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Maternal anaemia and maternal, fetal, and neonatal outcomes in a prospective cohort study in India and Pakistan

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Abstract

Objective—To describe the association of maternal anaemia with maternal, fetal, and neonatal outcomes.

Design—Prospective cohort study.

Setting—Rural India and Pakistan.

Population—Pregnant women residing in the study catchment area.

Methods—We performed an analysis of a prospective pregnancy registry in which haemoglobin is commonly obtained as well as maternal, fetal, and neonatal outcomes for 42 days post-delivery. Women 40 years or older who delivered before 20 weeks or had a haemoglobin level of <3.0 g/dl were excluded. Our primary exposure was maternal anaemia, which was categorised in keeping with World Health Organization criteria based on a normal (≥11 g/dl), mild (>10–10.9 g/dl),

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Contribution to authorship

SP, MKH, SSG, EMM, RJD designed the study.

SSG, AC, SS, SAA, RLG, PLH, JM, DW, EMM, RJD were responsible for data acquisition and oversight.

JM, DW performed data management and analysed statistics.

All authors reviewed the manuscript.

Disclosure of interests

None declared. Completed disclosure of interest forms are available to view online as supporting information.

Details of ethics approval

The following ethical approvals were obtained prior to the initiation of the study: Belgaum—University of Missouri, 28 April 2008, and JN Medical College, 17 January 2008 (FWA#00000766). Pakistan—Columbia University (FWA# 00005917), 14 March 2008, and Aga Khan University (FWA #00001177), 14 March 2008. Nagpur—Boston University (FWA# 00004517), 31 July 2008, and Lata Medical Research Foundation (FWA# 00012971), 2 April 2008; RTI (Data coordinating Center) (FWA #00003331), 28 January 2008.

moderate (7–9.9 g/dl) or severe (<7 g/dl). haemoglobin level. The primary maternal outcome was maternal death, the primary fetal outcome was stillbirth, and the primary neonatal outcome was neonatal mortality <28 days.

Results—A total of 92 247 deliveries and 93 107 infants were included, of which 87.8% were born to mothers who were anaemic (mild 37.9%, moderate 49.1%, and severe 0.7%). Maternal mortality (number per 100 000) was not associated with anaemia: normal 124, mild 106, moderate 135, and severe 325 ($P = 0.64$). Fetal and neonatal mortality was associated with severe anaemia: stillbirth rate (n/1000)—normal 27.7, mild 25.8, moderate 30.1, and severe 90.9; $P < 0.0001$; 28-day neonatal mortality (n/1000)—normal 24.7, mild 22.9, moderate 28.1, and severe 72.6 ($P < 0.0001$). Severe maternal anaemia was also associated with low birthweight (<2500 and <1500 g), preterm birth, and postpartum haemorrhage.

Conclusion—Severe maternal anaemia is associated with higher risks of poor maternal, fetal, and neonatal outcomes but other degrees of anaemia are not. Interventions directed at preventing severe anaemia in pregnant women should be considered.

Tweetable abstract

Severe maternal anaemia is associated with adverse fetal and neonatal outcomes in low/middle-income countries.

Keywords

Anaemia; low birthweight; postpartum haemorrhage; stillbirth

Introduction

The World Health Organization (WHO) estimates that over 2 billion people, roughly 30% of the world's population, are affected by anaemia and at least 50% of pregnant women are anaemic.[1] Although anaemia has been shown to affect women in both high- and low/middle-income nations, the major burden of disease is found in low/middle-income countries. The association of both the presence of anaemia and its severity to maternal and neonatal outcomes has not been well characterised.[2–6] Limited data suggest that severe anaemia is associated with an increased risk of low birthweight, but that mild anaemia may protect against low birthweight.[7] A study of 421 pregnant women in India indicated that there is a high prevalence of anaemia (85%) in this population as well as a correlation between anaemia severity and low birthweight as well as earlier gestational age at delivery.[8] Other studies have reported conflicting data on the effect of anaemia on preterm birth. A meta-analysis reported in the year 2000 showed an increased risk of preterm birth among women who experienced anaemia in the first trimester with an overall odds ratio of 1.32.[9] However, many of the studies reviewed in the meta-analysis were small and a high degree heterogeneity in outcomes was noted.[9] While this meta-analysis was inconclusive, the authors commented that in a few of the included studies, haemoglobin <8–8.5 g/dl was associated with an increased risk of poor outcome. One study found a linear relation between haemoglobin and the risk of stillbirth in a multi-ethnic population in England.[17] A retrospective cohort study in Scotland found that haemoglobin <10 g% was associated with increased risk of stillbirth.[18] Most recently, a study based on the WHO multi-country survey

including data from 312 281 pregnancies in 29 countries and focusing on maternal mortality, demonstrated that severe anaemia was associated with a two-fold increase in the risk of maternal death.[16]

