

EFFECTIVENESS OF PNEUMOCOCCAL CONJUGATE VACCINE -PCV10- IN A CITY OF THE COLOMBIAN CARIBBEAN: CASE-CONTROL STUDY NESTED IN A COHORT.

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BACKGROUND: Acute otitis media (AOM) is a common infection in childhood and one of the leading causes of morbidity. The role of pneumococcal conjugate vaccines (PCV) has been extensively studied in cases of invasive disease, but its role in non-invasive diseases such as AOM remains to be demonstrated.

OBJECTIVE: to evaluate the effectiveness of PCV against 10 serotypes to prevent cases of AOM in Cartagena, Colombia.

Enrollment period

December 10/2013 - March 31/2014



Cohort of term infant

METHODS

In a cohort of 876 patients followed prospectively from birth to 15 months of age the effectiveness of PCV-10 valent pneumococcal AOM was estimated using a nested case study in a cohort controls. Events with AOM were selected as cases and health infants were selected as control in the cohort follow-up, matched by age at diagnosis.



Otolaryngologist evaluated the patients by otoneumatoscopia and according to the **American Academy of Pediatrics** criteria for AOM was considered sampling (timpanoscentesis by CDT® Speculum

RESULTS

VARIABLES	Cohort of term infant
	876 (%) [IC95%]
Male sex	465(53.1) [49.7-56.4]
Subsidized	851(97.1) [95.8-98.1]
Contributory	13 (1.5) [0.8-2.6]
Low income	756(86.3) [83.8-88.5]
Urban	644(73.5) [70.4-36.4]
Education	
Never	36(4.1) [2.9-5.7]
Elementary school	228(26.0) [23.2-29.1]
Middle school	444(50.7) [47.3-54.0]
High school	139(15.9) [13.5-18.5]
University	29(3.3) [2.3-4.8]
Civil status	
Married	72(8.2) [6.5-10.3]
Cohabiting	703(80.3) [77.4-82.8]
unmarried	88(10.0) [8.2-12.3]
cigarette smoke exposure	206(23.5) [20.8-26.5]
Biomass smoke exposure	389(44.4) [41.1-47.8]
Kids under 10 years old	
≤ 2	583 (66.5) [63.2-69.7]
≥ 3	291 (33.2) [29.5-37.2]
N° people living at home	Mean ± SD
	5.4 ± 2.5
Number of rooms	Mean ± SD
	2.4 ± 1.0
Sibling with AOM	97(11.1) [9.1-13.4]
Weight	3200 [2945;4650]
Size	50.6 [49;52]
Gestacional age	39 [38;39.5]

