Risk factors for neonatal death obtained by Cox multivariate regression analysis

Fatores de risco para óbito neonatal obtidos pelo modelo de regressão multivariado de Cox

Factores de riesgo para óbito neonatal obtenidos por el modelo de regresión multivariante de Cox

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ABSTRACT

Objective: To identify the risk factors for neonatal death in São José dos Campos (SP) Brazil.

Methods: This longitudinal study retrieved data obtained from the Brazilian Birth and Death Certificates of neonates born to mothers living in São José dos Campos, Brazil, from 2003 up to 2004. Variables associated to neonatal death were analyzed by multivariate analysis using the Cox model. Independent variables were: maternal age, maternal educational level, number of previous stillbirths, number of children alive in the family, single or multiple pregnancy, gestation length, type of delivery, sex, birth weight, 1st and 5th minute Apgar scores. Significance was set at $p<0.05$

Results: There were 131 deaths up to the 28th day after birth during the study period. Results were expressed in relative risk (RR) and 95% confidence intervals (CI). Gestational age <37 weeks (RR 6.92; 95%CI 3.64-13.17), 5th minute Apgar score <7 (RR 3.14; 95%CI 1.95-5.04), 1st minute Apgar score <7 (RR 3.48; CI 2.17-5.60) and low birth weight (RR 4.49; 95%CI 3.36-8.53) were associated with neonatal death in the final model.

Conclusions: Variables associated with neonatal death in São José dos Campos, Brazil, are related to quality of health care during prenatal and perinatal periods.

Key-words: neonatal mortality; survival analysis; infant, newborn; infant, low birth weight; risk factors.

RESUMO

Objetivo: Identificar os fatores associados ao óbito neonatal em São José dos Campos (SP).

Métodos: Estudo epidemiológico do tipo longitudinal para o qual foi construído um banco de dados com informações do recém-nascido e da mãe obtidas a partir das Declarações de Nascido Vivo e de Óbito de neonatos de mães residentes em São José dos Campos, nos anos de 2003 e 2004. Definiu-se como variável dependente o óbito até o 28º dia após o nascimento. A análise multivariada, utilizando o modelo de Cox, foi aplicada para verificar a associação entre o óbito neonatal e as seguintes variáveis independentes: sexo, peso ao nascer, duração da gestação, Apgar no 1º e 5º minuto, idade materna, nível de instrução da mãe, número de óbitos fetais e de filhos vivos prévio, tipo de parto e gestação única ou múltipla. O nível de significância adotado foi $p<0,05$.

Resultados: No período analisado, foram identificados 131 óbitos neonatais. Os resultados foram expressos por risco relativo (RR) e intervalo de confiança de 95% (IC95%). Idade gestacional <37 semanas (RR 6,92; IC95% 3,64-13,17), Apgar no 5º minuto <7 (RR 3,14; IC95% 1,95-5,04), Apgar no 1º minuto <7 (RR 3,48; IC95% 2,17-5,60) e baixo peso ao nascimento (RR 4,49; IC95% 3,36-8,53) foram as variáveis associadas significativamente com a morte, no modelo final.

Conclusões: As variáveis associadas ao óbito neonatal em São José dos Campos estão relacionadas à qualidade da assistência pré-natal e perinatal.

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Palavras-chave: mortalidade neonatal; análise de sobrevida; recém-nascido; recém-nascido de baixo peso ao nascer; fatores de risco.

RESUMEN

Objetivo: Identificar los factores asociados al óbito neonatal en São José dos Campos.

Métodos: Se trata de estudio epistemológico de tipo longitudinal para el que se construyó una base de datos con informaciones del recién-nacido y de la madre, obtenidos a partir de las Declaraciones de Nacido Vivo y de óbito de neonatos y de madres residentes en São José dos Campos (São Paulo, Brasil), en los años de 2003 y 2004. Se definió como variable dependiente el óbito hasta el 28º día después del nacimiento. El análisis multivariado, utilizando el modelo de Cox, fue aplicado para verificar la asociación entre el óbito neonatal y las siguientes variables independientes: sexo, peso al nacer, duración de la gestación, Apgar en el 1er y 3er minuto, edad materna, nivel de instrucción de la madre, número de óbitos fetales y de hijos vivos previo, tipo de parto y gestación única o múltiple. El nivel de significancia adoptado fue $p<0,05$.