Because anaemia is a common medical condition affecting pregnancy, especially in low/middle-income countries, understanding the impact that various levels of anaemia have on pregnant women and their newborns is of paramount importance.[2] If anaemia is found to be associated with poor maternal and neonatal outcomes, meaningful interventions that improve the haemoglobin status of anaemic pregnant women could potentially have a large impact on global health. The objective of this investigation is to clarify further the correlation between the severity of maternal anaemia and important maternal, fetal, and neonatal outcomes.

Methods

This prospective cohort registry was conducted as part of the Global Network for Women and Children's Health, which is funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) (NICHD Global Network for Women's and Children's Health Maternal Newborn Health Registry; ClinicalTrials.gov Identifier: NCT01073475). The NICHD Global Network is a partnership between research institutions in low/lower middle-income countries paired with research institutions in the USA. This network's research includes a well-established, ongoing registry that identifies women early in pregnancy and documents maternal and neonatal outcomes until 42 days post-delivery.[10] This registry collects data from clusters, which are defined by geographical areas with approximately 300–500 deliveries per year where the mothers receive their primary prenatal care from specified healthcare facilities. For these study analyses, we used data collected in three Asian site (Nagpur and Belagavi, India, and Thatta, Sindh Province, Pakistan) from women who delivered between January 2012 and December 2016 and whose records contained an antenatal haemoglobin measurement. Women who were 40 years old or older, delivered before 20 weeks, had incomplete data or a haemoglobin level <3.0 g/dl were excluded. Women pregnant with multiple gestations were included.

Our primary exposure was maternal haemoglobin, which was categorised according to the WHO definitions of anaemia for pregnant women: severe (<7 g/dl), moderate (7 to <10 g/dl), mild (≥10–<11 g/dl) or normal (≥11 g/dl). The primary maternal outcome was maternal death. Secondary maternal outcomes included antepartum haemorrhage, postpartum haemorrhage, and caesarean delivery. The primary fetal outcome was stillbirth, and the primary neonatal outcome was neonatal mortality <28 days. Secondary neonatal outcomes include low birthweight (<2500 g), very low birthweight (<1500 g), and mean birthweight. A core outcome set was not chosen as part of the selection of these outcomes. Maternal demographical data reported were age, education, parity, and delivery location. For multiple gestations, the pregnancy was used as the unit of measurement for maternal outcome and anaemia status; however, for fetal outcomes, each baby was evaluated for the outcomes listed and served as the unit of measurement. Preterm birth was defined as birth prior to 37 weeks. Gestational age determination was made by self-reported last menstrual period or ultrasound dating when available. Births were classified as term regardless of gestational age

where the weight of the neonate was in the 99th percentile (site mean) or greater for 36 weeks.

Contingency tables stratified by cluster were used to assess the association between anaemia and categorical demographical variables, with Cochran–Mantel–Haenszel (CMH) tests used to assess evidence of association. For continuous demographical measures, linear models that control for cluster were used to generate point and interval estimates of the differences in mean values as a function of anaemia status. Similar contingency table methods with associated CMH tests were used to assess the association between the four levels of anaemia, as defined above, and the binary neonatal, fetal, and maternal outcomes. Multivariable model-based approaches were used to assess the correlation between anaemia and the outcome measures of interest controlling for potential confounders of age, education, and parity with all analyses controlling for within-cluster correlation by including cluster as a random effect. A linear mixed model was used for the continuous outcome of birthweight, and extensions of generalised linear models with a log link and binomial distribution assumption were used for the remaining binary measures.

Results

From the overall cohort, 180 053 women were screened for eligibility. Of those screened, 138 059 were less than 40 years old and had complete outcome data available. In 45 812 women no haemoglobin information was available and they were therefore excluded. A total of 92 247 deliveries (93 107 infants: 91 418 singletons, 831 twins, and nine triplets) were included in the study (Figure 1).

