Research article

Nomogram-based risk assessment for emergency cervical cerclage failure in patients with cervical insufficiency

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ABSTRACT

Background: Cervical insufficiency can lead to preterm birth and neonatal mortality. Emergency cervical cerclage is a surgical intervention aimed at preventing preterm birth in patients with cervical insufficiency. However, some patients may experience cerclage failure. This study aimed to identify the risk factors associated with cerclage failure and develop a predictive nomogram model for patients with cervical insufficiency undergoing emergency cervical cerclage.
Methods: Data of 200 patients who underwent emergency cervical cerclage for cervical insufficiency were retrospectively analyzed. Patients were categorized into successful and failed groups based on their ability to take the infant home. Univariate and multivariate logistic regression analyses were performed to identify risk factors for cerclage failure. A nomogram model was developed based on multivariate logistic regression results, and its performance was assessed using receiver operating characteristic curves, calibration plots, and decision curve analysis (DCA).
Results: Univariate logistic regression analysis identified 11 potential risk factors for cerclage failure, including the presence of polycystic ovary syndrome (PCOS), vaginitis, cervical dilation, preoperative C-reactive protein, routine vaginal lavage after cervical cerclage, delivery, gestational age, extended days, chorioamnionitis, intrauterine infection, cervical laceration, and premature rupture of membranes. Multivariate logistic regression analysis revealed that PCOS, cervical dilation after cervical cerclage were independent risk factors for cerclage failure while routine vaginal lavage was a protective factor against failure. The nomogram predictive model demonstrated an area under the curve value of 0.975, indicating excellent discriminatory ability. The calibration plot showed good consistency between the nomogram predictions and actual observations. DCA demonstrated the strong clinical applicability of the nomogram.
Conclusions: This study successfully identified risk factors associated with emergency cervical cerclage failure in patients with cervical insufficiency and developed a predictive nomogram model. This model can assist clinicians in making informed decisions and accurately predicting the risk of cerclage failure in these patients.

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1. Introduction

In recent decades, modern medicine has made significant strides, particularly in reducing maternal and infant mortality rates. However, recurrent miscarriages and preterm births, along with their associated complications, continue to pose a substantial public health challenge [1–3]. The etiology of recurrent miscarriages and preterm births is multifaceted, and cervical insufficiency is a common cause [4]. Evidence-based medicine has validated transvaginal cervical cerclage as an effective clinical treatment for cervical insufficiency [5,6].

Emergency cervical cerclage is primarily indicated for patients experiencing mid-trimester painless cervical dilation, with or without cervical funneling. This urgent surgical intervention is crucial for saving premature fetuses and preventing adverse pregnancy outcomes such as miscarriages. As a remedial procedure for such patients, emergency cervical cerclage plays an irreplaceable role in extending pregnancy duration and increasing live birth rates [6–9]. Considering the complex clinical scenarios, surgical challenges, uncertain outcomes, and potential complications associated with this procedure, the implementation of emergency cervical cerclage remains controversial [10].

Nomogram-predictive models are frequently used to predict individual disease risks. These models visually present the predictive results by integrating indicators with proven predictive values, thereby offering substantial clinical guidance. Nomograms have been used clinically to predict various diseases' prognoses [11–13]. However, an accurate predictive model for assessing the risk of emergency cervical cerclage failure has not yet been developed.

Clinical data and neonatal outcomes from 200 patients diagnosed with cervical insufficiency who underwent emergency cervical cerclage at Jinan Maternal and Child Health Hospital between January 1, 2016 and May 31, 2023 were retrospectively analyzed. The patients were categorized into successful and failed groups based on their ability to take the infant home. Using univariate and multivariate logistic regression analyses based on these results, this study aimed to construct and validate a model for predicting the risk of failure of emergency cervical cerclage treatment. This model serves as a reference for accurately assessing patient risk and aids in clinical decision-making.

2. Materials and methods

2.1. Study participants

This study was approved by the Ethics Committee of the Jinan Maternal and Child Health Hospital (no. 2023-1-045). Clinical data and neonatal outcomes from patients diagnosed with cervical insufficiency who underwent emergency cervical cerclage at Jinan Maternal and Child Health Hospital between January 1, 2016 and May 31, 2023 were retrospectively analyzed.

The inclusion criteria were as follows: (1) gestational age of ≥ 13 weeks and <28 weeks; (2) singleton pregnancy; (3) varying degrees of cervical dilation observed in vaginal examinations, with cervical dilation of ≥ 1 cm; (4) intact membranes; and (5) absence of vaginal bleeding.

The exclusion criteria were as follows: (1) labor onset; (2) ruptured membranes; (3) clinical chorioamnionitis, indicated by a temperature of ≥ 38.0 °C; heart rate of ≥ 100 beats/min; fetal heart rate of ≥ 160 beats/min; uterine tenderness; malodorous vaginal discharge; elevated peripheral blood leukocyte count (white blood cell count [WBC] $\geq 15 \times 10^9$/L or left shift in neutrophils); (4) placental abruption; (5) severe fetal congenital anomalies or significant maternal medical or surgical complications requiring termination of pregnancy; (6) twin or multiple pregnancies; and (7) incomplete or missing follow-up data.

