet Fourth Edition (SBIV) Composite and Nonverbal/Reasoning Visualization factor at age 3, but not at age 5, and the Carrow Elicited Language Inventory (CELI) and Goldman-Fristoe Articulation at age 5. There were several moderated effects for the SBIV, the Carrow Auditory Visual Test (CAVAT) and Test of Auditory Comprehension of Language-Revised (TACL-R) also at age 5. No significant relations were obtained at age 3 for the Sequenced Inventory of Communication Development. Prolonged OME, especially between 6-12 months, may put children at risk for language delays at age 5. Persistent OME also places children at risk for cognitive delays at age three, but delays were not apparent at age 5.

The Effects of Early Otitis Media with Effusion on
Child Language Development at Ages Three and Five

The question of whether persistent otitis media with effusion (OME) has lasting effects on child development continues to be unresolved, although the topic has been the subject of many theoretical and empirical studies. The problem may lie in the nature of the kind of hearing impairment that is presented by OME. It is intermittant rather than permanent, and partial rather than total. Thus, a child may have an episode of OME and experience some diminution of hearing acuity, typically estimated to be about 10 db, for a few days or even weeks, and when the episode is over hearing returns to full acuity. It would not be expected that this brief experience would have measurable effects on language or cognitive development. Other children, however, have OME episodes so often that much of their early life is with OME, and their hearing is impaired for a major proportion of their lives. These children, even with only partial hearing loss, may indeed suffer developmental impairments.

Feldman and Gelman (1986) have argued from a constructivist position that children afflicted with OME may overcome the difficulties posed by partial, intermittant hearing loss without lasting impairment. Taking a contrary position, Eimas and Clarkson (1986) stated that the effects of OME would "..make it exceedingly difficult for the child to learn just how the parental language maps very fine acoustic differences onto different, language-specific categories" (p. 157). Most published researchers have agreed that OME does have persistent effects, but the research results offered as evidence for these effects are such that acceptance of the conclusion must be withheld.

There have been numerous reports of effects of early OME on the language, cognitive, behavioral and achievement of children in school (See reviews by Reichman & Healy, 1983, and Stool et al, 1994). Most of these studies made use of retrospective reports of the presence of OME with control groups matched on age and other relevant variables. These studies have such methodological limitations including small sample sizes, weak outcome assessment measures, and inadequate assessment of the presence of OME, that they cannot provide convincing evidence of long-term OME effects.

Three prospective studies have been conducted with information on OME collected in infancy and children followed to age three, and into the school years.

The North Carolina group have reported the results of a series of studies with their sample of 55 children, all of low SES status, mostly Afro-American and all in a stimulating day care program. Ear status was assessed monthly from 6 weeks to 3 years of age. Outcome assessment was carried out at various ages, but our concern here is with the 3 to 5 year range. The relations of days of OME in the first 3 years and Stanford-Binet intelligence at 3 years and at 4 years was not significant, nor was the relation to McCarthy scores significant at 42 months (Roberts et al., 1991). Furthermore, there were no significant relations to measures of attention (Arcia & Roberts, 1993) or to phonological processes (Roberts et al., 1988) for young children. This research group has found significant associations of early OME to later language functioning and school achievement (Feagans et al., 1987; Roberts, Burchinal & Campbell, 1994)

Gravel and Wallace (1992) examined the effects of OME on the development of children at age 4. A total of only 23 children were followed from pregnancy with "frequent examinations of the middle ear status." Children were classified into high or low OME groups. Several tests yielding 15 outcome scores were used. Of these, results were reported for only 6. There was one significant group difference: On the PSI high OME children "..required a more advantageous signal-to-competing message ratio than did otitis negative children." The SBIV, PPVT-R and SICD did not yield significant results. This study had a small sample size and did not establish that the two groups did not differ on important background variables.

The most relevant prior research for the present study in terms of sample size and characteristics is that of the Greater Boston Otitis Media Study Group (Teale et al., 1984).

In this study 205 infants were recruited and first examined before three months of age. Middle ear status was examined when infants came to pediatric offices for any purpose and were examined by practitioners. Children were selected for the study if they had at least 3 episodes of acute OME by age 2 years and those who had no more than one episode by that age. The middle group was excluded. The two groups were not matched; instead statistical controls were applied to possibly confounding variables. All children included were white. The number of days with OME by age 3 was used as the predictor variable. Language abilities at age three were assessed with the Peabody Picture Vocabulary Test, Zimmerman Pre-school Language Scale, the Fisher-Logemann/Goldman-Fristoe Test of Articulation and measures of mean length of utterance, intelligibility, and number of grammatical transformations. After controlling for SES and gender, days with OME was significantly associated with PPVT scores. In a similar analysis of time of OME this association held for the first year of life, but not for the second or third. Correlations were higher for bilateral OME than for unilateral. On the Zimmerman Auditory Comprehension Quotient comparable results were obtained with a significant correlation for the OME in the first year and not for the second two years. The Zimmerman Verbal Ability Quotient correlations were not significant with one exception: time with bilateral OME in the first year was significant. Other outcome measures did not show significant relations.