The mean haemoglobin level for the cohort was 9.9 g/dl with a standard deviation of 1.0 g/dl. The overall prevalence of anaemia (3–11 g/dl) in our cohort was 87.8%. We noted that 0.7% of women had severe anaemia (<7 g/dl), 49.1% moderate anaemia (7–9 g/dl), and 37.9% mild anaemia (9–11 g/dl). Only 12.2% of women presented with a normal haemoglobin level (>11 g/dl). Pakistani women were more likely to have severe or moderate anaemia and less likely to have mild anaemia than were Indian women: Pakistan: severe 7.8%, moderate 48.7%, and mild 20.8% versus India: severe 0.2%, moderate 49.2%, and mild 39.0% ($P < 0.001$). Maternal demographical and clinical characteristics by anaemia status are displayed in Table 1. Aggregate data across all sites indicated that anaemia level was associated with a maternal age of more than 35 years, less education, higher parity, and non-facility births after controlling for geographical clustering. Women with severe anaemia were also less likely to be delivered by caesarean than were women in the remaining groups.

Maternal outcomes by anaemia level are displayed in Table 2. We did not find statistically significant differences in antepartum haemorrhage or maternal death, although women with severe anaemia had a non-significant higher rate of postpartum haemorrhage compared with the remaining cohort. In terms of fetal outcomes, we noted a higher rate of stillbirth in women with severe anaemia ($P < 0.001$). Although there was an overall increase in the rate of stillbirths amongst women with Severe Anemia compared to all other women, we were unable to establish any difference in the distribution between fresh stillbirths (generally a

marker of intrapartum events) and macerated stillbirths (a marker of antepartum events) and the degree of anaemia.

Neonatal outcomes were strongly associated with haemoglobin levels (Table 2). The risk of neonatal mortality at <28 days (primary outcome) was substantially increased in the cohort with severe anaemia. There was also a strong association of an increased risk of low birthweight (<2500 g), very low birthweight (<1500 g), preterm birth, and neonatal mortality at <7 days) with severe anaemia.

Recognising that significant confounding may exist with maternal age, education, parity, and cluster, we chose to examine the impact of the various anaemia categories using multivariable modelling to control for the impact of these variables (Table 3). Using a normal haemoglobin level (≥11 g/dl) as the comparison group, the risks of stillbirth, neonatal death <7 days, neonatal death <28 days, birth-weight, preterm birth, low birthweight (<2500 g), and very low birthweight (<1500 g) were associated with severe anaemia. Moderate anaemia was associated with worse birthweight outcomes (birthweight, preterm birth, birth-weight <2500 g and <1500 g) but the difference did not reach statistical significance with regard to neonatal mortality at 7 or 28 days ($P = 0.07$). No associations with mild anaemia could be detected.

Discussion

Main findings

Our study confirms that anaemia is pervasive among pregnant women South Asia. In particular, women with severe anaemia have worse fetal (stillbirth) and neonatal outcomes (mortality <28 days, preterm birth, low birthweight, and very low birthweight). We were able to document lower birthweights and the rate of preterm birth among women with moderate anaemia but did not find differences in the rate of stillbirth. From a maternal standpoint, we did note a higher rate of postpartum haemorrhage and a lower rate of caesarean delivery in women with severe anaemia. Although the differences in maternal mortality did not reach statistical significance, the mortality rate was highest for women with severe anaemia compared with the remaining groups. Mild anaemia was not associated with any adverse outcomes.

Strengths and limitations

One of the strengths of our study is the size of the cohort and our prospective design. Having such a large cohort increases both the validity and the precision of the associations between anaemia and the poor neonatal and maternal outcomes we studied. Additionally, we characterised anaemia using haemoglobin levels of the established WHO classification system for anaemia in pregnancy, which accounts for physiological changes of pregnancy. For a number of outcomes, we were able not only to establish an association with anaemia but also to demonstrate that the frequency of the outcome increases with the severity of the anaemia (preterm birth, low birthweight, and very low birthweight), suggesting a dose effect.

