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The comparison of gestational dating methods and implications for exposure-outcome associations: an example with PM_{2.5} and preterm birth

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Abstract

Objectives: Estimating gestational age is usually based on date of last menstrual period (LMP) or clinical estimation (CE); both approaches introduce potential bias. Differences in methods of estimation may lead to misclassification and inconsistencies in risk estimates, particularly if exposure assignment is also gestation-dependent. This paper examines a “what-if” scenario in which alternative methods are used and attempts to elucidate how method choice affects observed results. Methods: We constructed two 20-week gestational age cohorts of pregnancies between 2000–2005 (NJ, PA, OH) using live birth certificates: one defined preterm birth (PTB) status using CE and one using LMP. Within these, we estimated risk for 4 categories of preterm birth (PTBs per 10⁶ pregnancies) and risk differences (RD (95% confidence intervals)) associated with exposure to particulate matter (PM_{2.5}). Results: More births were classified preterm using LMP (16%) compared with CE (8%). RD divergences increased between cohorts as exposure period approached delivery. Among births between 28–31 weeks, week 7 PM_{2.5} exposure conveyed RDs of 44(21, 67) for CE and 50(18, 82) for LMP populations; while week 24 exposure conveyed RDs of 33(11, 56) and –20(–50, 10), respectively. Conclusions: Different results from analyses restricted to births with both CE and LMP are likely due to differences in dating methods rather than selection issues. Results are sensitive to choice of gestational age estimation, though degree of sensitivity can vary by the exposure timing. When both outcome and exposure depend on estimate of gestational age, awareness of nuances in method used for estimation is critical.

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Contributorship Statement

KMR conceived of and designed the study and statistical analysis plan with substantial input from DTL, LCM, CP, and JLD. KMR acquired, cleaned, linked, and analyzed data, and drafted and revised the manuscript. DTL acquired data, assisted with data interpretation, and revised the manuscript. LCM, CP, and JLD assisted with data interpretation, and revised the manuscript. JLD supervised study design and statistical analysis plan. KMR is guarantor.

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None declared.

Keywords

gestational dating; environmental exposure; particulate matter; preterm birth

INTRODUCTION

In research examining pregnancy-based outcomes and exposures, the estimation of gestational age (GA) is a critical step. This estimation is usually based on date of last menstrual period (LMP) or a clinical estimate of gestation (CE). There are benefits and detriments to either choice. LMP is simple, low cost, has a standard definition, and is widely available. However, LMP may be inaccurate for a number of reasons: it may be differential based on length of time required for recall or by education level, it shows digit preference, does not capture menstrual irregularities, light bleeding or spotting during early pregnancy which may be mistaken for a period, and produces a bimodal distribution in birth weights [1–6]. CE is a mixture of ultrasound dating and neonatal dating, typically based on Ballard scoring [3 7 8]; CE is not reliant on maternal recall, is unaffected by menstrual irregularities, and produces a single mode in birthweight distribution for births classified as preterm [1 5]. However, as CE is not a single method it may be inaccurate in ways that are difficult to predict. Ballard scoring, an evaluation of neuromuscular and physical maturation, is performed within 96 hours of birth by an attending physician. This method is “valid and accurate” but relies on typical maturation and tends to overestimate gestational age by 2 to 4 days for preterm births [8]. Ultrasounds are given as standard care during 1st trimester prenatal care visits and are the most accurate method of gestational dating [9]. As rates of prenatal care initiated in the 1st trimester have increased steadily since the 1990s [10], CE are often based primarily on ultrasounds and therefore generally accurate. Even through 20 weeks of completed gestation, ultrasounds are considered accurate as there is limited variability in fetal growth during this period [11]. However, many women, ~16% in 2011, either do not initiate prenatal care until the third trimester or never, and so do not get an ultrasound for dating purposes [10]; utilization of prenatal care and ultrasounds also differs by education, and accuracy of ultrasounds may differ by race/ethnicity [3 7 10]. Finally, ultrasounds have no way to detect if a fetus is unusually large or physically advanced for their actual gestational age [11].

