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Gestational age reference from crown-rump length during 11–14 weeks: a population-based multicenter cohort study in China

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Abstract

Background This study aimed to develop a new ultrasonographic dating formula to estimate gestational age (GA) based on fetal crown–rump length (CRL) in a Chinese population, evaluate model accuracy and compare its performance with established dating formulas.

Methods A prospective, multicenter study was conducted across mainland China. Participants included healthy, low-risk women with spontaneously conceived singleton pregnancies and a regular menstrual cycle in the preceding year. Ultrasonography was performed between 11 and 14 weeks of gestation, with GA determined based on the last menstrual period. Participants were randomly assigned to a development or validation cohort in a 7:3 ratio. A best-fit regression model was constructed for GA estimation based on CRL in the development cohort. For validation, mean differences between the new estimated GA and menstrual age were calculated and compared with those obtained using five established CRL-based dating formulas in the validation cohort. All participants were followed through to delivery.

Results The study recruited 4,710 women with singleton pregnancies, with 3,297 in the development cohort and 1,413 women in the validation cohort. The mean and standard deviation values of CRL changed linearly with GA during 11–14 weeks. CRL demonstrated a linear relationship with GA between 11 and 14 weeks, yielding the regression equation GA = 59.590085 + 0.458539×CRL (R^2 = 0.8042). The mean difference between estimated GA and menstrual age was 0.32 days (95% confidence interval 0.17–0.46), demonstrating a smaller error compared with those obtained from the five widely used CRL dating formulas.

Conclusions We derived a CRL-based dating formula applicable to naturally conceived pregnancies at 11–14 weeks. This new formula exhibits small residuals, providing a more accurate alternative to existing CRL-based dating formulas.

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Keywords Crown–rump length, Gestational age, Ultrasound

Background

Gestational age (GA) determination is fundamental to assessing neonatal maturity and is critical in obstetric management and clinical decision-making [1]. Errors and uncertainties in GA estimation are associated with a spectrum of adverse pregnancy outcomes, including small-for-gestational-age and preterm birth, as well as perinatal mortality [2–4]. Therefore, accurate GA assessment is essential in various aspects of perinatal care.

Ultrasonographic measurements of fetal anthropometric parameters provide an indirect, widely used approach for estimating GA. Over the past three decades, numerous studies have investigated ultrasound-based reference standards for GA estimation [5]. These studies, however, exhibit considerable heterogeneity in design, statistical methodologies, and reporting conventions, which complicates the comparison and application of findings [5]. Furthermore, some researchers have suggested that fetal crown–rump length (CRL), commonly used in GA prediction, may vary across ethnic populations. The majority of CRL-based dating algorithms have been derived from Western cohorts, limiting their applicability in Asian populations because of ethnic and racial variations [6–10]. The development of GA prediction models using extensive, prospectively gathered ultrasonographic data from Chinese populations across multiple centers could enhance accuracy for this demographic.

This study aims to establish an reference for predicting GA based on fetal CRL in a Chinese population. Additionally, we seek to evaluate the prediction error of this model and compare its accuracy with established reference standards.

Methods

This prospective cross-sectional, multicenter study was conducted in 13 tertiary hospitals across mainland China from 2008 to 2012. The study protocol was approved by the institutional ethics review boards at each participating site, and informed consent was obtained from all participants. The study was part of the Chinese Fetal Growth and Prenatal Screening Consortium, a large-scale initiative focused on fetal growth as well as prenatal anomaly screening and diagnosis.

Participants

The study enrolled pregnant Chinese women during their first trimester. Data on maternal, paternal, socioeconomic, and pregnancy characteristics were collected prospectively via a structured self-reported questionnaire. Gestational age was calculated based on the last menstrual period (LMP), and standardized ultrasound examinations were performed between 11^{+0} and 13^{+6} weeks of gestation. Each participant received a single ultrasound examination during the first trimester specifically for this study, followed by continuous ultrasound monitoring in the second and third trimesters, and was subsequently hospitalized for delivery. Follow-up information was primarily obtained through medical record reviews or telephone interviews.