Limitations of our study include being unable to specify when during pregnancy the haemoglobin was measured or find data on subsequent treatments that may have occurred

following the diagnosis. Likewise, although we demonstrated that preterm birth was associated with moderate and severe anaemia, we note that this was based largely on last menstrual period data, which has limitations. We were likewise able to establish a monotonic correlation between lower haemoglobin levels and birthweight. Birthweight is commonly utilised as a surrogate for preterm birth when dating information is absent or unreliable. Complicating this issue is that anaemia may negatively affect birthweight.

Finally, educational level, maternal age, parity, and access to hospital delivery may also be confounders in our study, as they were also associated with severe anaemia. It is not surprising that less educated older multiparous women who delivered outside of a hospital setting were more likely to have anaemia. Rural women are less likely to have access to a hospital for delivery or for prenatal care, and thus are more likely to have poor outcomes.[11,12] Studies have also shown that multiparous women are more likely to be anaemic,[13,14] as they are more likely to have short inter-pregnancy intervals, and are less likely to use birth control, more likely to breastfeed for extended periods of time without additional food/nutrition intake or supplements, and often last to eat following husbands and children.[15] Although we used multivariable modelling to control for these confounders, it is difficult to determine whether the poor outcomes are due to anaemia alone or to wider socio-economic factors that also contribute to women being anaemic, such as poverty, access to healthcare, and adequate nutrition.

Interpretation

Our study results show a significant association between poor neonatal and fetal outcomes and severe anaemia, and between adverse fetal outcomes and moderate anaemia. From a maternal standpoint, we noted a lower rate of caesarean delivery and higher rates of postpartum haemorrhage in women with severe anaemia. The lower rate of caesarean delivery may be reflective of multiparity among women with severe anaemia. Postpartum haemorrhage is noted to be a clinically assessed measure (estimated blood loss) and is therefore subject to the variations between individual clinicians. It is reasonable to posit that based on the valid concerns of caregivers of severely anaemic women, providers are more likely to over-assess blood loss, resulting in higher rates of postpartum haemorrhage. Although we saw a stochastic (‘dose effect’) correlation between maternal death and degree of anaemia, the correlation was not statistically significant. This may be the result of the relative rarity of this outcome and the size of our cohort. In contrast, Daru and colleagues[16] recently demonstrated a statistically significant correlation between maternal mortality and severe anaemia in a very large cohort of 312 281 women in low/middle-income countries.

Additionally, our demographical data demonstrate that anaemia is associated with a lower education level. If education level is a marker for socio-economic status, then anaemia is likely more prevalent among women with a lower socio-economic standing. Co-morbidities such as tuberculosis, HIV, and malnutrition are also known to be more common in this population, thus anaemia may be a marker for other co-morbidities in pregnancy. Therefore the discovery of anaemia in a pregnant woman may prompt evaluation and testing for other issues which, if untreated, could drastically alter the outcomes of the pregnancy for both the mother and the baby. From a clinical standpoint, our study establishes that poor fetal and

neonatal outcomes occur more frequently in women with severe anaemia. Mothers who were moderately anaemic were more likely to have children with lower birthweights but we were unable to establish any associations of poor outcomes with mild anaemia. As a prospective cohort study we can only determine that these outcomes are associated with moderate and severe anaemia but cannot confirm that they are the clear result of the anaemia. Global health interventions and policies that focus on identification and treatment of women with severe anaemia could potentially result in significant improvements in maternal–child outcomes, but large randomised trials are needed to demonstrate the effectiveness of such a strategy.

Conclusion

The results of our study show a significant association of poor fetal and neonatal outcomes with severe anaemia. This study has the potential to affect future interventions and public health policy. Randomised controlled trials of treatment are needed to determine whether identifying and treating anaemia can impact these important outcomes.