In studies of environmental exposures during pregnancy, gestational dating may affect exposure assignment and method differences may lead to differences in risk estimates. It is important to understand how the method of gestational dating used in analyses may affect estimated associations. In this analysis, we expanded upon a previous work, that examined PM_{2.5}-preterm birth (PTB) associations for live singleton births during 2000–2005 across three states (Pennsylvania (PA), Ohio (OH), and New Jersey (NJ)) [12], by examining differences in associations when using alternate methods of GA dating.

METHODS

We constructed two analytic populations based on different availability of LMP or CE data in birth records. In one population, we assigned gestational age based on CE and in the

other, gestational age was based on self-reported LMP. In the CE method, the GA reported on birth certificates was used, and estimated LMP (for purposes of exposure assignment) was calculated by subtracting the CE from the date of birth. In the LMP method, reported LMP was used and GA was calculated by subtracting LMP from date of birth. Both analytic populations were constructed from all live birth records provided by the State Health Departments of PA, NJ, and OH for the years 2000–2005, described in detail in Rappazzo et al. (2014) [12]. As in the previous analyses [12], the populations were restricted to singleton pregnancies with no recorded birth defects and with geocodeable addresses. Included births were required to have achieved gestational week 20 no earlier than 1 January 2000 and gestational week 45 no later than 31 December 2005, which ensured each pregnancy was entirely observable within the study period, and to avoid fixed-cohort bias. Pregnancies missing information on covariates were also excluded (maternal race/ethnicity, maternal education, marital status, and maternal age at delivery).

From all birth records ($n=2,495,350$) these restrictions led to analytic populations of 1,781,527 pregnancies for the CE method, and of 1,592,478 for the LMP method. Note that these analytic populations, women are overlapping, but not identical; e.g., women in the CE analytic population may also have had a recorded LMP, but dating for the CE cohort was based solely on the CE. Inclusion of women based on CE was similar across the three states (proportion of women in CE analytic population compared to initial birth records: NJ = 78%, OH = 76%, and PA = 79%), though LMP-based inclusion varied (NJ = 76%, OH = 68%, and PA = 66%). To further examine any differences in results, we also performed an analysis using only women who had both a LMP and a CE ($n=1,588,595$). This analysis allowed us to consider whether observed differences may be due to population selection (i.e., women with just one or the other dating method may be different, which could shift effect estimates) or whether observed differences may be due to differences in the dating methods and their influence on exposure and outcome assignment.

For the outcome, PTBs were divided into four categories based on definitions from the World Health Organization [13]: extremely PTB (ExPTB) 20–27 completed gestation weeks; very PTB (VPTB) 28–31 completed gestation weeks; moderate PTB (MPTB) 32–34 completed gestation weeks; and late PTB (LPTB) 35–36 completed gestational weeks. Term births were between 37–45 completed gestational weeks.

Exposure to air pollution was assigned based on a monitor-corrected Community Multiscale Air Quality Model estimate of $PM_{2.5}$ exposure during pregnancy, as detailed in Rappazzo et al., (2014) [12]. Model development is detailed in Hogrefe et al., (2009) [14]. Exposures were assigned daily from LMP (estimated based on CE or reported as LMP) to the birth date, then averaged to weekly concentrations for each week of gestation.

Risk differences (RD) and 95% confidence intervals (CI) for each PTB category were estimated for a $1\mu g/m^3$ increase in $PM_{2.5}$ using linear risk regression models, and were adjusted for: maternal race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, other) education (<8th grade, some high school, high school diploma, some college, bachelor's degree, graduate school), marital status, and maternal age at delivery (3-knot restricted quadratic spline). We used an at-risk approach in our models: all births that could

have experienced birth during the weeks of interest were included in the model. For example, VPTBs were included in ExPTB models as non-events, but ExPTBs were not included in VPTB models. RD measures were used in this study as a continuation of previous work, and because we believe they are informative for public health impact and decision making, and outcome severity. Effect measure modifiers were not considered in this study, as previous work showed no evidence for modification by infant sex, maternal parity, race/ethnicity, smoking status, state or region of birth, and census tract population density [12]. All analyses were performed using SAS version 9.3 (SAS Institute, Inc. Cary, NC).

