RESEARCH ARTICLE

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Elective cesarean delivery at term and its effects on respiratory distress at birth in Japan: The Japan Environment and Children's Study

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Abstract

Background and Aims: Early-term birth between 37 and 38 weeks of gestation increases the risk of mortality and morbidity. This study investigated the status and impact of early-term birth among neonates born by cesarean section in Japan.

Methods: All singleton live births that had data of gestational age at birth available in the Japan Environment and Children's Study (JECS), a nationwide birth cohort study launched in 2011, were eligible for this study. Neonates born by cesarean delivery at term without indications for early delivery were included to examine the association between early-term birth and respiratory distress at birth. The gestational age at birth was categorized as 37 weeks 0 day to 38 weeks 6 days (early-term), 39 weeks 0 day to 40 weeks 6 day (full-term), and 41 weeks 0 day to 41 weeks 6 days (late-term). Respiratory distress at birth included respiratory distress syndrome, transient tachypnea, and difficulty in breathing after birth. Univariable and multivariable analyses were performed using logistic regression models with a two-tailed significance level of 5%. All statistical analyses were performed using SAS, version 9.4, for Windows (SAS Institute, Cary, NC).

Results: In total, 32 078 of 100 011 (32.1%) neonates had early-term birth. At 37 gestational weeks, 49.7% of the deliveries were via cesarean section, and half of the cesarean deliveries were due to a previous cesarean section. Among the 10 051 neonates born by elective cesarean delivery at term, neonates with early-term births were more likely to have respiratory distress at birth (adjusted odds ratio: 4.19; 95% confidence interval, 1.70, 10.34) than those born at full term.

Conclusions: Early-term birth is associated with a high risk of respiratory distress in births involving cesarean delivery without indication for early delivery. There is a need for guidelines for early delivery considering adverse effects of early-term births.

1 | BACKGROUND

Worldwide, more than 1 in 10 children born in 2014 (approximately 15 million children) were preterm.[1] Preterm birth is associated with high mortality and morbidity rates. Globally, it is one of the leading causes of death among neonates and the second leading cause of death among children younger than 5 years of age.

Although preterm birth is defined as birth before 37 weeks of gestation, birth between 37 and 38 weeks of gestation (early-term birth) is considered suboptimal.[2] Early-term birth may increase the risk of mortality[3] and short-term and long-term morbidities, including respiratory,[4-6] allergic,[7] neurologic,[8,9] and metabolic disorders.[9] Risk factors of early-term deliveries were reported as socioeconomic factors, environmental factors, pregnancy-related complications, or medical indications; however, some of these deliveries were not medically indicated.[10,11]

As the number of elective deliveries that are not medically indicated contributes to the growing proportion of early-term births in the United States,[9,12,13] measures to reduce these deliveries have been undertaken in the country. Recent studies have reported a declining trend in early-term birth rates.[14-16] The avoidance of unnecessary early births has led to lower perinatal mortality rates between 2006 and 2014 in North America and Europe.[15]

Among high-income countries, Japan had the highest prevalence of early-term births (30.8%) in 2010.[17] The guideline on obstetric care in Japan does not provide a clear indication for early delivery,[21] and early-term deliveries might have been widely practiced. An increasing trend of low birth weights in Japan since the 1970s[18-20] suggests an increase in early-term births; however, a trend in early-term births and its impact on child health in Japan is unknown. The present study, therefore, investigated the frequency and reasons of early-term birth (birth between 37 weeks 0 day and 38 weeks 6 days) in Japan as well as the effects of early-term birth on neonatal health outcomes. These findings will be useful for determining when early-term deliveries should be performed.

