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ORIGINAL ARTICLE

The impact of the interaction between increasing gestational age and obstetrical risk on birth outcomes: evidence of a varying optimal time of delivery

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Objective: To estimate the gestational age ranges that result in optimal birth outcomes for each of four risk-defined groups.

Study Design: Retrospective cohort study of singleton late third-trimester deliveries at a large urban teaching hospital between July 1995 and September 2003. Low-risk, advanced maternal age, hypertensive and diabetic patients were identified and grouped. Rates, by day of gestation at delivery, of cesarean delivery, major maternal perineal trauma, low 5-min APGAR score and NICU admission were determined for each study group.

Results: Each study group had meaningful changes in rates of obstetric outcomes as a function of gestational age at delivery and these patterns differed from group to group. A unique optimal time of delivery (OTD) was estimated for each group. The low-risk group OTD was calculated to be 37 weeks 1 day to 41 weeks 0 day; the advanced maternal age group OTD was 38 weeks 5 days to 39 weeks 6 days; the hypertension group OTD was 39 weeks 2 days to 40 weeks 1 day; and the diabetes mellitus group OTD was 40 weeks 3 days to 41 weeks 1 day.

Conclusions: The OTD varied based on obstetrical risk. Strategies to increase the proportion of deliveries that occur within the OTD for specific risk-defined groups could theoretically improve birth outcomes.
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Keywords: gestational age; birth outcomes; cesarean delivery; NICU admission; obstetrical risk; optimal time of delivery

Introduction

The objective of obstetric care is to maximize favorable birth outcomes for both mother and neonate. Frequently, this involves the balancing of, or tradeoffs between, maternal and fetal outcomes, such as the management of severe pre-eclampsia in the early third trimester of pregnancy. In keeping with this concept of balancing tradeoffs, associations between various obstetric risk factors and adverse birth outcomes have been studied frequently and the results have had a major impact on the clinical management of pregnancy. For example, diabetic and hypertensive disorders have long been associated with higher rates of term stillbirth, cesarean delivery and neonatal intensive care unit admission,[1–5] and these associations have been influential in the development of high-risk obstetric management protocols.[6] Other investigations have identified an association between post-term pregnancy (>42 weeks gestation) and perinatal mortality,[7,8] and these associations have promoted the development of antenatal testing protocols and the determination of the timing for post-dates induction.[9,10] More recently, associations have been identified between delivery at increasing gestational age during the term period of pregnancy (37 to 42 weeks) and increasing risk of adverse birth outcomes.[11,12] However, other than the recent determination that labor induction at 41 weeks 0 days gestation is an acceptable strategy for reducing adverse birth outcomes,[13,14] these studies of the importance of gestational age on birth outcomes have not significantly changed the clinical management of term pregnancy.

One of the reasons that clinical practice has not been altered by studies of the negative impact of increasing gestational age at delivery on term birth outcomes is that such studies have primarily involved low-risk individuals.[11,12] Even at the extremes of the term period, low-risk patients generally have low rates of adverse birth outcomes relative to patients with various risk factors, and the need for intervention in low-risk patients is therefore less apparent. Moreover, findings involving low-risk cohorts cannot guide the management of individuals with increased obstetric risk.

This study broadens the investigation of the impact of increasing gestational age at delivery on term birth outcomes by determining if there is evidence to support three hypotheses about pregnancy at term: (1) that there is an optimal time of delivery (OTD) during the term period of low-risk pregnancy, wherein delivery is associated with the best set of outcomes for the mother–

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infant pair, (2) that there is also an OTD for groups of obstetric patients defined by specific prenatal risk factors and (3) that there are upper and lower limits of the OTD that vary in the presence of various prenatal risk factors.

Materials and methods

Between 1 July 1995 and 30 September 2003, approximately 26 132 patients delivered at the Hospital of the University of Pennsylvania (HUP). During each patient's maternity admission, data concerning basic demographics, estimated date of confinement (EDC), common prenatal risk factors, intrapartum events, basic nursery information and postpartum outcomes were entered into an electronic database. For this study, a set of inclusion and exclusion criteria were applied to identify a low-risk group and three increased risk groups based on the presence of three specific obstetric risk factors: advanced maternal age ($\geqslant$35 years at the time of delivery), hypertension (any type) and diabetes (any type). Rates of four major birth outcomes – cesarean delivery, major perineal trauma (third- or fourth-degree injury), low 5 min APGAR score ($\leqslant$6) and neonatal intensive care unit admission – were then determined for each group as a function of the number of days of gestation at the time of delivery (hereafter 'gestational age'). An estimate of the OTD for each study group was then determined. The Internal Review Board of the University of Pennsylvania approved the study protocol.

Subjects were included in this study if they were reasonable candidates for vaginal delivery. We excluded subjects who had one or more of a variety of potentially confounding variables including malpresentation (breech or transverse lie) (912), previous cesarean delivery or transmural uterine surgery (3584), non-singleton pregnancy (1321) and/or other maternal/fetal conditions precluding a trial of labor (e.g. placenta previa, active genital herpes, maternal HIV infection, hydrocephalus or other major fetal anomaly) (524). We also excluded subjects with incomplete prenatal and outcome data (204), age less than 16 years (512), pre-term delivery (<35 weeks gestation) (3414) and delivery after 42 weeks 0 days gestation (400). We excluded the post-term group because of our *a priori* concerns that this group would be composed of relatively few subjects, would contain gestational age miscalculations[14,15] and because expectant management beyond 42 weeks gestation is not currently recommended at our institution.

An EDC was available for each study subject based on last menstrual period and/or ultrasound dating. At our institution, if a first trimester ultrasound at $\leqslant$12 weeks of gestation based on crown-rump length was within 5 days of menstrual dating, if an early second trimester ultrasound at 13 to 20 weeks of gestation based on multiple measurements was within 8 days of menstrual dating, if a late second trimester ultrasound at 20 to 27 weeks of gestation based on multiple measurements was within 14 days of gestation or if a third trimester ultrasound at >27 weeks of gestation based on multiple measurements was within 21 days of menstrual dating, then menstrual dating alone was used to estimate the EDC. If LMP-based dating and ultrasound dating were more discordant than these levels, then the ultrasound dating alone was used. Most patients had first or early second trimester ultrasounds, and for patients with multiple ultrasounds, the earliest study (6 to 20 weeks of gestation) was used in the dating paradigm. The final EDC calculation based on these criteria, as well as an estimated gestational age at delivery, was available in the database. The gestational age at delivery for each subject was recalculated for this study by comparing the final EDC to each patient's delivery date. Because gestational age at delivery was of critical importance for this study, patients were excluded if their EDC was not recorded or was not calculable, or if the two methods of EDC estimations in the database disagreed by more than 7 days (2890). The remaining patients (15 036) were identified as eligible study subjects.