Healthy, low-risk, ethnically Chinese women, whose partners were also ethnically Chinese, were consecutively recruited upon their initial registration at the prenatal diagnosis center. All participants met the following inclusion criteria: spontaneously conceived singleton pregnancies, good nutritional status, and regular 28–30 day menstrual cycles for at least 12 months prior to conception. Serial ultrasound scans were conducted in each trimester. No participants were excluded based on fetal biometry or birth weight.

Exclusion criteria included the following: (i) women with an uncertain LMP or irregular menstrual cycles; (ii) pre-existing maternal diseases potentially impacting fetal growth (e.g., diabetes mellitus, renal disease, immunological conditions); (iii) severe pregnancy complications, including pre-eclampsia, pregnancy-induced hypertension, gestational diabetes, or third-trimester hemorrhage; (iv) adverse pregnancy outcomes, such as spontaneous abortions, fetal demise, congenital malformations, chromosomal anomalies, or neonatal death.

Ultrasound examination

Ultrasound assessments were conducted using commercially available ultrasound systems (GE Healthcare Voluson E8, GE Healthcare Voluson 730, and Philips IU22), each equipped with curvilinear transabdominal sector probes (C5-2, C6-3, and V7-3, respectively). Sonographers underwent rigorous standardized training to ensure protocol adherence and measurement reliability. CRL measurements were performed according to guidelines set by the Fetal Medicine Foundation [11, 12]. For each CRL measurement, the central sagittal section of the fetus was identified, ensuring a natural fetal body flexion with a clearly visible top of the head and sacral tail, and a fully sagittal view of the spine. Images were magnified such that the fetal body occupied approximately two-thirds to three-quarters of the display screen. The measurement cursor was positioned at the outer edge of the fetal head skin and extended to the outer edge of the sacrococcygeal skin, carefully avoiding inclusion of limbs and the yolk sac. Each CRL measurement was performed in triplicate, with the mean value employed for subsequent analyses.

Statistical analysis

Continuous data were expressed as mean ± standard deviation (SD) or median (interquartile) where appropriate. Categorical variables were summarized as number (percentage). Participants were randomly divided into either development or validation cohorts in a 7:3 ratio. Linear and polynomial regressions were modeled for GA using CRL in development cohort. The best-fitted model was determined based on the coefficient of determination (R^2) of the model, statistical significance of parameters in the model and scatter plot of GA versus CRL. Formula for GA using CRL derived from the best-fitted model was subsequently validated in the remaining 30% participants. The formula was compared with other GA prediction formulas reported in existing studies with similar sample size and methodological rigorousness. In order to validate the model accuracy, we assessed model fit by calculating differences between predicted GA derived from formulas and actual GA obtained from the LMP. The discrepancy, also known as residual, was presented as median (interquartile) given its non-normal distribution. Its 95% confidence interval (CI) was estimated under non-parametric assumption to evaluate error of the regression. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA), with statistical significance set at $P < 0.05$.

Table 1 Baseline information in all data, training dataset and testing dataset

Characteristics	All ($n = 4710$)	Training dataset ($n = 3297$)	Testing dataset ($n = 1413$)
Maternal age (years)*	29.4 ± 3.7	29.4 ± 3.7	29.5 ± 3.8
BMI (kg/m^2)	20.5 ± 2.6	20.5 ± 2.6	20.5 ± 2.5
Mean GA (days)	88.7 ± 4.5	88.7 ± 4.5	88.6 ± 4.5
Delivery outcome			
Natural delivery	1892 (40.17)	1336 (40.52)	556 (39.35)
Cesarean section	2818 (59.83)	1961 (59.48)	857 (60.65)
Fetal gender			
Male fetuses	2280 (48.41)	1563 (47.41)	717 (50.74)
Female fetuses	2430 (51.59)	1734 (52.59)	696 (49.26)
Number of maternal births			
0	4255 (90.34)	2981 (90.42)	1274 (90.16)
1	399 (8.47)	282 (8.55)	117 (8.28)
≥ 2	56 (1.19)	34 (1.03)	22 (1.56)
Ethnicity			
Han ethnicity	4527 (96.11)	3161 (95.88)	1366 (96.67)
Minority	183 (3.89)	136 (4.12)	47 (3.33)
Birth weight	3.4 ± 0.4	3.4 ± 0.4	3.4 ± 0.4
Follow-up time	276.6 ± 7.0	276.6 ± 7.0	276.7 ± 7.1
Menstrual cycle	29.2 ± 1.0	29.2 ± 1.0	29.2 ± 1.0
CRL (mm)*	63.5 ± 8.7	63.4 ± 8.7	63.6 ± 8.6
Fetal heart rate	161.1 ± 7.7	161.0 ± 7.7	161.1 ± 7.7

