Early-term birth and its association with universal two-child policy: a national cross-sectional study in China

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ABSTRACT

Objective To describe the epidemiology of early-term birth (ETB) at the national level in China, and explore the association and mediating factors between ETB and policy between universal two-child policy and ETB, so as to explain the potential reason for such a relationship and provide evidence for future ETB interventions in the era of the new birth control policy.

Design Cross-sectional study.

Participants The cross-sectional study used data from China Labour and Delivery Survey between 2015 and 2016. A total of 75 132 survey data collected from 89 hospitals in 25 provinces were included in the analysis. We further explored the association between the universal two-child policy and ETB.

Results The weighted incidence of ETB was 30.1 per 100 all births (95% CI 30.06% to 30.14%) or 29.88 per 100 live births (95% CI 29.97% to 30.05%) between 2015 and 2016 in China. There was an association between the universal two-child policy and ETB (relative risk, RR 1.19, 95% CI 1.13 to 1.22), previous uterine scars (RR 1.18, 95% CI 1.14 to 1.22), parity (RR 1.19, 95% CI 1.15 to 1.24) and other measured conditions (each p<0.05). Stratified analysis showed that the association between universal two-child policy and ETB was the strongest in multiparous young women or women without previous uterine scars (each p<0.05), and disappeared in all women of advanced maternal age (each p>0.05).

Conclusion The incidence of ETB was high in China when compared with most of reported countries, and there might be a link between two-child policy and ETB. Obstetric practice such as selective induced labour and caesarean section should be revised with ETB risks in mind, when ETB is more likely to happen under the universal two-child policy. Preventing ETB should not be neglected in multiparous young women or those without previous uterine scars under the new policy.

INTRODUCTION

Early-term birth (ETB) is defined as infants delivered at a gestation age between 370/7 and 386/7 weeks1, which accounts for 15%–31% of all deliveries, and far exceeds the number of preterm births.2 Preterm infants are often at a higher risk of morbidity and mortality compared with full-term infants,3 and recent reports also suggested that ETB is associated with significantly higher health risks, including higher neonatal, postnatal, and infant mortality and morbidity rates when compared with full-term infants (>38 gestational weeks)4; ETB can also have a long-term impact on children’s cognition and behaviour.5 However, the epidemiology of ETB is scarce in China despite a large number of studies on preterm birth.6–12

Since October 2015, China’s one-child policy has been replaced with a universal two-child policy (which allows a family to have two children). However, the relationship between universal two-child policy and newborn outcomes births is still unclear. Studies have reported that the change of the birth control policy might result in nationwide changes to a range of health outcomes, such as a more equal sex ratio, reduced neonatal mortality,13 and increased risk of birth defects.14 However, the new two-child policy might also be associated with outcomes related to birth term.

One of the potential consequences which is associated with the two-child policy might be an increased rate of ETB, which can be influenced by a range of factors, for example,
expressed an interest in taking part in the research were higher in women aged 30–34 years old when compared to their younger counterparts. Additionally, a higher primary caesarean section (C-Section) rate in China means that a more pregnant women who have had a previous birth have uterine scars. To avoid rupturing the uterus, early elective birth is more likely to be a decision for women with previous scars. The uterus scar site is more susceptible to tearing and rupture when subjected to pressure during labour. Therefore, with those possible influencing factors, a higher incidence of ETB might be observed after the implementation of the universal two-child policy.

Furthermore, studies showed that the relationship of universal two-child policy with obstetric issues can vary across different maternal characteristics. For example, it has been reported that the associations between the two-child policy and sex ratios differed by maternal age, parity, and history of C-section. It has also been found that the association of two-child policy with caesarean birth rate varies between nulliparous and multiparous women. Moreover, the risk of childbearing policy on incidence of birth defects has been found to be higher in women aged 30–34 years old when compared with their younger counterparts.