The authors noted that controlling for SES and gender was important for the analyses, but probably not sufficient. They suggested including birth order and day care participation, and did include analyses of these variables as they were related to days with OME. As these relations were not significant, the variables were not further studied. Mention was also made of quality of the parent-child relationship, but this was not measured. It should be noted that this group found several significant relations of OME to several school achievement and cognitive variables at child age 7 (Teele et al., 1990).

These results suggest that persistent OME may have an effect on cognitive, language or speech development, but new lines of investigations are also opened: 1) Which cognitive, language and speech functions are most affected by persistent OME? 2) Does OME at certain times in the first three years have more deleterious effects on cognitive, language and speech development? 3) Under what environmental conditions is persistent OME most harmful?

The purpose of the present investigation was to attempt to provide answers to these questions. The investigation was a prospective study which included a large sample of children with diverse ethnic and socioeconomic characteristics and outcomes analyses which included controls for potentially confounding demographic and environmental factors. In this report the focus is on relations between duration of OME in the first three years of life and language and speech measures at three and five years of age.

## Method

### Subjects

In the period 1984-1989, 698 children were recruited from three nurseries in Galveston County, Texas. At the time of enrollment, informed consent was obtained from the parents for participation in the project by means of a form approved by the institutional review board at the University of Texas Medical Branch in Galveston and the comparable board at the University of Houston. In addition, for subjects receiving tympanostomy tubes, a standard institutional surgical consent form was signed by a parent just before insertion of the tubes.

Infants were recruited at birth without respect to gender, ethnicity, or SES. Because language performance would be assessed, children were excluded if English was not the primary language spoken in the home. Other exclusion criteria were the presence of neonatal complications, craniofacial anomalies, risk factors for sensorineural deafness, lack of a home telephone, or plans to mover from the area in the next five years. Participation was offered to all who met the eligibility criteria.

Monitoring, definition, and calculation of duration of OME.

Home visits were scheduled every 2 to 4 weeks to determine the status of the middle ear whether symptoms were present or not. During the first 2 years of life, the mean and median number of visits per subject was 34 (SD 5.6; range 14 to 56).

The middle ear status of the child was assessed by technicians who used tympanometry, supplemented by acoustic reflectometry at 30% of the visits. The tympanometers were automated screening models that used a 226 Hz probe tone. The following models were used: Ear Scan II (Micro-Audiometrics, Port Orange, FL) at 79% of the visits, model 28 (Grason-Stadler, Littleton, MA) at 19% and other typanometers at 2%. Acoustic reflectivity was performed with the Acoustic Otoscope (Endeco Medical, Marion, MA). At each visit, if an abnormal reading was obtained, the test was repeated and the more normal result was used.

Otitis media with effusion was diagnosed if any one of the following three criteria was documented: (1) otorrhea visible without an otoscope, (2) an acoustic reflectivity $\geq 5$, (3) a type B tympanogram defined as compliance of 0.0 or 0.1 ml. These criteria are similar to those previously reported to be predictive of middle-ear effusion (Lampe, Weir, Spier & Rhodes, 1985; Schwartz & Schwartz, 1986).

For children with tympanostomy tubes, OME was diagnosed if one of the following was documented: (1) otorrhea or (2) a type B tympanogram only if the canal volume indicated that the tube was not patent (i.e., canal volume $< 1.0$ ml for children $< 6$ months of age or canal volume $< 1.4$ ml for children $\geq 6$ months). If a type B tympanogram was obtained at three consecutive visits after tube insertion, the tube was considered blocked or extruded and the parents were encouraged to see a physician to document the status of the tubes and ensure that tube function was restored.

At each visit, each ear was evaluated separately and a diagnosis of OME was made or the ear identified as normal on the basis of the criteria described above. A computer program calculated the percentage of time each child spent with unilateral, bilateral, and combination (unilateral plus bilateral) OME for a given period. If two consecutive visits showed OME, the intervening days were counted as days with OME. If one visit showed OME the next normal status, or vice versa, half of the intervening days were counted as days with OME. A maximum of 28 days of OME were calculated from any single abnormal visit.

Treatment of OME

Parents were informed about the status of their child's middle ears at each visit. If OME was diagnosed, they were advised to see their child's physician for care. All visits to the child's physician and any prescribed medications were recorded. However, no attempt was made to direct the treatment of the child, with one exception. The study was originally designed to include an experiment to test the efficacy of tube placement to reduce the duration of OME. In this experiment subjects who experienced more than 6 weeks of continuous OME in the first year of life were identified as at high risk, and were assigned randomly to one of two treatment groups: Conventional Therapy (CT) or Experimental Treatment (ET). Random assignments to the ET and CT groups were stratified by ethnicity (Afro-American and Euro-American/Hispanic). All remaining subjects were assigned to the Minimal OME (MO) group.

The CT group continued to be treated by their family physicians according to their usual practice. Most subjects in this group received antibiotic therapy and some received tympanostomy tube placement after experiencing OME for periods which varied widely between subjects and practitioners. The ET group was offered antibiotic therapy and placement of tympanostomy tubes as soon as possible after 6 weeks of continuous OME had been documented, with prophylactic antibiotic therapy thereafter. Tubes which were extruded were replaced if the condition of the subject warranted it. Subjects remained in this group even if parents chose to delay or refuse tube placement.