Unless otherwise specified, data are numbers of patients, with percentages in parentheses

*Data are mean, with standard deviation

CRL crown-rump length; GA, gestational age; BMI, Body Mass Index

Results

Baseline characteristics of the study population

A total of 4,710 pregnant women were enrolled in the study, with a mean maternal age of 29.4 ± 3.7 years (range, 18.2–47.5 years) and a mean maternal body mass index (BMI) of 20.5 ± 2.6 kg/m^2. Of these participants, 4,527 (96.11%) were of Han ethnicity, and 183 (3.89%) belonged to minority ethnic groups. The mean GA at the time of ultrasound examination was 88.7 ± 4.5 days, with a mean CRL of 63.48 ± 8.70 mm. Delivery outcomes included 1,892 (40.17%) natural deliveries and 2,818 (59.83%) cesarean sections. There were 2,430 male fetuses (51.59%) and 2,280 female fetuses (48.41%). Neonates with normal pediatric examination results were followed up to one month postpartum, confirming the absence of physical abnormalities. Baseline characteristics and pregnancy outcomes are detailed in Table 1.

To develop a model for estimating GA from CRL, participants who met the inclusion criteria were randomly allocated into a modeling cohort ($n = 3,297$) and a validation cohort ($n = 1,413$) in a 7:3 ratio. Detailed data for each group are presented in Table 1.

Establishment of a GA formula based on CRL

In the modeling cohort, a scatter plot of GA versus CRL (Fig. 1) revealed a robust linear correlation between these variables. Six models were tested to determine the best fit for the scatter plot. Model fit of linear and polynomial regression for gestational age predicted by CRL are detailed in Table 2. Taking the R^2, p-values and linear relationship depicted by the scatter plot into consideration, a simplified formula derived from Model 2 was selected as the optimal model for GA. This formula, based on simple linear regression analysis, was found to be both parsimonious and highly representative of the observed data. The final formula for predicting GA (in days) from CRL is:

$$GA = 59.590085 + 0.458539 \times CRL \ (R^2 = 0.8042).$$

Comparisons evaluation of GA prediction models

The predictive accuracy of the model was assessed using the independent validation cohort of 1,413 pregnant women. In this validation group, the median difference between predicted and observed GA was 0.32 days (95% CI: 0.17–0.46 days). Comparisons were made with models developed by Sahota et al. [6], Hadlock et al. [7], and Papageorghiou et al. [8], which produced systematic errors of 0.43, 0.79, and 0.31 days, respectively. Models from Robinson et al. [10] and McKenna et al. [9] demonstrated negative systematic errors of − 0.65 days and