In the current study, we aimed to describe the epidemiology of ETB in China by using a nationwide dataset from the China Labour and Delivery Survey (CLDS). Additionally, we analysed the association between the incidence of ETB and the two-child policy in terms of different maternal characteristics (such as maternal age, previous uterine scars and parity). We also explored the factors that might mediate the association between ETB and policy so as to explain such a relationship and offer evidence for future ETB interventions in the era of the new birth control policy.

METHODS

Sample

Data for this national cross-sectional study were acquired from the dataset of the CLDS, which is a population-based multicentre study that describes the incidence, risk factors and possible underlying causes of ETB in China. We extracted the data between 2015 and 2016 because the one-child policy has been replaced with a two-child policy since October 2015. Participation was solicited through a national obstetric conference hosted by Shanghai First Maternity and Infant Hospital, Tongji University School of Medicine.

We used the same methodology as the WHO Global Survey of Maternal and Perinatal Health and the WHO Multi-Country Survey of Maternal and Newborn Health to perform data collection. The hospitals that expressed an interest in taking part in the research were asked to provide basic information about the hospitals, and only those with 1000 or more deliveries per year (having sufficient obstetrical faculty) were eligible for being included in this study. To ensure that there was a representative sample of ETB, we selected the hospitals with 1000 or more deliveries per year which covered most Chinese provinces (25 out of 34). With reference with the WHO methodology, for hospitals with an annual rate of more than 6000 deliveries per year, we divided the 1-year period into 13 time-sections and randomly selected 6 weeks of records, whereas for hospitals with an annual delivery rate of less than 6000 per year, ten weeks were randomly selected within a 1-year period, divided into five time sections. Within each selected week, all births delivered at 24 or more completed weeks of gestation or weighing 500 grams or more at birth were eligible.

Medical records were retrieved and reviewed, and information was extracted by trained research nurses. The study design, organisation and implementation have also been reported in another study. Using the WHO methodology allows for comparability between these results and the studies of other countries.

A data coordination centre was established to take charge of establishing, managing and maintaining the database and website, coordination among hospitals and investigators’ training. This study did not involve individual informed consent because the centre collected anonymous clinical information only. All information was kept confidential, and only the cooperators of our research could access the database when their application was approved by the data coordination centre. Additionally, the centre was also responsible for data logic checking, assessing of study protocol and other quality control measures of the data.

A total of 75,132 birth records were initially included in the analysis from 89 hospitals in China between 1 March 2015 and 31 December 2016. Among these birth records, a total of 73,567 live birth were included for calculating the incidence of ETB at a national level. In order to further analyse the association of ETB with the implementation of the universal two-child policy, we chose the women who were pregnant after October 2015 (the universal two-child policy was announced) and gave birth to children after July 2016 (the effective period: 9 months after the announcement of the universal two-child policy) according to previous studies. The women who gave birth to a child before October 2015 (before the announcement of the universal two-child policy) were included as controls. A total of 28,966 live singleton full-term birth were included in the final analysis (figure 1).

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

Exposure, outcomes and other covariates

ETB, which was defined as newborn delivery occurring between 37+0/7 to 38+6/7 weeks of gestation, was the main
outcome of our study. Gestational age was determined by obstetrical providers with the use of standard criteria that took into consideration the clinical history and the results of the earliest ultrasound examination.\textsuperscript{28, 29} If the gestational age as calculated from an early ultrasound is contradictory to the one calculated directly from the last menstrual period, it is the age calculated from the early ultrasound that is used for the rest of the pregnancy.\textsuperscript{30, 31}

