J Pediatr Perinatol Child Health 2019; 3 (3): 140-151 *DOI: 10.26502/jppch.74050025*

Research Article

Anticipatory Ear Pain Counseling at a 12-15 Month Preventive Care Visit for Low Income Children

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Received: 12 August 2019; **Accepted:** 30 August 2019; **Published:** 05 September 2019

Abstract

Background: Determine the usefulness of ear pain anticipatory counseling for young children with public health plans to reduce visits for acute otitis media (AOM) and shift visits from urgent care/emergency department (UC/ED) settings to primary care clinic (PCC) settings.

Methods: We documented the AOM visit distribution and incidence rates by setting according to race/ethnicity from the EPIC electronic medical record system for 12 months following the enrollment of eligible 12-15 month old children in a single blind randomized control trial of ear pain counseling.

Results: Among the 310 children enrolled in the study, 30.6% of participants had at least 1 AOM visit and 4.5% had 3 or more AOM visits. The overall incidence was 490 AOM visit episodes per 1000 child years with rates of 232 in PCC and 226 in UC/ED settings. The difference in the proportion of Hispanic children with at least 1 AOM visit (33.5% 52/155) compared to Non-Hispanic children (24% 25/106) approached significance (p=0.08). The counseling intervention did not reduce the proportion of children with at least 1 AOM visit (counseling: 29.0%: 45/155; control: 32.3% 50/155 p=0.54); the proportion of children with 3 or more AOM visits (counseling: 5.8%: 9/155; control: 3.2% 5/155 p=0.41); or the AOM visit incidence rates (counseling: 471; control: 510) and did not shift AOM visits from the UC/ED to PCC setting.

Conclusions: Anticipatory ear pain counseling in a hospital based PCC serving children enrolled in public plans does not reduce PCC or UC/ED AOM visit incidence rates.

Keywords: Ear pain counseling; Acute otitis media

1. Introduction

Concepts regarding the diagnosis and management of acute otitis media (AOM) have evolved as our understanding of the adverse impact of excessive antibiotic usage on the spread of resistant bacterial pathogens increases [1]. Excessive antibiotic treatment also alters nasopharyngeal colonization predisposing to a subsequent episode, which may lead to recurrent AOM [2]. Antibiotic induced alterations to the microbiome in early childhood appears to predispose to childhood obesity [3, 4]. Young children during their second year of life have the highest AOM rates due to anatomic and immunologic reasons and children between the ages of 1 and 3 years account for over 40% of otitis related expenditures in children under age 14 [5]. Therefore interventions to limit excessive AOM related antibiotic use in this young, high risk population need further investigation. Two possible approaches to reducing excessive antibiotic use are first, shared decision making that provides parents an option for a safety net antibiotic prescription (SNAP) and second, anticipatory ear pain counseling to reduce parent initiated primary care (PC) and urgent care emergency department (UC/ED) visits.. Both of these approaches have the potential to reduce costs associated with unnecessary AOM visits especially in UC/ED settings as well as excessive antibiotic use.

Shared decision making provides parents with unbiased information on the risks and benefits of delaying antibiotic treatment for uncomplicated AOM episodes. While small studies suggest it is acceptable to parents and is viewed as beneficial, no large-scale studies have documented its impact [6-10]. Anticipatory ear pain counseling at 12 and 15 month routine preventive care visits can address home ear pain management including when and where to seek care. Watchful waiting for ear pain associated with uncomplicated AOM might reduce overall AOM visits, and UC/ED visits and therefore reduce antibiotics as well as costs. Ear pain counseling implemented in Rochester, Minnesota private practices reduced AOM visits in both settings but the unit of randomization was the practice rather than the patient [11]. We know of no studies that randomized at the child level, enrolled low income children on public health plans (Medicaid and Child Health Plan), or included clinic rather than private practice settings. We therefore undertook this study with the following aims:

1. Determine if a program of anticipatory ear pain counseling at the 12-15 month routine preventive care visit with largely Hispanic children enrolled in Medicaid reduces overall, PCC, and UC/ED AOM visits during the following year.
2. Determine whether socio-demographic characteristics affect the impact of anticipatory ear pain counseling on AOM visit incidence rates.