The original experimental design of this study was set aside in favor of general linear model analyses, including analysis of OME clusters. We abandoned the experiment because several uncontrollable design problems arose. About 20% of parents of subjects in the ET group refused early placement of tubes and many others delayed tube placement well beyond our target date (i.e., after 6 weeks of continuous OME). Furthermore, about 20% of subjects in the CT groups and even 8% of the MO group received tubes at the direction of their personal physicians. These deviations from the protocol greatly complicated our analysis of the data and made the results difficult to interpret. Controlling statistically for both group assignment and actual tube placement resulted in very small groups in some cells. Furthermore, a simple categorical variable for tube status (e.g., tubes/no tubes) was inadequate to express timing and duration of tube placement. We therefore refocused our attention on our primary research question, which was the relation of early OME to developmental outcomes. We abandoned the treatment group structure altogether and analyzed our data in terms of the duration of OME experienced by each child, regardless of group assignment or therapy. Hence, the study was analyzed as a prospective cohort study.

Demographic and environmental variables

General demographic information. At the time of enrollment, the subject's gender, ethnicity, and birth rank were obtained by parental report. Gender and ethnicity were analyzed as categorical variables. Birth order was analyzed as an ordinal variable.

Socioeconomic status. When children were two years of age, SES was measured with the Hollingshead Four Factor method which takes into account the education and occupation of both parents (Hollingshead, 1975). SES was measured as a continuous variable.

Home educational stimulation provided. At two years of age the mother was interviewed and observed with her child in her home using the Home Observation of the Environment (HOME) a measure of how educationally stimulating the home environment is (Caldwell & Bradley, 1984). HOME was measured as a continuous variable.

Mother's Intelligence. At child age two, mothers were tested in their homes with the Shipley Institute of Living Scale (Zachary, 1987).

Feeding Practices. The dates of the start and cessation of breast feeding, formula feeding, and feeding of other foods were recorded. The duration of breast feeding of any amount, irrespective of whether it was combined with other foods, was calculated and analyzed as a continuous variable.

Cigarette smoke exposure. The number of packs of cigarettes smoked per day by each member of the household was recorded at the time of recruitment. Because some of the homes had more than one smoker, the total number of packs of cigarettes smoked per day by all people in the home was calculated and analyzed as a continuous variable.

Group child care. Group child care was defined as child care in any environment where six or more nonsibling children were present. The age (in months) at the start of group day care was analyzed as a continuous variable and was not entered for children who never attended day care.

Outcome Measures

Data from all of the outcome measures were analyzed as continuous variables. Assessment instruments that were selected had satisfactory reliability and validity. Testing was done by six psychology or speech and communication disorder graduate students who were especially trained in the tests used. Examiners were blind to the child's OME status.

All assessments were carried out in the project research offices or at the child's home in quiet, non-distracting rooms. Parents were not present during the testing sessions, but were nearby. Behavioral audiometry with the children preceded cognitive and language assessment and children went on to have tests only if their hearing was in the normal range.

Stanford-Binet Fourth Edition (SBIV). This test assesses a wide range of cognitive abilities (Thorndike, Hagen & Sattler, 1981). The Composite score provides a measure of general intelligence. In addition, there are two factor scores, Verbal Comprehension (VC) comprised of Vocabulary, Comprehension, Absurdities and Memory for Sentences subtests, and Nonverbal Reasoning/Visualization (RV) comprised of Copying, Pattern Analysis, Bead Memory and Quantitative subtests.

Kaufman Assessment Battery for Children (KABC). The KABC (Kaufman & Kaufman, 1983) Achievement subtests were used at age 5. These include Expressive Vocabulary (name objects pictured in photographs), Faces and Places (name fictional characters, famous people, and well-known places), Arithmetic (identify numbers, count and compute), Riddles (name an abstract or concrete verbal concept), and Reading/Coding (identify letters and pronounce words). The Achievement scores are considered good predictors of later school performance.

Sequenced Inventory of Communication Development-Revised (SICD)(Hedrick, Prather, & Tobin, 1984). The test combines parental report with direct assessment of the child. Receptive and expressive skills are assessed in separate scales.

Carrow Auditory Visual Abilities Test(CAVAT)(Carrow-Woolfolk, 1981). Only the auditory subtests believed to be sensitive to OME effects were used. They are Auditory Blending and Auditory Discrimination in Quiet.

Carrow Elicited Language Inventory (CELI)(Carrow, 1974). The CELI measures the child's comprehension of grammar across a wide range of grammatical complexity.

Goldman Fristoe Test of Articulation (GF)(Goldman & Fristoe, 1986). The GF was used to measure intelligibility of the child's speech.

Test of Auditory Comprehension of Language-Revised (TACL-R)(Carrow-Woolfolk, 1985). The TACL-R measures the child's knowledge of specified lexical and grammatical forms. The Total score was used..

Statistical Analyses

The SAS General Linear Models (GLM) procedure was used to evaluate duration of time during the first three years in relation to language outcomes. Several environmental/biological factors were controlled: SES, ethnicity, gender, birth order, HOME, mother's intelligence, time spent in day care, mother's and father's smoking in the home, and breast feeding history. As father's smoking, time in day care, and birth order did not add significantly to the prediction of language outcomes, above and beyond other variables, they were not included in further analyses.