This research was approved by the University of North Carolina at Chapel Hill's Office of Human Research Ethics, the Pennsylvania Department of Health Bureau of Health Statistics and Research, New Jersey Department of Health and Senior Services Institutional Review Board, and the Ohio Department of Health Human Subjects Institutional Review Board. Informed consent was not required for this study as it was a secondary data analysis of existing data and no participant contact was attempted.

RESULTS

More births were classified as preterm in the LMP population (16%) than in the CE population (8%), distributions of covariates between the two populations were similar based on visual inspection and 95% CI, which almost completely overlapped (Table 1). Distribution of prenatal care initiation did vary somewhat, with the CE population missing more information (5.74% for CE, 3.40% for LMP, varying by outcome classification). Of the women not missing prenatal care information approximately 90% initiated care before the fifth month of pregnancy; note that due to birth certificate changes in 2003, PA prenatal care initiation for 2003–2005 births is estimated based on gestational age. The largest difference in gestational age category between the two populations appeared in post-term (< 43 weeks of completed gestation), with 992 births (0.06%) classified as post-term with the CE method and 57,114 births (3.6%) classified as post-term with the LMP method. For exposure, PM_{2.5} distributions were slightly lower in the LMP population (~1µg/m³) than the CE population (Table 2).

For the population restricted to women with both an LMP and a CE, loss of subjects from the initial analytic population was limited based on the LMP measure, (n = 3,883 births, <0.5%), but fairly substantial based on the CE measure (n = 192,932, >10%) (i.e., almost all women who had an LMP also had a CE, while the reverse was not the case). Covariate distributions were similar across all analytic populations (Supplemental materials eTable 2), and also among women with a CE but not LMP (data not shown). Preterm birth distributions in the restricted populations were similar to the distributions among the non-restricted populations. Distributions of PTB category differed substantially between the two methods (Table 3), with the Spearman correlation coefficient between PTB categories at 0.52.

Differences in RDs (PTBs per 10⁶ pregnancies) between the two populations arise both by exposure window and by age of PTB grouping (Figure 1, Supporting materials etable 1). Exposures in the later weeks of gestation appear to have the greatest divergence; though there is some variation, divergence primarily occurs in exposures after week 20. For

example, the RD [95% confidence interval] for VPTB with exposure at week 7 was 45.6 [22.5, 68.7] for the CE cohort and 44 [12.4, 75.7] for the LMP cohort, while with exposure at week 24 RDs were 33.4 [11.3, 55.6] for the CE cohort and -20 [-50, 10.3] for the LMP cohort. RDs also diverge with outcome classification of PTB, with differences appearing to increase with later gestational age outcomes. ExPTB, VPTB, and MPTB show mostly similar associations, except in later weeks (e.g., after week 20 in VPTB, after week 23 in MPTB) of exposure; whereas associations for the LPTB outcome are rarely in agreement between the two populations. For example, for exposures in gestational week 24 were: for VPTB, LMP -20 [-50, 10.3] and CE 35.9 [13.7, 58]; for MPTB, LMP -69 [-125, -13] and CE 9.8 [-23, 43.1]; and for LPTB, LMP -30 [-129, 70.2]; CE 81.7 [16, 147.4]. When they diverge, RDs for the two populations are often in opposite directions, with RDs for the LMP analytic population being negative and RDs for the CE analytic population being positive. Results for the populations restricted to women with both a LMP and CE, revealed patterns similar to those produced when all women were included for each gestational age dating method (Figure 2, supplemental materials eTable 1). RDs using the LMP cohort did not change between full and restricted analyses, while RDs using the CE cohort did shift somewhat, though not in any particular direction and not enough to change general patterns of association or interpretation of results.

DISCUSSION

In this analysis, we expanded upon previous work examining differences in PM_{2.5}-PTB associations by using alternate methods of GA dating to create analytic cohorts. We found differences in associations by GA dating method based on both exposure window and outcome classification. For exposure, RDs with early exposure windows were more likely to be null when the LMP method was used, while RDs with later exposure windows were more likely to be negative when the LMP method was used. For outcome classification, RDs were most divergent across the two gestational dating methods for PTBs classified as LPTB, occurring between 35–36 weeks of GA.