Resultados: En el periodo analizado se identificaron 131 óbitos neonatales. Edad gestacional menor que 37 semanas (RR 6,92; IC 95% 3,64-13,17), Apgar en el 5º minuto <7 (RR 3,14; IC 95% 1,95-5,04), Apgar en el 1er minuto <7 (RR 3,48; IC9%: 2,17-5,60) y bajo peso al nacimiento (RR 4,49; IC 95%: 3,36-8,53) fueron las variables asociadas significativamente con la muerte, en el modelo final.

Conclusiones: Las variables asociadas al óbito neonatal en São José dos Campos (São Paulo, Brasil), están relacionadas a la calidad de la asistencia pre-natal y perinatal.

Palabras clave: mortalidad neonatal; análisis de sobrevida; recién-nacido; bajo peso al nacer; factores de riesgo.

Introduction

Infant mortality may be considered one of the best indicators of healthcare quality and of the socioeconomic level of a population[1,2]. The concept of infant mortality encompasses all deaths occurring in the first year of life, and can be broken down into two components: neonatal mortality, which includes all deaths occurring before the 28th day of extrauterine life, and postneonatal mortality, which includes all deaths occurring between the 28th day of life and the day before the child's first birthday[1]. The determinants of neonatal mortality are manifold and complex, and are associated with the interaction of biological, socioeconomic, and care-related variables[2-4].

According to data obtained by Fundação Seade[5] in 2009, the average infant mortality rate for the state of São Paulo is one of the lowest in Brazil, at 12.5 deaths per 1000 live births (LB). Within the catchment area of the 17th Regional Health Department (DRS XVII), which includes 35 municipalities in the São Paulo portion of the Paraíba River valley, the 2009 infant mortality rate was 13.3 deaths/1000 LB. In the municipality of São José dos Campos, where the present study was conducted, the average rate was 10.8 deaths/1000 LB, lower than the averages of both the DRS XVII and the state of São Paulo.

Despite a downward trend, current rates show that neonatal deaths account for most of the infant mortality, and are still significantly high compared to the lower postneonatal mortality rates. This finding is confirmed by the 2009 Fundação Seade data, which show neonatal mortality rates of 8.7/1000 LB in the state of São Paulo, 10.0/1000 LB within the DRS XVII, and 7.9/1000 LB in São José dos Campos[5].

Any attempt to improve these rates will require identification of risk factors for neonatal mortality in the municipality of São José dos Campos, which will provide an understanding of possible causes and enable implementation of preventive actions. This process entails investing on higher-complexity, higher-technology hospital services and on educational and public health actions, geared particularly to improvement of neonatal care[1]. Countless study designs have been used for evaluation of neonatal care[6,7]. The approach proposed herein is the Cox model, which applies multivariate regression to survival analysis in order to determine the survival time of subjects after exposure to a certain variable believed to be a risk factor. The present study thus sought to identify risk factors for neonatal death among all infants born alive to mothers living in the municipality of São José dos Campos, state of São Paulo, between 2003 and 2004, by means of Cox survival analysis.

Methods

This longitudinal epidemiological study was approved by the relevant Research Ethics Committee. The data on which the study is based (2003–2004 data for the municipality of São José dos Campos) were obtained in late 2006 from the Health Information System (*Sistema de Informações à Saúde*) available on the São Paulo State Department of Health website[8], which provides access to Certificates of Live Birth and Death Certificates.

The study population was established by identification of all neonatal deaths (occurring within 28 days of birth) of infants

born to mothers living in the municipality of São José dos Campos, São Paulo, between January 1, 2003 and December 31, 2004, by means of the record linkage approach. Records were paired with those of all infants born alive on the date of birth of the deceased infants, thus compiling a database of all infants who died before the 28th day of life and all those who survived past this point during the study period[4]. The final database comprised 131 decedents and 2847 neonates who survived beyond the 28th day of life, for a 21:1 ratio of survivors to decedents. Infants who were born before December 31, 2004 and died before January 27, 2005 were also included in the sample.

The outcome variable was neonatal death. The independent variables of interest included maternal and neonatal information. Due to their quantitative nature, these variables were categorized according to classification schemes recommended in the literature, thus becoming qualitative. The following variables were defined, with their respective categories: birth weight, low (<2500g) or normal (≥2500g); duration of pregnancy, preterm (gestational age <37 weeks) or full-term (gestational age ≥37 weeks); Apgar scores at 1 and 5 minutes, low (<7) or adequate (≥7); maternal age, suboptimal (<20 or >35 years) or optimal (≥20 and ≤35 years); maternal educational achievement, low (<8 years' formal education) or high (≥8 years); number of stillborn and number of live offspring, none or ≥1; mode of delivery, vaginal or Cesarean; type or pregnancy, singleton or multiple.

