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Increased neonatal mortality among normal-weight births beyond 41 weeks of gestation in California

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OBJECTIVE: The purpose of this study was to examine whether postterm gestational age increases the risk of neonatal mortality.

STUDY DESIGN: We retrieved data from 1,815,811 liveborn infants in California from 1999 to 2003. We excluded multiple births and congenital anomalies, as well as infants with a gestational age of less than 38w0d, or greater than 42w6d, weeks. We used multivariable logistic regression models to adjust for demographic variables thought to confound the association.

RESULTS: Compared to infants born at 38, 39, or 40 weeks, those born at 41w0d to 42w6d have a greater odds of neonatal mortality (aOR: 1.34, 95% CI, 1.08-1.65). Subdividing by gestational week, infants delivered at 41w0d to 41w6d showed elevated mortality relative to earlier term births (aOR: 1.37, 95% CI, 1.08-1.73). Additional analyses support this increased neonatal mortality across all normal birthweight categories.

CONCLUSION: Infants born beyond 41w0d of gestation experience greater neonatal mortality relative to term infants born between 38w0d and 40w6d.

Key words: neonatal mortality, placental insufficiency, postterm

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It is widely accepted that pregnancies which progress beyond 42 weeks' gestation, known as postterm pregnancies, are associated with increased perinatal morbidity and mortality.[1-4] Based on this evidence, the American College of Obstetricians and Gynecologists has recommended antenatal fetal surveillance or induction of labor for women beyond 42 completed weeks (ie, 42w0d, or 294 days).[5] This seems somewhat conservative given the existing literature regarding perinatal outcomes prior to 42w0d and antenatal testing prior to 42w0d. Numerous studies find increased pregnancy complications[6-8] and stillbirths[3,9] associated with gestational ages of 41 completed weeks (ie, 41w0d) and even earlier. Additionally, one study found a reduced rate of stillbirths and fetal distress during labor among patients who initiated antenatal testing at 41w0d, as compared with a control population that began testing at 42w0d.[10] As a result, clinicians have sought testing strategies that begin at an earlier gestational age for postdates testing.

Based on these findings, some authors have questioned this designated threshold.[11] One concern is that if clinicians intervene earlier in pregnancy with induction of labor that they may further increase cesarean delivery rates. However, a recent meta-analysis reported that induction of labor at 41w0d in uncomplicated singleton pregnancies likely decreases fetal and neonatal complications and is associated with a reduced risk of cesarean delivery.[12] In light of these reports, clinicians must face the question: at what gestational age does the benefit of induction of labor outweigh that of expectant management?

Whereas previous studies report elevated intrauterine fetal demise among infants born beyond 41w0d, one area in which the literature does not converge involves neonatal mortality. Although rare, neonatal mortality represents one unambiguous pregnancy complication in which the causative role, if any, of advancing gestational age at 41w0d and beyond is not well understood. Population-based findings on neonatal mortality[3,9,13] remain inconclusive for several reasons. First, the studies appear to have inadequate statistical power to detect modest increases in the risk of neonatal mortality. Second, studies have included infants with intrauterine growth restriction (IUGR) and/or macrosomia; consequently, they cannot shed light on whether normal-weight, low-risk infants bear elevated neonatal mortality. Third, the studies examine births in the late 1980s and early 1990s. Ad-

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TABLE 1

Characteristics of normal weight, term births in California, 1999-2003 (N = 1,815,811)

	N	%	Neonatal deaths per 10,000 live births
Gestational age			
38w0d to 38w6d	430,004	23.68	2.46
39w0d to 39w6d	589,245	32.45	2.70
40w0d to 40w6d	485,004	26.71	2.54
41w0d to 41w6d	232,325	12.79	3.66
42w0d to 42w6d	79,233	4.36	3.28
Infant sex			
Male	914,500	50.36	2.95
Female	901,306	49.64	2.54
Maternal race/ethnicity			
White	592,445	32.63	3.27
Black	98,856	5.44	4.45
Hispanic	885,946	48.79	2.30
Asian/Pacific Islander	185,723	10.23	2.14
Other	52,841	2.91	2.25
Maternal age			
< 18 years	60,018	3.31	3.17
18-34 years	1,469,788	80.94	2.67
≥ 35 years	285,918	15.75	3.04
Maternal education (%)			
< High school	508,271	28.42	3.09
High school graduate	505,373	28.26	2.53
> High school	774,626	42.66	2.57
Parity			
1st birth	731,667	40.30	3.17
2nd to 5th birth	1,069,576	58.90	2.43
6th or later birth	14,568	0.80	4.12
Health insurance			
Public/MediCAL	816,600	44.97	3.00
Private/HMO	996,039	54.85	2.54