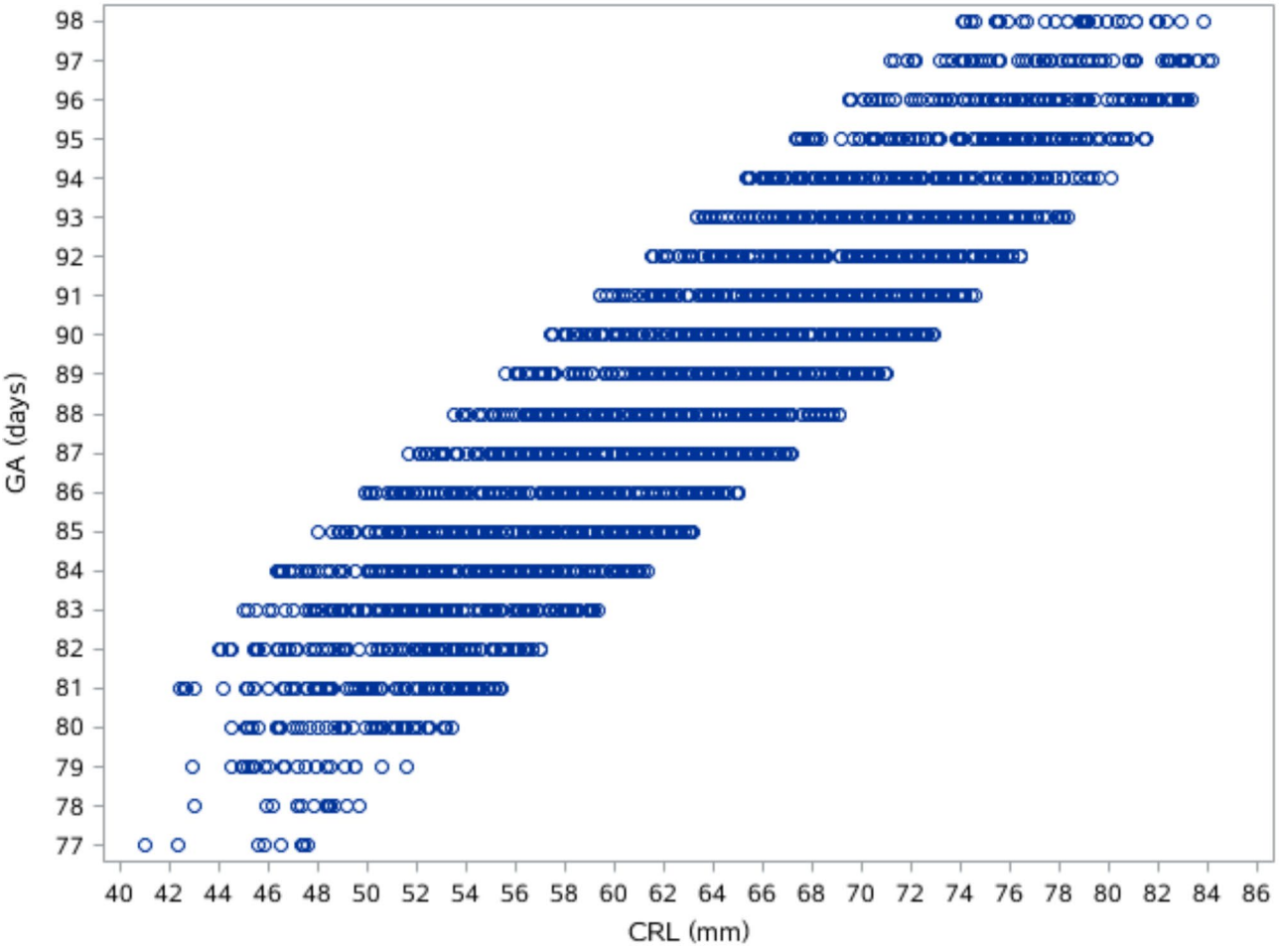

Fig. 1 Scatter plot between gestational age (GA) and gestational age (GA) in the training group

Table 2 Model fit of linear and polynomial regression for gestational age predicted by CRL

Model	Parameter	Estimate	Standard error	t value	Pr >|t|	*R* square	Formula
Model 1	Intercept	31.045180565311	0.49752889	62.40	< 0.0001	0.8035805603	$31.045181 + 7.253441 \times CRL^{0.5}$
	$CRL^{0.5}$	7.2534411835777	0.0624732223	116.10	< 0.0001		
Model 2	Intercept	59.5900847471184	0.252330388	236.16	< 0.0001	0.8042156026	$59.590085 + 0.458539 \times CRL$
	CRL	0.45853880551235	0.003941406	116.34	< 0.0001		
Model 3	Intercept	73.9553483661449	0.133731667	553.01	< 0.0001	0.7977637924	$73.955348 + 0.003591 \times CRL^{2}$
	CRL^{2}	0.00359067400813	0.0000314949	114.01	< 0.0001		
Model 4	Intercept	57.2509109549481	1.5921288762	35.96	< 0.0001	0.8043471175	$57.250911 + 0.533751 \times CRL + -0.000593 \times CRL^{2}$
	CRL	0.53375087637653	0.0506987529	10.53	< 0.0001		
	CRL^{2}	-0.00059313342553	0.0003986082	-1.49	0.1368		
Model 5	Intercept	93.7478125726752	9.3848011975	9.99	< 0.0001	0.805267851	$93.747813 + (-1.242790 \times CRL) + 0.027799 \times CRL^{2} + (-0.000149 \times CRL^{3})$
	CRL	-1.24278999051918	0.4530596868	-2.74	0.0061		
	CRL^{2}	0.027798578716	0.0072062622	3.86	0.0001		
	CRL^{3}	-0.0001490722679	0.0000377792	-3.95	< 0.0001		
Model 6	Intercept	52.4553913017327	6.1962361333	8.47	< 0.0001	0.8042945059	$52.455391 + (1.810789 \times CRL^{0.5}) + 0.344202 \times CRL$
	$CRL^{0.5}$	1.81078902991747	1.5713036604	1.15	0.2492		
	CRL	0.34420203134629	0.099293447	3.47	0.0005		