Univariate analysis was performed for screening, and variables with $p<0.20$ were included in the multivariate Cox proportional hazard regression model. Analyses were performed in the Stata 9 software environment. The Cox model yields hazard ratios (HR) with a 95% confidence interval, establishing the likelihood of neonatal death according to presence or absence of the condition of interest[9]. The final model thus enables assessment of possible associations between the study variables and neonatal death. Cox–Snell residuals can also be plotted for estimation of the fit of the model.

Results

In the years 2003 and 2004, a total of 18,013 infants were born alive to mothers living in the municipality of São José dos Campos, São Paulo. Of these, 131 died before the 28th day of extrauterine life, which corresponds to a neonatal mortality rate of 7.3 deaths/1000 LB. A total of 2,978 infants born on the same day of those who died survived the neonatal period; of these, 396 were randomly paired to each death record to serve as controls.

Mean maternal age was 26±1.2 years, mean 1- and 5-minute Apgar scores were 8.1±0.2 and 9.0±0.2, respectively, and mean birth weight was 3,037±131g. Tables 1 and 2 show that most infants who did not survive the neonatal period were male (59%), had 1-minute Apgar scores <7 (67%), 5-minute Apgar scores ≥7 (60%), low birth weight (80%) and were born preterm (78%), mostly as the product of singleton pregnancies (83%), delivered vaginally (60%), to mothers with more than eight years of formal education (71%), one or more living offspring (51%), no stillborn (86%), and within the optimal maternal age range (66%).

Most surviving infants were male (51%), with 1- and 5-minute Apgar scores ≥7 (95% and 97% respectively), birth weight ≥ 2500g (92%) and gestational age ≥37 weeks (93%), singletons (98%), delivered by Cesarean section (53%), to mothers with more than eight years of formal education (74%), one or more living offspring (66%), no stillborn (86%), and within the optimal maternal age range (70%).

Univariate analysis of these variables yielded p-values <0.20 for mode of delivery, duration of pregnancy, birth weight, Apgar scores at 1 and 5 minutes, and gender. Kaplan-Meier curves plotted for these variables were parallel and did not cross during the study period, confirming statistical significance (unpublished data).

These variables were then analyzed by Cox multivariate regression analysis, which revealed that the variables low birth weight, 1-minute Apgar score <7, 5-minute Apgar score <7, and preterm birth were risk factors for neonatal mortality in infants born in São José dos Campos between 2003 and 2004 (Table 3). The Cox-Snell plot indicated good model fit, with residuals nearly coinciding with the ideal curve (Figure 1).

Discussion

This study, performed on data obtained for the municipality of São José dos Campos, used Cox multivariate regression analysis, a statistical approach rarely used for analysis of neonatal mortality.

The results obtained showed higher mortality rates among male infants. However, according to the Cox model, this variable did not reach statistical significance. This finding is consistent with other published studies, which always take into account higher male than female mortality rates, usually regardless of age[2,3,10-12]. The biological mechanisms that underlie this gender divergence in mortality rates have yet to be fully elucidated, but some authors suggest that less maturity may play a role, with a higher incidence of respiratory syndromes in male neonates[11,12].

Table 1 – Maternal characteristics of liveborn infants who did or did not survive the neonatal period in São José dos Campos, São Paulo, 2003–2004.

	Survivors (%)	Deaths (%)	Total (%)	*p*-value
Educational achievement				
>8 years	2087 (74.0)	90 (71.0)	2177 (74.0)	0.506
<8 years	730 (26.0)	36 (29.0)	766 (26.0)	
Total	2817 (100.0)	126 (100.0)	2943 (100.0)	
Maternal age				
Optimal	1997 (70.0)	86 (66.0)	2083 (70.0)	0.262
Suboptimal	846(30.0)	45 (44.0)	891 (30.0)	
Total	2843 (100.0)	131 (100.0)	2974 (100.0)	
Living offspring				
None	1198 (44.0)	61 (49.0)	1259 (44.0)	0.259
One or more	1522 (66.0)	63 (51.0)	1584 (66.0)	
Total	2720 (100.0)	124 (100.0)	2844 (100.0)	
Stillborn				
None	2280 (86.0)	104 (86.0)	2384 (86.0)	0.839
One or more	353 (14.0)	17 (14.0)	370 (14.0)	
Total	2633 (100.0)	121 (100.0)	2754 (100.0)	
Mode of delivery				
Vaginal	1348 (47.0)	78 (60.0)	1426 (48.0)	0.006
Cesarean	1498 (53.0)	53 (40.0)	1551 (52.0)	
Total	2846 (100.0)	131 (100.0)	2977 (100.0)	
Duration of pregnancy				
Full-term	2644 (93.0)	26 (22.0)	2670 (90.0)	<0.001
Preterm	189 (7.0)	92 (78.0)	281 (10.0)	
Total	2833 (100.0)	118 (100.0)	2951 (100.0)	
Pregnancy				
Singleton	2781 (98.0)	109 (83.0)	2890 (97.0)	<0.001
Multiple	58 (2.0)	22 (17.0)	80(3.0)	
Total	2839 (100.0)	131 (100.0)	2970 (100.0)	