2 | METHODS

2.1 | Cohort

All babies who had live births and had data of gestational age at birth available in the Japan Environment and Children's Study (JECS) were eligible for this study to investigate the prevalence of early-term birth (Figure 1). Further, singleton live births by cesarean delivery at term without indications for early delivery were included to examine the association between early-term birth and respiratory distress at birth. As there is no clear indication for early delivery in Japan, we referred to the opinion of the American College of Obstetricians and Gynecologists (ACOG) for selecting indications for early delivery.[22] We decided to remove multiple births and obstetric complications such as hypertensive disorder, placenta previa, non-reassuring fetal status, delayed/obstructed labor, premature rupture of membranes, intrauterine infection, or other complications. Also excluded were neonates with congenital malformations of the head/brain (eg, anencephaly, encephalocele, microcephaly, hydrocephalus), eye (eg, eyelid coloboma, microphthalmia), or ear; orofacial anomalies; anomalies in the upper limb, chest (eg, congenital diaphragmatic hernia, pulmonary sequestration), abdomen (eg, umbilical hernia, gastroschisis, esophageal atresia), urogenital apparatus (eg, hydronephrosis, cystic renal anomalies, renal agenesis), lower limb, skin, or skeleton/muscle (eg, thanatophoric dysplasia, achondrogenesis, achondroplasia); myelomeningocele (eg, spina bifida); and chromosomal anomalies (eg, Down's syndrome, Trisomy 18, Trisomy 13). Post-term births (42 weeks of gestation and beyond) were excluded due to the limited number of cases.
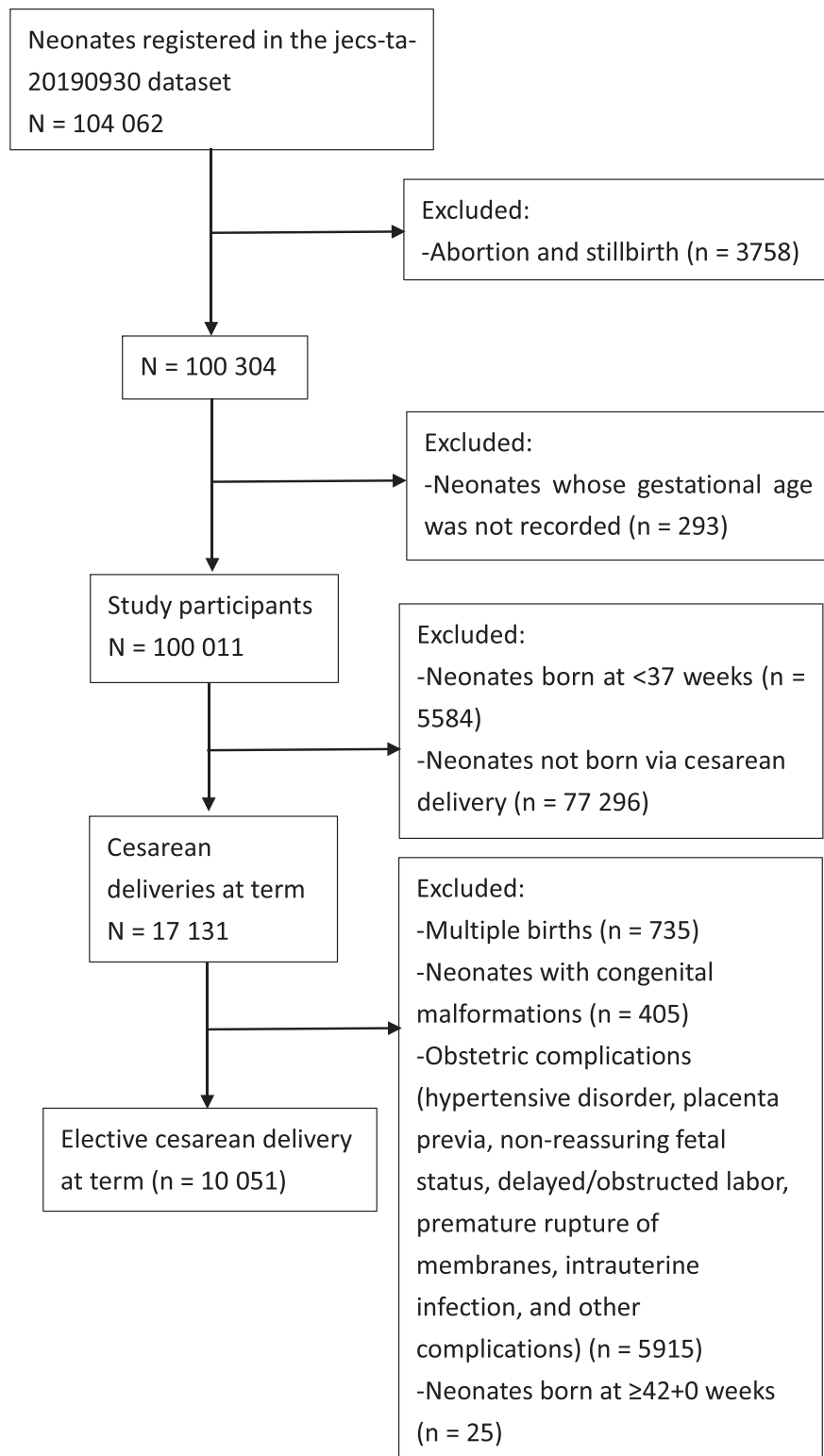
The JECS is an ongoing, nationwide, prospective birth cohort study that was launched in January 2011 under the initiative of the JECS Working Group to investigate the effects of environmental factors on child health and development.[23,24] The JECS included pregnant women who resided in the study areas with due dates between August 2011 and mid-2014 and had no difficulty understanding Japanese or completing the self-administered questionnaires. Women were recruited in the early stages of pregnancy, and the participants and their partners and offspring were followed up at 15 regional centers in Japan.[25] The representativeness of the study population to the Japanese general population was verified at baseline and 1 year after the study inception.[26,27]