2. Materials and Methods

2.1 Design

This was a randomized controlled trial of ear pain anticipatory counseling that began in 2009 and ended 2 years later in the Child Health Clinic at Children's Hospital Colorado, a large, metropolitan, hospital-based teaching clinic serving low-income families. Children assigned to the active arm in the current study received anticipatory ear pain

counseling. Counseling related to an early childhood language development program was used as the active control. The study was approved by the Colorado Multiple Institutional Review Board.

2.2 Participants

We enrolled children aged 12-15 months seen at the clinic for their routine preventive care visit in the study. Children were excluded if they had ventilating tubes or any condition that predisposed them to recurrent AOM such as Down's syndrome, cardiac disease, or an immunodeficiency disorder. Children were also excluded if their family's primary language was something other than English or Spanish. The research assistant approached eligible families during the child's office visit and obtained written informed consent from all agreeable participants. Since the research assistant was not present during all clinic hours, this was a convenience sample. Data on the mothers who refused to participate were not kept but the total number refusing was less than 10. Each family was then assigned using a computer generated randomization method to receive either the active ear pain anticipatory counseling program or the active control language development program, which were completed during the visit.

2.3 Counseling intervention

The research assistant provided a structured 10 minute counseling session using 10 PowerPoint slides specific to the subject's assigned group. This was done in the exam room during the child's clinic visit using a portable laptop computer to display the slides, and a copy of the slides was provided to each family at the end of the session. The ear pain counseling material was based on the materials used in the McWilliams study, which were provided to us. The material reviewed concepts such as how to recognize ear pain and safely provide pain relief, and how to recognize danger signs that require urgent medical attention. Families were also encouraged to schedule an appointment in the PCC for a possible ear infection rather than going to the UC/ED facility. The research assistant provided and reviewed proper dosing instructions for acetaminophen and ibuprofen, and provided a prescription for antipyrine/benzocaine analgesic ear drops to each family to use as pain relief if their child did develop ear pain in the subsequent 12 months.

The language development materials explained the importance of frequent conversations between parents and children and of using encouraging rather than discouraging comments. The research assistant reviewed the importance of daily reading using a provided children's book as an example.

2.4 Data collection and outcome measures

All participating families completed a demographics survey that included information on race/ethnicity, insurance status, language(s) spoken in the home (preferred language for the intervention material), and family composition. In addition, participants completed the StimQ, the Parent Evaluation of Developmental Status, and the MacArthur-Bates Communicative Development Inventory. The EPIC electronic medical records system was used to determine the number and site of visits for AOM, whether antibiotics were prescribed at the visit, and the number of antibiotic courses prescribed in the intervention and control groups. We counted visits if there was a primary or secondary International Classification of Diseases, Ninth Revision (ICD-9), diagnosis reflective of ear pain or otitis, including

ICD-9 codes 380.10, 380.22, 381.00, 381.01, 381.10, 381.4, 382.00, 382.01, 382.3, 382.4, 382.9, and 388.70. The electronic medical record for each child was reviewed for a diagnosis of AOM using all otitis related diagnostic codes for 12 months following their initial index visit. We did not review charts to validate clinical findings that met predefined AOM criteria.

The site of each subsequent AOM related visit was documented (primary care clinic, emergency department, urgent care clinic, otolaryngology clinic) within the 6 metropolitan Denver Children's Hospital Colorado network of care sites as well as the antibiotic that was prescribed. The electronic medical record review documented the number of AOM related visits for each child in total and by site of care as well as the time from the initial index visit to the first AOM related visit with an associated antibiotic prescription. The data did not include any AOM visits outside the network of care sites. We did not determine if any of the subjects no longer used primary care services at Children's Hospital Colorado.

2.5 Statistical analysis

We used the non-parametric Wilcoxon signed-rank test used to test for difference between groups for time to first AOM comparisons. Interactions between the study group and dichotomous demographic variables were tested in negative-binomial regression models. When socio-demographic data was missing, the enrollee was not included in that sub-analysis. Final stratified regression models represent the relationship between ear pain visits, the study group, and the dichotomous demographic characteristic. Each stratified model was analyzed to represent the appropriate intervention vs. control comparison for each level of the demographic factor [e.g., Post High School education (intervention vs. control) and ≤ High School education (intervention vs. control)].