Altogether, 200 patients were included in this study. The patients were divided into the successful (n = 149) and failed (n = 51) groups according to their ability to take the infant home, which is the primary indicator of surgical success. No significant differences in general patient data were observed between the two groups (Fig. S1).

2.2. Observation and analysis indicators

Through a careful review of clinical records in the hospital's Health Information System and follow-up by phone, data on patient age, preoperative body mass index (BMI), number of pregnancies, and history of adverse pregnancy outcomes were collected. Additionally, potential risk factors affecting the outcome of the cerclage were gathered, including gestational age at the time of cerclage, degree of cervical dilation, days of pregnancy prolongation, use of assisted reproductive technology (ART), presence of polycystic ovary syndrome (PCOS), vaginitis (defined as symptoms of vulvar and vaginal itching, dryness, pain, and/or abnormal discharge), preoperative inflammatory markers (WBC, neutrophil percentage [N%], procalcitonin [PCT], and C-reactive protein [CRP]), preoperative hemoglobin (Hb) levels, routine postoperative vaginal lavage, vaginal application of progesterone, mode of delivery, and cerclage-related complications. Neonatal outcomes, including mortality and morbidity rates, were also analyzed in detail.

2.3. Surgical procedure

A combined spinal–epidural anesthesia technique was used in this study. Following successful anesthesia, the patient was placed in the lithotomy position with the head down and the buttocks elevated. The external genitalia and vagina were disinfected with a 0.5 % povidone–iodine solution. A vaginal retractor was used to expose the vaginal vault and cervix. The cervix was examined for one-finger cervical dilation followed by additional disinfection of the surrounding cervix. The bladder was pushed upward, and a Mersilene suture

was applied around the cervix, avoiding the vascular bundles at the 3 and 9 o'clock positions. A needle was inserted near the internal cervical os at the 1 o'clock position, passed through the cervical muscle layers, and exited at the 4 o'clock position. This process was repeated at the 5–7 o'clock and 8–11 o'clock positions for circular suturing, with knots tightened to allow for a fingertip-sized cervical os, leaving approximately 3 cm of the suture tail. The second suture layer was applied to the cervix. The cervical area surrounding the vagina was disinfected. Soluble hemostatic collagen sponges were placed in areas with bleeding due to bladder detachment, and a benzalkonium chloride gauze was inserted into the vagina for compression hemostasis with the insertion of a urinary catheter. If the amniotic membrane protruded into the cervix, the membrane was repositioned. Gentle maneuvers were carefully performed to prevent membrane rupture [14].

2.4. Postoperative vaginal cleansing

The vagina was cleaned with povidone–iodine swabs, followed by irrigation with a metronidazole sodium chloride solution. Beginning 72 h postoperatively, the vagina was cleaned twice a week until delivery to prevent infection and assess the condition of the cervix and suture thread.

2.5. Definition of PCOS

The diagnostic criteria for PCOS were retrospectively applied based on clinical data of the included patients [15,16]. PCOS is a significant risk factor for cervical insufficiency and adverse pregnancy outcomes, including gestational diabetes, hypertension, and

Table 1
Demographic and clinical characteristics of patients in emergency cervical cerclage groups.

Clinical Characteristics	Successful (n = 149)	Failed (n = 51)	*P* value
Age (years)	31.3 ± 4.64	32.0 ± 4.91	0.41
BMI (Kg/m^2)	25.6 [22.2; 28.4]	26.5 [23.3; 29.0]	0.23
ART			0.52
No	122 (81.9 %)	39 (76.5 %)	
Yes	27 (18.1 %)	12 (23.5 %)	
PCOS			<0.001
No	142 (95.3 %)	25 (49.0 %)	
Yes	7 (4.70 %)	26 (51.0 %)	
Vaginitis			0.07
No	127 (85.2 %)	37 (72.5 %)	
Yes	22 (14.8 %)	14 (27.5 %)	
Cervical dilation (cm)	1.00 [1.00; 1.50]	2.50 [1.50; 4.75]	<0.001
Parity	2.00 [1.00; 3.00]	2.00 [1.00; 3.00]	0.87
History of prior preterm birth and second-trimester loss			0.26
No	113 (80.1 %)	34 (70.8 %)	
Yes	28 (19.9 %)	14 (29.2 %)	
Preoperative WBC	9.32 [8.29; 11.2]	10.3 [8.54; 11.8]	0.14
Preoperative N	0.81 [0.75; 74.2]	0.81 [0.77; 72.5]	0.90
Preoperative CRP	7.30 [3.70; 10.0]	7.00 [3.64; 13.1]	0.18
Preoperative PCT	0.05 [0.04; 0.05]	0.05 [0.04; 0.05]	0.63
Preoperative Hb (g/dL)	116 ± 10.8	113 ± 9.99	0.05
Postoperative vaginal use of vaginal microparticle progesterone			0.68
Yes	120 (80.5 %)	39 (76.5 %)	
No	29 (19.5 %)	12 (23.5 %)	
Regular vaginal irrigation after operation			0.003
Yes	82 (55.0 %)	15 (29.4 %)	
No	67 (45.0 %)	36 (70.6 %)	
Cervical cerclage gestational age (week)	24.3 [21.1; 26.0]	23.1 [21.1; 24.4]	0.04
Extended days (day)	88.0 [68.0; 110]	22.0 [9.50; 79.0]	<0.001
Complications related to cervical cerclage			
Chorioamnionitis			<0.001
No	121 (81.2 %)	27 (52.9 %)	
Yes	28 (18.8 %)	24 (47.1 %)	
Maternal sepsis			0.06
No	134 (89.9 %)	40 (78.4 %)	
Yes	15 (10.1 %)	11 (21.6 %)	
Cervical laceration			<0.001
No	138 (92.6 %)	36 (70.6 %)	
Yes	11 (7.38 %)	15 (29.4 %)	
Preterm premature rupture of membranes			0.03
No	109 (73.2 %)	28 (54.9 %)	
Yes	40 (26.8 %)	23 (45.1 %)	

