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Effects of Emergency Cervical Cerclage on Pregnancy Outcome: A Retrospective Study of 158 Cases

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Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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The aim of this study was to evaluate the effectiveness and safety of emergency cervical cerclage in women with advanced cervical dilatation and bulging of fetal membranes. The study included 158 women who underwent emergency cervical cerclage because of cervix dilatation and protruding membranes in mid-trimester at Sun Yat-sen Memorial Hospital of Sun Yat-sen University. Pregnancy outcomes and pregnancy outcome related to clinical features were analyzed retrospectively. Analysis revealed that the placement of emergency cerclage led to the delivery of live infants with a success rate of 82.28%. The mean interval between cerclage and delivery was 52.16.±26.62 days, with a mean gestation at delivery of 30.3±4.7 weeks and a mean birth weight of 1934.69±570.37 g. No severe maternal complications such as maternal death, hematosepsis, and hysterorrhexis occurred after the operation. Two women (1.25%) had laceration of the cervix, 1 woman (0.61%) suffered pulmonary edema, and 2 women (1.25%) developed deep vein thrombosis (DVT). There were significant correlations between the pregnancy outcome and risk factors, including any presenting symptoms, cervical dilatation, postoperative white blood cell count, and C-reactive protein (CRP) value. No significant difference was found in women with good *vs.* poor outcome in terms of maternal age and obstetric histories. Emergency cervical cerclage is effective in prolonging pregnancy and improving neonatal outcome in women with cervical incompetence. It should be considered a viable option for women with a dilated cervix in mid-trimester.

MeSH Keywords: C-Reactive Protein • Obstetric Labor, Premature • Uterine Cervical Incompetence

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Background

Cervical incompetence is an important contributor to preterm birth and second trimester pregnancy loss. It is defined as the inability to support a full-term pregnancy because of a functional or structural defect of the cervix [1]. The typical symptoms of cervical incompetence include history of recurrent mid-trimester losses or pre-term birth and painless cervical dilatation in the absence of contractions or intrauterine infections. Labor is often short and the premature fetus is born alive. It is reported that the rate of cervical incompetence is between 0.1% and 2%, and is estimated to account for 15% of the recurrent pregnancy losses between 16 and 28 weeks [2].

In cases with cervical incompetence, mechanical support of a weak cervix is thought to be the main factor required to prolong the pregnancy. Cervical cerclage has been used to treat cervical incompetence for more than 50 years, since it was first described by Shirodkar [3] and later modified by McDonald [4]. Emergency cervical cerclage has been used as a salvage procedure in women with cervical dilatation and bulging fetal membranes in mid-trimester, in an attempt to prolong the pregnancy to a viable gestation. However, emergency cervical cerclage is likely to increase the risk of infection, due to increased exposure of the fetal membranes to vaginal bacteria, and its effectiveness and safety remain controversial [5–7].

In this study, we report the neonatal outcomes and safety of emergency cervical cerclage placement in women with advanced cervical dilatation and bulging of fetal membranes in our setting, an advanced general hospital in China. Our aim was to evaluate the feasibility of emergency cervical cerclage and discuss our experience using this procedure, with the intention that it may be applicable in a similar setting elsewhere.

Material and Methods

This retrospective study was conducted in the Department of Obstetrics and Gynecology, Sun Yat-sen Memorial Hospital, China after being approved by the ethics committee. Medical records were reviewed for 163 patients who underwent emergency cervical cerclage because of cervix dilatation and intact fetal membranes protruding beyond the external cervical os in mid-trimester during the period of 01 January 2003 to 01 December 2013. Five cases were excluded from analysis because they were lost to follow-up after discharged from hospital. A total of 158 cases were included in the analysis.