3. Results

3.1 Study population

The socio-demographic characteristics of the total population studied and the cohorts that received and did not receive ear pain counseling are shown in Table 1. Each cohort included 155 children. Half of the families were Hispanic. Slightly over two thirds (67.2%) were either married or living as couples. Approximately one quarter of the mothers (22.8%) did not graduate high school or have a GED, 43.3% had some post high school education and 33.9% had a high school education. Nine of 10 children (89.9%) were enrolled in Medicaid. The ear pain counseling intervention cohort and control cohort were comparable with respect to all socio-demographic characteristics.

Baseline Demographic	**All n (%)**	**Intervention n (%)**	**Control n (%)**	**p-value***
Total participants	310	155	155	--
Mother's Age (years)	28.5	28.5	28.5	0.96
Child's ethnicity				**0.26**
African American	78 (25.2)	33 (21.3)	45 (29.0)	
Asian	4 (1.3)	3 (1.9)	1 (0.7)	
Caucasian	28 (9.0)	13 (8.4)	15 (9.7)	

Hispanic	155 (50.0)	79 (51.0)	76 (49.0)	
Native American	1 (0.3)	--	1 (0.7)	
Other	44 (14.2)	27 (17.4)	17 (11.0)	
Child's insurance				**0.83**
Private	29 (9.5)	15 (9.7)	14 (9.3)	
Medicaid	265 (86.9)	134 (87.0)	131 (86.8)	
CHP+	10 (3.3)	4 (2.6)	6 (4.0)	
Don't Know	1 (0.3)	1 (0.7)	--	
Mother's education				**0.09**
No High School	19 (6.6)	9 (6.1)	10 (7.0)	
Some High School	47 (16.3)	23 (15.7)	24 (16.9)	
HS Grad/GED	98 (33.9)	40 (27.2)	58 (40.9)	
Some College	75 (26.0)	42 (28.6)	33 (23.2)	
College Degree	47 (16.3)	31 (21.1)	16 (11.3)	
Graduate Work	3 (1.0)	2 (1.4)	1 (0.7)	
Mother's status				**0.19**
Single	100 (32.8)	50 (32.7)	50 (32.9)	
Married	134 (43.9)	67 (43.8)	67 (44.1)	
Divorced	11 (3.6)	2 (1.3)	9 (5.9)	
Living Together	53 (17.4)	31 (20.3)	22 (14.5)	
Other	7 (2.3)	3 (2.0)	4 (2.6)	

*represents the probability of a difference in the demographic characteristic and study group. Student's t-test used for mother's age at baseline. Chi-square test of proportions or Fisher's exact test (for small cell sizes) was used for all other tests.

Table 1: Socio-demographic characteristics of the study cohort, by who received (Intervention) and did not receive (Control) ear pain counseling.

3.2 Distribution of children according to the number of AOM visits by setting and the proportion of children with at least 1 AOM visit

Table 2 shows the distribution of the number of children according to the number of AOM visits during the 12 months following study enrollment by PCC and UC/ED settings. Among the 310 children enrolled in the study and followed for 12 months, 30.6% had at least 1 AOM visit and 4.5% had recurrent AOM defined as 3 or more AOM visits. Table 3 displays the number and percent of children with at least 1 AOM visit during follow-up by study group according to sociodemographic characteristics. The observed higher proportion of Hispanic children with at least 1 AOM visit (33.5% 52/155) compared to Non-Hispanic African American and White children with at least 1 AOM visit (24% 25/106) approached significance (p=0.08). The proportions of African American children (23%, 18/78) and White children (25%, 7/28) with at least 1 AOM visit were similar. The shorter time interval in days

from entry to their first AOM visit for Hispanic children (mean 111.2, median 94) compared to Non-Hispanic White and African American children (mean 148.3, median 139) also approached significance (p=0.07).

