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ORIGINAL RESEARCH ARTICLE

Risk of complications in the late vs early days of the 42nd week of pregnancy: A nationwide cohort study

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Abstract

Introduction: Uncertainty remains about the most appropriate timing of induction of labor in late-term pregnancies. To address this issue, this study aimed to compare the risk of neonatal morbidity and pregnancy- and birth-related complications between gestational age (GA) 41^{+4}–42^{+0} and GA 41^{+0}–41^{+3} weeks.

Material and methods: This nationwide registry-based cohort study included singleton births without major congenital malformations, with registered GA, and with intended vaginal delivery at GA 41^{+0}– 42^{+0} weeks between 2009 and 2018 in Denmark. Logistic regression models were used to estimate the crude risk ratio and adjusted risk ratio (RR_A) of neonatal and obstetric adverse outcomes in births at GA 41^{+4}–42^{+0} weeks compared with GA 41^{+0}– 41^{+3} weeks. The results were adjusted for relevant confounders, including induction of labor.

Results: A higher incidence of neonatal morbidity and birth complications was observed in births at GA 41^{+4}–42^{+0} weeks than in births at GA 41^{+0}–41^{+3} weeks. Neonatal morbidities included an increased risk of low Apgar score (Apgar 0–6 after 5 min; RR_A 1.17, 95% confidence interval [CI] 1.01–1.34), meconium aspiration (RR_A 1.25, 95% CI 1.06–1.48), need for respiratory support (continuous positive airway pressure; RR_A 1.09, 95% CI 1.03–1.15), and a composite outcome of need for comprehensive treatment at a neonatal department or neonatal death (RR_A 1.65, 95% CI 1.29–2.11). Birth complications included emergency cesarean section (RR_A 1.17, 95% CI 1.14–1.21), severe lacerations (RR_A 1.11, 95% CI 1.04–1.17), and increased blood loss after birth (RR_A 1.13, 95% CI 1.06–1.21).

Conclusions: Births at GA 41^{+4}–42^{+0} weeks were associated with an increased risk of neonatal morbidity and birth complications compared with births at GA 41^{+0}–41^{+3} weeks. The results of this study may aid clinicians in deciding when to recommend induction of labor in late-term pregnancies.

Abbreviations: BMI, body mass index; CI, confidence interval; CS, cesarean section; GA, gestational age; ICD-10, International Classification of Diseases 10th revision; RR_A, adjusted risk ratio.

KEYWORDS
cesarean, induction of labor, morbidity, mortality, neonatology, postpartum hemorrhage, stillbirth

1 | INTRODUCTION

The risk of complications in the perinatal period and during birth, including stillbirth and neonatal death, gradually increases from gestational age (GA) 40^{+0} weeks,[1–4] with a steep increase after GA 42^{+0} weeks.[3,4] Because of this increased complication risk, induction of labor is recommended to most women whose pregnancies continue beyond weeks 41–42 of gestation.[5,6]

The timing of induction of labor is controversial, and guidelines vary considerably nationally and internationally. The recommendations range from induction at GA 41^{+0} to induction at GA 42^{+0} weeks, or no recommendation of routine induction.[5,6] In general, the trend in the recommended time for induction has been toward lower GA, and the most recent World Health Organization recommendation in 2018 is to induce labor in all women who are known with certainty to have reached GA 41^{+0} weeks. However, the recommendation is weak and based on low-quality evidence.[7]

Most previous randomized trials or cohort studies compared the risk of complications in a group of induced births at a certain GA with that in a group with planned expectant management (induced or spontaneous delivery) and hence with a higher GA.[8–10] Consequently, induction of labor per se may have influenced the outcomes, which makes it difficult to determine the independent impact of GA.

In 2018, 24% of pregnancies in Denmark reached GA 41^{+0}weeks, whereas the proportion of pregnancies that reached GA 42^{+0} was 2.1%, which equals the proportion in the UK (2.0%).[11] These numbers differ from data in the USA, where only 6.5% of pregnancies progress to 41^{+0} weeks and 0.4% of pregnancies continue to GA 42^{+0} weeks or later.[4]We performed this cohort study to address the uncertainty in the appropriate timing of induction of labor in late-term pregnancies. We analyzed all singleton births with registered GA, without major congenital malformations and with intended vaginal delivery from 2009 through 2018 in Denmark and compared the risk of complications in births occurring at GA 41^{+0}–41^{+3} weeks with births at GA 41^{+4}–42^{+0} weeks while adjusting for potential confounding factors including induction of labor.

Key message

Data from singleton births without major congenital malformations, with registered gestational age, and with intended vaginal delivery in Denmark between 2009 and 2018 show that the risk of severe birth complications for both infant and mother increases through gestational week 41.

2 | MATERIAL AND METHODS

2.1 | Study design

This was a nationwide registry-based cohort study.

2.2 | Setting

In Denmark, approximately 97% of all births occur in public hospitals or clinics, with the rest being home births. All pregnant women in Denmark are offered free and comprehensive antenatal and obstetric care.

As part of the routine antenatal care, an ultrasound examination is performed early in the second trimester. In more than 90% of pregnancies, the due date is set by measuring the crown–rump length between GA 11^{+2} and GA 14^{+1} weeks.[12] The due date for most of the remaining pregnancies is estimated according to head circumference measurements in the late second-trimester ultrasound examination at approximately gestational week 19.

Further, as a part of antenatal care, multiple obstetric background factors, including maternal weight, height, smoking status, substance abuse, obstetric history, relevant comorbidities (eg, hypertension and insulin-dependent diabetes mellitus), mental illness, and socio-economic factors (eg, employment and ethnicity), are registered in the Danish National Patient Registry at the beginning of pregnancy and updated during regular antenatal controls.

