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Vaccine schedule compliance among very low birth weight infants in Lima, Peru

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Abstract

Objective—There is little information about vaccine schedule compliance in very-low-birthweight infants in developing countries. The aim of the study was to describe the compliance with the vaccine schedule among this population in Lima, Peru.

Patients and Methods—We conducted a prospective cohort study in four hospitals in Lima in infants with a birth-weight of less than 1500g, followed from birth up to 12 months of age every 2 weeks. The date and age at administration of each vacccine was recorded.

Results—222 infants were enrolled. The median birth-weight was 1,250g (range 550-1,499g) and the median gestational age was 30.0 weeks (range 23-37 weeks). The mean age for the first pentavalent (DPT, Hib, HepB) and oral polio vaccine administration was 4.3 ± 1.4 months in infants with a birth-weight of <1000g vs. 3.1 ± 1.0 in infants with a birth-weight 1000- 1500g (p<0.001); 4.1 ± 0.9 vs. 3.3 ± 1.1 for rotavirus (p<0.05); and 5.1 ± 2.1 vs. 4.3 ± 1.8 for the 7-valent pneumococcal conjugated vaccine. Only 35% had received the three doses of oral polio and pentavalent vaccine by seven months, although by nine months 81% had received these vaccines.

Conclusions—Vaccination of very-low-birth-weight infants in Peru is significantly delayed, especially in infants with a birth-weight of <1000g. Urgent educational interventions targeting physicians and nurses should be implemented in order to improve vaccination rates and timing in these high risk populations.

Conflict of interests: There are no competing interests for any of the authors.

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Vaccines; Very Low Birth Weight Infant; Developing Countries

INTRODUCTION

Premature infants are at increased risk of infectious diseases, including vaccine-preventable diseases (1-3), due to multiple factors like decreased IgG concentrations and impaired innate immunity (4-8). The number of reported cases of pertussis and pertussis-related hospitalizations are higher in low birth-weight infants (9). Pneumococcal diseases also are more common and severe in premature infants (1). Timely and complete immunization is extremely important in these infants.

Current recommendations state that premature infants should be immunized at the same chronological age as other infants, as long as they are clinically stable. The only exceptions for this rule are the dose of the hepatitis B vaccine given at birth and the BCG, which is only used in selected countries. No corrections should be made regarding gestational age or birth-weight when planning the immunization of premature infants (3,10).

Multiple studies in developed countries have shown that premature infants are immunized with a significant delay and it is more pronounced in infants with lower birth-weight (11-14). The most important reasons for this delay are the concerns by parents and providers, including pediatricians, about the immunogenicity and safety of vaccines in preterm infants (2).

Information on this topic in developing countries is lacking. Their immunization programs are typically less developed and access to medical care is more difficult. Also, the education level of the population is lower which could lead to a greater refusal of vaccination in premature infants. Accurate information about the magnitude of these problems is necessary to justify focused educational intervention for both families and medical personnel. To answer this question we conducted a prospective cohort study to describe the compliance with the vaccine schedule among very low birth-weight (VLBW) infants in Lima, Peru.

METHODS

We conducted a prospective cohort study in four hospitals in the city of Lima: Hospital Nacional Edgardo Rebagliati Martins, Instituto Nacional Marteno Perinatal, Hospital Nacional Guillermo Almenara Irigoyen and Hospital Nacional Madre Nino San Bartolome. All infants with a birth-weight <1500g and gestational age <37 weeks that were born or transferred to one of these hospitals were invited to participate. Infants who could not complete the one-year follow up due to social factors (e.g. no home phone or cell phone, or infants returning to a hometown outside of the city of Lima), had severe congenital malformations or were older than 6 months at hospital discharge were excluded. The patients were followed from the time of discharge until 12 months of age by clinic visits or phone calls to the parents every 2 weeks. This study was part of a larger cohort study aimed

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at determining the incidence of respiratory syncytial virus in premature infants during their first year of life (15).