CRL crown-rump length

Table 3 Comparison results of different GA evaluation models

Study	Country	Formula for estimating GA based on CRL	Error Median(95% CI)[a]	Residual Median (interquartile) [b]	Interquartile range of residual [b]
Our study	China	$59.590085 + 0.458539 \times CRL$	0.32 (0.17, 0.46)	0.32 (-1.34, 1.75)	3.09
Sahota et al. [6]	Hongkong	$26.643 + 7.822 \times CRL^{0.5}$	0.43 (0.28, 0.59)	0.43 (-1.25, 1.92)	3.17
Hadlock et al. [7]	Hadlock	$7x(\exp(1.684969 + 0.315646 \times (CRL/10) - 0.049306 \times ((CRL/10)^2) + 0.004057 \times ((CRL/10)^3) - 0.000120456 \times ((CRL/10)^4)))$	0.79 (0.62, 0.95)	0.79 (-0.94, 2.33)	3.27
Papageorghiou et al. [8]	Intergrowth	$40.9041 + (3.21585 \times CRL^{0.5}) + 0.348956 \times CRL$	0.31 (0.15, 0.46)	0.31 (-1.53, 1.91)	3.44
McLennan et al. [9]	Syndey	$32.61967 + 2.62975 \times CRL - 0.42399 \times \log(CRL) \times CRL$	-0.83 (-0.97, -0.69)	-0.83 (-2.49, 0.64)	3.13
Robinson et al. [10]	Robinson	$8.052 \times (CRL^{0.5}) + 23.73$	-0.65 (-0.80, -0.43)	-0.65 (-2.32, 0.88)	3.20

[a] Difference between predicted and actual gestational age was obtained by the predicted GA using the formula minus the actual GA. Due to the non-normal distribution of the difference, its mean was expressed as median and it 95% confidence interval was estimated under distribution free

[b] Given the non-normal distribution, the difference between predicted and actual GA was expressed as median (interquartile)

CRL crown-rump length; CI, Confidence interval

−0.83 days, respectively. The interquartile range for the difference between predicted and observed GA in our study was 3.09 days, which was notably lower than the interquartile ranges reported in the five comparative studies. Table 3 provides a detailed comparison of the performance of this study's formula against those from prior studies.

Discussion

Accurate estimation of GA is crucial for identifying fetuses at an elevated risk of adverse perinatal outcomes. This study established a formula to calculate GA based on CRL in a substantial sample of naturally conceived fetuses from a Chinese population at 11 and 14 weeks of gestation. Using this formula, GA was estimated with a mean deviation of 0.32 days compared with menstrual age, indicating high accuracy. Standardized enrollment criteria, clinical protocols, data collection procedures, and rigorous quality control were employed, enhancing the generalizability and applicability of these findings.

A meta-analysis revealed considerable heterogeneity in study designs, statistical approaches, and reporting in existing formulas for GA estimation [5]. To improve accuracy, this study imposed strict inclusion criteria, enrolling only women with spontaneously conceived singleton pregnancies and regular 28- to 30-day menstrual cycles in the 12 months preceding pregnancy. All measurements in this study were obtained from a specifically designed prospective study, and data collection followed a standardized methodology. The GA formula derived here represents one of the first gestational age prediction models for a large population in China and is tailored to Chinese fetuses. Based on these findings, an application (app) was developed and launched, allowing users to calculate gestational age by inputting CRL measurements. This app provides immediate GA estimates, offering a valuable tool for healthcare providers and pregnant women, particularly those with irregular menstrual cycles. Currently, the app is being promoted and implemented in numerous hospitals across China, facilitating accessible and accurate GA assessments.

