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Development and validation of a prediction model for intrapartum cesarean delivery based on the artificial neural networks approach: a protocol for a prospective nested case–control study

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ABSTRACT

Introduction Although intrapartum caesarean delivery can resolve dystocia, it would still lead to several adverse outcomes for mothers and children. The obstetric care professionals need effective tools that can help them to identify the possibility and risk factors of intrapartum caesarean delivery, and further implement interventions to avoid unnecessary caesarean birth. This study aims to develop a prediction model for intrapartum caesarean delivery with real-life data based on the artificial neural networks approach.

Methods and analysis This study is a prospective nested case–control design. Pregnant women who plan to deliver vaginally will be recruited in a tertiary hospital in Southwest China from March 2022 to March 2024. The clinical data of prelabour, intrapartum period and psychosocial information will be collected. The case group will be the women who finally have a baby with intrapartum caesarean deliveries, and the control group will be those who deliver a baby vaginally. An artificial neural networks approach with the backpropagation algorithm multilayer perceptron topology will be performed to construct the prediction model.

Ethics and dissemination Ethical approval for data collection was granted by the Ethics Committee of West China Second University Hospital, Sichuan University, and the ethical number is 2021 (204). Written informed consent will be obtained from all participants and they can withdraw from the study at any time. The results of this study will be published in peer-review journal.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study design is a prospective nested case–control study, which can minimise the selection bias and missing data.
⇒ This study will adopt the artificial neural networks approach to construct the prediction model for intrapartum caesarean delivery, which has been regarded as an ideal tool to deal with large medical databases and construct predictive models.
⇒ Due to the limitation of funding and resources, this study will be only conducted in a tertiary hospital.
⇒ The level of resilience is a self-report variable, so self-report bias cannot be avoided.

INTRODUCTION

Intrapartum caesarean delivery refers to the caesarean section that occurred after the onset of labour.[1] Although it can resolve dystocia and save maternal and newborn' lives on some occasions, it is a consensus that obstetricians and midwives should be active in preventing intrapartum caesarean delivery for its short-term and long-term adverse outcomes.[2] Intrapartum caesarean delivery can increase the mothers' risks of infection, severe postpartum haemorrhage, scarred uterus, prolonged postpartum recovery, increased healthcare costs and next caesarean section in a subsequent pregnancy.[3–6] It is also associated with hypoglycaemia, low Apgar scores, higher neonatal intensive care unit admission, asthma and respiratory distress in newborns.[7–9] Previous studies indicated that some risk factors (eg, macrosomia, maternal obesity during pregnancy) for intrapartum caesarean delivery could be handled or avoided.[10 11] Identifying the risk factors and reducing unnecessary intrapartum caesarean is thus a concern for medical professionals across the world.

Previous studies have attempted to construct prediction models to help medical professionals identify the risk factors associated with intrapartum caesarean delivery. For instance, Yang *et al*[12] employed the fetal biometry data measured by ultrasound to construct a model to predict intrapartum caesarean delivery, and the index of estimated fetal weight, biparietal diameter and abdominal circumference were included in the model. Similarly, Yang[13] developed an intrapartum calculator for predicting the risk of caesarean birth due to dystocia and found that both preactive labour variables and active labour variables could predict the caesarean birth due to dystocia. In addition, Sakala *et al*[14] indicated that parity, mothers' attitudes towards caesarean section, applying oxytocin during the first stage of labour and amniotomy were associated factors for intrapartum caesarean. Although these studies mentioned above had constructed various prediction models for intrapartum caesarean delivery, there were still several limitations that handicapped the application and effectiveness of those instruments. First, these studies were retrospective design, making it difficult to collect the synchronous data (eg, psychosocial status), which are associated with women's attitudes toward the intrapartum caesarean delivery.[15] Second, the variables used in published studies are also relatively single, which may lose sight of comprehensiveness. Furthermore, the main statistical method for constructing the models was multivariable logistic regression, which is a traditional and relatively simple algorithm and the validity of this model was highly dependent on the number and suitability of the measured independent predictors.[16] Therefore, these models might lack sufficient reliability and credibility. Applying a more intelligent algorithm to construct the model and provide a more accurate and reliable tool for medical professionals to assess the possibility and risk factors of intrapartum caesarean delivery is necessary.