3.3 AOM visit incidence rates

Table 4 displays the incidence rates of AOM visits per year, per 1,000 children, by setting and study group obtained by medical record review. In the total study population, the incidence was 490 AOM visit episodes per 1000 child years. The site of care for the first visit with AOM was almost equally distributed between the PCC (51.2%) and the UC/ED settings (48.8%). For all children, the PCC setting incidence rate (232) and the UC/ED setting rate (226) were similar. For all settings, Hispanic children had an incidence rate of 561 compared to 419 in Non-Hispanic children (p=0.18). Hispanic children had a higher PCC incidence rate (297) compared to Non-Hispanic children (168) (p=0.05). The rates in the UC/ED for Hispanics (219) and Non-Hispanics were similar (232) (p=0.85). Antibiotics were prescribed in 97% of the visits associated with an AOM diagnosis and were prescribed similarly in all settings for visits with an AOM diagnosis. We did not have data documenting the percentage of prescriptions that were filled.

Number of Visits	**All Visits (number of children)**			**CHC Visits (number of children)**			**ED/UC Visits (number of children)**		
	All	**Intervention**	**Control**	**All**	**Intervention**	**Control**	**All**	**Intervention**	**Control**
0	215	110	105	256	130	126	261	129	132
1	62	28	34	41	18	23	36	19	17
2	19	8	11	9	5	4	9	5	4
3	8	7	1	3	2	1	2	2	--
4	3	2	1	1	--	1	--	--	--
5	2	--	2	--	--	--	2	--	2
6	1	--	1	--	--	--	--	--	--
Total children:	310	155	155	310	155	155	310	155	155

CHC=Children's Health Clinic; ED/UC=emergency department or urgent care facility

Table 2: Distribution of the number of children to number of otitis related visits during the 12 months following study enrollment, by study site.

		All Patients n (%)	**Intervention n (%)**	**Control n (%)**	**p-value***
Total	--	95 (100.0)	45 (47.4)	50 (52.6)	0.54
Race/Ethnicity (child)	Hispanic	52 (54.7)	24 (53.3)	28 (56.0)	0.79
	Non-Hispanic	43 (45.3)	21 (46.7)	22 (44.0)	
Mother's education	< High School	21 (24.7)	8 (20.0)	13 (28.9)	0.003
	High School/GED	29 (34.1)	8 (20.0)	21 (46.7)	
	Post High School	35 (41.2)	24 (60.0)	11 (24.4)	
Mother's living status	Living alone	44 (46.8)	20 (44.4)	24 (49.0)	0.66
	Coupled	50 (53.2)	25 (55.6)	25 (51.0)	
Insurance	Private/CHP+	8 (8.6)	3 (6.8)	5 (10.2)	0.72
	Medicaid	85 (91.4)	41 (93.2)	44 (89.8)	

*Chi-square test of proportions or Fisher's exact test (for small cell sizes) used to test if there is a difference between demographic characteristic and study group, among patients with ≥ 1 visits during study follow-up

Table 3: Number and percent of children with at least one Otitis visit (≥ 1) during follow-up, by study group.

Category	**All Patients**	**Intervention (n=155) Number of Visits (rate*)**	**Control (n=155) Number of Visits (rate*)**	**Relative Risk (p-value**)**	**Hispanic (n=155) Number of Visits (rate*)**	**Non-Hispanic (n=155) Number of Visits (rate*)**	**Relative Risk (p-value**)**
Otitis Visits	152 (490)	73 (471)	79 (510)	0.92 (0.71)	87 (561)	65 (419)	1.34 (0.18)
Otitis Visits at CHC	72 (232)	34 (219)	38 (245)	0.89 (0.70)	46 (297)	26 (168)	1.77 (0.05)
Otitis Visits at ED/UC†	70 (226)	35 (226)	35 (226)	1.00 (1.00)	34 (219)	36 (232)	0.94 (0.85)
Otitis Visits w/Rx	143 (461)	68 (439)	75 (484)	0.91 (0.65)	82 (529)	61 (394)	1.34 (0.17)
Otitis Visits w/Rx at CHC	69 (223)	32 (206)	37 (239)	0.86 (0.61)	45 (290)	24 (155)	1.88 (0.03)

*rate of Otitis visits per year, per 1000 children; **estimated relative risk from negative binomial regression testing the likelihood there is no difference in the number of visits and study group. Model included number of visits and study group; †all Otitis visits to an emergency department (ED)/urgent care facility (UC) resulted in an antibiotic prescription, therefore, only ED/UC total visits were modeled

Table 4: Rate of Otitis visits per year, per 1,000 children, by site and study group.