We used cluster analyses to group subjects according to the temporal pattern of their OME experience over the first three years of life. Cluster analysis is used to identify groups of subjects who are more similar to each other with respect to certain specified parameters than they are to other groups of subjects. The parameters used in our analysis were: the proportion of days of bilateral OME experienced between 0-6 months, 6-12 months, 12-18 months, 18-24 months, and 24-36 months of age. The cluster analysis was performed in two stages. The first was a hierarchical agglomerative method using Ward's minimum variance technique (Ward, 1963). Pseudo F statistics were examined to estimate the number of clusters represented by the data. Four to six clusters were apparent. Because hierarchical methods do not allow for reassignment of subjects to other clusters once they have been assigned, the results were followed by a non-hierarchical K-means analysis (Anderberg, 1973) specifying six clusters with a minimum of 20 subjects per cluster. This sequential clustering method, which is most efficient for studies of large data sets, resulted in four clusters with a pseudo F statistic of 178.1. Figure 1 shows the mean percent of time with bilateral OME for each cluster in 6-month age blocks.

The results of the cluster analyses described in Method are shown in Figure 1. The Low OME group includes subjects with consistently low levels of OME across all time points. Two groups typically had intermittent episodes of OME during the first 0-18 months of life: the Early OME group, whose OME peaked before 6 months of age, and the Later OME group, whose OME peaked between 6 and 12 months. The High OME group had relatively higher levels of OME than the other clusters across all time periods.

Analyses of Relations between OME Clusters and Cognitive Outcomes

Once clusters were identified, a GLM procedure was used to analyze relations between OME cluster and language outcomes by a correlational design. OME cluster was the main variable, but the model also included language outcome variables, controlled environmental/biological variables, and interactions between the environmental/biological variables and language outcomes. If none of the interactions proved significant, a second analysis which eliminated the interactions was performed. The final model included the following control variables: ethnicity, SES, mother's smoking

Results

The sample originally recruited consisted of 698 infants and 379 children were available at age three and 294 at age five. Attrition was greatest between enrollment and 18months of age, before our measures SES, HOME and mother's intelligence were administered. Subjects who dropped out of the study were significantly more likely to be of Afro-American ethnicity and had experienced relatively little OME compared to other subjects, when they left the study.

Most of the children were Euro-American (56%), 30% were Afro-American and 14% were Hispanic (English-speaking homes only). The mean score for SES was 37.4 (S.d. = 12.5), with scores ranging from 9 to 66. Scores of the families on the HOME scale were typical of the normative group for this measure, with a mean of 39.1 (s.d. = 4.8) and a range from 18-45. The mother's intelligence (Shipley) mean score of 50 (s.d. = 10.1), range 18 to 68, is also typical of the normative sample.

SBIV at 3 years

Composite and Duration. GLM procedures were used which included in the model controls for gender, SES, HOME, mother's intelligence, ethnicity, and mother's smoking, along with duration of bilateral OME. With these variables and proportion of time with OME in the first three years entered into the model, we found that duration of OME from 0-36 months was inversely related to SBIV Composite scores, $t(336) = -1.79$; $p < .05$, one-tailed).

Composite and Clusters. The four OME clusters were first related to SBIV Composite scores, without controlling for environmental/biological characteristics. When background variables were controlled no direct relations between OME cluster and any

SBIV scores were found. When potential moderating effects were included, the difference between clusters on the Composite scores at age 3 was significantly moderated by SES ($F(3, 313) = 3.24$; $p < .05$) and HOME score ($F(3, 313) = 2.68$; $p < .05$), with a trend toward moderation by ethnicity ($F(6, 313) = 1.86$; $p = .09$). Examination of the parameter estimates and least squares means indicated that the mean Composite scores were lower for Afro-American children in the High OME cluster as compared to the other clusters. Afro-American children seemed more negatively affected by continuously high levels of OME. SES was less strongly related to Composite scores for subjects in the Early OME and Low OME clusters. Having consistently high levels of OME or having high levels during the 6-12 month period was somewhat moderated by SES; that is, in the High and Later OME clusters only, children with higher SES tended to have higher Composite scores. On the other hand, HOME environment was more positively related to Composite scores in the Early OME group. A more stimulating home environment was positively associated with higher Composite scores, but only in the Early OME group. Thus, children with high levels of OME in the first 6 months of life appeared most able to benefit from a more stimulating home environment, while children with higher levels of OME, or OME which peaked between 6 and 12 months, appeared more able to benefit from higher SES.

SBIV Factor Scores. The result was significant for the RV factor ($t(335) = -1.86$; $p < .05$, one tailed), but not for the VC factor ($t(336) = -0.86$; $p = .39$).

Clusters. Cluster and the cluster interactions added significantly to the prediction of RV Factor scores ($F(24, 312) = 1.69$; $p < .05$). This finding was primarily a function of an SES by cluster interaction ($F(3, 312) = 2.88$; $p = .04$), although a cluster by HOME score interaction approached significance ($F(3, 312) = 2.25$; $p = .08$). Parameter estimates from the model revealed that SES was not as related to RV Factor scores in the Early OME cluster, as it was in the others ($t(312) = -2.93$; $P < .01$). However, there was some indication that HOME scores were more positively related to the RV Factor in the Early OME cluster ($t(312) = 2.47$; $p = .02$). Cluster correlations were not significant for the Verbal Comprehension factor.