We included the maternal age, previous uterine scar, parity and precursors as mediating factors (which refer to the factors that could mediate the relationship between the independent and dependent variables so as to explain the reason for such a relationship to exist). Precursors for delivery were defined using the following four categories: spontaneous labour, premature rupture of membranes (PROM), indicated and elective induction or C-Section, which has also been used to assess the reasons for late preterm birth according to previous study.\textsuperscript{32} Spontaneous labour was defined as women with the spontaneous start of labour and with or without complications or rupture of membranes during pregnancy. PROM was defined where a woman presented with PROM and underwent induction labour or prelabour C-Section, but exclusive of spontaneous labour. Indicated deliveries included women without spontaneous labour or PROM who underwent induction labour or prelabour C-Section for maternal, fetal or obstetric complications.\textsuperscript{33, 34} We also categorised as indicated any delivery where induction of labour or indication for prelabour C-Section was not recorded, but the pregnancy had other complications such as hyperthyroidism or hypothyroidism, and hypertensive disease or gestational diabetes. Elective induction or C-Section included elective inductions or C-Section as identified by the site with no other obstetrical, fetal or maternal conditions, and there was no reason for induction or C-Section provided, or no other obstetrical, fetal or maternal conditions.\textsuperscript{35, 36}

Additionally, it has been reported that the pre-pregnancy body mass index (BMI) is related with gestational ages.\textsuperscript{37, 38} We included it as a potential confounder when considering the association between two-child policy and ETB. We used maternal prepregnancy weight and height to calculate BMI, which was grouped into three categories: underweight (<18.5 kg/m\textsuperscript{2}), normal weight (18.5–24.9 kg/m\textsuperscript{2}) and overweight or obesity (≥25 kg/m\textsuperscript{2}) according to the WHO BMI classification.\textsuperscript{39} Maternal height was presented in quartiles (Q1: 100–160 cm, Q2: 161–165 cm, Q3: 166–168 cm, Q4: 169–190 cm).

### Statistical analysis

To better represent the epidemiology of ETB in China, we calculated weight for each birth in the survey by using the number of deliveries in each province from the 2016 China Statistical Yearbook, compiled by the National Bureau of Statistics of China (http://www.stats.gov.cn/tjsj/ndsj/2016/indexch.htm). We calculated a 95% CI of the incidence of Early term with the Normal approximation. We analysed the difference between the precursors of delivery in ETB before and after the implementation of the universal two-child policy using the partitions of the $\chi^2$ method.

We presented the maternal and newborn’s characteristics in the study population by the status of birth control policy and by the different gestational ages (online supplemental file 1). These characteristics were considered as potential confounders (covariates) when we analysed the association between two-child policy and ETB. A multivariable regression model was used to analyse the associations between universal two-child policy and ETB when adjusting for or not adjusting for the maternal and newborn characteristics (as confounders).

We carried out a stratified analysis according to maternal age, parity, and previous uterine scar to explore potential disparities in the association of ETB with a universal two-child policy. To further clarify the association, we carried out analyses to detect the joint effect of each age group by subgroup of parity or previous uterine scar. We added the interaction term (maternal age ×parity or maternal age ×uterine scars) to the model. When an interaction is confirmed (with statistical significance), strata-specific estimates are reported.

Additionally, we did a series of sensitivity analyses by including all subjects and excluding women who had gestational week <37, with Gemellary pregnancy and stillbirth or newborn death, late-term and post-term birth,
missing of covariates on the association between two-child policy and ETB.

Relative risk (RR) and 95% CI was estimated using a multilevel modified Poisson regression approach.\(^\text{40}\) For controlling the unmeasured confounding factors from different hospitals, we used a multilevel model (considering the hospital as the cluster) in our study. The application of Poisson regression on multinominal data has been shown to overestimate the RR.\(^\text{40, 41}\) We rectified this using a robust error variance procedure known as sandwich estimation, in our modified Poisson regression\(^\text{40}\) using PROC GENMOD in SAS V.9.4 software. A p value of <0.05 was considered statistically significant.