The low-risk group (11 724) was created by identifying eligible subjects who met all inclusion criteria, did not have one of the three study risk factors and did not receive prenatal care in a high-risk clinic. The advanced maternal age (AMA) group (2373) was created by identifying all eligible subjects who were 35 years of age or older at the time of delivery. The hypertension (HTN) group (635) was created by identifying all eligible subjects who had a record of any kind of hypertensive disorder before delivery. The diabetes mellitus (DM) group (460) was created by identifying all eligible subjects who had a record of any type of diabetes before delivery. Subjects that had more than one study risk factor were included in all appropriate risk factor groups.

Overall levels of various demographic, prenatal and intrapartum variables in the four groups were determined. We compared levels of these variables in the low-risk group to levels in each of the three increased risk groups using χ^2 analysis (Fisher's exact method). Overall rates of important maternal and neonatal outcomes were similarly determined for each group and compared.

We then calculated, within each study group, the rates of the four major outcomes as a function of day of gestation at delivery. In addition, we created a summary variable called 'combined summary outcome' by first summing the number of major outcomes that occurred at each day of gestational age in each study group and then dividing this sum by the number of subjects who delivered in that group on that day of gestation. In creating the combined outcome variable, we assigned equal weight to each of the four major outcomes. Graphs were created to display the association between increasing day of gestational age and rates of the four study outcomes in the four groups. Trend lines based on weighted fractional polynomial regression were superimposed on the data and the summary statistics for these curves were determined.

In order to both emphasize the continuous nature of our data and present our results in tabular form, we identified 3-day intervals and averaged the rate of each outcome within each 3-day

interval for each group. Rates of outcomes before and after each interval were then determined and inflection points were identified within these data where rates of each birth outcome changed maximally. The statistical significance at each inflection point was measured using χ^2 techniques (Fisher's exact method). For all statistical tests, a *P*-value of $\leqslant 0.05$ identified statistical significance, and a *P*-value between 0.05 and 0.30 identified a statistical trend. Initial data stratification was performed with Statistica (version 6.1, StatSoft Inc., Tulsa, OK). Further analysis was performed using Stata (version 8, College Station, Texas, TX).

An OTD was then estimated for each study group using a two-step method. First, we identified 15% as a preferred maximum rate for cesarean delivery, based on the USA Public Health recommendations in Healthy People 2000,[16] and 15% as a preferred maximum rate for neonatal intensive care unit admission. The gestational age at delivery where the weighted fractional polynomial curve for NICU admission and cesarean delivery crossed these thresholds was used to define the lower and upper limits, respectively, of the OTD. This method of ideal outcome estimation has been used previously.[17] Second, if the outcome rates for NICU admission and cesarean delivery were too high to ever cross below these thresholds, we used the coordinates of the weighted fractional polynomial curve for the combined outcome for each risk group to estimate a 95% confidence interval (CI) around the minima of each curve. This 95% CI was estimated using a bootstrapping technique with 1000 repetitions.[18] Finally, we estimated the minima and 95% CI of the combined outcome weighted fractional polynomial curve for all groups so that this type of OTD estimate could be compared across all study groups.

Results

Table 1 demonstrates overall levels of various demographic, prenatal, intrapartum and outcome variables in the four groups. As expected, adverse outcomes, including the four major variables studied, were more frequent in the higher risk groups. Intrapartum mortality and neonatal death also trended higher in the high-risk groups. Although rates of these outcomes appeared to follow similar curves, with minimas in the mid-term period (data not shown), their low frequency precluded analysis by day of gestation within each group. Figure 1a–d illustrates relationships between increasing gestational age at delivery and rates of the four major outcomes in each of the four study groups. These data suggest strong associations between changing gestational age at delivery within the term period and rates of various outcomes. The curves for changing cesarean delivery rates and NICU admission rates are the most dramatic in each study group.

The summary statistics for the weighted fractional polynomial curves are contained in Table 2. Table 3a–d presents outcome results based on 3-day intervals for the four study groups organized according to gestational age at delivery. Three-day intervals were chosen instead of 1-day intervals because of the relatively small sample sizes in the 1-day strata. Although not ideal, this 3-day interval gives an approximation of the changes that occur by day of gestational age. A change in text type indicates an interval where there was a maximal change in pooled rates. Change from regular to bold italic text with parenthesis indicates a statistical trend toward change in outcome rates, and change from regular to bold roman text indicates a statistically significant change in outcome rates. Clinically important changes in rates of adverse birth outcomes occurred for most outcomes in all groups, but the timing of inflection points and the overall magnitude of the levels of the various outcomes were different within the different risk groups.

The OTD was calculated for each group. In the low-risk and AMA groups, the 15% threshold rate for cesarean delivery and NICU admission was utilized. In the HTN and DM groups, the daily rates of cesarean delivery and/or NICU admission never dropped below 15%, and their OTDs were estimated based on a 95% CI around the minima of the respective combined outcome's weighted fractional polynomial curve (see Table 2). Resultant OTDs were as follows: low-risk group, 37 weeks 1 day to 41 weeks 0 day; AMA group, 38 weeks 6 days to 39 weeks 6 days; HTN group, 39 weeks 2 days to 40 weeks 1 day; and DM group, 40 weeks 3 days to 41 weeks 1 day. Based on the 95% CI around the minima of the combined outcome, the OTD for low risk was within the initial estimate. However, using the bootstrapping method for the AMA group resulted in an OTD of 38 weeks 5 days to 39 weeks 2 days. This broadened the final OTD for the AMA group to 38 weeks 5 days to 39 weeks 6 days.

In Figure 2, the relationships between gestational age at delivery and the combined outcome variable for each study group are illustrated using weighted fractional polynomial curves. The final estimated OTD for each study group is superimposed under each curve. Table 4 describes subjects who delivered within each group's OTD as compared to subjects who delivered either before or after the OTD. Within each group, a clinically significant percentage of patients delivered within the OTD, and the likelihood of having adverse outcomes was significantly lower if delivery occurred within the group-specific OTD.