The results arising from analyses based on the two dating methods may differ for two primary reasons. First, if the method used for dating gestational age resulted in different samples of women depending on the dating method, then differences may be due to covariate differences in the two samples. Because the results between the main analyses that included all births with data available for a given method were similar to those for analyses restricted to only births with data available for both gestational dating methods. We did not see such differences, as results in the inclusive versus restricted analyses were the same. Another explanation, which seems more likely, is that there are underlying variances in the dating methods that lead to altered exposure or outcome classifications, which contribute to the divergence. The later explanation is supported by the similarities between results for the main and restricted analyses.

In this work, overall classification of preterm status had moderate agreement between the CE and LMP methods, but classification into preterm categories was very different for each method. For example, only 57% of those classified as ExPTB by CE were classified as ExPTB using LMP, with 21% of the others being classified as term births. Combining LMP

and CE methods has previously been used to fill data gaps that may be present when using either measure alone; however, using both LMP and CE methods may lead to muddled results resulting in more bias than using a single method [7]. A method introduced by Basso and Wilcox (2010) [15] that combines LMP and CE using standards of birthweight to assesses the plausibility of gestational age estimates may offer an improved method to simple substitution.

Our analysis shows some similarities to previously published work in this area, such as more births being classified as post-term with the LMP method [16]. However, much of the research examining differences between LMP and CE methods has focused on agreement between these methods, effects on metrics such as birth weight, or differences in demographic factors, but not the effects on specific exposure-outcome associations [17 18].

We focus on identifying differences the associations between PM_{2.5} exposure and PTB when using the two methods of gestational dating, which demonstrates potential issues with, or effects of, method choice. While in many studies gestational dating method will affect only the outcome under study, in our analysis, exposures are also affected. This will hold true for any exposure rooted in time, as timing of exposure is affected by the definition of pregnancy start and length. With air pollution exposures, particularly when looking over short-term periods, an inaccurate date will shift the concentration estimate; this is exemplified in our analysis in the PM_{2.5} concentrations being shifted by 1 µg/m³ between the two populations. While estimates may reflect general exposure levels due to temporal correlation, this shifting does introduce error. This complicates the choice of gestational age metric because the impact of misclassification may be amplified, although misclassification is almost certain to be present in either CE or LMP dating alone.

Perturbations of development at particular times may lead to different outcomes, or different levels of outcome severity (e.g., exposures early in pregnancy may lead to major birth defects, while later in utero exposures might lead to minor or no defects). In utero exposures to environmental contaminants have been linked to outcomes beyond birth, including childhood cancers and autism [19 20]. Understanding the critical timing of exposure to these contaminants relative to vulnerable developmental windows an important part of understanding outcome etiology.

Use of each gestational age dating method has benefits and limitations, with neither method being explicitly better or worse than the other. CE is not reliant on maternal recall, is unaffected by menstrual irregularities, includes ultrasound dating when available, and produces a single mode in birthweight distribution for preterm births; CE is also not a single method and may result in unpredictable inaccuracies [1–3 5 6 11]. LMP is simple, low cost, has a standard definition, and is widely available; however, LMP is also likely to be inaccurate and may be differentially so [21]. While neither method is perfect each has advantages to use that should be considered when developing research questions. Both CE and LMP may lead to bias in effect estimates. In our analyses, biases associated with CE may potentially indicate that results are biased in unpredictable directions; we don't know what proportion of CE measures were (more accurate) ultrasounds before 20 weeks, versus

ultrasounds after 20 weeks, or neonatal dating. That mixture could introduce outcome misclassification, and is likely to be differential by SES factors and thus we cannot accurately predict the direction (or magnitude) of bias. This could also lead to inappropriate distribution of exposure assignment based on pregnancy start date, which would likely induce exposure misclassification.