**RESULTS**

Among all births (n=75132) and live births (n=73567), the unweighted incidence of ETB was 31.88% per 100 all births (95% CI 31.55% to 32.21%) and 31.72% per 100 live births (95% CI 31.38% to 32.06%), respectively. After weighting adjustment, the weighted incidence of ETB was 30.1% per 100 all births (95% CI 30.06% to 30.14%) and 29.88% per 100 live births (95% CI 29.97% to 30.05%) in China, respectively. Of 75132 birth, 41.75% of all weighted births occurred with spontaneous labour, followed by indicated (41.32%), PROM (13.83%) and elective induction or C-Section (3.10%). Of 73567 live births, 41.75% occurred with spontaneous labour, followed by indicated (41.32%), PROM (14.09%) and elective induction or C-Section (2.45%). There were substantial variations of ETB according to maternal age, previous uterine scars and parity (table 1).

Of 28966 women, 7566 women were included in the exposure group (after the implementation of two-child policy) and 21400 women (before the implementation of two-child policy) were included in the control group. There was a statistically significant difference in most of the maternal and newborn characteristics between the exposure and control groups, and between ETB and completely full-term birth (p<0.05 online supplemental eTable 1), so these were included as mediating or confounding factor in our study. In table 2, the results showed there were associations between universal two-child policy and ETB when not adjusting for (RR 1.19, 95% CI 1.15 to 1.23, p<0.001) or adjusting for maternal age (RR 1.17, 95% CI 1.13 to 1.22, p<0.001), previous uterine scars (RR 1.18, 95% CI 1.14 to 1.22, p<0.001), parity (RR 1.19, 95% CI 1.15 to 1.24, p<0.001) and all above three conditions (RR 1.17, 95% CI 1.13 to 1.21, p<0.001). The statistical significance remained when precursors for delivery (RR 1.18, 95% CI 1.14 to 1.23, p<0.001) and all measured characteristics (RR 1.19, 95% CI 1.14 to 1.22, p<0.001) were added to the adjustment.

In the stratified analysis, we found that the association of universal two-child policy with ETB varied by different ages, previous uterine scars and parity (table 3). The association between universal two-child policy and ETB differed significantly by maternal age and uterine scars (p=0.0062). We analysed the association when stratified by age ×previous uterine scars (figure 2). The association of universal two-child policy with ETB was statistically significant in women younger than 30 years of age with previous uterine scars (adjusted RR=1.19,
p<0.05) and without previous uterine scars (adjusted RR=1.25, p<0.05). The association remained among those aged from 30 to 34 without previous uterine scars (adjusted RR=1.19, p<0.05), however, disappeared in those with previous uterine scars (p>0.05). The association disappeared for all women aged more than 34 years with and without previous uterine scars (each p>0.05). The crude RR and 95% CI of RR were shown in figure 2.

We found the associations between universal two-child policy and ETB differed significantly by maternal age and parity (p_interaction =0.0155). Therefore, we ran further analyses for strata-specific estimates by age ×parity (figure 1). The universal two-child policy was positively associated with ETB among nulliparous and multiparous women younger than 30 years old (adjusted RR were 1.23 and 1.31, respectively, p<0.05), nulliparous and multiparous women aged 30–40 years (adjusted RR were 1.14 and 1.16, respectively, each p<0.05), but the association disappeared among nulliparous and multiparous women older than 34 years when adjusting for maternal and newborn characteristics (each p>0.05). The crude RR and 95% CI of RR were shown in figure 3.

Sensitivity analyses, in which we did not exclude any variables or only excluded preterm births, gemellary pregnancy, stillbirth and neonatal death, and missing covariates yielded similar results when compared with our main analysis (each p>0.05). The finding changed with marginal significance, in contrast to our main analysis, when we excluded late-term and post-term birth from the overall subjects (p=0.05, online supplemental eFigure 1).

DISCUSSION

To our knowledge, the current study is the first to describe the incidence of ETB in China at a national level. We observed an incidence of about 30% of ETB between 2015 and 2016 in China and an increased risk of ETB after the announcement of the universal two-child policy. However, the association between ETB and the universal two-child policy was not mediated by maternal age, previous uterine scars, parity and other measured characteristics. Furthermore, the stratified analysis showed that the effects of the universal two-child policy on ETB was strongest in multiparous young women or those without previous uterine scars, and disappeared in all women aged 30–34 years with and without previous uterine scars (each p<0.05).