2.2 | Exposure

The present study explored the effects of early-term birth on the occurrence of respiratory distress at birth among neonates born by cesarean section in Japan. Data of the gestational age at birth were extracted from the medical record transcripts from the co-operating healthcare providers at which the study participants were born. The gestational age at birth was categorized as 37 weeks 0 day to 38 weeks 6 days (early-term birth) and 39 weeks 0 day to 41 weeks 6 days (full-term birth) or 41 weeks 0 day to 41 weeks 6 days (late-term birth).

2.3 | Outcomes

The outcome of the present study was respiratory distress at birth, including respiratory distress syndrome, transient tachypnea, and

FIGURE 1 Patient selection flowchart

Neonates registered in the jecs-ta-20190930 dataset
N = 104 062

Excluded:
-Abortion and stillbirth (n = 3758)

N = 100 304

Excluded:
-Neonates whose gestational age was not recorded (n = 293)

Study participants
N = 100 011

Excluded:
-Neonates born at <37 weeks (n = 5584)
-Neonates not born via cesarean delivery (n = 77 296)

Cesarean deliveries at term
N = 17 131

Excluded:
-Multiple births (n = 735)
-Neonates with congenital malformations (n = 405)
-Obstetric complications (hypertensive disorder, placenta previa, non-reassuring fetal status, delayed/obstructed labor, premature rupture of membranes, intrauterine infection, and other complications) (n = 5915)
-Neonates born at ≥42+0 weeks (n = 25)

Elective cesarean delivery at term (n = 10 051)

difficulty breathing after birth. Neonatal complications were reported by co-operating healthcare providers based on medical records.

Socioeconomic factors (including maternal occupation at conception and maternal educational status), child characteristics (such as sex), maternal behaviors, maternal medical history, and complications related to the pregnancy were considered potential confounders.[17]

Maternal age at study enrolment (during early pregnancy), mode of conception (including fertility treatments such as assisted reproductive technology),[28] maternal anxiety (Kessler Psychological Distress Scale [K6 score] ≥ 5[29,30]), maternal alcohol consumption, maternal smoking, maternal comorbidities during pregnancy, and maternal parity were considered maternal factors that affect gestational age and

neonatal health outcomes based on previous studies.[10,31-33] Maternal comorbidities included hypertension, thyroid disease, diabetes, autoimmune disease, heart disease, kidney disease, hepatitis, cerebral infarction, cerebral hemorrhage, epilepsy, hematologic disease, malignant tumor, mental disease, neurological disorder, and thrombosis. Data of the sex of the child, gestational age at birth, maternal comorbidities during pregnancy, and mode of conception were extracted from the medical record transcripts. Data of all other factors were collected from the mothers using questionnaires at the time of enrolment (during early pregnancy) and during mid- to late pregnancy.