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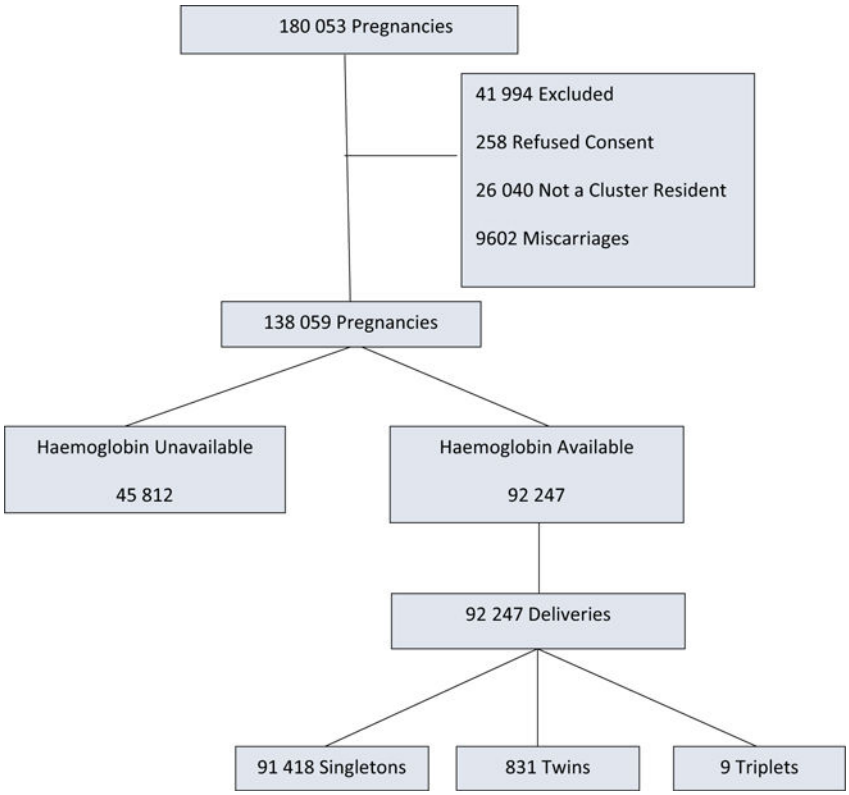

Figure 1.
Consort flow diagram of eligible patients.

Table 1.

Maternal demographical and clinical characteristics by anaemia status

Maternal characteristics	**Maternal haemoglobin, g/dl**				**P-value** *
	Severe <7.0 g/dl	**Moderate 7.0–9.9 g/dl**	**Mild 10.0–10.9 g/dl**	**Normal ≥11.0 g/dl**	
Deliveries, *n* (%)	621 (0.7)	45 334 (49.2)	35 001 (37.9)	11 291 (12.9)	
Maternal age, *n* (%)	621	45 313	34 992	11 289	0.0003
<20	31 (5.0)	2636 (5.8)	2105 (6.0)	791 (7.0)	
20–35	547 (88.1)	42 334 (93.4)	32 720 (93.5)	10 422 (92.3)	
>35	43 (6.9)	343 (0.8)	167 (0.5)	76 (0.7)	
Education, *n* (%)	621	45 283	34 950	11 277	<0.0001
No formal education	438 (70.5)	6986 (15.4)	4036 (11.5)	1677 (14.9)	
Primary	57 (9.2)	7689 (17.0)	5466 (15.6)	1661 (14.7)	
Secondary/University+	126 (20.3)	30 608 (67.6)	25 448 (72.8)	7939 (70.4)	
Parity, *n* (%)	603	45 117	34 837	11 194	<0.0001
0	137 (22.7)	17 761 (39.4)	15 827 (45.4)	5471 (48.9)	
1–2	211 (35.0)	23 669 (52.5)	17 299 (49.7)	4972 (44.4)	
≥3	255 (42.3)	3687 (8.2)	1711 (4.9)	751 (6.7)	
Delivery location, *n* (%)	621	45 313	34 984	11 288	<0.0001
Hospital	265 (42.7)	30 866 (68.1)	25 586 (73.1)	8469 (75.0)	
Clinic	183 (29.5)	12 116 (26.7)	8056 (23.0)	2252 (20.0)	
Home/Other	173 (27.9)	2331 (5.1)	1342 (3.8)	567 (5.0)	
Caesarean, *n* (%)	76 (12.2)	9333 (20.6)	8397 (24.0)	3146 (27.9)	<0.0001

** P*-values based on a Cochran–Mantel–Haenszel test for row mean differences based on standard mid-rank (modridit) scores stratified by maternal and newborn health (MNH) cluster.

Table 2.

