FETAL AND PERINATAL DETERMINANTS OF NEONATAL MORTALITY IN THE STATE OF QATAR: A PILOT PHASE UNIVARIATE AND MULTIVARIATE ANALYSIS BY PEARL STUDY

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ABSTRACT

Objective: *To analyze the fetal and perinatal determinants of neonatal mortality.*

Methodology: *This was a pilot National Prospective cohort-study done from the data source of Qatar Perinatal Registry (Q-Peri-Reg). National data on total deliveries, live births and neonatal mortality was ascertained from Qatar's national perinatal registry for the study period (1st January to 30th June 2011). Data on gender, fetal growth, birth weight, gestational age, presentation at birth, mode of delivery, APGAR score at one and five minutes and the need for delivery room resuscitation was ascertained for all neonatal deaths and a corresponding group of control babies and analyzed using a univariate and multivariate model.*

Results: *The total deliveries during the study period were 9797 resulting in 9738 live births. The preterm delivery rate was 4.9%(n=489) and low birth weight delivery rate 7.5%(n=739). The total numbers of neonatal deaths were 44(NMR 4.5/1000). Intrauterine growth restriction (IUGR), low birth weight, preterm delivery, breech presentation, delivery by C-section, low APGAR score at one and five minutes and the need for delivery room resuscitation were significantly associated (P<0.05) with neonatal mortality on univariate analysis. Low birth weight (p<0.001), breech presentation (p=0.041) and the need for delivery room resuscitation (p<0.001) had significant association with neonatal mortality on multivariate analysis.*

Conclusion: *Further improvement in neonatal survival is possible by decreasing the incidence of low birth weight and preterm deliveries as well as by better intra-partum care of breech presentations and fetuses in distress.*

Key Words: *Fetal determinants, Perinatal determinants, Neonatal mortality*

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INTRODUCTION

The reproductive outcomes in the State of Qatar have improved significantly over the last three decades[1-3]. Qatar's current neonatal, early neonatal, late neonatal and corrected neonatal mortality rates are comparable to many high income countries, both from the West and East[3]. However, the neonatal mortality rates now seem to have become static[4]. We conducted the current study to analyze the fetal and perinatal determinants of neonatal mortality in Qatar with the aim to produce strategic guidelines for further improvement in neonatal survival which would potentially be useful worldwide.

METHODOLOGY

PEARL Study:

PEARL Study (Perinatal Neonatal Outcomes Research Study in the Arabian Gulf) is Qatar's prospec-

tive National Perinatal Epidemiologic Study funded by QNRF (Qatar National Research Fund-grant # QN-RF-NPRP-09-390-3-097) for a period of three years (2011-2013). The study is a joint collaborative research project between Hamad Medical Corporation (HMC), Doha, Qatar and the University of Gloucestershire, Gloucester, United Kingdom. The project has established a National Neonatal Perinatal Registry for Qatar called Q-Peri-Reg, which is now being used to quantify maternal, neonatal and perinatal mortality, morbidities, and their correlates. The current pilot study is based on the data ascertained during the first six months of the project when the registry had yet not gone electronic. The PEARL Study has a 30 member multidisciplinary research team comprised of pediatricians, neonatologists, perinatologists, obstetricians, epidemiologists, statisticians and 15 full time physicians (including 1 research fellow, 2 research associates, and 12 research assistants) responsible for daily data collection, data entry, data cleaning and data organization. PEARL study is approved by the Research Ethics Committee (IRB) of Hamad Medical Corporation (protocol #9211/09).

PEARL study definitions of Neonatal Mortality

PEARL Study uses the following ICD-10[5] and WHO definitions[6], to ascertain, analyze and report its neonatal perinatal outcomes data.

Live Birth for reporting purposes: The birth of a fetus with a birth weight of ≥ 500 grams, or, if missing, ≥ 22 completed weeks of gestation, or if missing, crown heel length ≥ 25 cm, which after separation from his / her mother, has any signs of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscle, whether or not the umbilical cord has been cut or the placenta is attached.