2.4 | Statistical analyses

The distributions and frequencies of early-term births by mode of delivery and reason for delivery were examined, and the distributions and frequencies of exposure, outcomes, and covariates among the restricted study participants were analyzed and summarized as percentages or means, as appropriate. Univariable analyses were performed to assess the relationship between early-term birth and respiratory distress at birth using logistic regression models. Multivariable analyses were performed with all covariates using logistic regression models. A two-tailed significance level of 5% was used for all statistical tests. All statistical analyses were performed using SAS, version 9.4, for Windows (SAS Institute, Cary, North Carolina).

2.5 | Ethics approval

This study was conducted according to the principles of the World Medical Association Declaration of Helsinki and Ethical Guidelines for Medical and Health Research Involving Human Subjects promulgated by the Ministry of Health, Labour, and Welfare of Japan. The JECS protocol was approved by the Ministry of the Environment's Institutional Review Board on Epidemiological Studies (no. 100406001) and the ethics committees of all participating institutions. Written informed consent was obtained from all participants.

3 | RESULTS

The dataset of jecs-ta-20190930 was used for the analyses. The patient selection flowchart is shown in Figure 1. Among 104 062 registered, there were 3758 (3.5%) abortions and stillbirths and 293 (0.3%) neonates whose gestational age was not recorded. A total of 100 011 neonates were included in the present study, including 1231 (1.2%) born before 34 weeks of gestation, 4353 (4.4%) neonates born between 34 and 36 weeks of gestation, 32 078 (32.1%) neonates born between 37 and 38 weeks of gestation, 53 313 (53.3%) neonates born at 39 and 40 weeks of gestation, 8809 (8.8%) neonates born at 41 weeks of gestation, and 227 (0.2%) neonates born at 42 weeks or later. The mean gestational age at birth was 38.8 weeks (SD, 1.7) (Table 1). Planned or emergency cesarean sections were the most common delivery mode at 37 weeks (49.7%), 34 to 36 weeks (46.6%), and ≤33 weeks (75.3%) of gestational age (Table 1). At 38 weeks of gestation, the most common delivery mode was spontaneous (48.3%), followed by cesarean section (34.6%).

Repeated cesarean delivery was the most common reason for cesarean deliveries at 38 (60.3%) and 37 (51.5%) weeks of gestation (Table 2). In contrast, at 37 or 38 weeks of gestation, 23.9% of cesarean deliveries were due to complications such as gestational hypertensive disorder of pregnancy, placenta previa, non-reassuring fetal status, delayed/obstructed labor, premature rupture of membranes, intrauterine infection, and other complications. Complications were the most common reason for cesarean deliveries at 34 to 36 and ≤33 weeks of gestation.

The univariable and multivariable analyses included 10 051 neonates who were born by cesarean delivery at term without a clear indication for early delivery to investigate the effects of early-term birth on respiratory distress. Table 3 summarizes the characteristics of the neonates included in the univariable and multivariable analyses. Among the neonates delivered by cesarean section with no indications for early delivery, 87.4% were born at 37 or 38 weeks of gestation. Half of the neonates were male (49.5%), and the mean maternal age at enrolment was 32.1 years (SD, 4.9 years). More than half of the mothers were employed (57.7%), and only 6.8% underwent assisted

TABLE 1 Delivery mode according to gestational age at birth (N = 100 011)