Column totals may not sum to 100% due to missing data and rounding.

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vances over time in the accuracy of pregnancy dating[14,15] may limit the external validity of their results to contemporary births in the US.

In the current study, we addressed these limitations and examine whether infants born at 41w0d to 42w6d experience increased neonatal mortality relative to other term infants. Particularly, we focus on infants with a normal birthweight.

MATERIALS AND METHODS

The California Department of Health Services (CDHS) maintains a birth cohort file that links death records (including out-of-state deaths of California-born infants) to the corresponding birth certificates for all infants born in California or to California residents during a given calendar year. We acquired these data for the years spanning from 1999 to 2003. The Institutional Review Boards (IRB) of the California Department of Health Services, the University of California at Berkeley, School of Public Health, and the University of California, San Francisco approved the study. We used deidentified, publicly available vital statistics data; therefore, informed consent was not required. Definitions of neonatal mortality were consistently used during the time period of this study and include the last year of data available (ie, 2003) at the time of the tests. The reporting of births and infant deaths in California is believed to be nearly 100% complete.[16] CDHS codes the data according to uniform specifications, performs rigorous statistical quality checks, carefully reviews and edits the birth cohort file.

We classified a neonatal death as a death that occurs less than 28 days of delivering a live birth as indicated on the birth cohort file. We, therefore, excluded stillbirths from the analysis. In addition, we excluded births with congenital anomalies (based on the International Statistical Classification of Diseases and Related Health Problems, revision 10 [ICD-10] codes Q00-Q99) and multiple births from the analysis.

CDHS uses last menstrual period date (LMP) on the birth certificate to estimate gestational age of the infant. The data do not contain information on ultrasound and/or clinical estimate of gestational age. Much clinical and epidemiological research finds that, relative to ultrasound measurement and/or clinical judgment, LMP offers a suboptimal estimate of gestational age.[14,15,17] LMP data appear subject to inaccurate recall, as well as digit preference, due to the assumption of conception 14 days after the first day of menstrual bleeding. A recent study using California birth certificate data finds that, compared to ultrasound estimates as the "gold standard," LMP dating leads to a greater postterm (ie, 42w0d and beyond) birth rate.[17,18] This work implies that our CDHS data may shift classification of some term births to the postterm category.

We addressed this issue of misclassification in 3 ways. First, we restricted our analysis to normal weight births with plausible estimates of gestational age, as described by Alexander and colleagues.[19] Second, we excluded all births of greater than 42w6d, as pregnancies rarely progress to 43 completed weeks of gestation without provider intervention, thus they most likely represent a coding error. Third, our statistical methods adjust for the sociodemographic characteristics of mothers that the literature indicates predispose their infants to gestational age misclassification.[15] Inclusion of these covariates in our analysis controls for potential confounding due to misclassification of high-risk, term infants as postterm.

We first examined the crude associations between neonatal mortality and several sociodemographic variables. Next, we performed multivariable logistic regression analysis (SAS 9.0; SAS Institute, Cary, N.C.) to test the effect of late gestational age on neonatal mortality among those born at 41w0d to 42w6d relative to infants born from 38w0d to 40w6d. We classified infants born at 41w0d to 42w6d into one group since the risk of pregnancy complications and stillbirths increases beginning at 41 weeks' gestation and beyond.[3,9] Our analysis controls for variables that the literature suggests may confound the hypothesized association, including those that may lead to selective misclassification of gestational age (eg, infant sex, maternal age, parity, and maternal race/ethnicity). We present results as adjusted odds ratios (aOR); in this analysis, the odds ratio approximates the relative risk of neonatal mortality.