SBIV at 5 Years

The predictive model, which included SES, ethnicity, mother's intelligence, mother's smoking, and cluster membership, plus the interactions of cluster X control variables, accounted for 33% of the variance in SBIV Composite scores at 5 years ($F(23,253) = 5.32$; $p < .01$). However, neither cluster membership nor any interactions with cluster were related significantly to SBIV Composite scores at this age. When the interactions were eliminated, only ethnicity, SES, and mother's intelligence contributed significantly to the prediction of the Composite score ($R^2 = .30$; $F(8,268) = 14.36$; $p < .01$). Clusters were also not significantly related to any of the other SBIV scores at 5 years.

K-ABC at 5 Years

There were no relations of OME duration or cluster to KABC scores at age 5 for the Achievement subscales, nor were there any interactions with the environmental/biological variables.

SICD at 3 Years

There were no direct effects for either Expressive or Receptive language. However, differences for Expressive language by cluster were moderated by ethnicity

($F(6,278) = 2.45$; $p = .03$) and mother's IQ ($F(3, 278) = 2.91$; $p = .04$). Examination of the parameter estimates and the means indicated that Afro-American children scored significantly lower than Euro-American children in the High ($t(278) = -3.12$; $p < .01$), Early ($t(278) = -2.72$; $p < .01$), and Low ($t(278)= -2.23$; $p = .03$) OME clusters, but not in the Early cluster. In addition Hispanic children also did significantly more poorly than Euro-American children, but only in the High OME cluster ($t(278) = -3.12$; $p <$ ,01). While mother's IQ was positively related to Expressive language at age 3 ($t(278) = 3.09$; $p<.01$), it was less so in the Low ($t(278) = -1.85$; $p = .06$) and Early ($t(278) = -2.74$; $p < .01$) clusters. Thus, mother's IQ moderates the impact of OME when it occurs later than the first six months of life.

There was some indication that the home environment (as measured by the HOME scale) moderated the differences between the clusters on Receptive language at age 3 ($F(3,278) = 2.40$; $p = .07$). The relation of HOME scores to Receptive language was greater in the Early OME cluster as compared with the Later cluster ($t(278)$; $= 2.46$; $p = .01$).

CELI at 5 Years

OME Duration. More total OME was associated with lower CELI scores ($F(1, 267) = 5.82$; $p = .02$). Here, a difference of 20% in OME duration would be associated with a difference in CELI scores of 0.6 stanines, or about 22% of one standard deviation.

Clusters. The CELI also showed differences by cluster ($F(3, 287) = 5.88$; $p < .01$) with the Low group (mean = 7.1) having significantly higher scores than either the High (mean = 5.5) or Later (mean = 5.7) groups. The Early group (mean = 6.2) did not differ from any of the other groups.

G-F Articulation at 5 Years

A greater total proportion of time with OME was associated with more articulation errors ($F(1, 213) = 6.42$; $p = .01$) on the Goldman-Fristoe. A difference in total OME of 20% would be associated with a difference of 1.4 points on the Goldman-Fristoe, about 25% of one standard deviation. There were no significant results for clusters.

CAVAT at 5 years

Auditory Blending and Duration. With controls added, the amount of bilateral OME during the child's first three years was not predictive of Auditory Blending scores. However, when the moderating effects of the controls were included by entering interactions of background characteristics by proportion of time with OME, significant results were obtained. First, amount of OME from birth to 3 years was inversely related to Auditory Blending scores, above and beyond the control variables ($t(327) = -2.17$; $p = .03$). However, this result was moderated by ethnicity ($F(2, 237) = 5.51$; $p < .01$) and whether or not the mother breast fed the infant ($F(1, 237) = 4.86$; $p = .03$). In particular, the negative relation to Auditory Blending was not present in Afro-American children to the same degree as in Euro-American children ($t(237) - 3.31$; $p < .01$). Hispanic children were between the other ethnic groups and did not differ significantly from either one. Secondly, the negative relation of OME to Auditory Blending was moderated by breast feeding; i.e., the relation was not as strongly negative for children whose mothers breast fed ($t(237) = 2.20$; $p = .03$).

Auditory Blending and Cluster. When OME cluster was used to predict instead of duration of OME, the results indicated that children in the High ($t(217) = -2.72$; $p < .01$) and Early ($t(217) = -2.18$; $p < .03$) OME clusters had lower Auditory Blending scores than the Later cluster, all other things being equal. However, Afro-American children in the Low cluster had lower Auditory Blending scores than Euro-American children ($t(221) = -2.67$; $p < .01$). In addition, SES was positively related to Auditory Blending scores ($t(221) = 2.90$; $p < .01$), but the degree of relation was less for children in the Early ($t(221) = -2.77$; $p < .01$) and Low ($t(221) = -2.16$; $p < .03$) cluster groups. Also, mother's IQ was a moderating effect in that it was more positively related to Auditory Blending for those children in the High ($t(221) = 2.48$; $p < .01$) and Early ($t(221) = 2.13$; $p < .03$) groups compared to the Later cluster. It is also interesting to note that when amount of bilateral OME was the predictor, the result was moderated by ethnicity and breast feeding, but when OME cluster was used, the moderator variables were ethnicity and mother's IQ.