### Table 2: Association between universal two-child policy and early-term birth when adjusting for maternal and newborn’s characteristics (n=28966)

<table>
<thead>
<tr>
<th>Adjusting variables</th>
<th>Adjusted RR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crude*</td>
<td>1.19 (1.15 to 1.23)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Maternal age</td>
<td>1.17 (1.13 to 1.22)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Previous uterine scars</td>
<td>1.18 (1.14 to 1.22)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Parity</td>
<td>1.19 (1.15 to 1.24)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Maternal age + previous uterine scars + parity</td>
<td>1.17 (1.13 to 1.21)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Not adjusted for any variables.
†The other maternal and newborn characteristics were shown in online supplemental eTable 1.

RR, relative risk.

### Table 3: Association between universal two-child policy and early-term birth stratified by maternal age, previous uterine scars and parity (n=28966)

<table>
<thead>
<tr>
<th>Adjusted variables</th>
<th>Crude RR* (95% CI)</th>
<th>P value</th>
<th>Adjusted RR† (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30</td>
<td>1.22 (1.16 to 1.28)</td>
<td>&lt;0.0001</td>
<td>1.24 (1.18 to 1.30)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>30–34</td>
<td>1.15 (1.08 to 1.22)</td>
<td>&lt;0.0001</td>
<td>1.14 (1.07 to 1.22)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>≥35</td>
<td>1.06 (0.97 to 1.15)</td>
<td>0.1816</td>
<td>1.05 (0.97 to 1.15)</td>
<td>0.2241</td>
</tr>
<tr>
<td>Previous uterine scars</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.20 (1.16 to 1.25)</td>
<td>&lt;0.0001</td>
<td>1.21 (1.16 to 1.26)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Yes</td>
<td>1.08 (1.02 to 1.15)</td>
<td>0.0104</td>
<td>1.08 (1.01 to 1.15)</td>
<td>0.0263</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>1.18 (1.12 to 1.24)</td>
<td>&lt;0.0001</td>
<td>1.19 (1.13 to 1.26)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Multiparous</td>
<td>1.20 (1.14 to 1.25)</td>
<td>&lt;0.0001</td>
<td>1.17 (1.12 to 1.23)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

*Not adjusted for any variables.
†Adjusted for maternal sociodemographic status, maternal health conditions and newborn’s characteristic.
‡Adjusted for maternal sociodemographic status.
§Adjusted for maternal health conditions.
¶Adjusted for newborn’s characteristics.
RR, relative risk.
of advanced maternal age (irrespective of parity and previous uterine scars).

The incidence of ETB in different countries is varied. For example, a population study reported that the average incidence of ETB was 25.3% among six high-income countries. In that study, a lower incidence was reported in Denmark, Finland, Norway, and Sweden (all below 20%), and a higher incidence was reported in the USA and Canada (higher than 20%). In other countries, the reported incidence of ETB is fairly consistent. For example, a multicentred study from 44 hospitals in Portugal reported an incidence of ETB of 27%. Another national study in Brazil reported an incidence of ETB of 29.8% in singleton deliveries. The incidence of ETB in China of about 30% between 2015 and 2016 can be therefore considered as similar to Portugal and Brazil, but higher than most of reported countries. The variations of ETB across different maternal age, parity and women with or without previous uterine scars in China were consistent with previous studies.

Of the reported ETB cases in the current study, about 3% were due to having an elective delivery. It has been reported that the ETB rates in the USA decreased from 33.0% in 2006 to 21.1% in 2014 among births with clinician-initiated obstetric intervention, and from 29.7% in 2006 to 27.1% in 2014 among births without clinician-initiated obstetric intervention. These studies found that reductions in elective obstetric intervention at ETB may reflect the success of interdisciplinary healthcare teams that focus on decreasing elective births before 39 weeks. Therefore, our result suggests that the ETB rate in China may decrease if obstetric intervention reduces the number of unnecessary elective deliveries.