Since 2011, the national recommendation in Denmark has been to induce labor between GA 41^{+2} and GA 41^{+5} weeks, intending to ensure that all births occur before GA 42^{+0} weeks. In case of high-risk pregnancies (eg, maternal body mass index [BMI] >35 kg/m^2, age >40 years, and gestational diabetes mellitus), the recommendation is to induce labor at GA 41^{+0} weeks.[13]

2.3 | Population

This cohort study included singleton births in Denmark with GA 41^{+0} to 42^{+0} weeks in the period from 2009 to 2018. Births with no GA information; births via a planned cesarean section (CS); and births in which the infant had malformations of the heart, lungs, or nervous system were excluded (Figure 1).

2.4 | Data source

At birth or on immigration, residents in Denmark are assigned a unique 10-digit civil registration number, which allows unambiguous

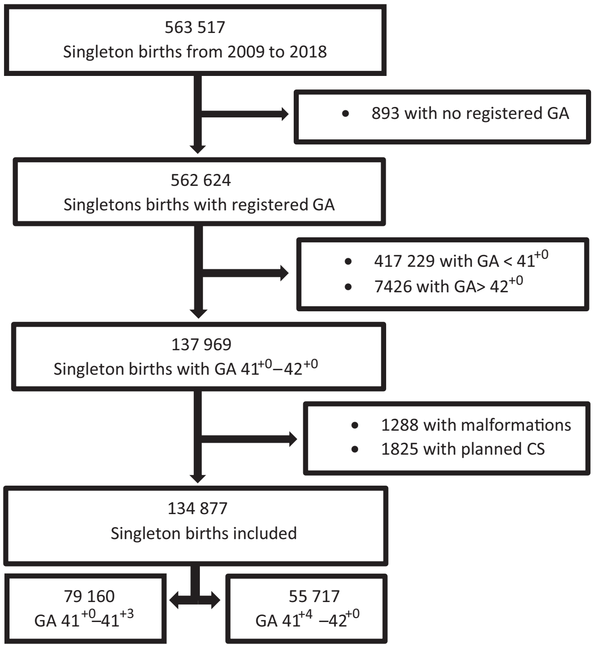

FIGURE 1 Flow diagram of the study population

individual-level identification and data linkage across nationwide registries and hospital records. The Danish National Patient Registry is a nationwide registry that holds information on all registered International Classification of Diseases 10th revision (ICD-10) codes on somatic hospitalizations, including births in Denmark since 1977.[14–17] Reporting to the Danish National Patient Registry is mandatory.

The data for this study were collected from the Danish National Patient Registry and linked to the Danish Register of Causes of Death and Statistics Denmark to obtain information on vital status and socio-economic factors (migrant status, education, and income).

See supplementary files for ICD-10 registrations (Table S1).

2.5 | Exposure

Births were divided into two groups according to GA: the first group included births occurring at GA 41^{+0}–41^{+3} weeks (reference), and the second group included births at GA 41^{+4}–42^{+0} weeks. We did not include births occurring after GA 42^{+0} weeks.

2.6 | Covariates

Potential covariates were identified as factors known from previous studies to influence both the risk of prolonged pregnancy and the risk of adverse neonatal and maternal outcomes.[18–20] Covariates for adjustment were identified using directed acyclic graphs and included maternal age, BMI, parity, and induction of labor. In addition, we adjusted for year of birth to account for any changes in clinical practice during the long study period. The causal model of the study is presented in Figure S1.

Maternal BMI was calculated from the pre-pregnancy weight and height, and maternal age was defined as the maternal age at delivery.

Induction of labor included medical induction with prostaglandins or oxytocin or mechanical induction including artificial rupture of membranes or induction with a balloon catheter.

2.7 | Outcomes

The outcomes were neonatal morbidity and mortality, fetal and maternal complications during birth, and maternal complications from birth. Neonatal outcomes included: low Apgar score after 1 and 5 min, severe or moderate hypoxia (umbilical cord pH <7.00 or 7.00–7.10), meconium aspiration, convulsions, need for continuous positive airway pressure, mechanical ventilation, central venous catheter placement, inhaled nitric oxide, hypothermia treatment, stillbirth, neonatal death within 28 days after birth, and weight deviation according to Scandinavian standard birthweight charts (small for gestational age defined as birthweight below the 10th centile, birthweight below the 2.3th percentile or large for gestational age defined as birthweight above the 90th centile).[21] As severe complications in term infants in Denmark are rare, a composite measure was defined. It included neonatal death (0–28 days after birth), need for hypothermia treatment, mechanical ventilation, or nitric oxide treatment.

Birth and maternal complications included: suspected fetal distress during birth (pathological signs on the cardiotocograph, meconium-stained amniotic fluid, pathological result in scalp blood sampling [pH <7.2 or lactate >4.8 mmol/L], signs of asphyxia on an ultrasound scan or a significant event on ST analysis), use of scalp pH/lactate sampling, maternal fever, operative vaginal delivery (vacuum extraction or forceps), emergency CS, shoulder dystocia, uterine rupture, severe perineal lacerations including the anal sphincter and severe postpartum hemorrhage ≥1000 mL.

A national recommendation on routine measurement of umbilical cord pH in all births was adopted in 2011. Since 2012, postpartum hemorrhage has been objectively measured (not merely estimated).[22,23]

All study variables were obtained from the Danish National Patient Registry. See supplementary files for ICD-10 registrations (Table S1).

2.8 | Statistical analyses

Logistic regression models were used to estimate the difference in complications between births at GA 41^{+0}–41^{+3} weeks and births at GA 41^{+4}–42^{+0} weeks.

The results were estimated as crude risks, risk differences, and risk ratios (RRs) with 95% confidence intervals (CIs). Further, the results were adjusted for age, BMI, parity, year of birth, and induction of labor (adjusted RR [RR_A]).