Note: BMI, body mass index; ART, assisted reproductive technology; PCOS, Polycystic ovary syndrome; WBC, white blood cells; CRP, C-reactive protein; PCT, Procalcitonin; N, Neutrophil; Hb, hemoglobin.

preterm birth. PCOS is diagnosed based on the Rotterdam criteria, which require the presence of two out of the three following features: oligoovulation/anovulation, clinical and/or biochemical signs of hyperandrogenism, and polycystic ovaries on ultrasound, while excluding other causes such as congenital adrenal hyperplasia, androgen-secreting tumors, or Cushing's syndrome.

2.6. Statistical analysis

Descriptive statistics were used to present baseline demographics and clinical characteristics. Skewed continuous data are described as medians and first and third quartiles. Categorical data are presented as frequencies and percentages. Differences between groups were evaluated using the chi-square test for categorical variables and Wilcoxon rank-sum test for skewed continuous variables. Univariate and multivariate logistic regression analyses were conducted to develop a predictive model for assessing the risk of emergency cervical cerclage failure. Variables with a *P*-value of <0.05 in the univariate analysis were included in the multivariate analysis to determine key risk factors associated with cerclage failure. A predictive nomogram was constructed using the final logistic model and relevant data.

Nomogram performance was assessed in terms of discriminative ability, predictive accuracy, and clinical utility using receiver operating characteristic (ROC) curve analysis, calibration plots, and decision curve analysis (DCA), respectively. The discriminative ability of the model was evaluated using the area under the ROC curve (AUC), which ranges from 0.5 (no discrimination) to 1 (perfect discrimination). Calibration plots were used to compare the actual risk of cerclage failure with that predicted by the nomogram. A DCA

Table 2
Neonatal outcomes following emergency cervical cerclage.

Pregnancy Outcome	Successful (n = 149)	Failed (n = 19)	P value
VLBW			0.146
No	131 (87.9)	14 (73.7)	
Yes	18 (12.1)	5 (26.3)	
ELBW			<0.001
No	144 (96.6)	10 (52.6)	
Yes	5 (3.36)	9 (47.4)	
NICU admission rate			<0.001[a]
No	94 (63.1)	0 (0.00)	
Yes	55 (36.9)	19 (100.0)	
Apgar scores at 1 min	10.0 [9.00; 10.0]	7.00 [5.00; 7.00]	<0.001
Apgar scores at 5 min	10.0 [10.0; 10.0]	8.00 [7.00; 8.50]	<0.001
NRDS			<0.001
No	111 (74.5)	6 (31.6)	
Yes	38 (25.5)	13 (68.4)	
IVH			0.016[a]
No	143 (96.0)	15 (78.9)	
Yes	6 (4.03)	4 (21.1)	
NEC			0.005[a]
No	148 (99.3)	16 (84.2)	
Yes	1 (0.67)	3 (15.8)	
Hyperbilirubinemia			0.003
No	126 (84.6)	10 (52.6)	
Yes	23 (15.4)	9 (47.4)	
ROP			0.034
No	131 (87.9)	13 (68.4)	
Yes	18 (12.1)	6 (31.6)	
PDA			<0.001
No	121 (81.2)	6 (31.6)	
Yes	28 (18.8)	13 (68.4)	
Neonatal sepsis			<0.001
No	136 (91.3)	9 (47.4)	
Yes	13 (8.72)	10 (52.6)	
Neonatal purulent meningitis			0.064[a]
No	147 (98.7)	17 (89.5)	
Yes	2 (1.34)	2 (10.5)	
BPD			<0.001
No	135 (90.6)	9 (47.4)	
Yes	14 (9.40)	10 (52.6)	
NPH			0.012[a]
No	149 (100)	17 (89.5)	
Yes	0 (0.00)	2 (10.5)	
Neonatal death within 7days of birth			<0.001[a]
No	149 (100)	11 (57.9)	
Yes	0 (0.00)	8 (42.1)	

Note: VLBW, very low birth weight infant; ELBW, extremely low birth weight infant; NRDS, neonatal respiratory distress syndrome; BPD, bronchopulmonary dysp lasia; PDA, patent ductus arteriosus; NEC, necrotizing enterocolitis; NICU, neonatal intensive care unit; ROP, retinopathy of prematurity; IVH, intraventricular hemorrhage; NPH, neonatal pulmonary hemorrhage.

was performed to determine the clinical usefulness of the nomograms. All statistical analyses were performed using the R software version 4.1.3 (available at http://www.R-project.org/). The tests were two-tailed, and significance was set at $P < 0.05$.