Gestational age at birth (weeks)	Total	Spontaneous delivery	Induced delivery	Vacuum extraction	Forceps delivery	Planned/emergent cesarean delivery
>41	227	32 (14.2)	104 (46.0)	10 (4.4)	0 (0.0)	80 (35.4)
41	8809	3586 (40.8)	3314 (37.7)	639 (7.3)	26 (0.3)	1221 (13.9)
40	25 849	16 975 (65.8)	5219 (20.2)	1867 (7.2)	94 (0.4)	1627 (6.3)
39	27 464	19 806 (72.3)	4261 (15.6)	1663 (6.1)	57 (0.2)	1618 (5.9)
38	22 053	10 629 (48.3)	2876 (13.1)	841 (3.8)	26 (0.1)	7617 (34.6)
37	10 025	3478 (34.8)	1238 (12.4)	307 (3.1)	7 (0.1)	4968 (49.7)
34-36	4353	1768 (40.7)	425 (9.8)	125 (2.9)	3 (0.1)	2021 (46.6)
≤33	1231	257 (21.1)	38 (3.1)	7 (0.6)	0 (0.0)	918 (75.3)
Total	100 011	56 531 (56.7)	17 475 (17.5)	5459 (5.5)	213 (0.2)	20 070 (20.1)

Note: Data are presented as numbers (percentages). Some data regarding the mode of delivery are missing (n = 263).

TABLE 2 Indications for cesarean delivery according to gestational age at birth (N = 20 070)

	Gestational age at birth (weeks)							
	>41	41	40	39	38	37	34-36	≤33
Repeat cesarean delivery	3 (3.8)	15 (1.2)	46 (2.8)	290 (17.9)	4590 (60.3)	2557 (51.5)	454 (22.5)	105 (11.4)
History of uterine surgery	0 (0.0)	2 (0.2)	2 (0.1)	8 (0.5)	230 (3.0)	153 (3.1)	20 (1.0)	5 (0.5)
Hypertensive disorder of pregnancy	1 (1.3)	33 (2.7)	75 (4.6)	114 (7.1)	136 (1.8)	161 (3.2)	255 (12.6)	156 (17.0)
Placenta previa	0 (0.0)	0 (0.0)	0 (0.0)	5 (0.3)	49 (0.6)	185 (3.7)	129 (6.4)	60 (6.5)
Non-reassuring fetal status	14 (17.5)	311 (25.5)	465 (28.6)	351 (21.7)	234 (3.1)	152 (3.1)	170 (8.4)	139 (15.1)
Fetal malpresentation	0 (0.0)	36 (3.0)	66 (4.1)	145 (9.0)	1279 (16.8)	699 (14.1)	214 (10.6)	110 (12.0)
Delayed/obstructed labor	33 (41.3)	410 (33.6)	496 (30.5)	322 (19.9)	142 (1.9)	65 (1.3)	24 (1.2)	3 (0.3)
Multiple birth	0 (0.0)	1 (0.1)	3 (0.2)	0 (0.0)	65 (0.9)	575 (11.6)	535 (26.5)	162 (17.7)
Premature rupture of membranes	2 (2.5)	72 (5.9)	143 (8.8)	143 (8.8)	175 (2.3)	200 (4.0)	306 (15.1)	222 (24.2)
Intrauterine infection	3 (3.8)	39 (3.2)	56 (3.4)	33 (2.0)	24 (0.3)	13 (0.3)	11 (0.5)	39 (4.3)
Cephalopelvic disproportion	17 (21.3)	305 (25.0)	358 (22.0)	245 (15.1)	212 (2.8)	92 (1.9)	12 (0.6)	0 (0.0)
Overdue pregnancy	35 (43.8)	221 (18.1)[a]	65 (4.0)[a]	1 (0.1)[a]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Other complications/reason	13 (16.3)	240 (19.7)	369 (22.7)	350 (21.6)	829 (10.9)	637 (12.8)	512 (25.3)	375 (40.9)

Note: Data are presented as numbers (percentages).
[a]Data are reported by co-operating healthcare providers. In Japan, delivery is planned at 40 weeks 0 day[21] and pregnancy over this date may be considered overdue. We decided to report these numbers because we considered that they might reflect the real situation in Japan.

reproductive technology treatments. Comorbidities were present in 14.9% of mothers during pregnancy.