Table 2 – Neonatal characteristics of liveborn infants who did or did not survive the neonatal period in São José dos Campos, São Paulo, 2003–2004.

	Survivors (%)	Deaths (%)	Total (%)	*p*-value
Normal weight	2579 (92.0)	26 (20.0)	2605 (88.0)	<0.001
Underweight	235 (8.0)	104 (80.0)	339 (12.0)	
Total	2814 (100.0)	130 (100.0)	2944 (100.0)	
5-min Apgar				
≥7	2830 (99.0)	72 (60.0)	2902 (98.0)	<0.001
<7	5 (1.0)	49 (40.0)	54 (2.0)	
Total	2835 (100.0)	121 (100.0)	2956 (100.0)	
1-min Apgar				
≥7	2687 (95.0)	40 (33.0)	2727 (92.0)	<0.001
<7	147 (5.0)	81(67.0)	228 (8.0)	
Total	2834 (100.0)	121 (100.0)	2955 (100.0)	
Gender				
Male	1457 (51.0)	77 (59.0)	1534 (51.0)	0.072
Female	1391 (49.0)	53 (41.0)	1444 (49.0)	
Total	2848 (100.0)	130 (100.0)	2978 (100.0)	

Table 3 – Cox multivariate regression analysis of factors associated with neonatal death, expressed as relative risk (RR), 95% confidence intervals (95%CI) and *p*-values

	RR	95%CI	*p*-value
Preterm birth	6.92	3.64 – 13.17	<0.001
Low birth weight	4.49	3.36 – 8.53	<0.001
One-minute Apgar <7	3.48	2.17 – 5.60	<0.001
Five-minute Apgar <7	3.14	1.95 – 5.04	<0.001

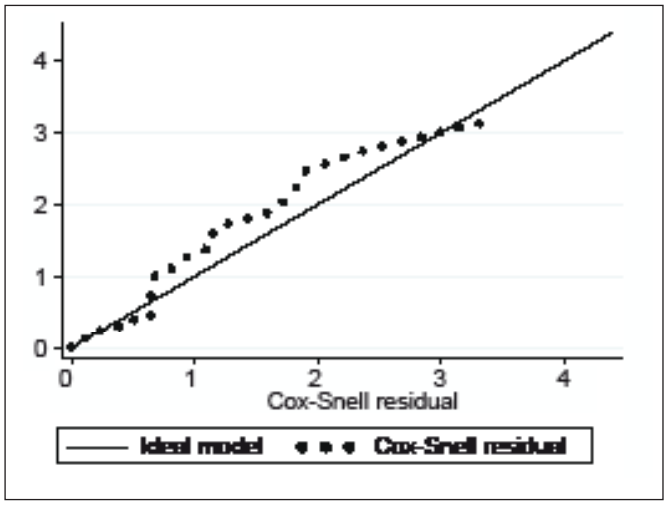

Figure 1 – Plot of Cox–Snell residuals for neonatal deaths in São José dos Campos, São Paulo, 2003–2004.

Some other variables also did not reach statistical significance as risk factors for neonatal death, but are epidemiologically important for outlining a profile of neonatal mortality in São José dos Campos, due to their care-related and socioeconomic nature: maternal educational achievement, pregnancy, and mode of delivery.

In the present study, maternal age was not significantly associated with neonatal death, but it bears noting that survival was lower in neonates whose mothers were not in the optimal age range (44% of the sample). Cesar *et al*[13] found this lower survival rate to be mostly due to low maternal socioeconomic status, which interferes directly with the manner in which the mother interprets and follows her pregnancy. The authors also stress the importance of cultural practices concerning care of the pregnant woman and newborn, as other studies have shown that proper prenatal care and adequate labor and delivery care have a direct influence on neonatal mortality rates, particularly where birth weight and prematurity are concerned[14].