3. Results

3.1. Clinical characteristics and complications of patients undergoing emergency cervical cerclage

During the study period, 200 patients underwent emergency cervical cerclage. The success of the procedure was indicated by the successful discharge of the infant, and the patients were divided into the success (n = 149) and failure groups (n = 51). The clinical characteristics of the two groups of patients who underwent emergency cervical cerclage are presented in Table 1.

In our study, we primarily focused on evaluating neonatal outcomes between the successful and unsuccessful cervical cerclage groups. The emphasis is on immediate surgical outcomes, particularly the ability to take the infant home, which is a primary indicator of cerclage success. Although newborn outcomes, including mortality and morbidity rates, were comprehensively followed up after the mothers underwent cerclage, a detailed analysis was restricted to infants directly affected by the cerclage outcome. This approach was selected because this study mainly aimed to assess the effectiveness of cerclage rather than to conduct an extensive study on neonatal outcomes.

No significant differences in age (31.3 ± 4.64 vs. 32.0 ± 4.91, $P > 0.05$) and BMI (25.6 [22.2; 28.4] vs. 26.5 [23.3; 29.0], $P > 0.05$)

Table 3
Univariate analysis of risk factors for failure in emergency cervical cerclage.

Factor	β	SE	Wald	OR(95%CI)	P value
Age	0.03	0.03	0.73	1.03 (0.96–1.10)	0.39
BMI	0.03	0.04	0.60	1.03 (0.96–1.11)	0.44
ART					
No	0.00			1.00	
Yes	0.33	0.39	0.70	1.39 (0.64–3.00)	0.40
PCOS					
No	0.00			1.00	
Yes	3.05	0.48	40.71	21.1 (8.27–53.83)	<0.001
Vaginitis					
No	0.00			1.00	
Yes	0.78	0.39	4.02	2.18 (1.02–4.69)	0.045
Cervical dilation	1.77	0.34	26.55	5.86 (2.99–11.47)	<0.001
Parity	−0.04	0.12	0.12	0.96 (0.76–1.21)	0.73
Adverse obstetric history					
No	0.00			1.00	
Yes	0.20	0.37	0.30	1.23 (0.59–2.55)	0.58
History of midterm miscarriage					
No	0.00			1.00	
Yes	0.51	0.38	1.77	1.66 (0.79–3.51)	0.18
Preoperative WBC	0.10	0.07	2.25	1.11 (0.97–1.26)	0.13
Preoperative NEUT%	0.00	0.00	0.65	1.00 (0.99–1.01)	0.42
Preoperative CRP	0.05	0.02	5.45	1.05 (1.01–1.10)	0.02
Preoperative PCT	−0.71	2.47	0.08	0.49 (0.00–62.32)	0.77
Preoperative Hb (g/dL)	−0.03	0.02	3.54	0.97 (0.94–1.00)	0.06
Preoperative progesterone use					
No	0.00			1.00	
Yes	0.24	0.39	0.38	1.27 (0.59–2.73)	0.54
Routine vaginal vavage after cervical cerclage					
Yes	0.00			1.00	
No	1.08	0.35	9.55	2.94 (1.48–5.82)	<0.001
Cervical cerclage gestational age	−0.04	0.04	1.01	0.96 (0.89–1.04)	0.32
Extended days	−0.03	0.01	37.63	0.97 (0.96–0.98)	<0.001
Chorioamnionitis					
No	0.00			1.00	
Yes	1.35	0.35	14.76	3.84 (1.93–7.63)	<0.001
Intrauterine infection					
No	0.00			1.00	
Yes	0.90	0.44	4.25	2.46 (1.05–5.77)	0.04
Cervical laceration					
No	0.00			1.00	
Yes	1.65	0.44	14.20	5.23 (2.21–12.35)	<0.001
Premature rupture of membranes					
No	0.00			1.00	
Yes	0.81	0.34	5.73	2.24 (1.16–4.33)	0.02

Note: BMI, body mass index; ART,assisted reproductive technology; PCOS, Polycystic ovary syndrome; WBC, white blood cells; NEUT%,neutrophilic granulocyte percentage; CRP, C-reactive protein; PCT,Procalcitonin:Hb,hemoglob; SE, standard error; OR, odds ratio; CI, confidence interval.