VARIABLES	CASES N 44 (%) [IC95%]	CONTROLS N 44 (%) [IC95%]	P VALUE	
Sex				
Female	21(47.7)[32.5-63.3]	21(47.7)[32.5-63.3]	1.0 [^]	
Male	23(52.3)[36.7-67.5]	23(52.3)[36.7-67.5]	1.0 [^]	
Estrato	Mean ± SD	Mean ± SD	1.0 [*]	
Urban	40(90.9)[78.3-97.5]	31(70.5)[54.8-83.2]	0.1 [^]	
Mothers age	Media ± DE	9.1 ± 5.1	0.90 [*]	
Median [IQR, IQR]	8.0 [5.0; 13.0]	8.0 [5.5; 12.5]	0.90 [*]	
Breastfeeding	Median [IQR, IQR]	3.0 [2.0;5.0]	0.90 [*]	
seated	14(31.8) [18.6-47.6]	16(36.4) [22.4-52.2]	0.6 [^]	
Form breastfeeding	lying	1 (2.3)[0.1-12.0]	1.0 [^]	
Mix	29(65.9) [50.1-79.5]	26(59.1) [43.2-73.7]	0.5 [^]	
Feeding bottle	Yes	30(68.2)[52.4-81.4]	0.81 [^]	
No	14(31.8)[18.6-47.6]	13(29.5)[16.8-45.2]	0.81 [^]	
Baby formula	Yes	33(75.0)[59.7-86.8]	0.59 [^]	
No	11(25.0)[13.2-40.3]	13(29.5)[16.8-45.2]	0.63 [^]	
Weaning	Median [IQR, IQR]	3.0 [2;4]	6.0 [4.0;6.0]	0.64 [*]
Pacifier	Yes	1 (2.3)[0.1-12.0]	0	0.31 [^]
No	43(97.7)[88.0-99.9]	44(100.0)	0.31 [^]	
Exposure to cigarette smoke	Yes	9(20.5)[9.8-35.3]	10(22.7)[11.5-37.8]	0.80 [^]
No	35(79.5)[64.7-90.2]	34(77.3)[62.2-88.5]	0.80 [^]	
Sleeps alone	Yes	1(2.3)[0.1-12.0]	0	0.31 [^]
No	43(97.7)[88.0-99.9]	44(100.0)	0.31 [^]	
N° people living at home	Mean ± SD	2.1 ± 0.9	2.5 ± 1.1	0.06 [*]
Vaccination update	Yes	27(61.4)[45.5-75.6]	31(70.5)[54.8-83.2]	0.36 [^]
No	17(38.6)[24.4-54.5]	13(29.5)[16.8-45.2]	0.36 [^]	
Brother history AOM	Yes	8(18.2)[8.2-32.7]	3(6.8)[1.4-18.7]	0.10 [^]
No	34(77.3)[62.2-88.5]	41(93.2)[81.3-98.6]	0.10 [^]	
Care attendance	Yes	8 (18.8) [4.0-45.6]	0	0.03
No	16 (37.5) [15.2-64.6]	20 (45.5) [24.4-67.8]	0.58	

DISCUSSION

Microbiology	Characteristics	N (%) [95%CI]	Serotype 6C (1)
Bacteria	<i>Streptococcus pneumoniae</i>	3 (6.8)[1.4-18.7]	Betalactamase negative (3)
	H. influenzae non-typeable	4(9.1)[2.5-21.7]	
	<i>S. aureus</i>	3 (6.8)[1.4-18.7]	
	<i>S. Pyogenes</i>	2(4.5)[0.6-15.5]	
	<i>P. aeruginosa</i>	4(9.1)[2.5-21.7]	
	No sample	24(54.5)[38.8-69.6]	
Polymicrobial	Others	7(15.9)[6.6-30.1]	
	<i>S. Pyogenes</i> + <i>S. aureus</i>	1 (2.2) [0.2-12.3]	
	H. influenzae no tipificable + <i>S. aureus</i>	1 (2.2) [0.2-12.3]	Betalactamase negative
AOM	H. influenzae non-typeable + <i>S. coagulase</i> negative	1 (2.2) [0.2-12.3]	Betalactamase negative
	Unilateral	35(79.5)[64.7-90.2]	
More one episode	Bilateral	9(24.3)[11.8-41.2]	
	Yes	3 (6.8)[1.4-18.7]	
	No	41(93.2)[81.3-98.6]	

OR of having AOM in infants was 0.66 [95% CI 0.27-1.61] and a vaccine effectiveness of 33.3% [95% CI -61 to 73].

CONCLUSION

Research	Run-time study (years)	Population Study	Efficiency (AOM) [95%CI]	Effectiveness (AOM)
Eskola	1995-1999	831- PCV7/ CRM197, 831- hepatitis B = 1662	6% (PCV-7) [-4 a 16]	
Fireman, Black	1995-1998	PCV 18926; Control 18942 = 37868	7% (PCV-7) [5.4 a 10.1]	
Prymula	2000-2002	PCV11:2455; control 2452 = 4907	33,6 % (PCV-11) [20.8 a 44.3]	
Coronell-R W.	2013-2015	876		33,3% (PCV-10) [-61 to 73]

PCV-10 was not effective in preventing AOM. Attendance at day care was the only risk factor associated with OMA (p 0.03). The use of pacifier, baby bottle and breastfeeding were not significant.