Educational achievement has been singled out as an important socioeconomic variable that interferes with the biological outcomes of pregnancy—such as low birth weight—and with infant mortality. Studies have shown that literacy increases awareness of and sensitivity to health education actions; rising educational achievement levels may thus act as protective factors by increasing assimilation of information on the various healthcare alternatives available to the population. This, in turn, leads to healthy personal health practices and behaviors[3]. Although this trend has been confirmed, it did not afford significant protection against neonatal mortality in the present study.

The risk of neonatal mortality in our sample was relatively higher after vaginal delivery then after Cesarean section, although this difference was again not significant. This finding is consistent with other studies that have identified Cesarean birth as a protective factor against neonatal mortality, whereas vaginal delivery may help reduce maternal morbidity and mortality[15,16]. A study conducted in Goiânia, state of Goiás, found a positive association between vaginal delivery and neonatal mortality on univariate analysis. This association was confirmed by logistic regression, but was later found to be due to selection bias—namely, a higher frequency of vaginal delivery in settings associated with high risk of neonatal death, versus near-universal performance of Cesarean section in low-risk settings[17]. Araújo *et al*[5] reported the opposite, with higher risk in mothers undergoing Cesarean section.

The association between neonatal mortality and prematurity was also stronger in this study: 78% of deaths occurred in preterm infants. This variable was statistically significant on both univariate and multivariate analysis, which attests to its importance as a determinant of neonatal mortality and contributing factor to low birth weight and to 5-minute Apgar scores <7.

Apgar scores were also associated with neonatal mortality in the present study. The accuracy of 1-minute Apgar as a diagnostic test or marker for asphyxia is questionable, as fewer than half of neonates with now Apgar scores at 1 minute are actually hypoxic on arterial blood gas studies. The sensitivity and specificity of 1-minute Apgar for detection of asphyxia range from 11–78% and 75–99% respectively, whereas the 5-minute Apgar score is more closely associated with the prognosis of infant survival and neurological function[18]. Pereira *et al*[18] note that roughly 840,000 of the 4 million neonates who develop moderate-to-severe asphyxia each year will die, with the same number surviving, but with sequelae. Overall asphyxia-related neonatal mortality may thus be estimated to range between 15% and 40%.

One-minute Apgar scores are rarely used as a study variable; in the present study, however, they affected the fit of the whole model, particularly on residuals analysis. Neonatal mortality studies have found that, the lower the 5-minute Apgar score, the lower the odds of survival[5]. However, it has been established that Apgar scores near 6 may occur in otherwise healthy preterm infants with poor muscle tone due to high-risk pregnancy,

Cesarean section or complications during delivery[18]. This finding was confirmed in the present study; survival was found to be lower in neonates with low Apgar scores, with the mortality rate reaching 40% when 5-minute Apgar scores were <7.

Low birth weight and prematurity are universally recognized as the single most important risk factors for neonatal death[15]. As was to be expected, this study found a significant association between neonatal mortality and birth weight, with 30% of low birth weight infants dying before the 28th day of life. The prevalence of low birth weight (<2500g) has been associated with unfavorable socioeconomic conditions, inadequate prenatal care, suboptimal maternal age, high parity, reduced birth interval, maternal malnutrition, and maternal smoking[5]. Araujo *et al*[10] believe low birth weight is associated with disadvantaged socioeconomic status, which renders neonates more vulnerable to unfavorable conditions such as preterm birth. Moreover, the frequency of low birth weight is clearly higher in multiparous women, usually due to shorter birth interval. This association is one possible explanation for the findings of this study, such as increased risk of mortality among infants born to multiple pregnancies.

In the present study, neonatal death was strongly associated with low birth weight, preterm birth, and 5-minute Apgar scores <7. These findings are consistent with those reported by other authors who have conducted studies focusing on risk factors for neonatal mortality[19-21], although the association between 1-minute Apgar scores and mortality has only rarely been researched. Our results thus confirm those of other authors who have pinpointed prematurity and low birth weight as universal risk factors for neonatal mortality. Furthermore, Apgar scores are closely related to other variables and can define prognosis in the first minutes of extrauterine life. It bears stressing that the above-listed factors should not be viewed in isolation, but rather as determinants of neonatal mortality.

The risk factors for neonatal death identified in the present study can be minimized, or even altogether avoided, if adequate measures are implemented to encourage prenatal care, improve labor and delivery, and ensure immediate postpartum care of the newborn. These actions would depend on human resources and equipment, but the key goal should be allowing pregnancy to occur and progress in the best possible biological, physical, and psychological setting. Furthermore, measures should be implemented to reduce social inequality, as the most significant risk factors for neonatal death are closely tied to low maternal socioeconomic status.

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