RESULTS

Of all live births in California over the test period (n = 2,667,938), we excluded from the analysis congenital anomalies (n = 5255) and multiple births (n = 76,587). Next, we removed infants with a gestational age of less than 38w0d (n = 464,268) or greater than 42w6d (n = 241,905). We then excluded infants weighing less than 2500 g (n = 29,987) or greater than 4500 g (n = 34,225). These restrictions yielded a study population of 1,815,811 normal weight term births.

TABLE 2

Adjusted odds ratios for a neonatal death among normal weight, term infants, California, 1999-2003

Characteristic	Odds ratio (95% CI)	*P* value
41w0d to 42w6d of gestation	1.34 (1.08-1.65)	.007
38w0d to 40w6d of gestation	1.0 —	—
Infant sex		
Male (vs female)	1.16 (0.98-1.39)	.09
Maternal race		
White	1.0 —	—
Black	1.23 (0.88-1.72)	.22
Hispanic	0.60 (0.47-0.75)	< .0001
Asian	0.66 (0.28-1.57)	.34
Other	1.00 (0.43-2.30)	.99
Maternal age		
< 18 years	0.95 (0.58-1.53)	.82
18-34 years	1.0 —	—
≥ 35 years	1.24 (0.97-1.59)	.08
Education		
< High school	1.01 (0.77-1.32)	.93
High school	1.0 —	—
> High school	0.80 (0.65-1.00)	.05
Parity		
1st birth	1.31 (1.09-1.58)	.004
2nd-5th birth	1.0 —	—
6th or later birth	1.33 (0.58-3.02)	.50
Health insurance		
Public/MediCAL	1.29 (1.04-1.58)	.02
Private/HMO	1.0 —	—

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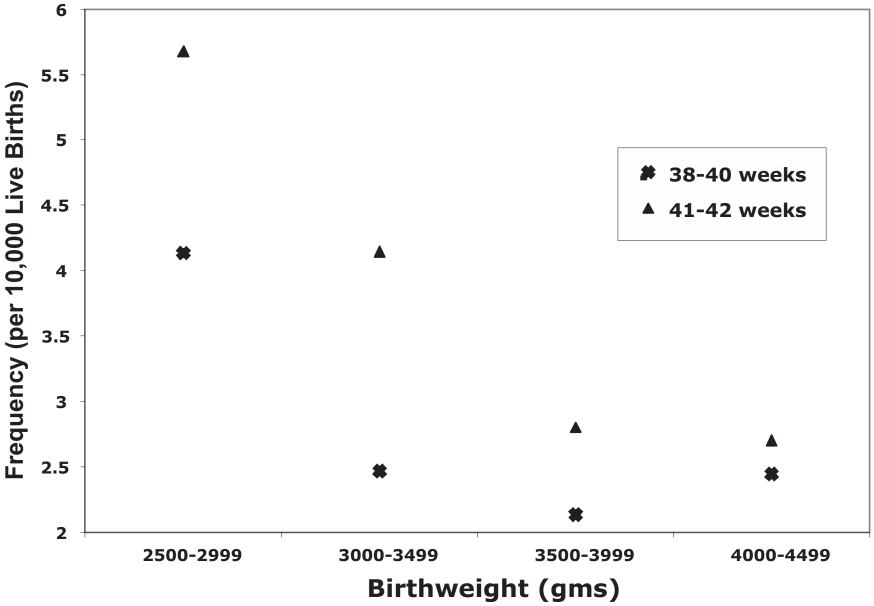
Table 1 shows the demographic characteristics of these births. Hispanic mothers account for almost half of all births. Over half of all mothers reported a private source of health insurance, and 80% of births occurred to mothers 18 to 34 years of age. The distribution of maternal characteristics varies across gestational age. Nulliparous mothers, for instance, account for 33% of births delivered at 38 completed weeks, whereas they comprise 48% of births delivered at 41 completed weeks (Appendix).