TABLE 1 Baseline characteristics of participants according to gestational age group. Values are numbers (percentages) unless otherwise stated

	Gestational age 41^{+0}–41^{+3} wk (n = 79 160)	Gestational age 41^{+4}–42^{+0} wk (n = 55 717)
Child		
Sex (male)	39 755 (50.2)	28 873 (51.8)
Birthweight (g), mean (interquartile range)	3745 (3450–4025)	3819 (3514–4110)
<2500	77 (0.1)	40 (0.1)
2501–3000	2792 (3.5)	1425 (2.6)
3001–3500	20 438 (25.8)	11 997 (21.5)
3501–4000	34 464 (43.5)	23 992 (42.9)
4001–4500	17 168 (21.7)	14 390 (25.8)
4501–5000	3300 (4.2)	3185 (5.7)
>5000	322 (0.4)	369 (0.7)
Mother		
Body mass index at start of pregnancy (kg/m^2)		
Mean (interquartile range)	24.68 (21.09–26.81)	24.30 (21.19–26.45)
0–20	10 327 (13.1)	6886 (12.4)
20–25	44 440 (56.1)	32 471 (58.3)
26–30	13 749 (17.4)	10 409 (18.7)
31–35	5447 (6.9)	3727 (6.7)
36–40	2405 (3.0)	698 (1.3)
>40	1052 (1.3)	260 (0.5)
Maternal age (years), mean (interquartile range)	29.87 (26–33)	29.78 (27–33)
0–20	1220 (1.5)	794 (1.4)
20–25	13 912 (17.6)	9442 (17.0)
26–30	29 283 (37.0)	21 100 (37.9)
31–35	24 100 (30.4)	17 707 (31.8)
36–40	9334 (11.8)	6270 (11.3)
>40	1311 (1.7)	404 (0.7)
First parity	33 456 (42.3)	26 628 (47.8)
Smoker	5273 (6.7)	3269 (5.9)
Previous cesarean section	5481 (6.9)	3652 (6.6)
Gestational diabetes mellitus	1506 (1.9)	137 (0.3)
Insulin-dependent diabetes mellitus	174 (0.2)	33 (0.1)
Hypertension	1359 (1.7)	782 (1.4)
Other medical diseases[a]	4123 (5.2)	2782 (5.0)
Abortus habitualis	198 (0.3)	102 (0.2)
Abuse	179 (0.2)	121 (0.2)
Minor mental illness	1512 (1.9)	940 (1.7)
Serious mental illness	152 (0.2)	104 (0.2)
Education		
0–10 years	9892 (12.8)	6405 (11.8)
10–12 years	25 192 (32.6)	17 215 (31.7)
>12 years	42 241 (54.6)	30 762 (56.6)
Equivalized disposable income (€)	30 055 (21 796–35 864)	30 543 (22 053–36 478)

TABLE 1 (Continued)

	Gestational age 41^{+0}–41^{+3} wk (n = 79 160)	Gestational age 41^{+4}–42^{+0} wk (n = 55 717)
Mean (interquartile range)[b]		
Ethnicity		
Danish origin/descendant	33 346 (91.1)	46 226 (90.9)
Immigrant	6500 (8.9)	4627 (9.1)
Birth		
Breech (vaginal delivery)	538 (0.7)	252 (0.5)
Induction of labor	18 270 (23.1)	30 563 (54.9)

[a]Other medical diseases: Respiratory diseases, hypothyroidism, hyperthyroidism, polycystic ovary syndrome, gastrointestinal diseases, neurological disease.

[b]The equivalized disposable income is the total income of a household, after tax and other deductions, that is available for spending or saving, divided by the number of household members converted into equalized adults; household members are equalized or made equivalent by weighting each according to their age, using the modified OECD equivalence scale (Anyaegbu, G. (2010). Using the OECD equivalence scale in taxes and benefits analysis. *Economic and Labour Market Review*, 4(1), 49–54).

Table S2 shows the results of a multivariate model adjusted for age, BMI, parity, and year of birth, but not for induction of labor.

In a pre-planned sensitivity analysis, we compared the risk of complications before and after the change in the recommendation for induction of labor in 2011.

STATA Release 15 was used for the analyses (StataCorp LLC).

2.9 | Post hoc analyses

In a post hoc sensitivity analysis, we additionally examined complications in a small group of births with no registered GA and with a birthweight of more than 3000 g (Table S3).

2.10 | Ethical approval

This study was approved by the Danish Data Protection Agency (June 19, 2018, dnr number 2018–107 under The Northern Region Denmark). According to Danish law, registry-based studies do not require ethical approval or patient consent.

3 | RESULTS

A total of 134 877 singleton births fulfilled the criteria for cohort entry, comprising 79 160 births at GA 41^{+0}–41^{+3} weeks and 55 717 births at GA 41^{+4}–42^{+0} weeks. Information on GA was missing in 893 of 563 517 (0.16%) singleton births. Among singleton births that occurred between GA 41^{+0} and 42^{+0} weeks, 1288 infants were born with malformations of the heart, lungs, or nervous system and 1825 infants were delivered by planned CS (Figure 1).

Table 1 shows the characteristics of the cohort. Women who gave birth at GA 41^{+0}–41^{+3} weeks had higher BMI, were older, and more often had medical diseases, whereas women who gave birth at GA 41^{+4}–42^{+0} weeks were more often primiparous and underwent labor induction (Table 1).

A full list of adjusted and unadjusted effect estimates is presented in Table 2. A forest plot of the estimated RR_A is presented in Figure 2. The risk of low Apgar score at 1 minute after birth was increased in the late GA group; the risk was increased from 1.0% to 1.3% for Apgar score 0–3 and from 3.0% to 3.7% for Apgar score 4–6. The RR_A for Apgar score 0–3 was 1.24 (95% CI 1.11–1.38), and that for Apgar score 4–6 was 1.14 (95% CI 1.07–1.22). The risk of Apgar score below 7 after 5 min was increased from 0.6% to 0.7% (RR_A 1.17, 95% CI 1.01–1.34). Only a small difference was observed in the risk of low umbilical cord pH from 1.0 to 1.1 (RR_A 1.10, 95% CI 0.97–1.24).