Maternal/fetal/neonatal outcomes by anaemia status

Maternal outcomes	**Maternal haemoglobin, g/dl**				***P*-value**
	Severe <7.0 g/dl	**Moderate 7.0–9.9 g/dl**	**Mild 10.0–10.9 g/dl**	**Normal ≥11.0 g/dl**	
Maternal outcomes *					
Deliveries, *n*	621	45 334	35 001	11 291	
Maternal death <42 days (rate/100 000 deliveries)	2 (325)	61 (135)	37 (106)	14 (124)	0.64
Antepartum haemorrhage, *n* (%)	17 (2.7)	397 (0.9)	228 (0.7)	114 (1.0)	0.08
Postpartum haemorrhage, *n* (%)	30 (4.9)	352 (0.8)	217 (0.6)	107 (1.0)	0.02
Fetal outcomes **					
Births, *n*	627	45 778	35 300	11 402	
Stillbirth, *n* (rate/1000)	57 (90.9)	1378 (30.1)	910 (25.8)	316 (27.7)	<0.0001
Macerated, *n* (% of stillbirths)	23 (45.1)	409 (31.2)	257 (29.6)	105 (35.1)	0.65
Fresh, *n* (% of stillbirths)	28 (54.9)	904 (68.8)	611 (70.4)	194 (64.9)	
Neonatal outcomes **					
Preterm, *n* (%)	169 (27.1)	6132 (13.4)	4028 (11.5)	1318 (11.6)	<0.0001
Very low birthweight (<1500 g), *n* (%)	39 (6.3)	1187 (2.6)	729 (2.1)	240 (2.1)	<0.0001
Low birthweight (<2500 g), *n* (%)	193 (31.2)	9526 (20.9)	6274 (17.8)	2034 (17.9)	<0.0001
Neonatal mortality <7 days, *n* (rate/1000)	35 (61.9)	1032 (23.3)	620 (18.1)	227 (20.5)	<0.0001
Neonatal mortality <28 days, *n* (rate/1000)	41 (72.6)	1248 (28.1)	785 (22.9)	273 (24.7)	<0.0001
Measured birthweight within 7 days, *n* (%)	576 (91.9)	45 008 (98.3)	34 819 (98.6)	11 198 (98.2)	
Birthweight, mean (SD)	2606 (557)	2686 (471)	2724 (451)	2756 (475)	<0.0001

***P*-values based on a Cochran–Mantel–Haenszel test for row mean differences based on standard mid-rank (modridit) scores stratified by MNH cluster.

****P*-values based on a Cochran-Mantel-Haenszel test for row mean differences based on standard mid-rank (modridit) scores stratified by MNH cluster for categorical outcomes and a mixed model with haemoglobin category as a fixed effect, and cluster as a random effect for continuous outcomes.

Table 3.

Adjusted risk of maternal/fetal/neonatal and maternal outcomes by anaemia status

Outcomes*	<7.0 g/dl versus ≥11.0 g/dl		7.0–9.9 g/dl versus ≥11 g/dl		10.0–10.9 g/dl versus ≥11.0 g/dl	
	RR/RD (95% CI)	*P* -value	RR/RD (95% CI)	*P* -value	RR/RD (95% CI)	*P*-value
Maternal deaths <42 days	1.70 (0.43, 6.65)	0.45	1.11 (0.65, 1.91)	0.70	0.89 (0.50, 1.60)	0.71
Preterm	1.57 (1.34, 1.84)	<0.0001	1.17 (1.09, 1.25)	<0.0001	1.04 (0.97, 1.11)	0.25
Stillbirth	2.32 (1.75, 3.07)	<0.0001	1.09 (0.98, 1.21)	0.11	0.97 (0.86, 1.09)	0.61
Neonatal mortality <7 days	2.31 (1.53, 3.47)	<0.0001	1.17 (0.99, 1.38)	0.07	0.93 (0.79, 1.09)	0.38
Neonatal mortality <28 days	2.16 (1.45, 3.22)	0.0002	1.16 (0.99, 1.37)	0.07	0.98 (0.84, 1.13)	0.75
Birthweight	–159.5 (–199.4, –119.7)	<0.0001	–62.9 (–72.9, –52.9)	<0.0001	–24.1 (–34.2, –14.0)	<.0001
Very low birthweight (<1500 g)	2.85 (2.07, 3.91)	<0.0001	1.31 (1.14, 1.52)	0.0002	1.05 (0.91, 1.21)	0.51
Low birthweight (<2500 g)	1.54 (1.34, 1.77)	<0.0001	1.17 (1.11, 1.23)	<0.0001	1.03 (0.99, 1.08)	0.17