3.4 Ear pain anticipatory counseling outcomes

The ear pain anticipatory guidance counseling did not reduce the proportion of children with at least 1 AOM visit (counseling: 29.0%: 45/155; control: 32.3%: 50/155 p=0.54); the proportion of children with 3 or more AOM visits (counseling: 5.8%: 9/155; control: 3.2%: 5/155 p=0.41); or the total AOM visit incidence rates (counseling: 471; control: 510; p=0.71). Table 4 displays the yearly AOM visit incidence rates by PCC and UC/ED settings for the counseling and control cohorts. The intervention did not shift AOM visits from the UC/ED settings to the PCC setting. There were no significant differences in the proportion of families seeking care at their PCC site between the cohorts (counseling: 51.2% vs. control: 57.8%, p=0.53) or in the AOM incidence rates in the settings.

3.5 Socio-demographic risk characteristics analyses

Analyses were carried out to determine if sociodemographic characteristics of race/ethnicity (Hispanic, African American, Non-Hispanic White), mothers living status (single parent, 2 parent) and mother's education (less than high school, high school/GED, Post high school) might influence the response to the ear pain anticipatory guidance. There were no significant differences in the proportion of children with at least 1 AOM visit when the cohorts were stratified by their socio-demographic characteristics (Table 3). However, a trend was identified as 20% (8/40) mothers with a high school education who received counseling compared to 36% (21/58) of mothers who did not receive counseling had at least 1 AOM visit (p=0.08). A regression analysis modeling the total number of AOM visits with interaction between the cohort, mother's education and Hispanic ethnicity is shown in Table 5.

	All Patients (n=310) Visits/Children (rate*, [95% CI])	**Intervention (n=155) Visits/Children (rate*, [95% CI])**	**Control (n=155) Visits/Children (rate*, [95% CI])**	**Relative Risk (p-value**)**
Model 1				
Post HS education	52/125 (416 [277, 555])	39/75 (520 [312, 728])	13/50 (260 [113, 407])	2.00 (0.08)
HS education or less	83/164 (506 [349, 663])	26/72 (361 [175, 547])	57/92 (620 [385, 855])	0.58 (0.08)
Model 2				
Hispanic	87/155 (561 [400, 722])	38/79 (481 [285, 677])	49/76 (645 [386, 904])	0.75 (0.32)
Not Hispanic	65/155 (419 [288, 550])	35/76 (461 [261, 661])	30/79 (380 [209, 551])	1.21 (0.54)

*rate of Otitis visits per year, per 1000 children; **estimated relative risk from negative binomial regression testing the likelihood there is no difference in the number of visits and study group. Model included number of visits, study group, education, ethnicity, and an interaction between education and ethnicity.

Table 5: Number of Otitis visits per total children in group, with rate and 95% confidence interval of Otitis visits per year, per 1000 children.

Among mothers with a high school education or less, the yearly incidence of AOM visits was less in the intervention group (361) compared to the control group (620). However the difference only approached significance (p=0.08). The effect of ear pain anticipatory guidance was in the opposite direction for mothers with greater than a high school

education as the yearly AOM visit incidence was greater in the intervention group (520) compared to the control group (260) (p=0.08). There were no AOM incidence differences with and without counseling noted between Hispanic and Non-Hispanic families. It is unclear why mothers with more education who did not receive counseling should have very low AOM visit incidence rates compared to mothers with counseling.