Live Birth for International comparison: The birth of a fetus with a birth weight of ≥ 1000 grams, or, if missing, ≥ 28 completed weeks of gestation, or if missing, crown heel length ≥ 35 cm, which after separation from his / her mother, has any signs of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscle, whether or not the umbilical cord has been cut or the placenta is attached.

Mortality Rates: All mortality rates are calculated per 1000 live births

Neonatal Mortality: Death of a live born term baby (37 completed weeks of gestation) during the first 28 days (day 0 to day 27) of life.

Early Neonatal Mortality: Death of a live born baby during first 7 days of life (day 0 to day 6 of life) irrespective of gestation at birth.

Late Neonatal Mortality: Death of a live born baby between day 7 and day 27 of life. Pearl study uses this criterion only for babies born at term (37 completed weeks of gestation). For preterm babies (≤ 36+6 weeks of gestation), PEARL Study has developed an intrinsic methodology of adjusting neonatal period for prematurity[1].

Prematurity Adjusted Neonatal Mortality

PEARL study's intrinsic methodology of calculating neonatal period for preterm babies (born ≤ 36+6 weeks of gestation), first extends the neonatal period to term gestation (37 weeks) in order to compensate for their prematurity and then adds another 28 post natal days to complete the neonatal period. The full methodology has recently been published in the Journal of Clinical Neonatology[1].

Corrected Neonatal Mortality

The neonatal mortality rate, corrected for futility and lethal congenital malformations, is used for inter country comparisons. The rationale for correction has recently been published in the Journal of Clinical Neonatology[1] and book on Perinatal Medicine.

Data Collection

Data on all live births, and neonatal mortality was collected using predesigned, structured questionnaire. The State of Qatar had completely moved from home deliveries to hospital based deliveries by 1974 and currently 99.5% of State's deliveries take place in a maternity hospital. Hence facility based perinatal data virtually represents national data. PEARL Study data was collected prospectively by a trained full time research team from all five maternity units in Qatar that includes 2 public maternity hospitals (Women Hospital and Al Khor Hospital) and three private maternity hospitals (Al Ahli Hospital, Doha clinic and Al Emadi Hospital). Data was also collected from Hamad General Hospital, which does not have a maternity unit. However, it does have the largest emergency department, general paediatric and Paediatric Intensive Care Unit where neonatal deaths can happen. The neonatal mortality data was verified from multiple resources including records of Department of Medical Statistics and hospital mortuary. All babies with a birth weight of ≥ 500 grams who were born with any signs of life were included in birth and death statistics irrespective of gestational age at birth or futility. The current pilot study was conducted to assess the fe-

tal and perinatal determinants of neonatal mortality during the pilot phase of PEARL Study (January 1st to June 30th 2011). The project was testing and validating its data collection tools and data analysis system at this stage. During this phase the registry had not yet gone electronic and data collection and analysis was being done on paper. All prematurity adjusted neonatal deaths (n=44) were assembled into the study group while a group of 117 live babies, of all gestational age and birth weights, born during the same study period were randomly selected as a control group. Both study and control groups had similar ethnicity, gender, gestational age and birth weight characteristics.

Study Variables

The primary outcome was neonatal death as defined above. For preterm babies we used adjusted neonatal mortality. However, we did not correct the mortality for futility or lethal congenital anomalies because the objective was not to use the mortality rate for inter-country comparison. The explanatory fetal and perinatal variables were gender, fetal growth, birth weight, gestational age, presentation at birth, mode of delivery, APGAR score at one and five minutes and the need for delivery room resuscitation. Data on these variables was ascertained from collected data for both groups.