Auditory Discrimination in Quiet (ADQ) and Duration. ADQ was inversely related to duration of bilateral OME from birth to 3 years ($t(255) = -2.49$; $p < .01$), but this effect was moderated by HOME scores ($t(255) = 2.64$; $p < .01$), in that children from homes with higher HOME scores had less relation of OME to ADQ. There is some indication that the relation of OME to ADQ was greater for girls than for boys ($t(255) = -1.65$; $p < .10$).

Auditory Discrimination in Quiet and Cluster. When the OME clusters were used in the model instead of duration of OME, thus taking into account the pattern of OME as well as the duration, similar results were found. There were significant differences by cluster ($F(3, 235) = -3.75$; $p = .01$) that were moderated by HOME scores ($F(3, 235) = 2.97$; $p = .03$). Examination of the parameter estimates from the model indicated that the High OME cluster had significantly lower ADQ scores than the other clusters, but that this relation was muted if HOME scores were higher.

TACL-R Total Score at 5 Years

On the Total score there was a significant interaction of OME cluster by whether or not the mother breast fed ($F(3, 212) = 2.81$; $p = .04$). There were large differences in Total score means between children who were breast fed and those who were not, but only for the High and Early OME clusters. Again, this may indicate that the 0-6 month period is critical and since this is the period when most of the breast feeding occurred, it would seem that breast feeding might moderate the impact of OME during this time.

## Discussion

From the perspective of the retrospective studies, OME early in life is seen as the cause of many developmental problems. The picture is different if one looks at the results of prospective studies which show either no effects or a mixed pattern of relations. Our findings fit with the mixed pattern group. We found a direct relation of persistent OME with SBIV Composite at age three, and CELI and Goldman-Fristoe scores at age 5. We also found moderated effects for CAVAT Auditory Blending and Auditory Discrimination in Quiet, and TACL-R Total score. However we found no significant relations for the SBIV and K-ABC at age 5 or the SICD at age 3.

The results will be discussed in three ways: 1) the importance of the amount and time of OME on speech, language and related areas, 2) the variables that seem to moderate the effects of OME and 3) the absence of a significant effect of OME on language in the early language assessments.

The data analysis examined OME in two steps, duration of time during the first three years and the pattern of OME over that period of time. Four clusters resulted when looking at the pattern; two clusters were differentiated by overall OME, cluster one having high levels of OME across the entire range (High), while cluster three had low levels of OME across the range (low). Clusters two and four had variable patterns of OME differentiated by when the peak amount occurred. Cluster two peaked during the first 6 months of life (early), while cluster four peaked between 6 and 12 months (later). In looking at the results of the CELI, it would seem that the children who experienced much OME over time (duration and cluster one) or if the child's OME was greatest between 6 and 12 months (cluster four) these children had most difficulty. Fluctuating hearing loss during the early years of life presents the child with a degraded and inconsistent speech signal on which to base language learning. An inconsistent auditory signal may make the stream of speech difficult to segment and may impede the child's ability to form certain linguistic categories, such as morphological endings (Berko-Gleason, 1985). Also, from 6 to 12 months of age the child learns to listen selectively and to imitate whatever adult sounds are in his or her repertoire (Owens, 1996). OME during this time period would tend to make imitation inaccurate and selective listening difficult.

With the Goldman-Fristoe, however, the amount of time seemed to be a more critical factor than the time period. Again, this finding seems logical given the fact that, over time, if a child has a fluctuating hearing loss, there might be expected to be a distortion of the speech signal resulting in incorrect or incomplete perception of phonemes. Children learn the phonetic structure of their language by listening to adult models. If the model is distorted over time, the child may very learn an incorrect phoneme production.

We also found that the amount of OME was inversely related to Auditory Blending with a moderating effect of ethnicity, SES, mother's IQ, and breast feeding. The moderating effects were different depending upon the type of analysis. For example, the effect of the duration of OME was moderated by breast feeding and ethnicity whereas when cluster was used instead of duration., results were moderated by ethnicity, SES and mother's IQ. In terms of the moderating effects of ethnicity and breast feeding, it appears that the association of more OME with poorer Auditory Blending was less evident in African-Americans that in Euro-Americans and children whose mothers had breast fed them. Also, it would appear that the effects of having continuously high levels of OME or high levels during the first six months of life were moderated to some extent by SES and/or mother's intelligence. It is perplexing as to why these variables would moderated the effect of OME. Auditory Blending evaluates a child's ability to synthesize articulated phonemes into words; that is, the ability to bring meaningful closure to seemingly unrelated speech sounds (Carrow-Woolford, 1981). It may be that children who are breast fed have a different type of mother-child interaction pattern one that involves more vocal play with phonemes, and this would facilitate the development of auditory blending skills. Further, as mother's IQ and SES increase, there may be a greater emphasis in the home on activities that are pre-academic. Auditory Blending is closely related to the word attack skills that are taught in kindergarten and first grade as children are learning to read. More research is necessary before clarity can be achieved about why breast feeding, mother's IQ, SES or ethnic group moderate the effect of OME on auditory blending ability.