Biases associated with LMP may lead to results that are less generalizable to a broad population, as women with no recorded LMP or unreliable LMP (negative, longer than possible pregnancy) are removed (~12% of our initial population had missing or unreliable LMP). We observed divergence in preterm classification and in our estimated associations, and others have observed disagreement between methods with factors such as maternal age, odds of PTB for maternal race, or utilization of prenatal care between CE and LMP methods [7 16 22]. Factors such as timing of prenatal care, ultrasound utilization, and homogeneity or standards of neonatal practice are useful in the evaluation of gestational dating method, though not always available to researchers. It would be informative for future research to break down CE into its main components, particularly if ultrasound-based or not, to examine if further differences exist. This information could lead to more accurate gestational dating in research and better effect estimation; unfortunately, those components are not currently recorded in registry data.

In this work we observed higher effect estimates with CE dating, which may mean there is the potential for underestimation of effects with LMP gestational dating. Substitution of the two methods for one another is likely to produce more bias in effect estimation than use of a single method or a more complex combination algorithm. Awareness of methods used in current research, and differences in these methods even within the same person, may help evaluate potential uncertainties within that body of work and inform later policies decisions. In general, relevance for a specific research question should be taken into consideration when choosing the method of GA dating, and that method should be clearly indicated when presenting the study methods to help consumers evaluate inferences of one study within a greater body of literature.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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What this paper adds

- Choice of gestational dating method (clinical estimate or last-menstrual period) may influence effect estimation through either outcome or exposure timing. Previous research has explored differences in demographic distributions of gestational dating methods, but there is limited work exploring alterations in effect estimates.
- In our study, divergences in risk differences were increased for outcome defined at later gestational ages, and also with later exposure weeks. Our results may indicate that the observed differences in risk differences are due to differences in the dating methods themselves rather than issues of selection.

Figure 1.

: Risk differences per 1,000,000 pregnancies for 1 µg/m³ increases in PM_{2.5}. Models adjusted for maternal education, race/ethnicity, marital status, age at delivery. Effects for clinical estimate (CE) population shown in black, and for date of last menstrual period (LMP) population in gray. ExPTB: 20–27 completed gestation weeks; VPTB: 28–31 completed gestation weeks; MPTB: 32–34 completed gestation weeks; and LPTB: 35–36 completed gestational weeks.

Figure 2.

: Risk differences per 1,000,000 pregnancies for 1 $\mu\text{g}/\text{m}^3$ increases in $\text{PM}_{2.5}$ for populations restricted to those births with both a clinical estimate (CE) and date of last menstrual period (LMP). Models adjusted for maternal education, race/ethnicity, marital status, age at delivery. Effects for CE population shown in black, and for LMP population in gray. ExPTB: 20–27 completed gestation weeks; VPTB: 28–31 completed gestation weeks; MPTB: 32–34 completed gestation weeks; and LPTB: 35–36 completed gestational weeks.

Table 1

: Distribution of demographic characteristics by gestational outcome classification and gestational dating method: Number (percentages)

Factor	ExPTB			VPTB			MPTB			LPTB			Term		
	CE	LMP		CE	LMP		CE	LMP		CE	LMP		CE	LMP	
Maternal Education															
Some college	3,476 (40)	4,220 (39)		5,188 (43)	7,931 (43)		14,535 (46)	25,972 (46)		44,635 (50)	87,942 (52)		901,061 (55)	754,669 (56)	
High School diploma	3,221 (37)	4,062 (38)		4,227 (35)	6,458 (35)		10,789 (34)	19,187 (34)		29,566 (33)	53,639 (32)		491,888 (30)	394,839 (29)	
< High School	1,967 (23)	2,507 (23)		2,589 (22)	4,136 (22)		6,122 (19)	11,334 (20)		15,836 (18)	26,284 (16)		246,427 (15)	189,298 (14)	
Maternal Race/Ethnicity															
Non-Hispanic White	4,120 (48)	5,311 (49)		6,549 (55)	10,208 (55)		18,848 (60)	33,921 (60)		58,868 (65)	112,190 (67)		1,152,731 (70)	954,358 (71)	
Non-Hispanic Black	3,279 (38)	3,723 (35)		3,671 (31)	4,913 (27)		7,781 (25)	12,076 (21)		17,034 (19)	27,627 (16)		225,430 (14)	167,757 (13)	
Hispanic	256 (3)	372 (3)		447 (4)	817 (4)		1,382 (4)	2,653 (5)		4,131 (5)	8,406 (5)		83,507 (5)	70,379 (5)	
Other	1,009 (12)	1,383 (13)		1,337 (11)	2,587 (14)		3,435 (11)	7,843 (14)		10,004 (11)	19,642 (12)		177,708 (11)	146,312 (11)	
Maternal Age															
<20	1,354 (16)	1,702 (16)		1,549 (13)	2,491 (13)		3,549 (11)	6,482 (11)		9,133 (10)	14,545 (9)		139,192 (8)	105,099 (8)	
20–29	4,145 (48)	5,196 (48)		5,566 (46)	8,705 (47)		14,748 (47)	26,872 (48)		43,259 (48)	78,884 (47)		790,998 (48)	642,307 (48)	
30–39	2,888 (33)	3,539 (33)		4,441 (37)	6,666 (36)		11,971 (38)	21,178 (37)		34,657 (38)	68,740 (41)		664,625 (41)	555,450 (41)	
40+	277 (3)	352 (3)		448 (4)	663 (4)		1,178 (4)	1,961 (3)		2,988 (3)	5,696 (3)		44,561 (3)	35,950 (3)	
Marital Status															
Married	3,891 (45)	4,822 (45)		6,055 (50)	9,539 (51)		17,481 (56)	32,611 (58)		55,582 (62)	110,762 (66)		1,118,053 (68)	939,300 (70)	
Unmarried	4,773 (55)	5,967 (55)		5,949 (50)	8,986 (49)		13,965 (44)	23,882 (42)		34,455 (38)	57,103 (34)		521,323 (32)	399,506 (30)	