Discussion

This paper uses a large hospital-based electronic database to explore the concept that there was an estimable, but variable, OTD in each of four risk factor-defined study groups. Rates of four major birth outcomes changed continuously within these groups as a function of day of gestational age, and the timing and magnitude of these changes varied depending upon the presence of certain common obstetric risk factors. The lower limit of the OTD (LL-OTD) was primarily defined by decreasing rates of NICU admission and low 5-minute APGAR score early in the near-term

Table 1 Demographics, prenatal variables, intrapartum variables by study group, and comparisons between the low-risk group and each increased risk group

	Low risk *(%)* *(N = 11 724)*	***AMA*** *(%)* *(N = 2373)*	*RR*	P-*value*	***HTN*** *(%)* *(N = 635)*	*RR*	P-*value*	***DM*** *(%)* *(N = 460)*	*RR*	P-*value*
Demographics										
Ethnicity										
African American	75.8 (8886)	46.9 (1114)	*0.62*	*<0.001*	79.8 (507)	*1.05*	*0.02*	70.2 (323)	*0.93*	*0.01*
Asian	7.1 (838)	8.5 (202)	*1.19*	*0.02*	18.8 (120)	*2.64*	*<0.001*	6.1 (28)	*0.85*	*0.46*
Caucasian	13.1 (1541)	39.9 (947)	*3.04*	*<0.001*	15.4 (98)	*1.17*	*0.10*	18.0 (83)	*1.37*	*0.003*
Hispanic	1.7 (198)	1.0 (23)	*0.72*	*0.11*	1.3 (8)	*0.75*	*0.52*	3.3 (15)	*1.93*	*0.02*
Other	2.2 (261)	3.5 (82)	*1.59*	*<0.001*	1.6 (10)	*0.71*	*0.33*	2.4 (11)	*1.07*	*0.75*
Education										
Elem and/or HS only	49.3 (5777)	27.5 (652)	*0.56*	*<0.001*	51.8 (329)	*1.05*	*0.22*	47.6 (219)	*0.97*	*0.51*
College, undergraduate	27.3 (3195)	33.0 (782)	*1.20*	*<0.001*	26.3 (168)	*0.97*	*0.68*	27.6 (127)	*1.01*	*0.87*
College, advanced										
Degree	8.2 (967)	24.7 (585)	*3.03*	*<0.001*	6.1 (39)	*0.74*	*0.06*	7.6 (35)	*0.92*	*0.73*
Unknown	15.2 (1785)	14.9 (354)	*0.98*	*0.73*	16.2 (103)	*1.07*	*0.50*	17.8 (82)	*1.17*	*0.13*
Marital status										
Single	60.3 (7073)	24.1 (572)	*0.40*	*<0.001*	62.2 (395)	*1.03*	*0.36*	47.2 (217)	*0.78*	*<0.001*
Married	26.8 (3139)	59.3 (1407)	*2.22*	*<0.001*	23.0 (146)	*0.86*	*0.04*	29.1 (134)	*1.09*	*0.26*
Unknown	12.9 (1512)	16.6 (394)	*1.28*	*<0.001*	14.8 (94)	*1.15*	*0.16*	15.0 (69)	*1.16*	*0.20*
Insurance status										
Medicaid or uninsured	62.1 (7286)	29.5 (700)	*0.47*	*<0.001*	60.2 (382)	*0.97*	*0.31*	49.1 (226)	*0.79*	*<0.001*
Private insurance	27.9 (3270)	49.1 (1164)	*1.76*	*<0.001*	23.6 (150)	*0.85*	*0.02*	25.0 (115)	*0.90*	*0.18*
Unknown	10.0 (1168)	21.4 (509)	*2.15*	*<0.001*	16.2 (103)	*1.63*	*<0.001*	25.9 (119)	*2.60*	*<0.001*
Prenatal										
Parity										
Nulliparous	50.2 (5883)	31.0 (735)	*0.62*	*<0.001*	54.2 (344)	*1.08*	*0.05*	33.9 (156)	*0.68*	*<0.001*
Multiparous	49.8 (5841)	69.0 (1638)	*1.38*	*<0.001*	45.8 (291)	*0.92*	*0.05*	66.1 (304)	*1.33*	*<0.001*
Prior TAB or SAB	39.6 (4645)	51.3 (1218)	*1.30*	*<0.001*	41.9 (266)	*1.06*	*0.26*	48.0 (221)	*1.21*	*<0.001*
Labor and delivery										
Mode of labor onset										
Spontaneous labor	81.8 (9593)	71.8 (1703)	*0.88*	*<0.001*	35.7 (227)	*0.44*	*<0.001*	61.5 (283)	*0.75*	*<0.001*
Induction of labor	18.2 (2131)	28.2 (670)	*1.55*	*<0.001*	64.3 (408)	*3.53*	*<0.001*	38.5 (177)	*2.12*	*<0.001*
Premature ROM	12.8 (1497)	14.6 (346)	*1.14*	*0.02*	6.7 (43)	*0.53*	*<0.001*	11.3 (52)	*0.89*	*0.39*
Major outcomes	(11 724)	(2386)			(635)					
SVD	79.5 (9323)	73.6 (1746)	*0.93*	*<0.001*	67.9 (431)	*0.85*	*<0.001*	64.8 (298)	*0.81*	*<0.001*
Operative vag. del.	11.3 (1325)	12.1 (288)	*1.07*	*0.24*	10.6 (67)	*0.93*	*0.61*	10.4 (48)	*0.93*	*0.60*
Cesarean section	9.2 (1076)	14.3 (339)	*1.56*	*<0.001*	21.6 (137)	*2.35*	*<0.001*	24.8 (114)	*2.70*	*<0.001*
NICU admission	10.2 (1190)	15.5 (369)	*1.53*	*<0.001*	21.6 (137)	*2.13*	*<0.001*	40.0 (184)	*3.94*	*<0.001*
Major perineal trauma	6.5 (765)	6.2 (147)	*0.95*	*0.58*	5.4 (34)	*0.82*	*0.28*	5.9 (27)	*0.90*	*0.63*
Five minute APGAR <7	1.4 (163)	1.8 (43)	*1.30*	*0.13*	4.1 (26)	*2.95*	*<0.001*	2.6 (12)	*1.88*	*0.04*
Perinatal mortality	0.21 (25)	0.25 (6)	*1.19*	*0.64*	0.63 (4)	*2.95*	*0.06*	0.44 (2)	*2.04*	*0.27*

Abbreviations: AMA, advanced maternal age; DM, diabetes mellitus; HNT, hypertension.
*$P<0.05$, **$P = 0.05–0.30$.

period of pregnancy (between 35 and 38 weeks gestation), and the upper limit of the OTD (UL-OTD) was primarily defined by increasing rates of cesarean delivery, major perineal trauma and NICU admission late in the term period of pregnancy (between 39 and 42 weeks gestation). Although the general patterns of this variability were somewhat similar, the specific relationships of the variations of these outcomes to gestational age were different from group to group, thereby producing a different OTD for each group.