In the late GA group, the proportion of infants with meconium aspiration syndrome was increased from 4.4‰ to 5.4‰ (RR_A 1.25, 95% CI 1.06–1.48); more infants were treated with continuous positive airway pressure, indicating respiratory insufficiency (4.7% vs 4.2%; RR_A 1.09, 95% CI 1.03–1.15); and there was an increased need for mechanical ventilation (2.0‰ vs 1.4‰; RR_A 1.61, 95% CI 1.21–2.14) and hypothermia treatment (0.9‰ vs 0.7‰; RR_A 1.54, 95% CI 1.01–2.36). The risk of nitric oxide treatment was seldom observed and was only slightly increased. The risk of stillbirth was very low, and we did not find an increased risk in the late GA group (Table 2). The risk of neonatal death within 28 days was 0.3‰ in the early GA group and 0.4‰ in the late GA group (RR_A 1.44, 95% CI 0.76–2.75).

The risk of neonatal death or need for comprehensive treatment at a neonatal department, defined by the composite end point, was increased in the late GA group from 1.9‰ to 2.7‰ (RR_A 1.65, 95% CI 1.29–2.11).

There was a difference in the risk of birthweight below the 10th centile in the two GA groups (11.5% vs 10.4% RR 1.11, 95% CI 1.08–1.15). After adjusting for maternal age, BMI, parity, and year of birth the risk was still increased (RR 1.06, 95% CI 1.03–1.10) (Table S2). The risk of birthweight above the 90th centile was lower in the late GA group (7.1% vs 7.9%; RR_A 0.95, 95% CI 0.91–0.99). The sensitivity

TABLE 2 Outcomes of births at gestational ages 41^{+0}–41^{+3} and 41^{+4}–42^{+0}. Values are numbers (percentages) unless otherwise stated

	Study population				
	Gestational age 41^{+0}–41^{+3} wk (n = 79 160)	Gestational age 41^{+4}–42^{+0} wk (n = 55 717)	Risk difference (%) (95% CI)	Risk ratio (95% CI)	Risk ratio (95% CI) Adjusted for maternal age, BMI, parity, year of birth, and induction of labor
Neonatal outcomes					
Apgar 0–3/1 min	791 (1.0)	711 (1.3)	0.28 (0.16–0.39)	1.28 (1.15–1.41)	1.24 (1.11–1.38)
Apgar 4–6 /1 min	2375 (3.0)	2038 (3.7)	0.66 (0.46–0.85)	1.22 (1.15–1.29)	1.14 (1.07–1.22)
Apgar 0–6/5 min	490 (0.6)	405 (0.7)	0.11 (0.02–0.20)	1.17 (1.03–1.34)	1.17 (1.01–1.34)
Umbilical cord pH <7.0[a]	684 (1.0)	548 (1.1)	0.11 (0.02–0.23)	1.12 (1.00–1.25)	1.10 (0.97–1.24)
Umbilical cord pH 7.0–7.10[a]	1845 (2.6)	1477 (2.9)	0.32 (0.13–0.50)	1.12 (1.05–1.20)	1.06 (0.99–1.14)
Meconium aspiration	345 (0.4)	299 (0.5)	0.10 (0.02–0.18)	1.23 (1.06–1.44)	1.25 (1.06–1.48)
Convulsions	120 (0.2)	101 (0.2)	0.03 (0.01–0.07)	1.20 (0.92–1.56)	1.27 (0.96–1.68)
CPAP	3296 (4.2)	2629 (4.7)	0.55 (0.33–0.78)	1.13 (1.08–1.19)	1.09 (1.03–1.15)
Mechanical ventilation	107 (0.1)	110 (0.2)	0.06 (0.02–0.11)	1.46 (1.12–1.91)	1.61 (1.21–2.14)
NO treatment	32 (0.0)	23 (0.0)	–	1.02 (0.60–1.74)	1.27 (0.73–2.22)
CVC	101 (0.1)	91 (0.2)	0.04 (0.01–0.08)	1.28 (0.96–1.70)	1.31 (0.96–1.78)
Hypothermia treatment	52 (0.1)	50 (0.1)	0.03 (0.00–0.06)	1.48 (1.00–2.18)	1.54 (1.01–2.36)
Stillborn	48 (0.1)	29 (0.1)	- 0.01 (- 0.03–0.02)	0.86 (0.54–1.36)	0.88 (0.53–1.44)
Neonatal death (0–28 days)	21 (0.0)	22 (0.0)	0.01 (0.00–0.03)	1.48 (0.81–2.71)	1.45 (0.76–2.75)
Composite neonatal outcome[b]	138 (0.2)	152 (0.3)	0.10 (0.05–0.15)	1.56 (1.24–1.97)	1.65 (1.29–2.11)
Small for gestational age					
<10th centile (−15%)	8198 (10.4)	6408 (11.5)	1.14 (0.81–1.48)	1.11 (1.08–1.15)	1.02 (0.99–1.06)
<2.3th percentile (−22%)	2075 (2.6)	1599 (2.9)	0.25 (0.07–0.43)	1.09 (1.03–1.17)	0.96 (0.89–1.02)
Large for gestational age >90th centile	6249 (7.9)	3969 (7.1)	- 0.77 (−1.060–.48)	0.90 (0.87–0.94)	0.95 (0.91–0.99)
Birth outcomes					
Suspected fetal distress during birth[c]	18 778 (23.7)	16 168 (29.0)	5.30 (4.82–5.78)	1.22 (1.20–1.25)	1.11 (1.09–1.13)
Scalp pH/lactate	12 966 (16.4)	11 744 (21.1)	4.70 (4.27–5.12)	1.29 (1.26–1.32)	1.12 (1.10–1.15)
Intrapartum fever	2545 (3.2)	2534 (4.6)	1.33 (1.12–1.55)	1.42 (1.34–1.49)	1.18 (1.11–1.25)
Emergency cesarean section	8684 (11.0)	8503 (15.3)	4.29 (3.92–4.66)	1.39 (1.35–1.43)	1.17 (1.14–1.21)
Operative vaginal delivery	7260 (9.2)	6293 (11.3)	2.12 (1.79–2.45)	1.23 (1.19–1.27)	1.12 (1.09–1.16)
Shoulder dystocia	1085 (1.4)	848 (1.5)	0.15 (0.00–0.28)	1.11 (1.02–1.21)	1.11 (1.01–1.22)
Uterine rupture	191 (0.2)	115 (0.2)	– 0.03 (−0.09–0.02)	0.86 (0.68–1.08)	0.88 (0.68–1.12)
Maternal outcomes					
Severe lacerations[d]	2799 (3.5)	2257 (4.1)	0.51 (0.31–0.72)	1.15 (1.09–1.21)	1.11 (1.04–1.17)
Hemorrhage[e]					
1000–1500 ml	2215 (4.0)	2016 (5.1)	1.16 (0.89–1.43)	1.29 (1.22–1.37)	1.13 (1.06–1.21)
>1500 ml	1044 (1.9)	918 (2.3)	0.46 (0.28–0.65)	1.25 (1.14–1.36)	1.10 (1.00–1.21)