Auditory Discrimination in Quiet and its inverse relation to duration of OME with the moderating effect of the HOME scores is another interesting finding. The amount of bilateral OME as well as the high OME group had significantly lower scores. Auditory discrimination is a skill that is developmental and, as with the other measures, if there is a disruption of learning the skill owing to fluctuating hearing loss, the development of auditory discrimination may be delayed or impaired in some way. The fact that this relation was moderated by HOME scores suggests that a home environment that provides consistent cognitive stimulation can reduce the effects of high levels of OME.

The absence of significant direct effects on language at age 3 may be a function of child language immaturity and associated lower test reliability. Examiners reported difficulty in obtaining responses from many children and it sometimes seemed their speech away from the testing situation was more mature than in the testing room.

The significant relation found between OME duration and three-year-old SBIV Composite scores, which is our most reliable and valid measure of child cognition, suggests that persistent OME can have deleterious effects on child cognitive development. We estimate that a reduction of amount of OME by 50% during the first three years would be associated with an increase of the child's intelligence by 3.5 SBIV Composite points. This amount is not large, but is still considerable. For the sake of comparison, one year in a Head Start program is estimated to raise intelligence of low-income children by 5 IQ points, on average.

The presence of statistically significant results for the Nonverbal Reasoning/Visualization factor of the SBIV suggests that OME has broad associations with cognitive abilities in general, not just with verbal abilities.

The absence of significant effects at age 5 for any of the cognitive measures suggests that negative effects of OME may disappear in time. It should be noted that this study was of children whose duration of OME was measured up to age 3; subsequent OME experiences were not included in the predictive equation. Epidemiological studies of OME have shown lower incidence rates after age three (Teele, et al, 1989).

Our results differ from those of Gravel and Wallace (1992) and Roberts et al., 1991, 1994) who found no OME effects on cognitive development early in the child's life. Teele et al (1984) did obtain significant results at 3 years of age with one measure, the PPVT, that is sometimes regarded as a measure of verbal intelligence. Thus, it appears that our study is the first prospective research which suggests negative relations between OME duration and child cognition, broadly defined, at age 3.

The use of cluster analysis to evaluate patterns of OME over time in our sample did not result in an increase in the number of significant relations obtained. With environmental variables controlled, moderated but not direct effects were found. Thus, the pattern of OME exposure, i.e., whether the exposure came mainly in the first or second half of the first year, or was consistently low or high over the first 3 years, was not related in a direct way to measures of cognitive outcome.

Cluster analysis did show moderated effects for five of the measures of cognitive development at age 3. The most important of these measures, SBIV Composite scores, which are a measure of general cognitive development, were negatively related to OME for children who have most of their OME between 6 and 12 months of age. The relation between SBIV Composite scores and the High OME cluster was greater for Euro-American and Hispanic children than for Afro-American children, perhaps because Afro-American children are more burdened by unfavorable socioeconomic circumstances. SES also had a moderating influence on the effects of OME. Again, children with OME between 6 and 12 months who were from low SES backgrounds had lower Composite scores. In general, high SES appeared to blunt the potentially harmful effects of OME.

Home stimulation is more positively related to intelligence in the Early OME group. A stimulating home environment appears to be more advantageous if one does not have OME between 6 and 12 months, or prolonged OME throughout the first three years of life.

Do the moderated effects present a pattern? These effects are complex because typically they involve an interaction between a cluster and ethnicity. Effects of OME, when they did appear, seemed to be stronger for the Later OME cluster than for the other three clusters, including the High OME group. For none of the outcome measures were children in the Low or Early OME groups more adversely affected by OME. It is unclear why the period from 6 to 12 months might be one of special vulnerability to transitory hearing problems. If the Later OME group was more adversely affected than the High OME group, this result would suggest that interruption of hearing acuity during this period of language learning is more significant to developmental outcomes than the more frequent interruptions of hearing acuity over a longer period experienced by the High OME group.

Teele et al (1984) found stronger effects for early OME, as measured by proportion of days with ear effusion in the first year, as compared with the second and third years of life. Since our method of defining time periods was different from that of Teele et al, comparing our results with theirs is problematic. An important methodological difference between our clustering study and that of Teele et al.(1984, 1990) is that they included only the two extreme OME groups in their analysis, low and high OME duration, omitting the middle group. We included the full range of OME durations in our analysis, an analytic method generally accepted to be more powerful. We also studied a more diverse sample of children, including those of three ethnic groups and low SES, while their sample included only Euro-Americans and mostly middle-class children. However, when we ran our analyses with only the Euro-American ethnic group, our results were substantially the same as when all ethnicities were included. Furthermore, ethnicity was controlled statistically in all of our major analyses. The analyses by OME cluster resulted in another pattern. OME appears to have less impact on cognition if SES is high. If the child has not had much OME, the SES effect is not so important, and home stimulation is more important. It appears that with less OME, the child can take advantage of more educational stimulation in the home. It has become conventional in textbooks on speech and hearing disorders to warn about the deleterious effects of persistent OME on child development. Our findings suggest that these warnings may have some merit for children with prolonged or repeated OME episodes, but for most children, there is little cause for alarm. Negative relations at age three were not found at age five. Results of our cluster analyses suggest that if aggressive intervention is planned, however, it should be done early, in the first year of life.