Among normal-weight, term births, CDHS registered 499 neonatal deaths, for an overall rate of 2.75 deaths per 10,000 live births. Neonatal mortality appears highest at 41w0d to 41w6d. Consistent with previous reports, bivariate results indicate that males experience greater neonatal mortality relative to females. Asian/Pacific Islanders exhibit the lowest, whereas blacks exhibit the highest, race/ethnic-specific neonatal mortality (Table 1). Table 2 displays the multivariate logistic regression results. Infants born at 41w0d to 42w6d of gestation appear at increased risk of neonatal mortality as compared with those born at 38w0d to 40w6d of gestation

FIGURE 1

For each weight group, births at 41 or 42 weeks exhibit elevated neonatal mortality, although the gap lessens with increasing birthweight



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(aOR: 1.34; 95% confidence interval [CI], 1.08-1.65). Of note, gestational age of 41w0d to 42w6d confers a greater neonatal mortality risk than any other variable included in the analysis.

We tested whether our results remained robust to alternative referent group specification. We restricted the referent group to infants at 40w0d to 40w6d of gestation (rather than 38w0d to 40w6d) and reestimated the logistic regression equation. Results remained essentially unchanged in that infants born at 41w0d to 42w6d show a 1.37-fold increased odds of neonatal mortality (95% CI, 1.06-1.77). We also tested whether our findings changed with the addition of macrosomic (ie, > 4500 g) infants by including this group in the multivariate analysis. The aOR differed slightly from that of the original test (aOR: 1.32; 95% CI, 1.08-1.63) and remained statistically significant.

Next, we examined the risk of neonatal mortality separately for those born at 41w0d to 41w6d and 42w0d to 42w6d relative to the 38w0d to 40w6d group. Adjusted logistic regression results show elevated neonatal mortality for both infants at 41w0d to 41w6d and 42w0d to 42w6d. However, the odds ratio for the 42w0d to 42w6d infants does not reach statistical significance (aOR for 41w0d to 41w6d: 1.37, 95% CI, 1.08-1.73; aOR for 42w0d to 42w6d: 1.24, 95% CI, 0.83-1.84).

Figure 1 plots the neonatal deaths per 10,000 live births for the 38w0d to 40w6d vs 41w0d to 42w6d gestation categories across 500 g birthweight groups. For each weight group, births at 41w0d to 42w6d exhibit elevated neonatal mortality, though the gap lessens with increasing birthweight.

Comment

Analysis of over 1.8 million normal weight live births in California from 1999 to 2003 indicates that infants delivered at 41w0d to 42w6d of gestation have increased neonatal mortality relative to those delivered at 38w0d to 40w6d. The elevated mortality in these births at 41w0d to 42w6d of gestation, moreover, persisted across the entire range of normal birthweights.

Strengths of our analysis include its population-based nature in that, among California mothers, we examined all recorded, normal weight births from 38w0d to 42w6d of gestation. California, moreover, consists of an ethnically diverse population, which, as compared with studies from Scandinavia,[9,13] may make our findings more generalizable to gravid women in the United States. In addition, unlike previous work,[3,9] the large number of births in our test period confers sufficient analytic power to detect modest differences in neonatal mortality by gestational age. We also restricted the study to normal weight infants, thereby minimizing the possibility that severe IUGR or macrosomia specifically account for the discovered associations. Furthermore, our logistic regression methods control for sociodemographic variables that may confound the association between postterm delivery and neonatal mortality.

The principal limitation of our study involves the reliance on LMP dating on the birth certificate to assess gestational age at delivery. Recent research of US live births reports that, as compared with the "gold standard" of ultrasound dating, LMP dating generally overestimates the "true" proportion of infants greater than or equal to 42w0d of gestation. By using LMP dating, we risk misclassifying "true" term infants as postterm infants. This error would make term (ie, 38, 39, and 40 weeks) and postterm (41 and 42 weeks) infants more similar with respect to neonatal mortality risk, or bias findings towards the null.[6,13] As it relates to our principal findings, LMP dating may underestimate the "true" increased risk of late term gestational age on neonatal mortality.