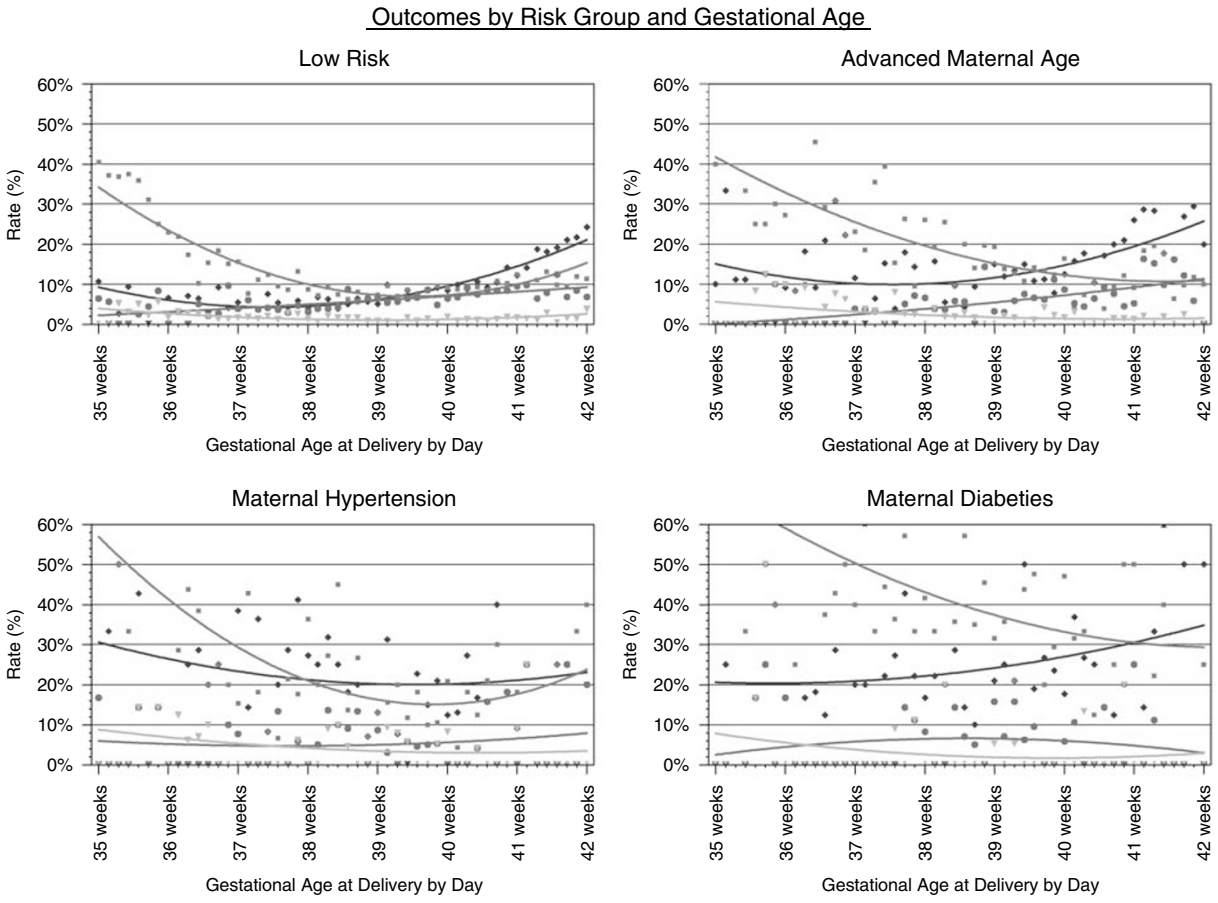

Figure 1 Outcomes as a function of day of delivery and risk group. Maternal Cesarian Section Rate; Newborn NICU Admission Rate; Maternal 3rd & 4th Degree Perineal Tear Rate; Newborn 5 Minute APGAR 0–6 Rate.

The identification of an optimal gestational period based on the presence of specific risk factors is not new to obstetrics. In years past, early-term labor induction was used to deliver patients with known Rh sensitization to prevent stillbirth.[19,20] More recently, early-term labor induction has been used in pregnant patients with insulin-requiring diabetes mellitus to lower the incidence of perinatal mortality, shoulder dystocia and cesarean delivery.[21,22] We propose that similar strategies might be employed in pregnancies affected by advanced maternal age, hypertensive disorders and milder forms of gestational diabetes. Delivery within each patient's OTD might reduce rates of cesarean delivery, NICU admission and major perineal trauma. The concept of a reduction of morbidity by encouraging delivery within the OTD is supported by the results of recently reported retrospective studies.[21–25]

The findings of this paper suggest that, at our institution and within the current standard of care, the LL-OTD for each identified risk group was related to the respective risk factor's impact on NICU admission rates. The low-risk, AMA, HTN and DM groups had, respectively, increasing overall NICU admission rates and progressively higher LL-OTDs. We hypothesize that an estimation of the LL-OTD for any risk factor-defined group could be estimated based on the quantification of that risk factor's overall impact on NICU admission. We also found that, within the current standard of care, the UL-OTD for the first three risk groups was related to the respective risk factor's impact on cesarean delivery rates. The low-risk, AMA and HTN groups had increasing overall cesarean delivery rates and a trend toward lower UL-OTDs (data not shown), and we believe that an estimation of the UL-OTD for any risk factor-defined group could be estimated based on the quantification of that risk factor's overall impact on cesarean delivery. The UL-OTD for the DM group was substantially affected by very high NICU admission rates at relatively late gestational ages and this occurrence dramatically elevated the UL-OTD for this group. We theorize that this high NICU admission rate was due at least in part to short (<24 h) stays for glucose stabilization and/or as a precautionary measure. A differential coding of this type of NICU admission might result in a downward modification of the UL-OTD for this group.