Abbreviations: CPAP, continuous positive airway pressure; CVC, central venous catheter; NO treatment, treatment with inhaled nitric oxide.

[a]Only birth with at least one umbilical cord pH measured were included (n = 121 445).

[b]Composite neonatal outcome: neonatal death (0–28 days), hypothermia treatment, mechanical ventilation or NO treatment.

[c]Suspected fetal distress: pathological signs on the cardiotocograph, meconium-stained amnion fluid, pathological result of a scalp blood sampling, sign of asphyxia on a UL scan or a significant event on ST analysis (STAN). Registration is used when it leads to an intervention.

[d]Severe lacerations: perineal lacerations including the anal sphincter muscle.

[e]The volume of hemorrhage after birth was measured and reported from 2012. The results are based on data from 2012 (n = 95 509).

analysis comparing births before and after 2011 showed that the risk of birthweight below the 2,3th centile (−22%) was reduced after 2011 (Table 3).

The risk of clinical signs of fetal distress during birth was 23.7% in infants born at GA 41^{+0}–41^{+3} weeks and 29.0% in those born at GA 41^{+4}–42^{+0} weeks (RR_A 1.12, 95% CI 1.09–1.13), with a corresponding

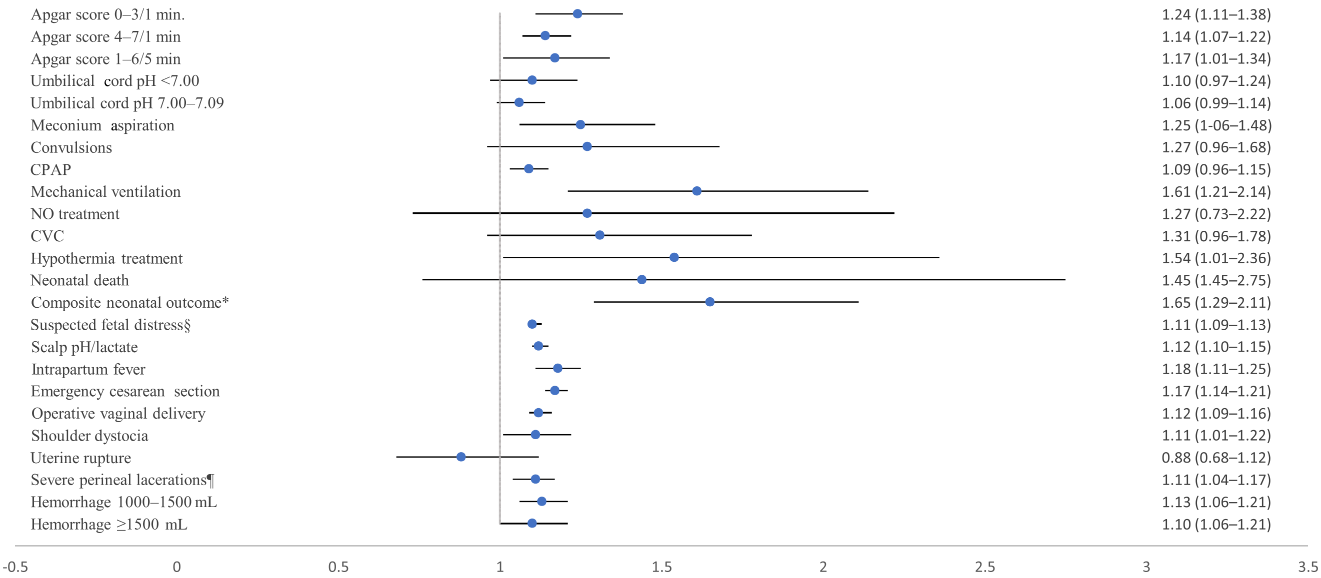

FIGURE 2 Forest plot illustrating adjusted risk ratios for complications in births at gestational age (GA) 41^{+4}–42^{+0} compared with births at GA 41^{+0}–41^{+3}

increase in the use of scalp blood sampling during delivery (21.1% vs 16.4%; RR_A 1.12, 95% CI 1.10–1.15).

We found an increased risk of complications from birth in the late GA group. The risk of severe perineal laceration including the anal sphincter muscle was 3.5% in births at GA 41^{+0}–41^{+3} weeks and 4.1% in births at GA 41^{+4}–42^{+0} weeks (RR_A 1.11, 95% CI 1.04–1.17). The risk of postpartum hemorrhage between 1000 and 1500 mL was increased from 4.0% to 5.1% (RR_A 1.13, 95% CI 1.06–1.21), and that of postpartum hemorrhage greater than 1500 mL was increased from 1.9% to 2.3% (RR_A 1.10, 95% CI 1.00–1.21).