were observed between the two groups. Other parameters such as gravidity (2.00 [1.00; 3.00] vs. 2.00 [1.00; 3.00], $P > 0.05$), history of preterm birth or mid-trimester miscarriage [28 (19.9 %) vs. 14 (29.2 %), $P > 0.05$], ART [27 (18.1 %) vs. 12 (23.5 %), $P > 0.05$], preoperative vaginal infection [22 (14.8 %) vs. 14 (27.5 %), $P > 0.05$], and postoperative vaginal use of micronized progesterone [120 (80.5 %) vs. 39 (76.5 %), $P > 0.05$] did not show significant differences between the two groups. However, significant differences in PCOS [7 (4.70 %) vs. 26 (51.0 %), $P < 0.05$], cervical dilation (1.00 [1.00; 1.50] vs. 2.50 [1.50; 4.75], $P < 0.05$), gestational age at placement (24.3 [21.1; 26.0] vs. 23.1 [21.1; 24.4], $P < 0.05$), regular postoperative vaginal douching [82 (55.0 %) vs. 15 (29.4 %), $P < 0.05$]), and prolongation of pregnancy days [88.0 [68.0; 110] vs. 22.0 [9.50; 79.0], $P < 0.05$] were observed between the two groups.

Our study also analyzed cerclage-related complications, revealing significant differences in cervical tears [11 (7.38 %) vs. 15 (29.4 %), $P < 0.05$], preterm premature rupture of membranes (PROM) [40 (26.8 %) vs. 23 (45.1 %), $P < 0.05$], and chorioamnionitis [28 (18.8 %) vs. 24 (47.1 %), $P < 0.05$] between the two groups. No significant difference in the incidence of maternal sepsis [15 (10.1 %) vs. 11 (21.6 %); $P < 0.05$] was observed between the two groups. Preoperative inflammatory markers, such as WBC, neutrophil percentage (N%), as well as CRP, PCT, and Hb levels, were not significantly different between the two groups ($P > 0.05$) (Table 1).

3.2. Comparison of neonatal outcomes between the successful and failed cervical cerclage groups

We comprehensively followed up the newborn outcomes after the mothers underwent cervical cerclage (Table 2). In the failed group, 19 live-born infants were delivered, although unfortunately all died because of complications. Compared with the successful group, the failed group had a higher incidence of extremely low birth weight premature infants (47.4 % vs. 3.36 %), lower 1-min Apgar scores (7.00 [5.00; 7.00] vs. 10.0 [9.00; 10.0], $P < 0.05$), lower 5-min Apgar scores (8.00 [7.00; 8.50] vs. 10.0 [10.0; 10.0], $P < 0.05$), and a higher rate of neonatal intensive care unit (NICU) admission (68.4 % vs. NaN). The failed group also had significantly higher rates of neonatal complications including acute respiratory distress syndrome (ARDS) (68.4 % vs. 25.5 %), intraventricular hemorrhage (IVH) (21.1 % vs. 4.03 %), necrotizing enterocolitis (NEC) (15.8 % vs. 0.67 %), hyperbilirubinemia (47.4 % vs. 15.4 %), retinopathy of premature infants (31.6 % vs. 12.1 %), patent ductus arteriosus (PDA) (68.4 % vs. 18.8 %), neonatal sepsis (52.6 % vs. 8.72 %), bronchial dysplasia (52.6 % vs. 9.4 %), and pulmonary hemorrhage (10.5 % vs. 0.00 %) than the successful group. However, no significant difference in the incidence of purulent meningitis was noted between the two groups (10.5 % vs. 1.34 %). The failed group also had a significantly higher rate of neonatal death within 7 days of birth than the successful group ($P < 0.05$).

3.3. Analysis of factors influencing the failure of emergency cervical cerclage and risk prediction

Logistic regression analysis was performed to investigate the factors influencing the failure of emergency cervical cerclage, with the outcome variable being whether the procedure failed (coded 1 for occurrence and 0 for no occurrence) (Table 3). Variables with significant differences in the univariate analysis were included in a multivariable logistic regression model, including PCOS, vaginitis, cervical dilation, preoperative CRP, routine vaginal lavage after cervical cerclage, extended days, chorioamnionitis, intrauterine infection, cervical laceration, and PROM.

As shown in Table 4, PCOS (odds ratio [OR] $= 24.78$, 95 % confidence interval [CI]: 3.71–165.46, $P < 0.001$), and cervical dilation

Table 4
Multivariate logistic regression analysis for predicting failure of emergency cervical cerclage.

Factor	β	SE	Wald	OR(95%CI)	P value
PCOS					
No	0.00			1.00	
Yes	3.21	0.97	10.98	24.78 (3.71–165.46)	<0.001
Vaginitis					
No	0.00			1.00	
Yes	−0.15	0.94	0.02	0.86 (0.14–5.47)	0.88
Cervical dilation	1.65	0.57	8.44	5.20 (1.71–15.82)	<0.001
Preoperative CRP	−0.02	0.05	0.27	0.98 (0.89–1.07)	0.60
Routine vaginal vavage after cervical cerclage					
No	0.00			1.00	
Yes	−3.89	1.29	9.02	0.02 (0.01–0.26)	<0.001
Extended days	0.01	0.01	0.24	1.01 (0.98–1.03)	0.62
Chorioamnionitis					
No	0.00			1.00	
Yes	−0.37	1.10	0.11	0.69 (0.08–5.94)	0.74
Intrauterine infection					
No	0.00			1.00	
Yes	−0.88	1.18	0.56	0.42 (0.04–4.17)	0.46
Cervical laceration					
No	0.00			1.00	
Yes	−0.10	0.92	0.01	0.90 (0.15–5.50)	0.91
Premature rupture of membranes					
No	0.00			1.00	
Yes	0.43	0.77	0.31	1.53 (0.34–6.93)	0.58

Note: PCOS, Polycystic ovary syndrome; CRP, C-reactive protein; SE, standard error; OR, odds ratio; CI, confidence interval.