Diagnosis of cervix dilatation and membrane protruding was made by physical examination (Figure 1A) as patients complained about pelvic pressure sensation or increased vaginal discharge and others who had no clinical symptoms were

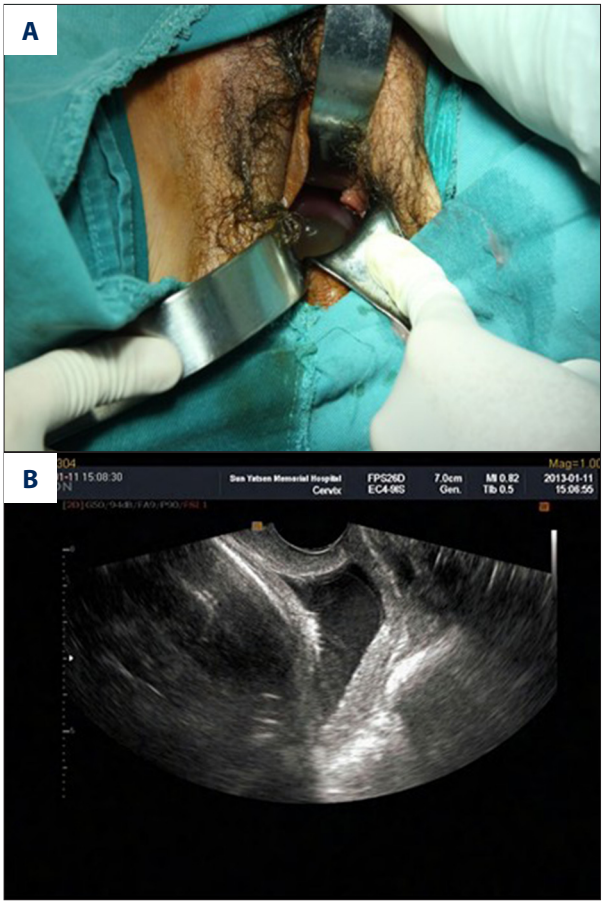

Figure 1. Diagnosis of cervical incompetence. (**A**) Diagnosis by physical examination. (**B**) Diagnosis by transvaginal ultrasound.

diagnosed by cervical ultrasound screening (Figure 1B) as they had a past history of at least one mid-trimester loss. The criteria for cerclage were that there must be no significant contractions or rupture of the membranes; no heavy bleeding; and no evidence of infection (axillary temperature <37.5°C, serum WBC less than 14×10^9, C-reactive protein (CRP) less than 10 mg/dL) [8]. Pre-operative microbiological analyses and drugs sensitivity were done by vaginal swabs, but no amniotic fluid cultures were taken; because the result could not be available at the time of emergency cerclage, it was done for the postoperative guidance on antibiotic use. Fetal anomalies were excluded by obstetric ultrasounds before the cerclage procedure.

McDonald procedure [9] (Figure 2) was performed under spinal anesthesia. Double '0' silk thread was used to suture the cervix, while a sterile moist gauze was used with gentle pressure to replace the membranes into the uterus and to push the membranes to allow suturing. All subjects were given prophylactic tocolytics (Ritodrine hydrochloride or atosiban infusion) and prophylactic broad-spectrum antibiotics before, during, and after the cerclage. Tocolytics and antibiotics were continued