The addition of induction of labor to the covariates did not markedly change the RRs (Table S2).

The pre-planned sensitivity analysis stratified according to calendar time (before and after 2011) showed no systematic differences (Table 3). We observed a change in the incidence of some of the outcomes from 2009–2010 to 2012–2018; however, the magnitude of the changes was comparable between the two groups.

In the post hoc sensitivity analysis of births with no registered GA but with a birthweight of more than 3000 g ($n = 510$), we found no marked differences in neonatal or maternal outcomes when compared with those with a registered GA (Table S3).

4 | DISCUSSION

This study confirmed that the risk of most complications increased with advancing GA within a range of 8 days. We found an increased risk of adverse neonatal outcomes including: low Apgar score, meconium aspiration, need for continuous positive airway pressure, hypothermia treatment, mechanical ventilation, and the composite outcome measure of nitric oxide treatment, hypothermia treatment, mechanical ventilation, and neonatal death. The risk of birth complications was increased, including fetal distress, maternal fever, operative vaginal delivery, shoulder dystocia, and emergency CS, as well as severe lacerations and postpartum hemorrhage.

The strength of this study lies in the nationwide study design with the inclusion of all singleton deliveries in Denmark at GA between 41^{+0} and 42^{+0} weeks for more than a decade. The large sample size allowed us to include rare complications such as hypothermia treatment and neonatal death.

A prerequisite for this study is an exact knowledge of the GA at birth. Setting the due date by measuring the crown–rump length in the early second trimester, instead of calculating the due date from the first day of the last menstrual period, is more accurate and is performed in more than 90% of all pregnancies in Denmark.[16]

Knowledge of the due date set on the basis of ultrasound findings also made it possible to exclude pregnancies that continued beyond GA 42^{+0} weeks. Including births after GA 42^{+0} weeks in the late GA group would have greatly influenced the results, as the risk of adverse neonatal and maternal outcomes substantially increases after GA 42^{+0} weeks.[1,2,24]

The consistent registration of background factors (eg, maternal BMI) in the first trimester made it possible to adjust for factors that may influence the outcome.

In the period from 2009 to 2018, there have been changes in antenatal and neonatal care in Denmark. The most important change was the recommendation of induction of labor before week 42^{+0} in 2011.[17] In addition, there has been a nationwide program on fetal surveillance, including education and certification of all doctors and midwives on cardiotocograph interpretation,[25] and a change in the recommendations on dystocia.[26] Modification of the guideline on induction occurred at a fixed date, but other changes were unmeasured but expected to have gradually occurred during the study period. To consider all these changes, the results were adjusted for

TABLE 3 Results of sensitivity analysis showing the outcomes for the period 2009–2010 compared with 2012–2018. Values are numbers (percentages) unless otherwise stated

	Study population			
	Gestational age 41^{+0}–41^{+3} 2009–2010 *n* = 15 070 2012–2018 *n* = 56 055	Gestational age 41^{+4}–42^{+0} 2009–2010 *n* = 10 997 2012–2018 *n* = 39 454	Risk ratio (95% CI)	Risk ratio (95% CI) Adjusted for maternal age, BMI, parity, year of birth and induction of labor
Neonatal outcomes				
Apgar 0–3/1 min				
2009–2010	109 (0.7)	117 (1.1)	1.47 (1.13–1.91)	1.48 (1.13–1.94)
2012–2018	614 (1.1)	539 (1.4)	1.24 (1.11–1.40)	1.18 (1.04–1.34)
Apgar 4–6/1 min				
2009–2010	434 (2.9)	352 (3.2)	1.11 (0.97–1.28)	1.06 (0.91–1.22)
2012–2018	1731 (3.1)	1502 (3.8)	1.23 (1.15–1.32)	1.15 (1.07–1.24)
Apgar 0–6/5 min				
2009–2010	90 (0.6)	84 (0.8)	1.28 (0.95–1.72)	1.37 (1.00–1.86)
2012–2018	356 (0.6)	280 (0.7)	1.12 (0.96–1.31)	1.05 (0.88–1.24)
Umbilical cord pH <7.0[a]				
2009–2010	68 (0.6)	63 (0.8)	1.25 (0.89–1.76)	1.23 (0.86–1.75)
2012–2018	564 (1.1)	446 (1.2)	1.11 (0.98–1.26)	1.11 (0.97–1.27)
Umbilical cord pH 7.00–7.09				
2009–2010	210 (1.9)	192 (2.3)	1.23 (1.01–1.49)	1.17 (0.96–1.43)
2012–2018	1484 (2.8)	1159 (3.1)	1.10 (1.02–1.18)	1.03 (0.95–1.12)
Meconium aspiration				
2009–2010	64 (0.4)	74 (0.7)	1.58 (1.13–2.21)	1.61 (1.14–2.29)
2012–2018	249 (0.4)	204 (0.5)	1.16 (0.97–1.40)	1.16 (0.95–1.42)
Convulsions				
2009–2010	19 (0.1)	24 (0.2)	1.73 (0.95–3.16)	2.07 (1.10–3.90)
2012–2018	91 (0.2)	71 (0.2)	1.11 (0.81–1.51)	1.10 (0.79–1.55)
CPAP				
2009–2010	564 (3.7)	539 (4.9)	1.31 (1.17–1.47)	1.23 (1.09–1.39)
2012–2018	2481 (4.4)	1871 (4.7)	1.07 (1.01–1.14)	1.01 (0.95–1.08)
Mechanical ventilation				
2009–2010	12 (0.1)	26 (0.2)	2.97 (1.50–5.88)	3.23 (1.58–6.62)
2012–2018	88 (0.2)	76 (0.2)	1.23 (0.90–1.67)	1.36 (0.97–1.90)
NO treatment				
2009–2010	8 (0.0)	<5[e]		-
2012–2018	27 (0.1)	15 (0.0)	0.79 (0.42–1.48)	1.09 (0.56–2.11)
CVC				
2009–2010	12 (0.1)	12 (0.1)	1.37 (0.62–3.05)	1.29 (0.57–2.96)
2012–2018	86 (0.2)	72 (0.2)	1.19 (0.87–1.63)	1.22 (0.86–1.72)
Hypothermia treatment				
2009–2010	5 (0.0)	6 (0.0)	1.64 (0.50–5.39)	1.96 (0.54–7.20)
2012–2018	41 (0.1)	42 (0.1)	1.46 (0.95–2.24)	1.48 (0.92–2.38)
Stillborn				
2009–2010	10 (0.1)	7 (0.1)	0.96 (0.37–2.52)	0.95 (0.34–2.64)