We also performed a sensitivity analysis (Appendix) which found that, to render our findings nonsignificant, misclassification of "true" term infants as postterm infants would have to occur in more than 50% of the deaths misplaced in the 41w0d to 42w6d category. In addition, the misclassified subjects would have to retain the mortality risk of infants born at 41w0d to 42w6d when they were in fact delivered at 38w0d to 40w6d. Moreover, statistical inference would not change with lower levels of misclassification (eg, a shift of 10% to 20% of deaths).

We analyzed neonatal mortality before and after the 41w0d threshold based on a priori considerations and earlier reports that find elevated intrauterine fetal demise and perinatal complications after 41w0d. Researchers may prefer to explore whether neonatal mortality increases with gestational age in a continuous, rather than a threshold, fashion. Such an exploration could classify neonatal mortality by ½ week of gestation.

However, given the limitations of LMP dating in our data and the welcomed rarity of neonatal death by ½ week of gestation, we did not perform such a test. A continuous analysis would have insufficient power to detect subtle differences in neonatal mortality; this test may also include substantial error in gestational age measurement. These limitations may make continuous findings difficult to interpret.

We caution that clinicians should not use our discovered effects to estimate overall perinatal mortality attributable to prolonged gestations. Our analyses did not examine intrauterine fetal demise or postneonatal mortality. Moreover, we did not focus on infants previously shown to exhibit increased perinatal mortality (eg, IUGR or macrosomic infants). Rather, our results pertain to the excess neonatal mortality risk of the overwhelming majority (ie, 93%) of all deliveries at 38 completed weeks and beyond.

Contrary to our expectation, we found that the increased neonatal mortality seen at 41 weeks of gestation did not further increase at 42 weeks of gestation. We offer 2 post hoc explanations. First, gestational age misclassification, as documented by Pearl and colleagues,[17] may be especially high for 42w0d to 42w6d births and could bias the results towards the null. Second, only 26 neonatal deaths occurred in this group, thereby leading to imprecise confidence intervals in our multivariate regression analysis.

We await large population-based studies with ultrasound-based measurements to arrive at more precise estimates of the effect of late term gestational age on neonatal mortality. Beginning in 2007, the California Birth Certificate includes ultrasound-based estimates of gestational age. These data, as well as its linked cohort infant mortality file, should be available to researchers by late 2009.

We view our results as informing the debate regarding at what gestational age clinicians should consider offering induction of labor or antepartum surveillance to women with term pregnancies. Our findings add to the growing literature that reports an elevated risk of adverse birth outcomes among infants at 41w0d of gestation and beyond.[6-8] Results also generally agree with previous studies on neonatal mortality. In a population-based analysis of Swedish births, Divon et al's gestational age point estimates of neonatal mortality among non-IUGR infants, although not statistically significant at $P < .05$, appear similar to ours.[9] In an analysis of births in London, Hilder et al also found elevated perinatal mortality with prolonged pregnancy after 37w0d of gestation.[3] Unlike our work, however, the researchers did not restrict their analysis to normal weight births, did not evaluate neonatal mortality exclusively, and did not control for sociodemographic variables that might confound the associations.

When confronted with management of pregnant women whose gestations progress beyond their date of confinement, clinicians attempt to minimize maternal and neonatal complications. Clinicians may opt for labor induction over expectant management if research finds that the health benefits outweigh the risks. A randomized trial by Hannah et al,[20] as well as improvements in induction methods, suggest that labor induction at gestational ages of 41 completed weeks may lead to a lower rate of cesarean delivery. This circumstance, combined with the reports alluded to above, may compel obstetricians to proceed with antenatal fetal testing and labor induction at gestational ages earlier than the currently recommended threshold of 42 completed weeks. ■

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APPENDIX
SENSITIVITY ANALYSIS OF GESTATIONAL AGE MISCLASSIFICATION

To address in more detail the role of gestational age misclassification as a source of bias in our study, we conducted a sensitivity analysis to determine whether statistical inference changes with the shifting of neonatal deaths from 41w0d to 42w6d to the 38w0d to 40w6d category. We first assumed that the misclassification of 38w0d to 40w6d infants as 41w0d to 42w6d infants occurs independently of neonatal mortality risk (i.e., non-differential misclassification). This notion appears consistent with findings from Pearl and colleagues that assesses LMP dating in California births.[17]