The overall incidence of respiratory distress was 2.5% (250/10051) (Table 4). The incidence was highest at 37 weeks (3.5%) and decreased each week after 37 weeks.

Early-term birth was found to increase the risk of respiratory distress at birth compared with full-term birth (adjusted OR, 4.19; 95% CI 1.70, 10.34) (Table 5, Figure 2).

4 | COMMENT

4.1 | Principle findings

Among the live births between 2011 and 2014, 32.1% were early term. Nearly half of the early-term births were due to cesarean delivery; half of the early-term births via cesarean deliveries were indicated because of a history of cesarean delivery regardless of the existence of maternal complications during the current pregnancy. Among neonates born by cesarean delivery, early-term birth was associated with an increased risk of respiratory distress at birth compared with full-term birth.

4.2 | Strengths of the study

This was a large nationwide cohort study that represents the Japanese population well. The modes of delivery and reasons for performing cesarean deliveries in the present study reflect actual obstetric care in Japan.

4.3 | Limitations of the data

This study is not without limitations. Detailed information that was necessary to evaluate the risk of uterine rupture such as type of previous cesarean section, conditions of wound and myometrium after previous cesarean section, and history of uterine rupture was not available; therefore, the assessment of the appropriateness of the early initiation of cesarean delivery was challenging.

4.4 | Interpretation

In this study, 32.1% of live births were early term, suggesting a stable or slight increase in the prevalence of early-term births since 2010 (early-term birth rate: 30.8%).[17] This study also identified a lower proportion of spontaneous deliveries at early term in Japan (44.0%) compared with that in the United States (53.6%).[6] Although it is not well documented, elective early-term births might be widely performed without recognition of its potential negative impact on children in Japan. The Guideline for Obstetrics in Japan (2020 edition) provides guidance for the elective induction of labor at 37 to 41 weeks of gestation without any indications for early-term birth.[21] This may partly explain the higher proportion of early-term births and lower proportion of spontaneous deliveries at early term in Japan compared with the United States.

Approximately half of the early-term births in this study were cesarean deliveries, and half of these were indicated due to a history of cesarean delivery with no maternal complications in the current pregnancy. Cesarean deliveries for fetal malpresentation, which is not an indication for early delivery according to ACOG,[22] were performed

TABLE 3 Characteristics of the children included in the multiple regression analyses (N = 10 051)

	Mean [SD]	Number (%)
Gestational age at birth (weeks)	37.9 [0.9]	
41		318 (3.2)
40		373 (3.7)
39		573 (5.7)
38		5853 (58.2)
37		2934 (29.2)
Sex of the child		
Male		4971 (49.5)
Female and unclassified		5080 (50.5)
Maternal age at study entry (years)	32.1 [4.9]	
Parity		
0		2181 (21.7)
1		5240 (52.1)
2		2082 (20.7)
≥3		485 (4.8)
Missing data		63 (0.6)
Mode of conception		
Spontaneous		9296 (92.5)
Ovulation induction/AIH		295 (2.9)
Assisted reproductive technology		389 (3.9)
Missing data		71 (0.7)
Maternal comorbidities during pregnancy		
No		8314 (82.7)
Yes		1499 (14.9)
Missing data		238 (2.4)
Maternal job type at conception		
Employed		5801 (57.7)
Homemaker/student, unemployed, or other		3822 (38.0)
Missing data		428 (4.3)
Maternal educational status		
Secondary/high school		3591 (35.7)
Vocational school/junior college		4242 (42.2)
University and higher education		1978 (19.7)
Missing data		240 (2.4)
Maternal anxiety during pregnancy		
No		2743 (27.3)
Yes		7090 (70.5)
Missing data		218 (2.2)
Maternal alcohol consumption during pregnancy		
No		3310 (32.9)
Quit		6180 (61.5)
Continued		301 (3.0)
Missing data		260 (2.6)

TABLE 3 (Continued)

	Mean [SD]	Number (%)
Maternal smoking during pregnancy		
No		8034 (79.9)
Quit		1259 (12.5)
Continued		497 (4.9)
Missing data		261 (2.6)

Abbreviations: AIH, artificial insemination with husband's semen; SD, standard deviation.
Note: Data are presented as numbers (percentages) or mean [SD].