TABLE 3 (Continued)

	Study population			
	Gestational age 41^{+0}–41^{+3} 2009–2010 *n* = 15 070 2012–2018 *n* = 56 055	Gestational age 41^{+4}–42^{+0} 2009–2010 *n* = 10 997 2012–2018 *n* = 39 454	Risk ratio (95% CI)	Risk ratio (95% CI) Adjusted for maternal age, BMI, parity, year of birth and induction of labor
2012–2018	35 (0.1)	19 (0.1)	0.77 (0.44–1.35)	0.74 (0.40–1.37)
Neonatal death (0–28 days)				
2009–2010	5[e]	<5[e]	-	-
2012–2018	14 (0.0)	17 (0.0)	1.72 (0.85–3.50)	2.05 (0.97–4.36)
Composite measure[b]				
2009–2010	16 (0.1)	29 (0.3)	2.48 (1.35–4.57)	2.63 (1.39–4.97)
2012–2018	113 (0.2)	111 (0.3)	1.40 (1.07–1.81)	1.50 (1.12–1.99)
SGA				
<10th centile				
2009–2010	1515 (10.1)	1354 (12.3)	1.22 (1.14–1.31)	1.19 (1.11–1.28)
2012–2018	5861 (10.5)	4467 (11.3)	1.08 (1.04–1.12)	1.18 (1.04–1.34)
<2.3th percentile				
2009–2010	415 (2.8)	364 (3.3)	1.20 (1.05–1.38)	1.15 (0.99–1.33)
2012–2018	1444 (2.5)	1089 (2.8)	1.07 (0.99–1.26)	0.91 (0.83–0.99)
LGA				
>90th centile				
2009–2010	1248 (8.3)	867 (7.9)	0.95 (0.88–1.03)	0.96 (0.88–1.04)
2012–2018	4370 (7.8)	2753 (7.0)	0.90 (0.85–0.9)	0.95 (0.90–1.00)
Birth outcomes				
Suspected fetal distress[c]				
2009–2010	3417 (22.7)	2919 (26.5)	1.17 (1.12–1.22)	1.11 (1.06–1.16)
2012–2018	13 407 (23.9)	11 621 (29.5)	1.23 (1.21–1.26)	1.11 (1.08–1.13)
Scalp pH/lactate				
2009–2010	1345 (8.9)	1165 (10.6)	1.19 (1.10–2.28)	1.17 (1.09–1.27)
2012–2018	10 719 (19.1)	9844 (25.0)	1.30 (1.27–1.34)	1.13 (1.10–1.16)
Intrapartum fever				
2009–2010	316 (2.1)	265 (2.4)	1.15 (0.98–1.35)	1.07 (0.90–1.26)
2012–2018	2025 (3.6)	2095 (5.3)	1.47 (1.38–1.56)	1.21 (1.13–1.29)
Emergency CS				
2009–2010	1680 (11.1)	1603 (14.6)	1.31 (1.23–1.39)	1.11 (1.04–1.20)
2012–2018	6189 (11.0)	6128 (15.5)	1.41 (1.36–1.45)	1.11 (1.08–1.13)
Operative vaginal delivery				
2009–2010	1515 (10.1)	1234 (11.2)	1.12 (1.04–1.20)	1.10 (1.00–1.18)
2012–2018	4989 (8.9)	4418 (11.2)	1.26 (1.21–1.31)	1.12 (1.08–1.17)
Shoulder dystocia				
2009–2010	225 (1.5)	183 (1.7)	1.11 (0.92–1.35)	1.10 (0.90–1.35)
2012–2018	741 (1.3)	580 (1.5)	1.11 (1.00–1.24)	1.09 (0.97–1.23)
Uterine rupture				
2009–2010	60 (0.4)	36 (0.3)	0.82 (0.54–1.24)	0.73 (0.47–1.14)
2012–2018	106 (0.2)	67 (0.2)	0.90 (0.66–1.22)	0.94 (0.68–1.31)

(Continues)

TABLE 3 (Continued)

	Study population			
	Gestational age 41^{+0}–41^{+3} 2009–2010 *n* = 15 070 2012–2018 *n* = 56 055	Gestational age 41^{+4}–42^{+0} 2009–2010 *n* = 10 997 2012–2018 *n* = 39 454	Risk ratio (95% CI)	Risk ratio (95% CI) Adjusted for maternal age, BMI, parity, year of birth and induction of labor
Severe lacerations[d]				
2009–2010	612 (4.1)	463 (4.2)	1.04 (0.92–1.17)	1.07 (0.95–1.21)
2012–2018	1807 (3.2)	1540 (3.9)	1.21 (1.23–1.29)	1.14 (1.06–1.23)

Abbreviations: CPAP, continuous positive airway pressure; CS, cesarean section; CVC, central venous catheter; NO treatment, treatment with inhaled nitric oxide; SGA, small for gestational age; LGA, Large for gestational age.