Statistical Analysis

Data from the study and control groups were analyzed using SPSS version 19. Fisher Exact and Chi-square tests were performed to test for differences in proportions of categorical variables between two or more groups. Univariate logistic regression analyses were carried out to identify possible predictors of neonatal mortality (1=yes, 0=no). Adjusted odds ratios for all variables that were significantly associated with neonatal mortality were computed using a multivariable logistic regression model for controlling the simultaneous confounding effects of possible confounders. Hosmer-Lemeshow goodness-of-fit test was used to assess the model adequacy. In these analyses, the outcome was neonatal deaths recoded as a binary variable. All statistical tests were two-sided and $P < 0.05$ was considered statistically significant.

RESULTS

The total deliveries during the study period were 9797 resulting in 9738 live births. 68.2% deliveries were normal vaginal (n =6685) and 21.2% (n 2078) by Caesarean section. 76.9% (n7542) were singleton and 1.6% (161) multiple. The preterm delivery (≤36+6 weeks) rate was 4.9% (n =489) and low birth weight delivery rate (<2500 grams) was 7.5% (n =739). The total numbers of neonatal deaths were 44. Neonatal Mortality Rate (NMR) was 4.5/1000, Early Neonatal Mortality Rate ENMR) 2.05/1000 and Late Neonatal Mortality Rate (LNMR) 2.46/1000. Intrauterine growth restriction (IUGR), low birth weight, preterm delivery, breech presentation, delivery by C-section, low APGAR score at one and five minutes and the need for delivery room resuscitation were significantly associated ($P<0.05$) with neonatal mortality on a Univariate analysis (Table 1) while the baby's gender had a non-significant association ($p=0.718$). Low birth weight (OR 10.29, 95%CI 2.53-21.77, $p<0.001$), breech presentation (OR 3.10, 95% CI 1.50-7.18, $p=0.041$) and the need for delivery room resuscitation (OR 11.07, 95% CI 3.53-18.75, $p<0.001$) had significant association with neonatal mortality on multivariate analysis (Table 2).

DISCUSSION

According to the most recent international report on the achievement of MDG-4 and MDG-5, tremendous progress has been made, between 1990 and 2011, in reducing under five childhood mortality[7]. However, neonatal mortality still accounts for more than 40 per cent of global under-five child mortality[7]. In absolute numbers this means 2.9 million neonatal deaths per year during 2011[7]. Hence, for any further progress, an understanding of the factors related to neonatal mortality is important to guide the development of focused and evidence-based health interventions to prevent neonatal deaths. Our study identified three significant independent determinants of neonatal mortality on multilevel logistic regression; low birth weight, breech presentation and need for delivery room resuscitation.

The association between birth weight and mortality is the strongest in epidemiology[8]. Although birth weight alone may not be the cause of mortality; the association is robust[8]. The current study has reconfirmed this finding. Babies weighing less than 1500 g have a mortality risk at least 100-fold higher than those with an optimal weight (the weight associated with the lowest mortality)[8]. In its recent publication PEARL study has reported that the RR of neonatal mortality decreases significantly with increasing birth weight[9]. As compared to babies with birth weight ≥2500 g, the RR of mortality was 25 times, 17 times, and 5.5 times higher ($P<0.001$) in babies with birth weight 500–750 g, 751–1000 g, and 1001–1500 g, respectively[9]. Low birth weight has been identified as a strong predictor of neonatal mortality by a number of studies[10-12]. In addition, birth weight has also been identified as a very strong indicator of an individual baby's intact survival[13]. Low birth weight babies are at a higher risk of a poor perinatal outcome and long-term cognitive and