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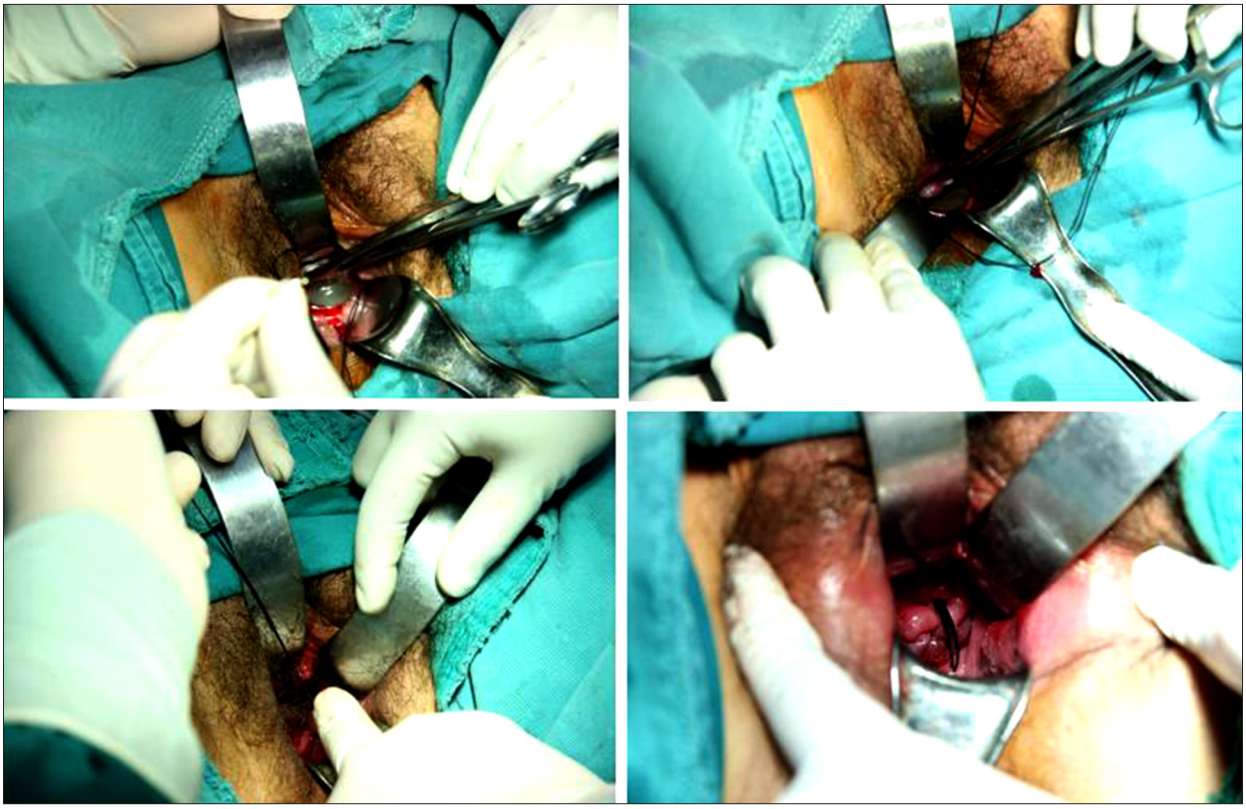

Figure 2. McDonald procedure.

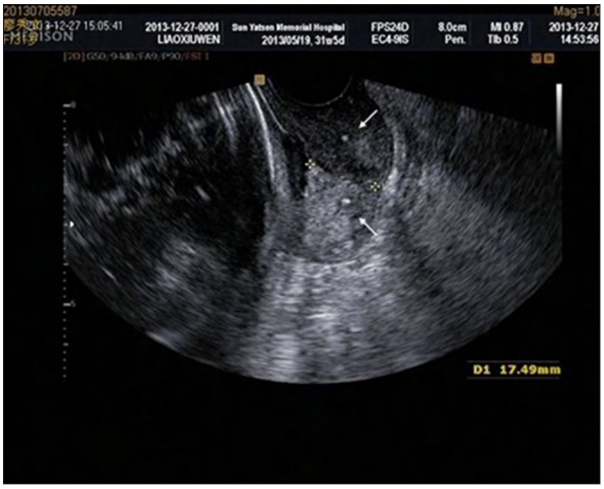

Figure 3. Transvaginal ultrasonographic assessment of the cervix after the operation. White arrow points point to "cerclage wires".

for at least 7 days postoperatively if delivery did not occur. The serum level of CRP and the WBC count were determined every 3 days in the first week after operation. Postoperative management included bed rest, abstinence from intercourse, follow-up fetal fibronectin (fFN) testing, and transvaginal ultrasonographic assessment of the cervix every 2–3weeks until 32 weeks (Figure 3). The sutures were removed in all women who labored, ruptured their membranes, and developed clear evidence of infection, or on reaching 37 weeks of gestation.

The following data were gathered from the medical records: clinical and demographic data, gestational age, cervical dilatation at time of cerclage, cerclage-delivery interval, gestational age at time of delivery, fetal survival rate, neonatal birth weight, and maternal complications.

Analyzed data are represented either as number and percent, or mean ±SD. The statistical analyses involved two-sample t-test and chi-squared test, as appropriate. P value of <0.05 was considered significant.

Results

At the time of cerclage, the mean maternal age was 29.18±3.52 years (range: 23–37 years), the mean gestational age was 21.45±2.23 weeks (range: 18–27 weeks), and the cervical dilatation was 2.79±1.38 cm (range: 1–7 cm). The clinical and demographic data is displayed in Table 1.

Neonatal outcomes are presented in Table 2. Emergency cerclage led to live-births, with a success rate of 82.28%. The mean interval between cerclage and delivery was 52.16±26.62

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Table 1. Clinical and demographic data.