Artificial neural networks (ANNs) have been widely used to construct risk model in medical science because it is an ideal tool to deal with large medical databases, especially when the association between the variables and the outcomes is multidimensional and non-linear.[17–19] ANNs have also been used to estimate perinatal-related outcomes. For instance, estimating umbilical cord blood leptin and insulin based on anthropometric data,[20] diagnosing neonatal diseases[21 22] and establishing a predictive mortality risk model for children's admission to a paediatric intensive care unit.[23] As we aim to construct a prediction model for intrapartum caesarean delivery with prelabour, intrapartum and psychosocial variables of women, which would certainly produce big data in structural and unstructured forms. Under such a circumstance, ANNs might be a more reasonable choice in this study to synthesise the structural and unstructured data to develop the prediction model. This study will be conducted to develop a prediction model based on ANNs, which would further provide a useful tool in clinical practice to predict the risk of intrapartum caesarean delivery, and help medical professionals actively take measures to prevent unnecessary intrapartum caesarean delivery.

METHODS AND ANALYSIS

Study design and setting

This study is a prospective nested case–control study and will be conducted in a tertiary women's and children's hospital in Chengdu, China. This tertiary hospital is the largest women's and children's hospital in Western China, with over 18 000 deliveries and about 8500 vaginal delivery every year. It could provide a rich source of samples.

Participants

We plan to recruit pregnant women in the clinics and obstetric wards from March 2022 to March 2024. The inclusion criteria are as follows: (1) female age ≥18 years; (2) singleton pregnancy; (3) gestation age ≥37 weeks and <42 weeks; and (4) planning a vaginal delivery. The women who meet the inclusion criteria will be invited by researchers with an explanation about the study. They will be included in this study after signing informed consent. The woman with induction of labour will be excluded. Considering the pregnant is a relatively vulnerable population, only the pregnant woman without signs of labour will be invited so that they can have enough time to decide whether to participate in this study.

Selection of cases and controls

The base cohort included the participants who met the inclusion criteria during the study period, and the cohort will be followed up until their placentas are delivered. The case group will be the women who receive intrapartum caesarean delivery finally, while the control group will be those who vaginally deliver their live babies. Intrapartum caesarean delivery is defined as a final caesarean section for women who planned vaginally deliver and had entered the latent phase of labour process. The signs of entering the latent phase are regular and gradually increased uterus contractions that occur at 5–6 min intervals and last for at least 30 s, accompanied by the cervical canal efface, the dilatation of the cervix and the decreasing fetal presentation.[24] Each cohort case will be matched with two controls on age (within 2 years), gestational week (within 2 weeks) and same parity. The technical protocol of this study is shown in figure 1.

Data collection

A self-designed information form including sociodemographic information, prelabour information and intrapartum information of participants (table 1) will be used to collect the data, which will be extracted from the hospital medical record system by researchers.

As resilience is a mental defence mechanism, a number of studies suggested that understanding resilience is crucial for developing interventions to prevent and treat common mental disorders (ie, anxiety, depression and stress).[25 26] Thus, this study will use the Connor-Davidson Resilience Scale (CD-RISC) to survey pregnant women's capability to maintain mental health. CD-RISC was developed by Connor and Davidson and could assess individuals' resilience levels.[27] The CD-RISC consists of 25 items