We recorded the age at administration of each immunization during the first year of life. According to the Peruvian vaccination calendar the diphtheria-pertussis-tetanus (DPT), Haemophilus influenza type b (Hib), Hepatitis B (HepB), and oral polio vaccine (OPV) is administered at 2, 4 and 6 months with two boosters of the DPT vaccine at 18 and 48 months. The 7-valent conjugated pneumococcal vaccine (7vCPV) is given in a 2 + 1schedule, the first two doses at 2 and 4 months (in some hospitals at 3 and 5 months) and a booster at 12 months. The monovalent rotavirus vaccine is given at 2 and 4 months. We evaluated the compliance for the first three doses of the DPT-Hib-HepB (pentavalent vaccine) and OPV and the first two doses of the 7vCPV and the rotavirus vaccine. We selected these vaccines because they are scheduled to be administered before 7 months of age; this allowed us to have a follow up of 5 months to evaluate the delay in the immunizations. BCG vaccine was excluded because in premature infants it is given based on weight, rather than age, and this was not recorded in all cases. The measles, mumps and rubella vaccine and the third dose of the 7vCPV was excluded from the analysis because they are administrated at 12 months and the delay of administration could not be measured accurately since the follow up ended at this age.

Differences in proportions (vaccination rates) were calculated using Fisher's exact test. We tested differences in the age of vaccine administration between groups of birth weight (<1000g vs. 1000-1500g) and gestational age (<32 weeks vs 32 or more weeks) using Two-sample Wilcoxon rank-sum (Mann-Whitney) test. A p < 0.05 was considered significant. Statistical analysis was performed using STATA 11 (StataCorp LP, College Station, Texas, United States). The study was reviewed and approved by the Institutional Ethics Review Boards of Universidad Peruana Cayetano Heredia and of each of the participating hospitals.

RESULTS

Characteristics of study population

From March 2009 to March 2010, 335 infants were assessed for eligibility. Of these, 222 (66.3%) were enrolled; 21 (6.3%) parents did not consent to participate, 57(17%) could not complete the follow up and 35 (10.4%) had some other exclusion criteria (4 congenital malformation, 11 transferred to other hospital before discharge, 1 older than 6 months of age at hospital discharge and 15 with other reasons). On-hundred and ninety-eight children completed the study, 14 were lost during follow up, and 10 children died. We only included the infants that completed the follow up in the analysis.

Forty-eight infants had a birth-weight less than 1,000g and 157 had a birth-weight between 1,000g and 1,500g. Male infants represented 44.6% of the study population. The median birth-weight was 1,250g (range 550-1,499g), the median gestational age was 30.0 weeks (range 23-37 weeks) and 36.5% of infants were small for gestational age. The mean duration of hospitalization was 82.1 days (range 36-153) for infants with a birth-weight less than 1 000g and 42.7 days (range 8-126) for infants with a birth-weight of 1000-1500g.

Vaccination rate

The first doses of the DPT-Hib-HepB and OPV were the only immunizations that were administered to all infants. The second dose of the DPT-Hib-HepB and OPV and the first dose of the 7vCPV were administered to 97.5% of infants. The rotavirus vaccine rate was the lowest among the analyzed immunizations with only 74.2% and 62.1% of infants receiving the first and second dose, respectively. Infants with a birth-weight of less than 1000g were less likely to be immunized compared to infants with a birth-weight of 1000g-1500g. This difference was statistically significant for all immunizations except for the second dose of the rotavirus vaccine (p=0.11) (Table 1). Also, infants with a gestational age of less than 32 weeks were less likely to be immunized than those born at 32 weeks or more.

Vaccination age

The mean age for the first DPT-Hib-HepB and OPV administration was 3.4 ± 1.2 months; 5.5 ± 1.3 for the second and 7.7 ± 1.3 for the third administration. The first 7vCPV was administered at a mean age of 4.4 ± 1.9 months and the second at 6.5 ± 1.8 months. Mean age at the first rotavirus vaccination was 3.4 ± 1.1 months and 5.3 ± 1 months for the second dose. Figure 1 show the ages at vaccination according to birth-weight. Infants with a birth-weight less than 1000g were immunized at significantly higher ages (p<0.05), except in the case of the first 7vCPV (p=0.57). Infants with a gestational age of less than 32 weeks were immunized at latter ages than those born at 32 weeks or more. None of the newborns received any of the evaluated vaccination prior to discharge.