4. Discussion

We studied AOM visits during the second year of life; the age shown to have the highest annual incidence rates in order to be consistent with the McWilliams study [11, 14]. The AOM incidence rate during the second year of life calculated from 209,180 children with commercial insurance included in the Truven Market Scan database for 2009 reported by Tong et al. was 516 AOM visits per 1000 child years (95% CI: 513.3-517.7) [13]. The mean incidence from 2008-2014 was 503.9 with a range of 479-521. Race/ethnicity data was not reported. Kaur et al. reported a slightly lower AOM incidence rate of 480 for 523 children followed closely in a Rochester, New York private pediatric practice during their second year of life [15]. The children enrolled in this prospective study were 68.9% Non-Hispanic White, 12% African American, 3.6% Hispanic, and other 15.4%. A large European prospective study reported by Liese et al., carried out from 2008-2010, followed 1113 children aged 0-2 years of age and documented slightly lower incidence rates: 392 (95% CI 342-447) for Spain, 344 (298-394) for Sweden, 311 (267-359) for Germany 247 (203-298) for the UK, and 193 (160-232) for Italy [16]. Our 490 AOM visit incidence rate for 310 children with Medicaid was almost midway between the Rochester study and the national Truven Market database study. However, our Hispanic rate of 561 was slightly higher than the rates from all of these cited studies. While nationally, approximately 50% of births in the United States are covered by Medicaid and Hispanic children account for an increasing proportion of these Medicaid births [12] there is limited data on the incidence of AOM for Hispanic children enrolled in Medicaid, after the introduction of pneumococcal vaccine [13]. Our study suggests this population may have a higher risk of these early infections.

Study limitations included our inability to review charts to validate clinical findings that met predefined AOM criteria, having a .convenience sample that could lead to bias dependent on those who elect to participate (only 10 mothers refused to participate), and our inability to capture AOM visits outside of the Children's Hospital Colorado network of care system. However, the system is quite extensive with 6 UC/ED sites in the Denver metropolitan area. However, Hispanic families may be likely to stay in the system then Non-Hispanic families.

In our study 30.6% of children had at least 1 AOM visit during the year of monitoring and 4.5% had 3 or more infections. The higher rate for Hispanic children (34%) compared to African American (23%) and Non-Hispanic white (25%) children approached significance. Kaur reported that 23% of their population had at least 1 AOM episode during the first year of life, but he did not report the number of episodes during the second year of life.

There were substantial differences in the relative AOM visit incidence rates for PCC versus UC/ED settings in our population predominately on a public plan compared to children with commercial insurance. In our study, the site of care was almost equally distributed between the PCC (51.2%) and the UC/ED (48.8%) settings and the incidence of

AOM visit episodes seen in the PCC setting was 232 compared to 226 in the UC/ED setting. In the Tong et al study of children with commercial insurance the incidence rate in the primary care outpatient setting (479.5) was much higher compared to the UC/ED setting (35.7) [14].

Several studies have documented that children enrolled in Medicaid have high rates of UC/ED utilization for non-acute care [17-20]. Improving federal qualified health center access in California did not appear to decrease ED visit rates for children enrolled in Medicaid [21]. The reasons for the high utilization of UC/ED settings by children with Medicaid are multifactorial. They include the organizational structure of the primary care setting (the degree of clinician continuity, the length of waiting times before seeing the clinician, the ease of same day appointment scheduling, and the availability of after-work hour appointments), parental work demands, accessibility, financial implications, and care seeking behaviors. Work demands limit the ability of working parents to leave work to take their children for care. Parents may choose to go to closer, more convenient UC/ED settings, especially if they are in the same hospital system. The lack of financial disincentives to UC/ED use may also impact decision-making. Finally, care-seeking behaviors may be influenced by cultural factors as well as past experiences.

We could not replicate the outcomes of an ear pain counseling program reported by McWilliams et al, who randomized at the practice level. Our study unlike the Mayo Clinic program enrolled a low income, predominantly Hispanic and African American population who were randomized at the patient level. Many of the factors that appear to influence the use of UC/ED settings by children enrolled in Medicaid may also influence their response to ear pain counseling.

5. Conclusion

Anticipatory ear pain counseling in a hospital based PCC serving children enrolled in public plans does not reduce PCC or UC/ED AOM visit incidence rates. The higher proportion of Hispanic children with at least 1 AOM visit compared to Non-Hispanic children approached significance and Hispanic children also tended to have a shorter interval from entry to their first AOM visit.

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Citation: Stephen Berman, Amy Shriver, Lauren Mehner, Bryan Wallace, Anna Furniss, Meghan Treitz. Anticipatory Ear Pain Counseling at a 12-15 Month Preventive Care Visit for Low Income Children. Journal of Pediatrics, Perinatology and Child Health 3 (2019): 140-151.