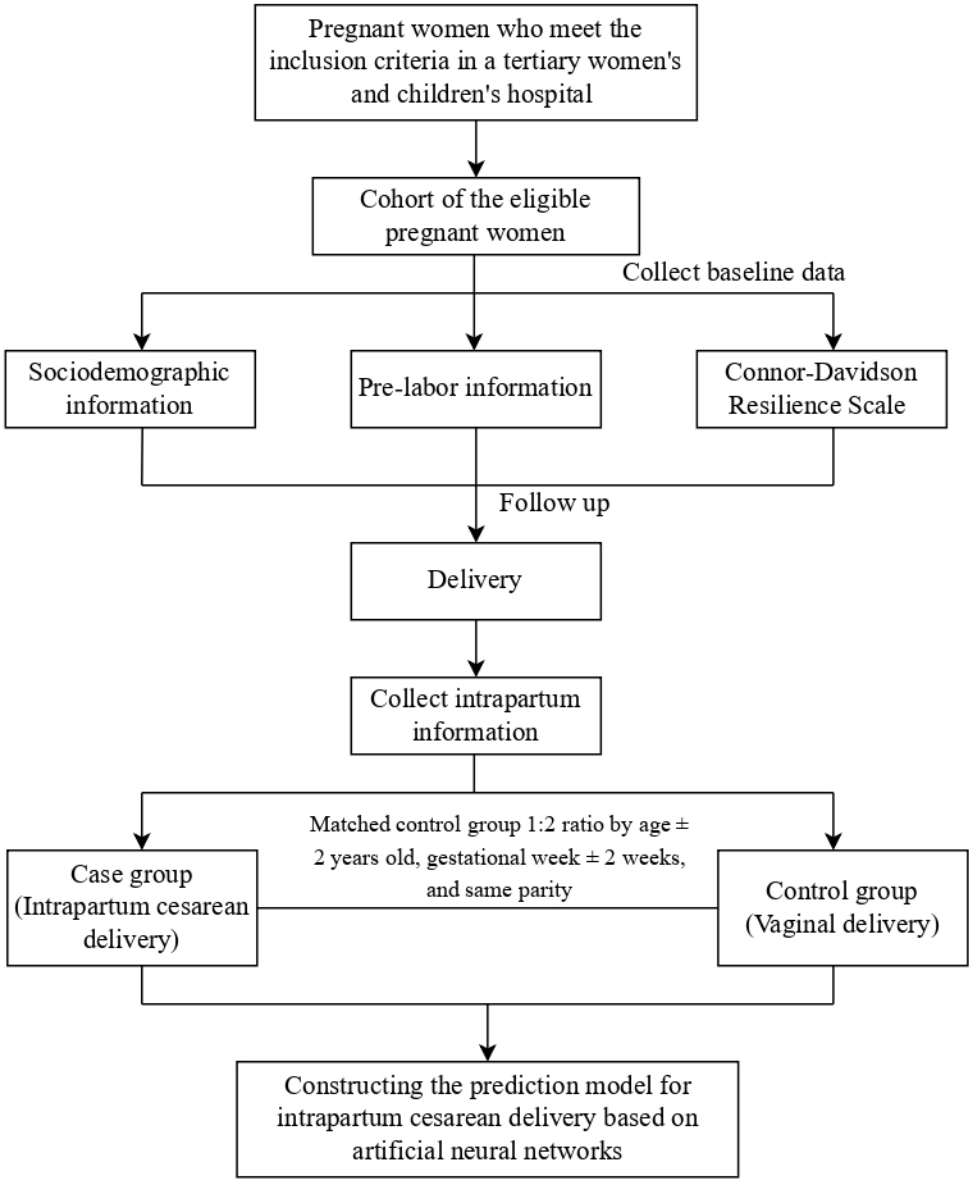

Figure 1 Technical protocol of this study. **Note:** inclusion criteria: female age ≥18 years, singleton pregnancy, gestation age ≥37 weeks and <42 weeks, and planning a vaginal delivery. Exclusion criteria: the induction of labor.

and each one scored from 0 to 4 points. The total score of the CD-RISC ranges from 0 to 100, and the higher score indicates greater resilience. After the informed consent is obtained from the participant, the participant will be invited to fill in the CD-RISC scale (table 2).