In our observed data, a crude 2 by 2 table appears as follows:

	neonatal death	non-death
41w0d to 42w6d	111	311,447
38w0d to 40w6d	388	1,503,865

OR: 1.38 (1.11-1.70), $P = .0035$

This crude OR for neonatal mortality appears quite similar to our discovered aOR (1.34) in the multivariable regression, which indicates little to no confounding by individual-level variables (e.g., race/ethnicity, maternal age). We therefore proceed with a 2 by 2 table analysis of misclassification.

In the sensitivity analysis, we assumed that 50% of all neonatal deaths in the 41w0d to 42w6d group were misclassified. We shifted these subjects to the 38w0d to 40w6d group, assuming that they exhibited the neonatal mortality risk of the 38w0d to 40w6d infants (i.e., 2.58 deaths per 10,000 live births). The results appear below:

	neonatal death	non-death
41w0d to 42w6d	56	98,186
38w0d to 40w6d	443	1,717,569

OR: 2.21 (1.67-2.92), $P < .0001$

Consistent with the Discussion from the original manuscript, this correction would result in a stronger effect than what we actually reported.

Next, we assumed that 50% of all neonatal deaths in the 41w0d to 42w6d group were misclassified, but now shifted these subjects to the 38w0d to 40w6d group, assuming that they *exhibited the neonatal mortality risk of the 41w0d to 42w6d infants (i.e., 3.56 deaths per 10,000 live births)*. Results appear below:

	neonatal death	non-death
41w0d to 42w6d	56	156,953
38w0d to 40w6d	443	1,658,359

OR: 1.34 (1.01-1.76), $P = .046$

This result implies that, to render our results non-significant, over 50% of deaths in the 41w0d to 42w6d group would have to be misclassified, *and these misclassified subjects would have to exhibit the risk of mortality of the* 41w0d to 42w6d *infants when they are truly* 38w0d to 40w6d *infants.* Based on our review of the literature concerned with LMP dating, we do not believe that such a circumstance pertains to our data. Moreover, this simulation suggests that more modest misclassification (e.g., shift of 10 to 20% of deaths) would not render our original findings non-significant.

TABLE

Percentage distribution of sociodemographic characteristics, by gestational age, of normal weight term births in California (N=1,815,811)

	Gestational Age (Completed Weeks)					
Characteristic	**38**	**39**	**40**	**41**	**42**	***P* value**[a]
Infant Sex						$< .0001$
Male	52.6	50.5	49.2	48.7	49.1	
Female	47.4	49.5	50.8	51.3	50.9	
Maternal Race/Ethnicity						$< .0001$
White	31.6	32.1	33.4	34.5	32.5	
Black	5.5	5.3	5.4	5.6	5.8	
Hispanic	48.6	48.9	48.7	48.6	50.3	
Asian / Pacific Islander	13.1	12.5	11.2	9.9	9.8	
Other	13.7	13.1	11.9	10.6	10.7	
Maternal Age						$< .0001$
$<$ 18 years	2.9	3.1	3.6	3.8	4.1	
18-34 years	78.7	80.5	82.0	83.1	83.5	
$\geq$ 35 years	18.4	16.4	14.4	13.1	12.4	
Maternal Education						$< .0001$
$<$ High School	27.6	27.8	27.9	28.5	30.4	
High School Graduate	28.1	27.9	28.2	28.9	30.2	
$>$ High School	44.3	44.3	43.9	42.6	39.4	
Parity						$< .0001$
1st birth	33.9	38.1	44.5	48.0	42.8	
2nd to 5th birth	65.2	61.1	54.8	51.2	56.3	
6th or later birth	0.9	0.8	0.7	0.8	0.9	
Health insurance						$< .0001$
Public / MediCAL	44.1	44.2	45.2	46.6	48.9	
Private / HMO	55.7	55.6	54.6	53.3	50.9	

Note: column totals may not sum to 100% due to missing data and rounding

[a] Determined by Pearson χ^2

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