TABLE 4 Incidence of respiratory distress at birth according to gestational week (N = 10 051)

	Number of patients with respiratory distress/number at risk	Incidence (%)
Overall	250/10051	2.5
Gestational age at birth (weeks)		
41	3/318	0.9
40	0/373	0.0
39	5/573	0.9
38	139/5853	2.4
37	103/2934	3.5

TABLE 5 Crude and adjusted odds ratios of respiratory distress at birth in relation to early-term birth (N = 10 051)
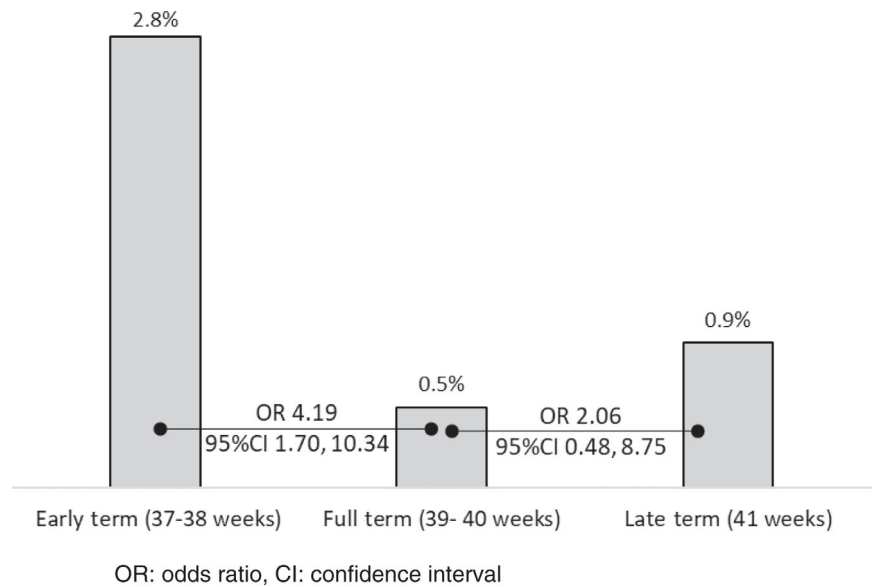
	Crude OR (95% CI)	Adjusted OR (95% CI)[a] (N = 9043)
Gestational age		
39 weeks 0 day to 40 weeks 6 days	1.00	1.00
41 weeks 0 day to 41 weeks 6 days	1.79 (0.43-7.54)	2.06 (0.48-8.75)
37 weeks 0 day to 38 weeks 6 days	5.33 (2.19-12.95)	4.19 (1.70-10.34)

Abbreviations: CI: confidence interval; OR: odds ratio.
[a]Adjusted for child sex, maternal age at study entry, maternal comorbidities during pregnancy, maternal job at conception, maternal educational status, maternal parity, mode of conception, maternal anxiety during pregnancy, maternal alcohol consumption during pregnancy, and maternal smoking during pregnancy.

most frequently between 37 and 38 weeks of gestation. It was reported that the frequency of early-term births decreased in the United States between 2006 and 2014 in relation to significant reduction in clinician-initiated delivery.[16] The authors discussed that the reduction in clinician-initiated deliveries reflected successful implementation of quality initiatives that aimed to reduce elective deliveries before 39 weeks of gestation. A similar effort will be necessary for Japan to address early deliveries that are not medically indicated.