Sample size

The sample size was estimated by the proportions of intrapartum caesarean delivery among the total delivery through PASS V.15.0. A previous study reported the proportion of intrapartum caesarean delivery was 8%.[12] A sample size of 1323 produces a two-sided 95% CI with a width equal to 0.03 when the sample proportion is 0.08. Considering a drop-out rate of 10%, the recruitment of 1455 participants in the case group is planned. As for each case, two controls will be selected to match the case, 2910 participants are planned in the control group. Hence, a total of 4365 participants are planned to recruit.

Statistics analysis

Continuous variables will be described as mean±SD or median (IQR), and the Mann-Whitney U test and t-test will be used to identify the differences between the case group and the control group. Categorical variables will be described as numbers and percentages (%), and Pearson's χ^2 and Fisher's exact probability test will be used to identify differences between the two groups.

The techniques of reduction, preparation and balancing will be used to preprocess the original data. Data reduction refers to discarding the attributes that are unimportant, duplicated or having some linear relationship with other attributes in constructing the prediction

Table 1 Data collection form

A. sociodemographic data		
A1. Name: ______	A2. Identification number: ______	A3. Age (years) :______
A4. Nationality：□Han □Hui □Zang □Yi □Wei □Others: ______		
A5. Registered residence： □City □Town □Rural		
A6. Current residence：□City □Town □Rural		
A7. Occupation：□Professional technicians (□Medical □Others) □Civil servant □Ordinary staff □Farmer □Worker □Businessman □Teacher □Lawyer □Others :______		
A8. Education：□Junior high school and below □High school or technical secondary school □Junior college □College and above		
A9. Length of marriage(years): ______		
A10. Smoking: □Yes □No	A11. Drink alcohol: □Yes □No	
A12. Monthly income: ______		
B. Prelabour information		
B1. Number of pregnancies (including this pregnancy): ______	B2. Parity (including this delivery) :______	
B3. Mode of last deliveries (if applicable): □elective caesarean section □vaignal delivery □ vacuum extraction □forceps operation □ breech extraction □intrapartum caesarean delivery		
B4. Years from last delivery (if applicable): ______	B5. Number of fetuses in this pregnancy: ______	
B6. Height (cm): ______	B7. Weight before pregnancy(kg) :______	
B8. Weight before delivery (kg): ______		
B9：Pregnancy complications: □Hypertension □ Gestational diabetes mellitus □ Intrahepatic cholestasis of pregnancy □ Heart disease □ Premature rupture of membranes □ Placenta previa □ Uterine fibroids □ Others: ______		
B10. Blood pressure before pregnancy (mm Hg): ______		
B11. Blood pressure before delivery (mm Hg): ______		
B12. Pregnancy complicated with infectious diseases：□None □Acquired Immune Deficiency Syndrome □Syphilis □Hepatitis A □Hepatitis B □Hepatitis C □Others		
B13. Estimated fetal weight(g): ______	B14. Biparietal diameter (cm): ______	B15. Femur length: cm
B16. Uterine height(cm):	B17. Abdominal circumference(cm): ______	B18. Fetal position: ______
B19. Results of laboratory test (Last antenatal visit) ：		
B19.1 Total lymphocyte count ($\times10^9$/L) :______	B19.2 Haemoglobin (g/L) :______	
B19.3 White blood cell ($\times10^9$/L) :______	B19.4 Blood platelet ($\times10^9$/L) :______	
B19.5 Neutrophils: ______	B19.6 Haematocrit: ______	
B19.7 Blood potassium (mmol/L) ：	B19.8 C reactive protein: ______	
B19.9 Urine protein: ______	B19.10 24-hour urinary protein: ______	
B19.11 Procalcitonin: ______	B19.12 Coagulation function: □Normal □Abnormal	
B20. Position of placental: ______	B21. Thickness of placental	
B22. Placental maturity: ______	B23. Diameter of ischial tubercle (cm): ______	
B24. Depth of amniotic fluid(cm): ______	B25. Amniotic fluid index(cm): ______	
B26. S/D value:		
C. Intrapartum information		
C1. Delivery time (for intrapartum caesarean delivery)：□8:00-12:00 □12:00-18:00 □18:00-0:00 □0:00-8:00 Operation time (for vaginal delivery)：□8:00-12:00 □12:00-18:00 □18:00-0:00 □0:00-8:00		
C2 Blood pressure：C2.1 First stage of labour (mm Hg): _____ C2.2 Second stage of labour (mm Hg): _____		
C3 Body temperature: C3.1 First stage of labour (℃): _____ C3.2 Second stage of labour (℃): _____		
C4. Fetal monitoring during the first stage of labour: □Normal □Late deceleration □Frequent mutation deceleration □Baseline anomaly □Abnormal variation □Sine wave □Others:______		