(OR = 5.20, 95%CI: 1.71–15.82, $P < 0.001$) after cervical cerclage (OR = 48.75, 95%CI: 3.86–615.6, $P < 0.001$) were independently associated with an increased risk of failure of emergency cervical cerclage. Moreover, routine vaginal lavage after cervical cerclage (OR = 0.02, 95%CI: 0.01–0.26, $P < 0.001$) was a protective factor against failure. The risk of failed emergency cervical cerclage was 24.78 times higher in patients with PCOS than in those without PCOS. Compared to patients who undergo regular vaginal lavage after cervical cerclage, those who do not undergo routine lavage face a 48.75-fold increase in the risk of failure. Cervical dilation has been identified as a risk factor for failed emergency cervical cerclage. Similarly, gestational age at delivery was a protective factor against failure.

Based on the results of logistic regression analysis, a risk prediction nomogram for emergency cervical cerclage failure was constructed (Fig. 1). Each predictive variable in the nomogram was aligned vertically with the reference line at the top, and the corresponding score for each variable was obtained. The sum of all variable scores represents the total score, and the corresponding failure risk on the vertical axis aligned with the total score indicates the risk of failure for the patient. A higher total score indicated a higher risk of failure.

3.4. Validation and performance evaluation of the predictive model for emergency cervical cerclage failure

To assess the accuracy of the line plot model in predicting the risk of failed emergency cervical cerclage, we evaluated its discriminative ability, predictive accuracy, and clinical utility using ROC curve analysis, calibration plots, and decision curve analysis. As shown in Fig. 2, the results yielded an AUC value of 0.975 (95%CI: 0.954–0.995), indicating a high level of accuracy in predicting the occurrence of failed cerclage. The calibration plots demonstrated a close alignment between the predicted and observed risks, with a slope near 1, suggesting good consistency between the model predictions and actual outcomes. Furthermore, decision curve analysis indicated strong clinical utility for the line plot model.

4. Discussion

The management of patients with cervical insufficiency and protrusion of fetal membranes into the vagina is challenging in clinical practice because preventing preterm birth in these patients is a major concern for obstetricians. Several domestic and international clinical studies conducted in recent years have demonstrated the positive effects of emergency cervical cerclage in prolonging gestational time and improving perinatal outcomes [8,17,18]. However, owing to medical ethical considerations, most data evaluating the effectiveness of emergency cervical cerclage come from retrospective analyses, which are mostly small-sample studies and lack high-level large-sample randomized controlled trials for validation. Moreover, the clinical condition of patients in this category is complex and variable, surgery is challenging, and the outcomes and potential complications of the procedure remain uncertain. The use of emergency cervical cerclage in such cases is controversial [19]. Thus, identifying the risk factors for the failure of emergency cervical cerclage and accurately predicting such failures could strengthen and optimize the treatment of these patients and ensure efficient use of medical resources.

This study employed a multifactor logistic regression analysis based on the patients' antenatal clinical characteristics and laboratory results. PCOS after cervical cerclage, and cervical dilation were identified as independent risk factors for the failure of emergency cervical cerclage, whereas routine vaginal lavage was a protective factor against such failures. Based on these findings, we successfully constructed a prediction model in the form of a risk nomogram that can identify the risk factors for the failure of emergency cervical cerclage in patients with cervical insufficiency. The AUC of the nomogram for predicting the risk of failure was 0.975, indicating its high accuracy in risk prediction and its potential for assisting healthcare professionals in clinical decision-making.

Advanced cervical dilation with or without protrusion of the amniotic membrane into the vagina is one of the most critical risk factors for failure of emergency cervical cerclage surgeries. Schneider et al. retrospectively analyzed the pregnancy outcomes following emergency cervical cerclage surgery in 130 pregnant women [20]. They observed that complications, such as chorioamnionitis and treatment failure, were associated with cervical dilation exceeding 5 cm and prolapse of the amniotic membranes into the vagina. Similarly, UzunCilingir et al. concluded in their study of 21 pregnant women with cervical dilation of >4 cm and amniotic membrane
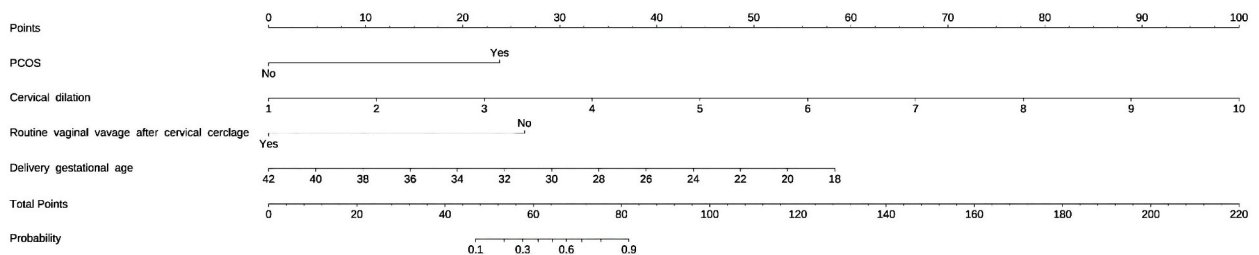