Previous studies have proposed various equations correlating CRL with GA; however, considerable variation in clinical practice persists, and no consensus has been reached on the optimal formula for precise pregnancy dating. In this study, high-quality studies were selected to serve as benchmarks for GA evaluation accuracy, including those by Sahota et al. [6], Hadlock et al. [7], Papageorghiou et al. [8], McLennan et al. [9], and Robinson et al. [10]. Among these, three studies exhibited GA overestimation, whereas two studies presented underestimation, compared with our findings. Our results closely align with recent high-quality studies by Sahota et al. [6] and Papageorghiou et al. [8], showing median prediction differences of +0.32, +0.43, and +0.31 days, respectively. However, our findings diverged significantly from those reported in earlier studies by Hadlock et al. [7], McLennan et al. [9], and Robinson et al. [10]. These differences underscore that, when appropriate selection criteria and standardized methodologies are applied, fetal growth trajectories appear broadly similar across populations.

Gestational age in this study was calculated from the first day of the LMP. None of the participants had taken ovulation-inducing agents, contraceptives, or other estrogenic hormones within the six months preceding pregnancy. However, biological discrepancies likely exist between IVF-derived and naturally conceived fetuses, including potential variances in the timing of ovulation

and conception. Additionally, fetal growth rates in IVF pregnancies may differ during the first trimester, and biological differences between women conceiving via assisted reproductive technologies (ART) and low-risk women with natural conceptions may exist. Prior studies have developed a CRL reference chart based on true gestational age in an IVF cohort, accurately determining gestational age between 6 and 9 weeks of gestation [13]. Current ultrasound-based reference charts exhibit limitations in accuracy. Therefore, we propose that the use of GA evaluation formulas derived from ART-conceived fetuses may be inappropriate for application to naturally conceived pregnancies.

To enhance the accuracy of GA estimation, it is essential to recognize the limitations inherent in using fetal CRL measurements obtained through ultrasound in isolation. The biological variation of CRL during the first trimester introduces uncertainty into GA estimations. Therefore, we recommend that all relevant information, including LMP data and an assessment of its reliability, be collected from pregnant women at their initial first-trimester visit [14]. When GA estimates derived from ultrasound CRL measurements align closely with those based on LMP, GA may be calculated from the LMP date. However, if LMP timing is highly accurate and reliable yet diverges substantially from GA based on CRL measurements, clinicians should consider the possibility of underlying fetal growth or developmental abnormalities, warranting additional monitoring and diagnostic evaluation [15, 16].

This study acknowledges several limitations. First, intra- and inter-observer reliability of CRL measurements was not formally tested, which may affect the robustness of the findings. To mitigate potential measurement bias, we used the mean of three CRL measurements in our analyses. Prior to the initiation of this multi-center study, obstetricians with substantial clinical experience from each participating center underwent standardized training through direct observation, operational demonstrations, and hands-on practice sessions. Additionally, all data and ultrasound images were independently reviewed by three seasoned radiologists at our institutions. Any discrepancies in interpretation were resolved through consensus. Second, other relevant factors, such as chronic stress, mental health status, and lifestyle characteristics, were not thoroughly investigated in this study. These factors, although not fully elucidated, may influence pregnancy outcomes and potentially affect CRL.

Conclusions

This study established and validated a formula for estimating GA based on CRL measurements in Chinese fetuses at 11–14 weeks of gestation. The resulting formula demonstrated high consistency with those from recent, high-quality studies, showing no significant differences, thereby reinforcing its applicability within the clinical setting.

Abbreviations

GA	Gestational age
LMP	Last menstrual period
CRL	Crown–rump length
CI	Confidence interval

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Author contributions

HM and YXJ conceived the idea, wrote the protocol, submitted the ethics approval form.FD primarily analysed the data. YXZ, ZHN and FD analyzed parts of the data and drafted the final manuscript for submission. ZHX, YSOY, SLL, QC, QQW, RL, TR, ALC, XLC, TZY, PC, HNX, HL, QD, MY, XY, JL, JWT, KS, HL checked the patient and got the data. All authors have read and approved the manuscript.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Peking Union Medical College Hospital and other relevant hospitals. All pregnant women participating in this study signed informed consent forms.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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