There are several limitations to this paper. First, our data were obtained from a tertiary care institution and as such generalizability of the data to other populations is uncertain. However, such care should not change the trends by gestational age

Table 2 Statistical information for weighted fractional polynomial curves

	R-*squared*	*Best power (1)*	*Coef (1)*	P-*value (1)*	*Best power (2)*	*Coef (2)*	P-*value (2)*	*Minima rate (with 95% CI)*	*Gestational age for the 95% CI for the minima*
Low-risk group									
Cesarean	0.8650	3	−0.0005	<0.001	3	0.0001	<0.001	4.41% (4.41–4.45)	37w 2d–37w 6d
NICU	0.8156	−2	84 921	<0.001	−2	−267 630	<0.001	7.49% (7.49–7.60)	39w 1d–39w 7d
Perineal trauma	0.4869	−2	3957	0.48	−2	−1349	0.44	2.28% (2.28–2.83)	35w 0d–35w 7d
Low APGAR-5	0.1684	3	−0.0001	0.003	3	0.0000	0.003	1.03% (1.03–1.05)	38w 6d–39w 4d
Combination	0.8953	−2	159 797	<0.001	−2	−50 792	<0.001	19.96% (19.96–20.28)	38w 0d–38w 6d
AMA group									
Cesarean	0.3841	3	−0.0006	0.006	3	0.0001	0.005	10.07% (10.07–10.14)	37w 3d–37w 6d
NICU	0.4960	3	−0.604	0.006	3	0.1491	0.007	10.73% (10.73–10.84)	40w 6d–41w 6d
Perineal trauma	0.3366	3	−0.00003	0.80	3	8.56×10^{-6}	0.77	0.09% (0.09–0.84)	35w 0d–35w 4d
Low APGAR-5	0.1277	3	−0.0001	0.118	3	0.00002	0.122	1.29% (1.29–1.32)	40w 2d–41w 0d
Combination	0.2586	3	−0.0012	<0.001	3	0.0003	<0.001	33.84% (33.84–34.16)	38w 5d–39w 2d
Hypertension group									
Cesarean	0.0299	3	−0.00037	0.39	3	0.00009	0.39	19.94% (19.94–19.99)	39w 2d–39w 6d
NICU	0.3772	2	−0.0193	0.001	3	0.00032	0.002	14.85% (14.85 -14.98)	39w 5d–40w 1d
Perineal trauma	0.0131	3	−0.00011	0.57	3	0.00003	0.57	4.73% (4.73–4.77)	37w 2d–38w 2d
Low APGAR-5	0.0429	−2	11428	0.58	−2	−3565	0.59	3.08% (3.08–3.09)	39w 5d–39w 6d
Combination	0.2081	3	−0.00195	0.022	3	0.00048	0.023	43.28% (43.28–43.69)	39w 2d – 40w 1d
Diabetes group									
Cesarean	0.0658	3	−0.00022	0.62	3	0.00006	0.61	20.36% (20.36–20.40)	35w 4d–36w 0d
NICU	0.2733	3	−0.00063	0.24	3	0.00016	0.25	29.69% (29.69–30.02)	41w 3d–42w 0d
Perineal trauma	0.0198	3	0.00022	0.34	3	−0.0005	0.34	2.63% (2.63–3.54)	35w 0d–35w 4d
Low APGAR-5	0.0359	−2	16 084	0.50	−2	−5052	0.50	1.82% (1.82–1.84)	39w 5d–40w 1d
Combination	0.0844	−2	63 988	0.46	−2	−19 952	0.47	67.7% (67.72–67.80)	40w 3d–41w 1d

Abbreviations: CI, confidence interval; d, day; w, week.

that likely exist in other populations. Second, the accuracy of data entry into the database has not been validated, leading to the possibility of information bias. For example, within the database, we could not reliably differentiate between gestational diabetes and pre-existing diabetes, and we could not reliably differentiate between chronic hypertension and pregnancy-induced hypertension. However, these sets of related conditions probably affected the relationship between the frequency of major birth outcomes and gestational age similarly, and therefore the impact of this information bias should be minimal. Third, the number of hypertensive and diabetic patients in our data set was relatively low and this limited the reliability of some of our findings. Larger databases could be used to investigate these and other increased risk groups. Fourth, we did not use logistic regression to control for potential confounding factors (e.g., age, parity, race, marital status, height, high body mass index (BMI)) in the gestational age-dependent associations between the four risk groups and the four major outcomes. This is largely owing to lack of capture of some important variables (e.g., height, BMI) and concerns about the validity of the data collection for other variables (e.g., weight gain, past medical problems). Rather, we chose the combination of exclusion of conditions not compatible with a trial of labor, and stratification based on the four risk states (low risk, advanced maternal age, hypertensive disorders and diabetes conditions), as a way to minimize the impact of major confounding factors on our findings. Finally, this investigation is based on population data. Additional study will be needed before our findings can be applied to the management of individual patients.

In the creation of our combined summary outcome, we made certain decisions. We identified only four major adverse outcomes for inclusion in our model, we weighed these outcomes equally, and we utilized a simple additive model. However, we chose outcomes that are common, that balance maternal and neonatal health, and that serve as proxies for other adverse outcomes. For

Table 3 (a) Cesarean delivery rates as a function of gestational age at delivery (totaled every 3 days); (b) neonatal intensive care unit rates as a function of gestational age at delivery (totaled every 3 days); (c) major perineal trauma rates as a function of gestational age at delivery (totaled every 3 days); (d) low APGAR − 5 min (<7) rates as a function of gestational age at delivery (totaled every 3 days)