[a]Only birth with at least one UC pH measured were included.

[b]Composite neonatal outcome: neonatal death (0–28 days), hypothermia treatment, mechanical ventilation or NO treatment.

[c]Suspected fetal distress: pathological signs on the cardiotocograph, meconium-stained amnion fluid, pathological result of a scalp blood sampling, sign of asphyxia on an ultrasound scan or a significant event on ST analysis (STAN). Registration is used when it leads to an intervention.

[d]Severe lacerations: perineal lacerations including the anal sphincter muscle.

[e]For legal reasons, this notation (<5) is used to avoid potential identification of single cases.

year of birth, although the directed acyclic graph did not indicate the necessity for this process.

The validity of the study depends on valid registrations by clinicians, and most of the included variables have not been validated for scientific purposes. The registration practice in obstetrics and neonatology has improved, beause quality indicators in these areas have been implemented by the five administrative regions in Denmark from 2010 onward.[22,23] When designing the study, we expected that the registrations for some clinical outcomes could be less precise; for example, meconium aspiration is known to be used for different conditions, ranging from vomiting to severe meconium aspiration syndrome. The registration of treatments and interventions (eg, hypothermia treatment and mechanical ventilation) is a central element in the financial reimbursement to Danish neonatal units and, consequently, is subject to rigorous clinical and administrative attention. Accordingly, we expected these registrations to be more valid and defined the composite measure of neonatal morbidity based on treatments or death. In general, we found no indications of differences in registration between the two GA groups. Thereby, we expected potential misclassifications to introduce bias in the effect estimates toward the null, which means that the true association is most likely underestimated.

Some aspects of prenatal and intrapartum care were specific to Denmark, including the high rates of prenatal care, standardized approaches to intrapartum care, and certification of doctors and midwives in cardiotocograph interpretation. This may limit the generalizability of the results.

The lack of GA information in 833 births is a potential source of bias. These births represent unrecognized pregnancies or registration failures. Among these births, we observed no marked difference in neonatal or maternal outcomes (Table S3).

The design of this study differs from that of previous studies, as the results were adjusted for induction of labor. Induction of labor is known to influence the risk of interventions and complications from birth.[4,8,10,20,27] The indications for induction of labor are generally different between the first days of gestational week 41, during which induction is most often performed because of medical diseases, pregnancy complications, advanced maternal age, or high BMI (factors that are known to influence the risk of neonatal and birth complications),[28–30] and the last days of gestational week 41, during which induction of labor is most often performed according to the recommendation of labor induction before GA 42^{+0} weeks. Adjusting for induction of labor in the multivariable analyses reduced this difference between the two groups.

The composite measure was, in addition to neonatal death, based on procedures used in the treatment of severe hypoxia or respiratory complications. It is known from previous studies that the risk of respiratory complications increases with increasing GA, and several studies found an increased risk of admittance to an intensive care unit, indicating the use of some procedures included in the composite measure.[1,2,4,31]

The increased risk of neonatal death found in this study is in accordance with the findings of previous studies.[4,32] A systematic review by Muglu et al. in 2019 showed an increased risk of neonatal death in pregnancies that continued beyond 41 weeks, in which the risk significantly increased for deliveries at 42 vs 41 weeks of gestation (RR 1.87).[33]

Most previous studies have shown an increased risk of stillbirth with increasing GA from week 40^{+0},[2–4,33] and Lidegaard et al. reported an increase in the cumulative risk of stillbirths at GA 41^{+0}–41^{+6} weeks (from 0.16‰ to 2.46‰).[34] Our study on a population of infants with no malformations, in which induction of labor was recommended at GA 41^{+0} weeks for high-risk pregnancies and at GA 41^{+2}–41^{+5} weeks in uncomplicated pregnancies (from 2011), showed that the risk of stillbirth was 0.6‰ at GA

41^{+0}–41^{+3} weeks and 0.5‰ at GA 41^{+4}–42^{+0} weeks (RR_A 0.88, 95% CI 0.53–1.44).

The increased risk of interventions in births at advanced GA is supported by previous studies.[1,4] In most recent studies, induction of labor at a late GA has been shown to reduce the risk of emergency CS.[4] Hence, both induction of labor and lower GA favor vaginal delivery. In our study, after adjusting for induction of labor, the risk of CS was still higher in the late GA group.

A cohort study from Denmark comparing the risk of complications from birth between 2000–2010 and 2012–2016 showed an increased risk of uterine rupture from 2012 onward.[35] We did not observe the same trend. The sensitivity analysis showed that the risk of uterine rupture in births occurring at GA 41^{+0}–42^{+0} weeks decreased from 3.7‰ to 1.8‰ after 2012 (Table 3).

The results of this study may guide clinicians in deciding when to recommend or offer induction of labor in late-term pregnancies. The discussion has previously been focused on the risk of stillbirth and neonatal death. This study offers an opportunity to consider other serious complications. Further, our results may guide the design and direction of future studies, as we demonstrated an association for rare but serious complications. Specifically, this study may have implications for pre-study power calculations.

5 | CONCLUSION

The risk of neonatal morbidity, need for interventions during birth, and maternal complications was increased in births occurring at GA 41^{+4}–42^{+0} weeks compared with GA 41^{+0}–41^{+3} weeks. The results of the current study may aid clinicians in deciding when to recommend or offer induction of labor in late-term pregnancies.

CONFLICT OF INTERESTS

None.

AUTHOR CONTRIBUTIONS

CA, USK, JP and SPJ designed the study. CA and SPJ acquired the data and CA and MJ did the data management. CA, USK, JP and SPJ analyzed and interpreted the data. The manuscript was drafted by CA, with all other authors critically revising the paper. CA is guarantor of the study. CA, SPJ and MJ had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. CA is responsible for the overall content as guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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