FIGURE 2 Adjusted odds ratios of respiratory distress at birth in relation to early-term births among neonates born by cesarean section without indication for early delivery

2.8%

OR 4.19
95%CI 1.70, 10.34

0.5%

0.9%

OR 2.06
95%CI 0.48, 8.75

Early term (37-38 weeks)   Full term (39- 40 weeks)   Late term (41 weeks)

OR: odds ratio, CI: confidence interval

This study also showed that early-term birth was associated with an increased risk of respiratory distress among neonates delivered via cesarean delivery at term with no indications for early delivery. This result is consistent with previous studies that showed the effects of early-term birth on neonatal respiratory morbidity[34,35] and highlights the significance of the increasing frequency of early-term births on neonatal health.

Early-term births may be beneficial to maternal and child health when signs of uterine rupture or severe complications are present and earlier termination of pregnancy is considered optimal.[12] Nonetheless, this study showed that a history of cesarean delivery was the most common reason for early-term birth. The results of this study suggest that healthcare providers may plan early-term deliveries to avoid the need for an emergency obstetric response when a woman with a history of a cesarean delivery presents with contractions, regardless of the existence of complications. The number of hospitals in Japan that can provide obstetric care decreased from 2459 to 1313 facilities between 1990 and 2017.[36] These reduced resources have made it difficult to respond to obstetric emergencies, especially in rural areas and during shifts with reduced staff.[37] Early-term elective deliveries that are not medically indicated may be scheduled due to limited facilities and medical resources for trials of labor after cesarean deliveries or perinatal care during obstetric emergencies. Early-term elective deliveries may be appropriate in some patients with previous cesarean deliveries to avoid uterine rupture. However, this study did not include sufficient data to determine if the medical indications for cesarean deliveries were appropriate. Further research at the facility level is needed to investigate the causes of early-term births in Japan and what measures can be taken to prevent them.

Regardless of the high prevalence of early-term births and the accumulated evidence of the adverse effects of early-term birth on children's health, little efforts to reduce early-term births have been made in Japan. Guidelines regarding the appropriate timing of delivery

should be discussed by considering situations in health facilities and feasibilities. Additionally, the occurrence of early-term birth should be continuously monitored to provide timely feedback to medical professionals.[38] The long-term impact of early-term birth in Japan also needs to be investigated to understand the significance of early-term births among the Japanese population.

5 | CONCLUSIONS

This study showed a slight increase in the prevalence of early-term births in Japan. The results suggest that early-term birth is associated with an increased risk of respiratory distress in neonates born by cesarean delivery without an indication for early delivery. Early-term births are often elective and may not be medically indicated. The adverse effects of early-term births should be considered, and guidelines regarding the appropriate timing of delivery should be discussed. Facility-level research is needed to elucidate the reasons for early-term births and to determine what actions can be taken to decrease their prevalence. Investigations regarding the long-term impact of early-term birth on children's health and development in Japan are also necessary.

CONFLICT OF INTEREST

None declared.

AUTHOR CONTRIBUTION

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All authors have read and approved the final version of the manuscript.

Sayaka Horiuchi had full access to all data in this study and takes complete responsibility for the integrity of the data and the accuracy of the data analysis.

TRANSPARENCY STATEMENT

Sayaka Horiuchi affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

DATA AVAILABILITY STATEMENT

Data are unavailable for public deposition due to ethical restrictions and the legal framework of Japan. It is prohibited by the Act on the Protection of Personal Information (Act No. 57 of May 30, 2003; amendment on September 9, 2015) to publicly deposit data containing personal information. Ethical Guidelines for Medical and Health Research Involving Human Subjects enforced by the Japan Ministry of Education, Culture, Sports, Science, and Technology and the Ministry of Health, Labour, and Welfare also restrict the open sharing of epidemiologic data. All inquiries regarding access to data should be sent to Dr Shoji F. Nakayama, JECS Programme Office, National Institute for Environmental Studies at jecs-en@nies.go.jp.

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