	35w 1d	*35w 4d*	*36w 0d*	*36w 3d*	*36w 6d*	*37w 2d*	*37w 5d*	*38w 1d*	*38w 4d*	*39w 0d*	*39w 3d*	*39w 6d*	*40w 2d*	*40w 5d*	*41w 1d*	*41w 4d*	*42w 0d*
(a) Cesarean delivery rates as a function of gestational age at delivery (totaled every 3 days)																	
Low risk				**5.4% (185/3431): RR 0.70, *P*<0.001**						7.7% (301/3894)				**13.4% (590/4399): RR 1.74, *P*<0.001**			
Rate (%)	**5.0**	**3.4**	**5.6**	**5.3**	**6.1**	**5.8**	**5.2**	**5.7**	**5.2**	6.9	7.4	8.7	**9.7**	**11.0**	**14.8**	**19.3**	**22.9**
Number (*n*)	**6**	**4**	**9**	**13**	**17**	**23**	**26**	**41**	**46**	80	100	121	**135**	**123**	**140**	**129**	**63**
Total (*N*)	**120**	**117**	**161**	**247**	**277**	**398**	**498**	**724**	**889**	1157	1344	1393	**1392**	**1116**	**947**	**669**	**275**
AMA				***(13.9% (26/187): RR 1.24, P=0.27)***						11.1% (157/1406)				**19.8% (157/793): RR 1.77, *P*<0.001**			
Rate (%)	***(13.6)***	***(6.9)***	***(6.1)***	***(17.4)***	***(19.3)***	7.7	13.1	9.2	7.5	13.6	13.2	10.8	**14.6**	**19.2**	**27.3**	**20.3**	**24.3**
Number (*n*)	***3***	***2***	***2***	***8***	***11***	7	14	14	14	34	40	34	**35**	**40**	**47**	**25**	**9**
Total (*N*)	***22***	***29***	***33***	***46***	***57***	91	107	152	186	250	304	316	**240**	**208**	**172**	**123**	**37**
HTN				**24.3 (89/367): RR 1.67, *P*=0.01**						14.5% (27/186)				**25.6% (21/82): RR 1.76, *P*=0.04**			
Rate (%)	**18.2**	**38.5**	**19.0**	**25.0**	**25.9**	**20.0**	**30.4**	**28.3**	**21.1**	**20.3**	10.8	15.9	17.2	**35.0**	**9.1**	**16.7**	**37.5**
Number (*n*)	**2**	**5**	**4**	**10**	**7**	**6**	**14**	**15**	**12**	**14**	7	10	10	**14**	**2**	**2**	**3**
Total (*N*)	**11**	**13**	**21**	**40**	**27**	**30**	**46**	**53**	**57**	**69**	65	63	58	**40**	**22**	**12**	**8**
Diabetes				20.0% (39/195)										**28.3% (75/265): RR 1.42, p=0.05**			
Rate (%)	20.0	23.1	20.0	16.0	21.4	17.6	29.6	19.4	16.7	**31.0**	**28.6**	**22.4**	**30.0**	**15.0**	**25.0**	**62.5**	**50.0**
Number (*n*)	1	3	3	4	3	3	8	6	8	**18**	**16**	**11**	**15**	**3**	**5**	**5**	**2**
Total (*N*)	5	13	15	25	14	17	27	31	48	**58**	**56**	**49**	**50**	**20**	**20**	**8**	**4**
(b) Neonatal intensive care unit rates as a function of gestational age at delivery (totaled every 3 days)																	
Low risk				**16.4% (298/1818): RR 1.98, *P*<0.001**						8.3% (572/6899)				**10.6% (320/3007): RR 1.28, *P*<0.001**			
Rate (%)	**38.3**	**34.2**	**23.0**	**14.2**	**16.2**	**10.6**	**10.6**	8.5	7.2	8.0	7.6	9.0	9.1	**9.7**	**11.3**	**11.0**	**11.6**
Number (*n*)	**46**	**40**	**37**	**35**	**45**	**42**	**53**	62	64	92	102	126	126	**108**	**107**	**73**	**32**
Total (*N*)	**120**	**117**	**161**	**247**	**277**	**398**	**498**	724	889	1157	1344	1393	1392	**1116**	**947**	**669**	**275**
AMA				**29.9% (83/278): RR 2.95, *P*<0.001**						15.8% (208/1315)				**10.0% (79/793): RR 0.63, *P*<0.001**			
Rate (%)	**54.5**	**27.6**	**21.2**	**28.3**	**24.6**	**31.9**	16.8	23.7	15.1	17.2	12.5	14.2	**7.1**	**8.2**	**14.5**	**12.2**	**10.8**
Number (*n*)	**12**	**8**	**7**	**13**	**14**	**29**	18	36	28	43	38	45	**17**	**17**	**25**	**15**	**4**
Total (*N*)	**22**	**29**	**33**	**46**	**57**	**91**	107	152	186	250	304	316	**240**	**208**	**172**	**123**	**37**
HTN				**28.9% (86/298): RR 2.10, *P*=<0.001**							13.7% (35/255)			(***19.6% (16/82): RR 1.42, P=0.22***)			
Rate (%)	**36.4**	**69.2**	**52.4**	**35.0**	**18.5**	**20.0**	**15.2**	**26.4**	**28.1**	13.0	16.9	14.3	10.3	(***22.5***)	(***13.6***)	(***8.3***)	***37.5***
Number (*n*)	**4**	**9**	**11**	**14**	**5**	**6**	**7**	**14**	**16**	9	11	9	6	***9***	***3***	***1***	***3***