Completion of programed vaccine doses

At 7 months of age only 34.3% and 35.4% of infants had received three doses of the DPT-Hib-HepB and OPV, respectively. By 9 months, 80.8% had received the three doses of the DPT-Hib-HepB and OPV. The 7vCPV coverage was slightly higher with 84.3% of infants vaccinated with two doses by 9 months of age. The percentage of infants vaccinated against rotavirus was the lowest; only 61.6% had received two doses by 9 months. Figure 2 shows the cumulative incidences for the administration of the primary course of the DPT-Hib-HepB, OPV, 7vCPV and rotavirus vaccine. Vaccine coverage of infants with a birth-weight less than 1000g was lower than infants with a birth-weight of 1000-1500g throughout the entire follow up. The coverage in infants with a gestational age less than 32 weeks was lower than infants of 32 weeks or more.

DISCUSION

We found that very-low-birth-weight infants are immunized with a delay. The mean age for vaccination was more than one month after the recommended age; this is considered the grace period to define the upper limit for age-appropriate vaccination (11,14,16). By 7 months of age all of the evaluated vaccines should have been administered; nevertheless vaccination rates at this age were less than 70%. Most infants received the third dose of the DPT-Hib-HepB and OPV between 7 and 10 months of age, and the second dose of the 7vCPV between 5 and 9 month of age. The delay in vaccination was more pronounced in infants with lower birth-weight or lower gestational age.

Studies conducted in developed countries have obtained similar results (11-14). Langkamp et al found that low birth-weight infants received the first two doses of polio and the first three doses of DPT at significantly older ages than normal birth-weight infants (12). The same was observed in Switzerland and France (13,17). More recently Batra et al. found that infants with a birth-weight of less than 1500g were less likely to be immunized at an appropriate age compared to normal birth-weight infants. Additionally, extremely-low-birth-weight infants (<1000g) had lower age appropriate immunization rates than larger premature infants (1000-1500g) (11). On the other hand Davis et al concluded than premature infants were vaccinated at levels approaching that of the general population. However, when considering only VLBW infants the immunization levels were significantly lower than normal birth-weight infants (14). This delay is more pronounced during the first year of life and reduced after this (11,12,14). Extremely-low-birth-weight infants are the exception since they continue to receive immunizations at significantly higher ages after 12 months (14).

There are concerns regarding the effectiveness and safety of immunizations in VLBW (2), despite multiple studies showing that immunizations are both safe and effective in VLBW infants (2,8,18). VLBW infants may have lower antibody responses initially, but most of them achieve protective antibody titers after vaccination (19-26). Even in extremely premature infants, where an initial appropriate response is not achieved by all, protective antibody concentrations are obtained by 9-12 months (2,27-29). Regarding safety, the severity and frequency of most vaccine-related adverse events in VLBW infants does not differ from that observed in normal birth-weight infants (2,3,8).

Only apnea associated with the DPT vaccine has been reported consistently, yet this is still widely debated and seems to only affect patients with the most severe illnesses (2,30-33). Most vaccination centers in Lima are not managed by neonatologist but instead by nurses that are not familiarized with VLBW vaccination guidelines. Also most parents are not informed of VLBW vaccination schedule and may have safety concerns. These two factors lead to unjustified immunization postponement.

It is recommended that vaccination schedule should be started during hospitalization to improve long term coverage of preterm infants. (10,34) However this is not always followed, as showed in a recent study. (35) In the evaluated NICUs the standard practice is to start immunizations after the patient is discharged which could be after 2 months for VLBW infants. This practice also contribute of the delay in immunizations.

More premature newborns are surviving the neonatal period in developing countries; this brings a new challenge to pediatricians who are not used to managing this population. Also, infectious diseases are more common and health services less available. In these settings vaccination is an essential tool against transmissible diseases in these countries. A previous study from South America concluded that premature infants were immunized with a significant delay and this delay was considered unjustifiable 76% of the time. (36).

Most studies in this topic were made before the implementation of the pneumococcal and rotavirus vaccine (11-14), so the compliance for these vaccines has not been well studied. Because of their recent inclusion in the immunization calendar we expected to find lower

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immunization rates and a more pronounced delay in administration. This was true for the rotavirus vaccine but not for the 7vCPV which achieved immunizations levels near those of older vaccines like the DPT-Hib-HepB. The reasons for this are unclear but it may be due to a high population awareness of the severity of the diseases prevented by the vaccine. When the pneumococcal vaccine was introduced it was accompanied by an aggressive advertising campaign, this caused parents to demand the vaccination of their children. Advertising campaigns focused on improving public awareness may be an effective method to increase vaccination rate in VLBW infants.