CE: clinical estimate of gestation; LMP: date of last menstrual period; ExPTB: 20–27 completed gestation weeks; VPTB: 28–31 completed gestation weeks; MPTB: 32–34 completed gestation weeks; and LPTB: 35–36 completed gestational weeks.

Table 2

: Distribution of PM_{2.5} (µg/m³) concentrations, averaged over all weeks of exposure.

Statistic	ExPTB		VPTB		MPTB		LPTB		Term births	
	CE	LMP	CE	LMP	CE	LMP	CE	LMP	CE	LMP
Min	3.73	2.62	3.55	2.4	3.15	1.94	2.84	1.72	2.45	1.39
25th	11	9.91	10.93	9.82	10.87	9.74	10.76	9.69	10.74	9.7
50th	13.8	12.73	13.72	12.61	13.65	12.51	13.54	12.45	13.51	12.46
75th	17.33	16.29	17.24	16.12	17.17	16.02	17.04	15.95	16.98	15.94
Max	50.82	48.84	50.87	52.36	53.33	54.13	55.19	55.9	58.25	58.43
Mean	14.62	13.56	14.54	13.43	14.47	13.34	14.36	13.28	14.31	13.28
SD	5.07	5.1	5.04	5.05	5.03	5.03	5.01	5.01	4.98	4.99
IQR	6.33	6.38	6.31	6.3	6.3	6.28	6.28	6.27	6.24	6.24

CE: clinical estimate of gestation; LMP: date of last menstrual period; ExPTB: 20–27 completed gestation weeks; VPTB: 28–31 completed gestation weeks; MPTB: 32–34 completed gestation weeks; and LPTB: 35–36 completed gestational weeks.

Table 3

: Distribution of preterm birth category assignment by clinical estimate of gestation method (CE, horizontal) and date of last menstrual period method (LMP, vertical) for population restricted to women with both methods.

LMP	CE					Total
	ExPTB	VPTB	MPTB	LPTB	Term	
ExPTB	5,946	1,611	366	371	2,155	10,449
VPTB	490	6,580	4,342	1,280	5,583	18,275
MPTB	115	806	16,946	19,113	19,123	56,103
LPTB	57	233	2,269	43,543	121,290	167,392
Term	180	563	2,395	13,764	1,319,474	1,336,376
Total	6,788	9,793	26,318	78,071	1,467,625	1,588,595

CE: clinical estimate of gestation; LMP: date of last menstrual period; ExPTB: 20–27 completed gestation weeks; VPTB: 28–31 completed gestation weeks; MPTB: 32–34 completed gestation weeks; and LPTB: 35–36 completed gestational weeks.