Table 3 Continued

	35w 1d	*35w 4d*	*36w 0d*	*36w 3d*	*36w 6d*	*37w 2d*	*37w 5d*	*38w 1d*	*38w 4d*	*39w 0d*	*39w 3d*	*39w 6d*	*40w 2d*	*40w 5d*	*41w 1d*	*41w 4d*	*42w 0d*
Total (*N*)	**11**	**13**	**21**	**40**	**27**	**30**	**46**	**53**	**57**	69	65	63	58	***40***	***22***	***12***	***8***
Diabetes				**49.2% (96/195): RR 1.48, $P<0.001$**									33.2% (88/265)				
Rate (%)	**80.0**	**61.5**	**46.7**	**64.0**	**42.9**	**47.1**	**40.7**	**51.6**	**41.7**	36.2	37.5	32.7	26.0	20.0	45.0	37.5	25.0
Number (*n*)	**4**	**8**	**7**	**16**	**6**	**8**	**11**	**16**	**20**	21	21	16	13	4	9	3	1
Total (*N*)	**5**	**13**	**15**	**25**	**14**	**17**	**27**	**31**	**48**	58	56	49	50	20	20	8	4
(c) Major perineal trauma rates as a function of gestational age at delivery (totaled every 3 days)																	
Low risk				3.8% (96/2542)										**7.3% (669/9182): RR 1.93, $P<0.001$**			
Rate (%)	4.2	2.6	3.1	2.4	5.1	4.5	3.8	3.6	6.4	**6.1**	**6.2**	**6.6**	**7.8**	**8.3**	**8.6**	**9.1**	**7.6**
Number (*n*)	5	3	5	6	14	18	19	26	57	**71**	**84**	**92**	**109**	**93**	**81**	**61**	**21**
Total (*N*)	120	117	161	247	277	398	498	724	889	**1157**	**1344**	**1393**	**1392**	**1116**	**947**	**669**	**275**
AMA				3.2% (23/723)										**7.6% (127/1663): RR 2.4, $P<0.001$**			
Rate (%)	0.0	0.0	3.0	0.0	1.8	2.2	4.7	4.6	3.8	**5.6**	**6.6**	**8.5**	**5.4**	**7.2**	**11.0**	**12.2**	**2.7**
Number (*n*)	0	0	1	0	1	2	5	7	7	**14**	**20**	**27**	**13**	**15**	**19**	**15**	**1**
Total (*N*)	22	29	33	46	57	91	107	152	186	**250**	**304**	**316**	**240**	**208**	**172**	**123**	**37**
HTN			***(5.7% (21/367): RR 2.13, $P=0.14$)***								2.7% (5/186)			**9.8% (8/82): RR 3.54, $P=0.03$**			
Rate (%)	***(9.0)***)	***(7.7)***	***(4.8)***	***(0.0)***	***(7.4)***	***(0.0)***)	***(6.5)***)	***(7.6)***	***(10.5)***	***(4.4)***	3.1	3.2	1.7	**12.5**	**4.6**	**8.3**	**12.5**
Number (*n*)	***1***	***1***	***1***	***0***	***2***	***0***	***3***	***4***	***6***	***3***	2	2	1	**5**	**1**	**1**	**1**
Total (*N*)	***11***	***13***	***21***	***40***	***27***	***30***	***46***	***53***	***57***	***69***	65	63	58	**40**	**22**	**12**	**8**
Diabetes				4.1% (6/147)					***6.7% (21/313): RR 1.64, $P=0.30$***								
Rate (%)	0.0	15.4	6.7	0.0	0.0	0.0	7.4	3.2	***8.3***	***8.6***	***10.7***	***2.0***	***4.0***	***5.0%***	***10.0***	***0.0***	***0.0***
Number (*n*)	0	2	1	0	0	0	2	1	***4***	***5***	***6***	***1***	***2***	***1***	***2***	***0***	***0***
Total (*N*)	5	13	15	25	14	17	27	31	***48***	***58***	***56***	***49***	***50***	***20***	***20***	***8***	***4***
(d) Low APGAR – 5 min (<7) rates as a function of gestational age at delivery (totaled every 3 days)																	
Low risk					**18.4% (63/3431): RR 1.70, $P=0.002$**						10.8 (69/6402)			**1.6%(31/1891)RR 1.52, $P=.05$**			
Rate (%)	**1.7**	**3.4**	**3.1**	**2.4**	**1.4**	**1.8**	**2.2**	**1.4**	**1.6**	0.8	1.0	1.3	1.1	1.2	**1.4**	**1.6**	**2.5**
Number (*n*)	**2**	**4**	**5**	**6**	**4**	**7**	**11**	**10**	**14**	9	13	18	15	14	**13**	**11**	**7**
Total (*N*)	**120**	**117**	**161**	**247**	**277**	**398**	**498**	**724**	**889**	1157	1344	1393	1392	1116	**947**	**669**	**275**
AMA			**3.6% (14/385): RR 2.42, $P=0.01$**										1.5% (30/2001)				
Rate (%)	**0**	**6.9**	**6.1**	**4.3**	**3.5**	**2.2**	**3.7**	2.0	2.2	0.8	1.0	2.5	1.2	1.0	1.2	1.6	0.0
Number (*n*)	**0**	**2**	**2**	**2**	**2**	**2**	**4**	3	4	2	3	8	3	2	2	2	0

Table 3 Continued

	35w 1d	*35w 4d*	*36w 0d*	*36w 3d*	*36w 6d*	*37w 2d*	*37w 5d*	*38w 1d*	*38w 4d*	*39w 0d*	*39w 3d*	*39w 6d*	*40w 2d*	*40w 5d*	*41w 1d*	*41w 4d*	*42w 0d*
Total (*N*)	**22**	**29**	**33**	**46**	**57**	**91**	**107**	152	186	250	304	316	240	208	172	123	37
HTN							***(4.6% (23/495); RR 2.17, P = 0.23)***								2.1% (3/140)		
Rate (%)	***(0)***	***(23.1)***	***(9.5)***	***(7.5)***	***(0.0)***	***(0.0)***	***(2.2)***	***(3.8)***	***(5.3)***	***(4.4)***	***(4.6)***	***(4.8)***	1.7	0.0	9.1	0.0	0.0
Number (*n*)	***0***	***3***	***2***	***3***	***0***	***0***	***1***	***2***	***3***	***3***	***3***	***3***	1	0	2	0	0
Total (*N*)	***11***	***13***	***21***	***40***	***27***	***30***	***46***	***53***	***57***	***69***	***65***	***63***	58	40	22	12	8
Diabetes			***4.8% (7/147)RR 2.98, P = 0.06***										1.6% (5/313)				
Rate (%)	***(0.0)***	***(23.1)***	***(0.0)***	***(0.0)***	***(0.0)***	***(0.0)***	***(7.4)***	***(6.5)***	0.0	1.7	1.8	0.0	4.0	5.0	0.0	0.0	0.0
Number (*n*)	***0***	***3***	***0***	***0***	***0***	***0***	***2***	***2***	0	1	1	0	2	1	0	0	0
Total (*N*)	***5***	***13***	***15***	***25***	***14***	***17***	***27***	***31***	48	58	56	49	50	20	20	8	4

Abbreviations: AMA, advanced maternal age; d, day; HNT, hypertension; w, week.
Change from regular to bold italic text indicates a statistical trend toward change in outcome rates, and change from regular to bold roman text indicates a statistically significant change in outcome rates.

example, NICU admission is a proxy for respiratory distress syndrome, meconium aspiration syndrome, hypoxic–ischemic encephalopathy and neonatal seizure; major perineal trauma is a proxy for severe shoulder dystocia and fetal macrosomia; and cesarean delivery is a proxy for high estimated blood loss, endometritis and prolonged length of stay. Our database was not large enough to examine extremely serious but rare outcomes such as Erb's palsy, cerebral palsy, neonatal death or maternal death. Returning to the concept of balance, it would be important to eventually investigate the tradeoffs between major outcomes and extremely serious outcomes as a function of both differing gestational age at delivery and differing modes of labor onset. Furthermore, decisions on how to weight outcomes will have to be made. For instance, how many additional cesarean deliveries would we tolerate in order to prevent one case of permanent severe Erb's palsy? How many early-term labor inductions would we consider in order to prevent one late-term stillbirth? In theory, we believe that a detailed, multifactorial weighted model could be used to accurately estimate an OTD for every pregnancy. Such a model might use preference metrics to estimate the differential value of these and other pregnancy outcomes. The current study is an example of birth-outcome modeling and we hope it encourages others to attempt this kind of modeling in a more sophisticated and robust fashion.