Table 1: Univariate analysis of determinants of neonatal mortality in qatar

Neonatal determinants	Dead (n=44)	Alive (n=117)	Odds Ratio (95%CI)	p value
Birth weight				
<2500 g	32(72.7)	14(12.0)	19.6(7.6-51.8)	**<0.001**
≥2500 g	12(27.3)	103(88.0)	1 ref	
Fetal growth				
AGA	36(81.8)	92(78.6)	1 ref	**0.036**
SGA	7(15.9)	7(6.0)	2.6(1.1-7.8)	
LGA	1(2.3)	18(15.4)	0.2(0.1-1.1)	
Mode of delivery				
Vaginal	24(54.5)	88(75.2)	1 ref	**0.012**
C-Section	20(45.5)	29(24.8)	2.5(1.2-5.2)	
Gestational age				
<37 weeks	27(61.4)	12(10.3)	13.9(5.5-35.9)	**<0.001**
≥37 weeks	17(38.6)	105(89.7)	1 ref	
Presentation at Birth				
Cephalic	37(84.1)	113(96.6)	1 ref	**0.010**
Breech	7(15.9)	4(3.4)	5.3(1.3-23.3)	
APGAR Score at 1 minute				
≤6	26(60.5)	1(0.9)		**<0.001**
>6	17(36.5)	116(99.1)	*	
Apgar Score at 5 minutes ∞				
≤6	14(32.6)	0		**<0.001**
>6	29(67.4)	117(99.1)	*	
Delivery Room Resuscitation				
Yes	27(61.4)	7(6.0)	24.9(8.6-75.4)	**<0.001**
No	17(38.6)	110(94.0)	1 ref	
Gender				
Male	20(45.5)	58(49.6)	1 ref	**0.718**
Female	24(54.5)	59(50.4)	1.2(0.5-3.0)	

* Valid odds ratio cannot be calculated due to very few numbers in one category.
ref=reference category
p-value based on chi square or Fisher exact test where the expected cell count is <5
odds ratio based on univariate logistic regression,
∞Apgar score missing for one baby with anencephaly.

motor impairments[13]. Hence, the proportion of babies with birth weight under 2500 g is a widely used indicator for assessing the population at risk, and historical series exist for many countries.

On a Univariate analysis, our current study has identified that both small for gestational age (SGA); also called intrauterine growth restriction (IUGR) babies, and preterm births were associated with increased neonatal mortality (Table 1). Another publication from Qatar showed that the relative risk (RR) of neonatal mortality decreased with increasing gestational age ($p < 0.0001$)[14]. The RR was 4.28 (95% CI 1.97-9.31; $p < 0.0001$) among extremely preterm as compared to very preterm which in turn had a RR of 3.60 (1.5-8.7; $p < 0.0001$) as compared to moderately preterm babies. The RR of death among moderately preterm babies as compared to term babies was 7.32 (3.63-14.75; $p < 0.0001$)[14]. There is no doubt that prematurity remains the commonest

Table 2: Multivariable logistic regression analysis of neonatal mortality in qatar

Determinants	Adjusted Odds Ratio (95%CI)	p value*
Birth Weight		
<2500g	10.29(2.53-21.77)	0.001
≥2500 g	1 ref	
Delivery Room Resuscitation		
Yes	11.07(3.53-18.75)	<0.001
No	1 ref	
Gestational Age		
<37 weeks	1.15(0.23-5.28)	0.814
≥37 weeks	1 ref	
Presentations at Birth		
Cephalic	1 ref	0.041
Breech	3.10(1.50-7.18)	

*Two sided p-values based on -2 log likelihood ratio test.
Outcome variable=neonatal mortality (1=yes, 0=no).
Gestational age (though insignificant) was included in the model to adjust for its strong confounding effect on neonatal mortality.

cause of neonatal mortality, not only in Qatar[14] but worldwide[15-17]. A study from Bangladesh has reported that approximately 75 per cent of neonatal deaths associated with low birth weight were attributed to preterm birth rather than small for gestational age infants[15]. The sample of low birth weight babies in our current analysis included both SGA and preterm babies. PEARL Study will undertake a similar analysis on a bigger sample size, with discrete analysis of SGA and preterm babies, once the electronic data base is fully established.