Owing to the timing of the initiation of the universal two-child policy across the research period, we explored ETB rate changes after the implementation of the universal two-child policy, so as to provide evidence for future ETB interventions in the era of the new policy. Our study reported that the incidence of ETB increased after the implementation of the universal two-child policy; however, the association stayed statistically significant after mediated by maternal age, previous uterine scar, parity and the other maternal and newborn factors in etable1. The results suggest that the two-child policy might bring other risk factors that were not included in our study. A recent study suggested that under the newly relaxed universal two-child policy, women may experience higher risk of mental health difficulties during their second pregnancy, and poorer mental health may lead to a higher chance of ETB. Further research is necessary to explore the association between ETB and maternal and newborn outcomes, to reveal more details of the underlying mechanisms of ETB, and inform new interventions for pregnant women.

We found that there was an association between China’s two-child policy and ETB which differed across countries.
subjects with different maternal characteristics, especially, maternal age. One likely explanation for why the association was not present in women of advanced maternal age (but remained in women with younger age), is a ‘ceiling effect’. Women of advanced maternal age are at risk of higher rates of ETB as they are more vulnerable to maternal complications and adverse birth outcomes. Obstetric complications such as placental abruption,56 malpresentation and postpartum haemorrhage45 46 57 58 are higher in women of advanced maternal age. Unexplained stillbirths increase with advancing maternal age and with increasing gestational age in both nulliparous and multiparous women. Therefore, the induction of labour or prelabour C-Section in women of advanced maternal age is widely practiced as an intervention perceived to reduce the risk of adverse perinatal outcomes.46 Those factors may reduce the difference in ETB rates in women of advanced maternal age before and after the implementation of the universal two-child policy.

We also found that the effect of the universal two-child policy on ETB was the strongest in young women without previous uterine scars, or who are multiparous. It has been reported that early elective birth before 39 weeks is more likely to occur in women with previous scars when obstetricians do not appreciate the risk of morbidity of infants before 39 weeks and prefer to maintain autonomy in determining the timing of delivery.3 Those factors may moderate the difference in ETB before and after the implementation of the universal two-child policy. One possible explanation is that first-time mothers are more likely to have a spontaneous vaginal delivery, instead of an elective birth week, so that they are able to reduce the risk of potential health complications that might arise from a second pregnancy,39 thus reducing the difference in ETB rate in nulliparous women before and after the implementation of the universal two-child policy.

**Strengths and limitations**

With the large sample in our study, we first reported the incidence of ETB at a national level and found an association between universal two-child policy and ETB. However, there were several limitations to our study. First, we do not have a complete profile of factors that may influence the association between universal two-child policy and ETB. Those factors may reduce the difference in ETB rates in women of advanced maternal age before and after the implementation of the universal two-child policy.

**Figure 3** Association between universal two-child policy and early-term birth (ETB) in nulliparous women when not adjusting other variables (A), in nulliparous women when adjusting other variables (B), in multiparous women when not adjusting other variables (C), in multiparous women when adjusting other variables (D), by maternal age group (n=28966). The diagram analysed the association between universal two-child policy and ETB when stratified by age ×parity. RR, relative risk.

*p<0.05,**p<0.01
CONCLUSION

The incidence of ETB was high in China when compared with most of reported countries and practice patterns should be adjusted to respond to ETB, when ETB was found to be more likely to happen under the universal policy with most of reported countries and practice patterns.

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Contributors JH conceptualized and designed the study, reviewed and critically revised the manuscript. JZ, GW and WD drafted the initial manuscript. JH, JZ, JC and WD conducted the data analysis. JC, JZ, J2 and MZ established the cohort and provided intellectual inputs to the manuscript. GW was responsible for and supervising data collection and critical revision of the manuscript for important intellectual content. All authors reviewed and approved the final version of the manuscript.

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Competing interests None declared.

Patient consent for publication Not applicable.

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Provenance and peer review Not commissioned; externally peer reviewed.

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