By introducing the concept of a variable OTD, this paper raises multiple questions that deserve further study. What outcomes should be considered in developing a summary estimation of maternal/neonatal health, and how should differential weighting be generated and utilized?[23] Is the OTD that range of gestational age that is bounded by generally acceptable levels of birth outcomes, such as a lower limit defined by an NICU admission rate of 15% and an upper limit defined by a cesarean delivery rate of 15% (this would make the OTD for low-risk patients fairly broad – 37 weeks 1 day to 40 weeks 0 day)? Or should the OTD be viewed as the gestational age range where overall birth outcomes are fully optimized for each specific risk-defined group (this would make the OTD for low-risk subjects fairly narrow – 38 weeks 0 day to 38 weeks 6 days)? Finally, would the promotion of labor on or before each patient's UL-OTD, by induction of labor if necessary, provide outcomes that are better, worse or similar to the outcomes obtained when early-term labor is not promoted, and would such a program be cost effective?[26] Currently, there are no clear answers to these questions, but they provide a road map for future research.

Our findings support the concept that there is an OTD for low-risk patients, and for patients in each of three risk-defined groups. Specifically, our findings suggest that common obstetric risk factors and gestational age interact, and that these interactions promote relatively high levels of adverse birth outcomes at the beginning and the end of the term period of pregnancy. The results of this study could be corroborated through the analysis of other large obstetric databases, and other databases could be used to estimate

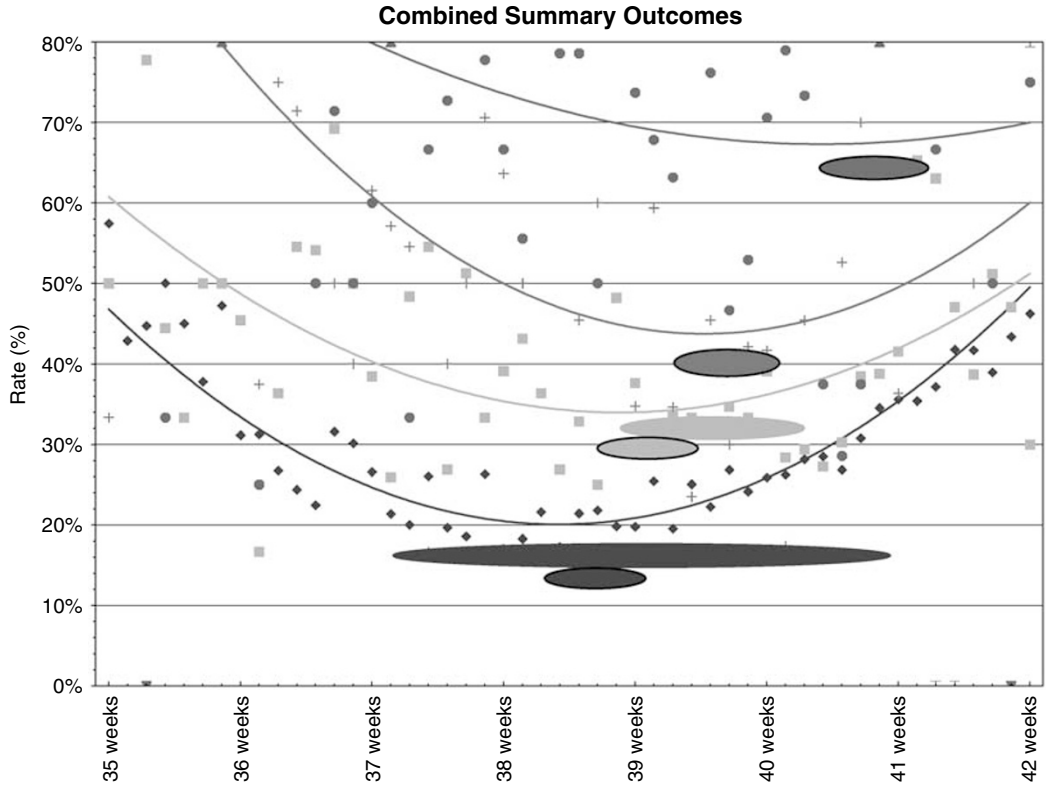

Figure 2 Combined Summary Outcomes for each Study Group by Day of Gestational Age at Delivery. Low Risk; Maternal Hypertension; Advanced Maternal Age; Diabetes Melltus.

Table 4 Information concerning delivery within and outside of estimated group OTD

Group	*Low risk*	*AMA*	*HTN*	*DM*
OTD	38w 0d–38w 6d	38w 5d–39w 2d	39w 2d–40w 1d	40w 3d–41w 1d
% of group in OTD	16.8%	18.2%	23.8%	10.2%
Number in OTD	1966	433	151	47
Total group (*N*)	11 724	2373	635	460
Average combined summary outcome rate within the OTD	19.8%	34.4%	33.8%	53.2%
Average combined summary outcome rate outside the OTD	28.7%	38.6%	58.5%	75.5%
P-value	< 0.001[a]	0.05[a]	< 0.001[a]	0.001[a]

Abbreviations: AMA, advanced maternal age; DM, diabetes mellitus; HNT, hypertension; ODT, optimal time of delivery.
[a]Based on χ^2 test of proportions.

the OTD for groups defined by other important obstetric risk factors. Whether birth outcomes could be improved by increasing the proportion of patients who deliver within these estimated OTDs, through induction of labor if necessary, is a question that can only be answered through prospective randomized research. However, we believe that our data, and the results of other recent studies,[11,24–26] provide plausible evidence that a preventive approach to the reduction of adverse birth outcomes is possible. Such an approach would need to be based on accurate gestational age determination, thorough prenatal risk assessment and an increased use of risk-guided prostaglandin-assisted labor induction. A prospective randomized trial is warranted to evaluate the impact, on birth outcomes, of methods of care that encourage delivery within each pregnant woman's estimated OTD.

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