Our current study identified that the risk of neonatal mortality is three times higher in breech presentation as compared to cephalic presentation(OR 3.10, 95% CI 1.50-7.18, p=0.041). Back in 1992, Thorpe-Beeston and his colleagues had reported a twenty times higher relative risk of intra-partum and neonatal death in vaginal delivery as compared to caesarian section in term singleton breech presentation[18]. A decade later, the data from a randomized controlled trial[19] as well as data from a large registry based cohort[20] re confirmed that there is an increase in early neonatal morbidity and mortality following a trial of labor in cases of term breech presentation. Both vaginal delivery as well as emergency caesarian section in term breech presentation resulted in a seven fold increase in low APGAR score[20]. There was also a threefold increase in birth trauma and a two fold increase in perinatal mortality when compared with the results of planned caesarian section[20]. The Cochrane meta-analysis based on three trials, concluded that planned caesarian section compared with planned vaginal birth reduced perinatal or neonatal death or serious neonatal morbidity, at the expense of somewhat increased maternal morbidity[21]. These results have serious implications on the obstetric practice in a country like Qatar where the C Section rate is already 25%. Hence, there is a need for consensus on national guidelines keeping in view both risks and benefits of planned caesarian section in term singleton breech delivery.

The relative risk of neonatal mortality, according to our study, was eleven times higher in babies requiring delivery room resuscitation as compared to those who did not require any resuscitation (RR 11.07, 95% CI 3.53-18.75, p<0.001). Since its first description by Virginia Apgar in 1953[22], the very simple APGAR score has been used as a standard clinical tool throughout the world for the assessment of newborn condition at birth, the need for resuscitation at birth and the prognosis of neurological outcome at a later age. Although questions have been raised about its accuracy and validity, the two recent large studies re-confirmed its usefulness. The study on one million term births from the Swedish birth registry reported an odds ratio (OR) of 14.4 for infant mortality rate, 31.4 for cerebral palsy, 7.9 for epilepsy and 9.5 for mental retardation in babies who had an APGAR score of less than 7 at five minutes after birth[23]. The large retrospective cohort study from Texas concluded that the APGAR scoring system remains as relevant for the prediction of neonatal survival today as it was almost 50 years ago[24]. Irrespective of the varying views about the usefulness of APGAR score or otherwise, the simple fact that a baby requires assistance at birth, signifies a disadvantaged start of life. The fetal and perinatal circumstances leading to this scenario must

be addressed to reduce the neonatal mortality. This challenge is now evidently pointed out in PEARL Study findings.

LIMITATIONS

Our study was a pilot phase study with a number of limitations. The variables tested are limited to those around the time of delivery. To address the problems of neonatal survival at a wider scale and bring a meaningful change in the health care systems, we need to analyze the relevant socio-demographic, economic and health system variables using a multilevel regression model. This will help develop a bigger picture and a broader vision which is crucial to making a difference in the reproductive outcomes. We hope, once fully established, the Q-Peri-Reg will provide the required level of knowledge and vision to influence the health policy and systems.

CONCLUSION

Although State of Qatar has achieved excellent neonatal survival which is comparable to a number of high income countries, both from the West and East, further improvement in neonatal survival is possible by addressing the issues of high numbers of preterm and low birth weight babies in this State as well as improving the circumstances which lead to the need for neonatal resuscitation at birth. This includes better antenatal and intra-partum monitoring, right perinatal interventions at the right time and in right place and national guidelines on the safer modes of delivery, particularly when the presentation is not normal.

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ETHICAL APPROVAL

PEARL study is approved by the Institutional Research Ethics Committee of Hamad Medical Corporation State of Qatar (protocol #9211/09).

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CONTRIBUTORS

SE prepared the first draft of manuscript and did the data collection. SR review the paper for finalization. WEA did the manuscript review. NN & EL did data collection provision of references and review of manuscript. MTY did statistical analysis of data and review of manuscript. All the authors contributed significantly to the research that resulted in the submitted manuscript.