Fig. 1. Nomogram for predicting the risk of emergency cervical cerclage failure.
Note: This nomogram was designed to estimate the risk of failure of emergency cervical cerclage procedures. Each predictive variable is represented vertically against a reference line, with individual scores assigned to these variables. The cumulative score derived from the sum of these individual scores was correlated with the patient's risk of failure, as indicated on the vertical axis. A higher total score on the nomogram indicates an increased risk of cerclage failure. This tool aids in quantifying risk and facilitates informed clinical decision-making.
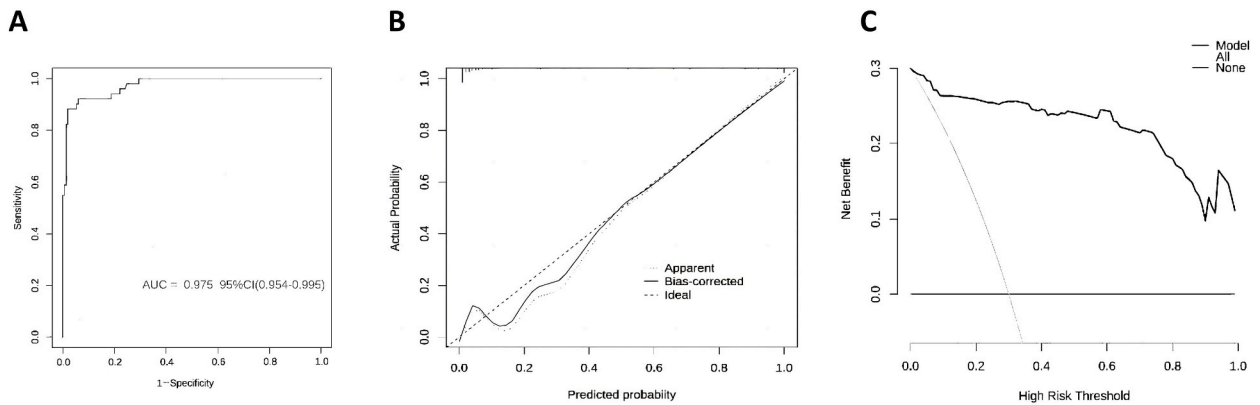
Fig. 2. Performance evaluation of the nomogram for predicting emergency cervical cerclage failure.
Note: (A) Receiver operating characteristic (ROC) curve: demonstrating the nomogram's discriminative ability with an area under the curve (AUC) value of 0.975, signifying high accuracy in predicting failure. (B) Calibration plot: illustrating the congruence between the predicted and actual risks of cerclage failure. The closer the solid line (performance of the nomogram) is to the dotted line (ideal model), the higher the prediction accuracy. (C) Decision curve analysis (DCA): assessment of clinical utility of the nomogram. The blue solid line represents predictions from the model, the gray line indicates scenarios in which all participants experienced cerclage failure, and the solid horizontal line depicts scenarios of universal cerclage success. Using the nomogram, the graph displays the expected net benefit per patient concerning the predicted risk of cerclage failure.

prolapse that emergency cervical cerclage surgery is not recommended for managing such advanced cases because of the high complication and low success rates [19]. This study demonstrated that the degree of cervical dilation is a risk factor for the failure of emergency cervical cerclage surgery, with a higher risk associated with a larger cervical dilation. However, no consensus on the upper limit of cervical dilation for performing surgery has been reached because domestic and international guidelines have not established unified criteria. Based on the extensive experience of our medical center, as long as the cervix is not completely effaced and the anterior and posterior lips are still visible upon examination, emergency cervical cerclage surgery can be performed to salvage the pregnancy. Further clinical trials are required to confirm these findings.

PCOS is a common reproductive endocrine and metabolic disorder in women and is a high risk factor for adverse pregnancy complications. PCOS in pregnant women has been associated with higher rates of gestational diabetes, hypertension, postpartum hemorrhage, preterm labor, macrosomia, and cervical incompetence [21–24]. Wu et al. performed a multivariate logistic regression analysis of Chinese women treated with ART [25]. They identified a significant association between PCOS and cervical incompetence (OR = 2.05, 95%CI: 1.009–4.206; $P = 0.048$). PCOS and cervical incompetence negatively affect the prognosis and increase the likelihood of preterm delivery or miscarriage occurring at an earlier gestational age ([31.2 ± 5.7] weeks vs. [33.6 ± 5.1] weeks, $P < 0.01$). The specific mechanisms underlying the development of cervical incompetence in women with PCOS remain unclear; however, current evidence suggests that hyperandrogenism and insulin resistance may contribute to its occurrence [21]. In this study, PCOS was identified as a risk factor for the failure of emergency cervical cerclage surgeries. This highlights the importance of early transvaginal ultrasound monitoring of cervical length and increasing surveillance frequency during pregnancy in patients with PCOS without a history of cervical incompetence to detect cervical incompetence early and provide prompt intervention.