The main limitation of this study is its low number of subjects. Unlike previous studies (11,12,14) we didn't try to obtain national representative samples. These studies were made using national registries, which are not available or are incomplete in Peru, and used retrospective cohorts. The prospective design allowed us to get accurate and reliable information. Unfortunately this approach dictated that a limited the number of patients could be followed. Another limitation is the lack of a comparison group of term neonates. Because our cohort is part of a larger cohort focusing on RSV infection in VLBW infants we couldn't compare it to normal birth-weight infants. However, because of the reasons exposed above, we believe our results suggests a delay in immunizations in VLBW infants. Unfortunately, these limitations are difficult to assess in a country like Peru due to the lack of systematic registries of vaccinations. Future studies should address these limitations.

CONCLUSION

VLBW infants are vaccinated with a delay despite current guidelines which advise following the same vaccination schedule used in normal birth-weight infants. This is true for all evaluated vaccines but the delay is more prominent in the rotavirus vaccine. Extreme low birth-weight infants are vaccinated at even later ages than patients with a birth-weight from 1000-1500g. Urgent educational interventions targeting physicians and nurses, as well as the general population, should be implemented in order to improve vaccination rates and timing in these high risk populations.

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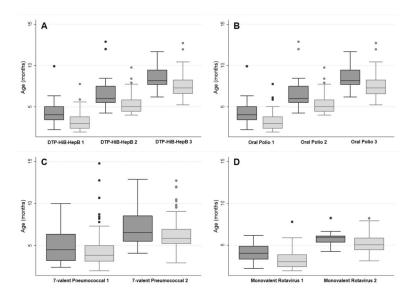


Figure 1.

Age of administration of (A) the three doses of the pentavalent vaccine (DTP-HiB-HepB); (B) the three doses of the oral polio vaccine; (C) the two doses of the 7-valent conjugated pneumococcal vaccine; (D) the two doses of the monovalent rotavirus vaccine. Dark grey boxes: <1000g; Light grey boxes: 1000-1500g.

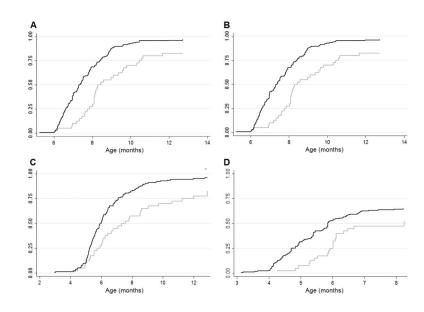


Figure 2.

Cumulative administration of (A) third dose of the pentavalent vaccine (DTP-HiB-HepB); (B) third dose of the oral polio vaccine; (C) second dose of the 7-valent conjugated pneumococcal vaccine; (D) second dose of the monovalent rotavirus vaccine. Light grey line: <1000g; Dark grey line: 1000-1500g.

Table 1

Vaccination rates by birth-weight group in premature infants

	Total (N=198)		<1000g (N=41)		1000-1500g (N=157)		P**
	n	%	n	%	n	%	
DPT-Hib-HepB [*] 1	198	100.0	41	100.0	157	100.0	-
DPT-Hib-HepB [*] 2	193	97.5	38	92.7	155	98.7	0.028
DPT-Hib-HepB [*] 3	185	93.4	33	80.5	152	96.8	< 0.001
Oral Polio 1	198	100.0	41	100.0	157	100.0	-
Oral Polio 2	193	97.5	38	92.7	155	98.7	0.28
Oral Polio 3	185	93.4	33	80.5	152	96.8	< 0.001
7-valent Pneumococcal 1	193	97.5	37	90.2	156	99.4	0.001
7-valent Pneumococcal 2	184	92.9	33	80.5	151	96.4	0.001
Monovalent Rotavirus 1	147	74.2	23	56.1	124	79.0	0.003
Monovalent Rotavirus 2	123	62.1	21	51.2	102	65.0	0.106

* Diphtheria-pertussis-tetanus, Haemophilus influenza type b and Hepatitis B vaccine

** For the comparison between birth weight groups