The strengths of our study include its relatively large sample of children who were generally representative of the Galveston County area in which the research was conducted, and according to most of our outcome measures, were also representative of children throughout the United States. The OME status of the children was prospectively and closely monitored. Hearing was screened prior to cognitive assessment to rule out measurement error associated with intercurrent hearing loss. Cognitive outcomes at ages 3 and 5 were assessed by several standard, reliable and valid measures of child intelligence. Background characteristics of the children that are known to be related to the development of OME and/or to have an effect on developmental outcomes were controlled. The statistical methods used for analyses were comprehensive and sensitive. Our results are essentially in accord with the findings of other investigators who have used prospective methods.

In conclusion, the results of this research suggest that OME can have an impact on certain aspects of speech, language and auditory processing, and that for certain of these processes, the impact occurs only under specific environmental conditions. Children from low SES homes or children whose homes provide little cognitive stimulation as well as children who are not breast fed seem to be at greatest risk. Future research needs to explore the reasons for the moderating effects of OME since, in addition to standard medical treatments, OME continues to be a serious problem for many young children. Some of these moderating effects may lend themselves to being part of a treatment program. Additionally, research is needed to follow children through the primary and elementary grades to determine how these early difficulties may carry over into the academic arena. It may be that some of the effects of OME are subtle enough to be missed until the child begins to experience learning difficulties in school.

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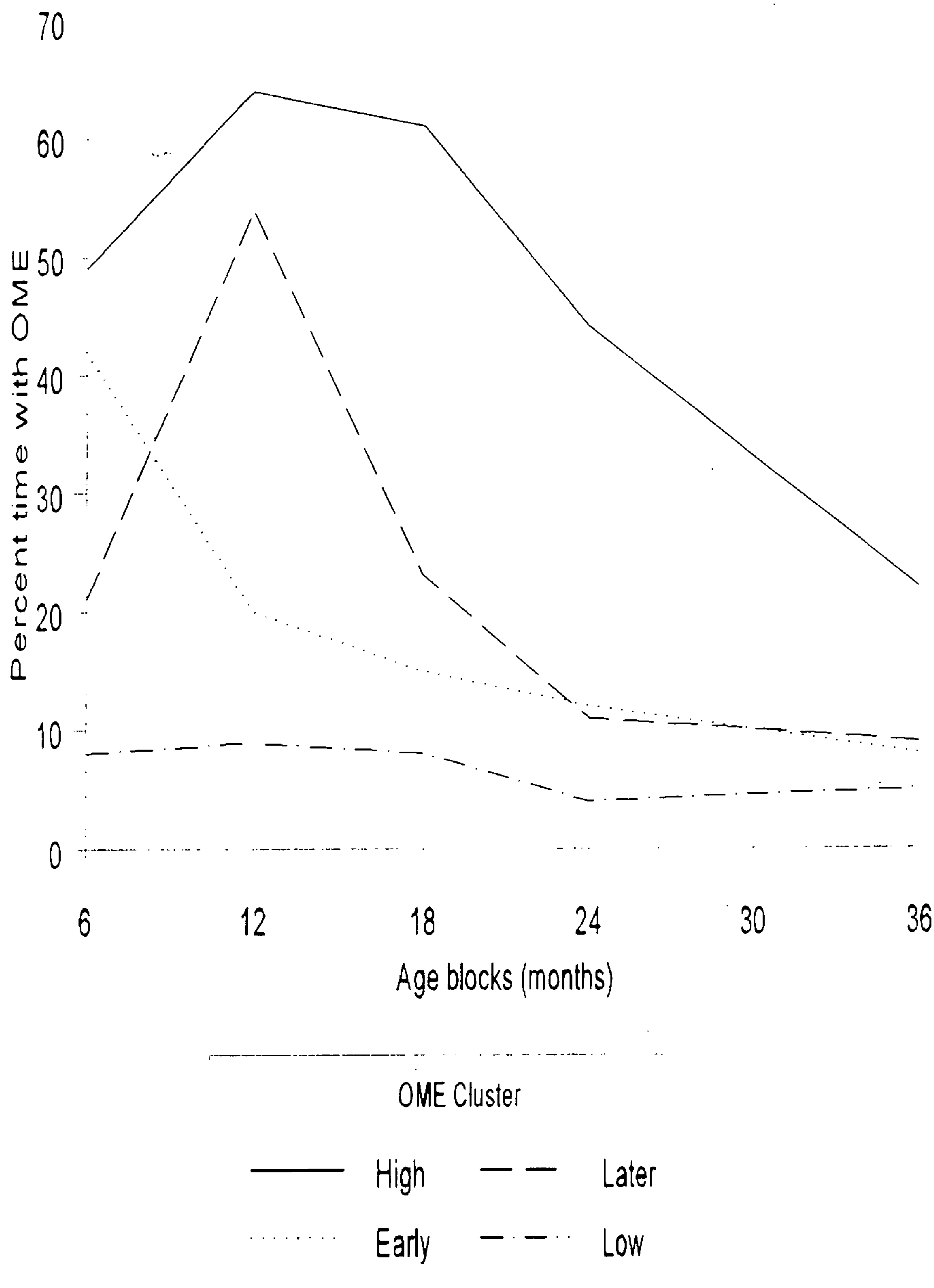
Figure 1



70
60
50
40
30
20
10
0
Percent time with OME
6
12
18
24
30
36
Age blocks (months)
OME Cluster
High
Later
Early
Low

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