Research conducted abroad has demonstrated that the vaginal microbiota of pregnant women undergoing cervical cerclage procedures changes [26]. However, these studies did not verify whether altering the vaginal microbiota improves the therapeutic efficacy of cervical cerclage, and subsequently improves pregnancy outcomes. Kindinger et al. have suggested that cervical cerclage, an invasive procedure, carries an increased risk of infection owing to cerclage sutures [27]. Their research indicated that compared with a single filament cerclage, the use of a wider woven cerclage tape is more likely to induce dysbiosis in the vaginal microbiota. Dysbiosis is characterized by an increase in genera such as *Prevotella* and *Clostridia* and a decrease in *Lactobacillus*, along with elevated levels of pro-inflammatory cytokines in the cervicovaginal fluid, such as interleukin (IL)-1β, IL-6, tumor necrosis factor-α, which increase the risk of preterm birth. In 2019, Brown et al. have reported that satisfactory therapeutic outcomes were more likely to be achieved in cases in which the pre-cerclage vaginal microbiota was dominated by *Lactobacillus* or *Bifidobacterium* [28].

Zhou et al. conducted a study that showed that, compared to the pre-cerclage vaginal microbiota, the post-cerclage vaginal microbiota exhibited greater richness, increased abundance of *Lactobacillus*, and decreased abundance of *Gardnerella* [29]. Improvements in the vaginal environment and pregnancy outcomes were also observed after cervical cerclage. However, similar to previous studies, they did not verify whether altering the vaginal microbiota improved the therapeutic efficacy of cervical cerclage and subsequently improved pregnancy outcomes. The current study determined that postoperative unregulated vaginal lavage is a risk factor for failure of emergency cervical cerclage. We hypothesized that postoperative vaginal lavage may improve the vaginal microbiota environment and allow for accurate assessment of cervical cerclage status, leading to timely medical intervention and extension of pregnancy duration. We anticipate future large-scale, high-quality studies exploring the effects of cervical cerclage on the vaginal microbiota and its metabolites using metagenomic and metabolomic approaches.

One controversial issue in current clinical practice is whether the implementation of emergency cervical cerclage while prolonging the gestational age effectively mitigates the adverse effects of the procedure and ultimately improves neonatal outcomes. In a Cochrane

review, Alfirevic et al. argued that although cervical cerclage reduces the risk of preterm birth, it does not significantly decrease neonatal morbidity or mortality [30]. Our study revealed a significant increase in complications such as cervical laceration, PROM, and clinical chorioamnionitis in the cervical cerclage failure group. Although no significant differences were observed in the subsequent multivariate analysis, the small sample size may have influenced this outcome. Golbasi et al. have indicated that cervical cerclage procedures based on physical examination criteria yield higher rates of low birth weight, low APGAR scores, neonatal intensive care unit admissions, and neonatal mortality than procedures based on medical history and ultrasound criteria, although these differences lack statistical significance [31]. In this study, we extended the evaluation period of neonatal outcomes to include the total time spent in the NICU. We retrospectively analyzed medical documents from the relevant neonatology departments during NICU admission to compare the incidence of neonatal morbidity and mortality between the two groups. The failure group had a higher incidence of complications, such as ARDS, IVH, NEC, hyperbilirubinemia, retinopathy of prematurity, PDA, neonatal sepsis, bronchial dysplasia, and pulmonary hemorrhage than the successful group. Thus, the fewer the short-term complications in newborns, the greater their chances of survival. The potential adverse effects of the procedure, particularly its impact on neonatal outcomes and long-term prognosis, needs to be carefully considered before performing cervical cerclage.

5. Conclusions

In this study, we successfully constructed a risk nomogram predictive model for the occurrence of emergency cervical cerclage treatment failure in patients with cervical insufficiency (Fig. S2). The model exhibited relatively high accuracy, enabling physicians to make informed decisions and accurately predict patient outcomes. By estimating the individual risks, healthcare professionals and patients can implement the necessary measures for lifestyle monitoring and medical interventions. This nomogram requires external validation and further research to determine whether individual interventions based on the nomogram can reduce the risk of medication non-compliance and improve treatment outcomes.

Ethics approval and consent to participate

Consent for publication

Not applicable.

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Data availability statement

All data are available upon reasonable request.

CRediT authorship contribution statement

Caixia Chen: Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization. **Shun Guo:** Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization. **Changyou Fan:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Funding acquisition, Data curation. **Fengchun Gao:** Writing – review & editing, Writing – original draft, Software, Investigation, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e32923.

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