Continued

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Table 1 Continued

A. sociodemographic data		
C5. Fetal monitoring during the second stage of labour：☐Normal ☐Late deceleration ☐Frequent mutation deceleration ☐Baseline anomaly ☐Abnormal variation ☐Sine wave ☐Others:______		
C6. Postpartum diagnosis: ____		
C7. Onset of the first stage of labour(yy/mm/dd) :______		
C8. Duration of intubation period: ____	C9. Duration of active period: ____	C10. Perineal Condition Score: ____
C11. Delivery mode of placenta: ☐Complete ☐Incomplete ☐Manual removal ☐Uterine curettage		
C12. Intrapartum blood loss (mL):	C13. Size of placenta(cm×cm×cm): ____	C14. Weight of placenta (g): ____
C15. Length of umbilical cord (cm): _____		
C16. Management of pain：☐Doula ☐ Intraspinal analgesia ☐Others:____		
C17. Interventions to promote labour: ☐None ☐Artificial rupture of membranes ☐Oxytocin ☐Balloon ☐Dinoprostone Suppositories ☐ Episiotomy		
C18. Onset of the second stage of labour (yy/mm/dd): ____		
C19. Onset of the third stage of labour (yy/mm/dd): ____ (for vaginal delivery) Time of intrapartum caesarean delivery(yy/mm/dd): ____ (for intrapartum caesarean delivery)		
C20. Reasons for intrapartum caesarean delivery (if applicable): ____		
C21. Amniotic fluid condition: ☐Normal ☐I ☐II ☐III		

model, which can reduce the dimensionality of the data and improve the efficiency of the algorithm. The data with missing values, incorrect format, inconsistent characteristics and outliers will be discarded. Data preparation is the process of properly initialising the data that will be used as input to the algorithm. After the reduction and preparation stages, the imbalanced data may emerge, which will be handled by random downsampling.

For ANNs, we will train and test a backpropagation (BP) algorithm multilayer perceptron topology with an input layer, one or more hidden layer/s and an output layer. The prelabour, intrapartum and psychosocial variables that are significantly associated with the presence of intrapartum caesarean delivery according to the results of the univariate analysis will be selected as the input layer neurons. One variable (intrapartum caesarean delivery or vaginal delivery) will be served as the output layer neuron. The input layer neurons receive and propagate the input parameters to the output layer through the hidden layers. The BP algorithm compares the output results with the expected results, and the inconsistent results will be propagated backward through the hidden layers, which will continue and repeat until the network model outputs the correct results.

If the available data set is large, it is a stronger design to split the data set by time and develop the prediction model using data set from one period and validate the model using data from another period, because this design allows for non-random variation between the two data sets.[28] Hence, the original data set of this study will be split into a training set (80%) and a test set (20%) by time. The test set will be used to validate the prediction model. Furthermore, a multivariable logistic regression model will be developed to compare with the final ANNs model. The confusion matrix, precision, recall, F1 score, accuracy and area under the receiver operating characteristic curve (AUC) are the metrics that will be used to evaluate the performance of these models. The F1 score refers to a measure of accuracy on test data and is a weighted average between precision and recall. An AUC of 0.5 indicates no discrimination, while an AUC of 1.0 indicates perfect discrimination.

Statistical analyses will be performed in IBM SPSS Statistics χ2.25.0 and Python V.3.7. A two-tailed $p<0.05$ will be considered statistically significant.

Patient and public involvement

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

DISCUSSION

This study aims to construct a prediction model for intrapartum caesarean delivery based on the ANNs approach. As previous studies have explored the relevant factors associated with intrapartum caesarean delivery, as well as the adverse outcomes after intrapartum caesarean delivery, we believe that the findings of this study will further contribute to the field of decreasing caesarean section rates and further improve the maternal and newborn outcomes.

Our study has several advantages. First, the study design is a prospective nested case–control study. Compared

Table 2 Content of the Connor-Davidson Resilience Scale

Item	0 point	1 point	2 points	3 points	4 points
1. Able to adapt to change					
2. Close and secure relationships					
3. Sometimes fate or God can help					
4. Can deal with whatever comes					
5. Past success gives confidence for new challenge					
6. See the humorous side of things					
7. Coping with stress strengthens					
8. Tend to bounce back after illness or hardship					
9. Things happen for a reason					
10. Best effort no matter what					
11. You can achieve your goals					
12. When things look hopeless, I don't give up					
13. Know where to turn for help					
14. Under pressure, focus and think clearly					
15. Prefer to take the lead in problem solving					
16. Not easily discouraged by failure					
17. Think of self as strong person					
18. Make unpopular or difficult decisions					
19. Can handle unpleasant feelings					
20. Have to act on a hunch					
21. Strong sense of purpose					
22. In control of your life					
23. I like challenges					
24. You work to attain your goals					
25. Pride in your achievements					

with the previous prediction models based on the retrospective study, the prospective nested case–control study can minimise the selection bias and missing data.[29] Second, we will collect the resilience level of pregnant women assessed by the CD-RISC scale. As previous studies have shown that if pregnant can have well childbirth preparation and psychosocial status, the intrapartum caesarean delivery can be decreased.[30 31] However, the constructed prediction models reported by previous studies have not involved the resilience level of pregnant women in the models, which may affect the decision of women to choose intrapartum caesarean delivery. Last, the ANNs approach will be performed to construct the final model, which has higher accuracy when compared with the traditional regression model. However, due to the limitation of funding and resources, this study will only conduct in a tertiary hospital. To mitigate this problem, the hospital we have chosen has over 18000 deliveries every year so that the sample size we need can be met. Furthermore, the validation of the final model will also use the sample from the same hospital, which makes the external validation immeasurable. However, we will adopt the design with temporal splitting and model validation, which can be considered intermediate between internal and external validation. Additionally, as the level of resilience is a self-report variable, self-report bias cannot be avoided. If resilience is included in the prediction model, a sensitive analysis will be conducted with and without resilience.

In conclusion, we believe this prediction model for intrapartum caesarean delivery based on the ANNs approach will be helpful for early identification and intervention for risk factors, and further decrease the caesarean section rates, as well as improves the maternal and newborn outcomes.

Ethics and dissemination

This study was approved by the Ethics Committee of West China Second University Hospital, Sichuan University, and the ethical number is 2021 (204). The date of approval was 17 December 2021. All methods were performed by the relevant guidelines and regulations. Written informed consent will be obtained from all participants and they can withdraw from the study at any time. The results of this study will be published in peer-review journal.

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Contributors All authors read and approved the final manuscript. JR, CH and GW designed and conducted the research study. CH wrote the original manuscript and conceptualised the analysis. CH and PC performed the analysis. JR, B-RL and GW reviewed and contributed to the final draft.

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