	Mean ± standard	Range
Maternal age	29.18±3.52	23–37
History of live birth	0.52±0.31	0–1
Number of previous miscarriages	1.63±0.87	0–3
Gestation at cerclage (weeks)	21.45±2.23	18–27
Cervical dilatation (cm)	2.79±1.38	1–7

Table 2. Neonatal outcomes of emergency cerclage.

	Mean ± standard/rate	Range
Suture to delivery interval (days)	52.16±26.62	5–125
Gestation at delivery (weeks)	30.32±4.75 weeks	25–39.6
<24 weeks (%)	8.23% (13/158)	
24–27^{+6} weeks (%)	12.66% (20/158)	
28–31^{+6} weeks (%)	29.11% (46/158)	
32–36^{+6} weeks (%)	39.24% (62/158)	
≥37 weeks (%)	10.76% (17/158)	
Survival (%)	82.28% (130/158)	
Birth weight (g)	1934.69±570.37	880–3350

Table 3. Maternal outcomes of emergency cerclage.

	Incidence rate (%)
Maternal death	0
Hematosepsis	0
Laceration of cervix	1.25% (2/158)
Hysterorrhexis	0
Pulmonary edema	0.61% (1/158)
Deep Vein Thrombosis (DVT)	1.25% (2/158)

days (range: 5–125 days) with a mean gestation at delivery of 30.3±4.7 weeks (range: 25–39.6 weeks) and a mean birth weight of 1934.69±570.37 g (range: 880–3350 g). As shown in Table 3, there were no severe maternal complications such as maternal death, hematosepsis and hysterorrhexis. Two women (1.25%) had laceration of cervix, 1 woman (0.61%) suffered pulmonary edema, and 2 another women (1.25%) developed DVT.

Clinical features that could eventually predict the pregnancy outcome, such as maternal age, obstetric history, presenting symptoms (vaginal bleeding, discharge, or pelvic pressure sensation), if any, before the procedure, cervical dilatation, postoperative white blood cell (WBC) counts, and CRP value were analyzed and compared among women with good pregnancy outcome (live births) to those with poor outcome (miscarriage). As shown in the Table 4, statistical analysis revealed significant correlation between pregnancy outcome and any symptoms before operation, cervical dilatation, post-operative WBC counts, and CRP value (P=0.01, P<0.001, P<0.001, P=0.02, respectively). However, analysis of maternal age and obstetric history showed no significant difference in women with good *vs.* poor outcome (P=0.73, P=0.59).

Of the 158 cases, 85 women had cervical dilatation ≥3 cm and 73 had cervical dilatation <3 cm at the time of cerclage. When comparing the clinical features and the outcome within these two groups (shown in Table 5), it was noted that there were significant differences in the operation duration, postoperative WBC counts, CRP value, and neonatal outcomes. Patients with cervical dilatation ≥3 cm tend to have longer operation duration, higher WBC count, and CRP level after operation (P<0.001, P=0.03, P=0.01). The suture-to-delivery interval was longer and neonatal outcomes (survival and birth weight) were better in patients with cervical dilatation <3 cm (P<0.001, P=0.01, P=0.004).

Discussion

In the last several decades a number of studies have attempted to evaluate the advantages and disadvantages of emergency

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Table 4. Pregnancy outcome related to clinical features: Good *vs*. Poor.

	Good pregnancy outcome (n=130)	Poor pregnancy Outcome (n=28)	P value
Maternal age (years)	29.22±3.56	28.96±3.39	0.73
Number of previous miscarriages	1.62±0.88	1.71±0.81	0.59
Presenting symptoms, if any (%)	17.69% (23/130)	39.29% (11/28)	0.01
Cervical dilatation (cm)	2.45±1.14	3.97±1.48	<0.001
Postoperative WBC counta ($\times 10^9$/L)	10.01±2.12	12.21±2.24	<0.001
Postoperative CRP (mg/L)	12.22±4.78	14.68±6.48	0.02

Good pregnancy outcome = live births. Poor pregnancy outcome = miscarriage P value of <0.05 was considered significant.

Table 5. Pregnancy outcome related to clinical features: based on cervical dilatation.

	Cervical dilatation ≥3 cm (n=85)	Cervical dilatation <3 cm (n=73)	P value
Operation duration (min)	30.31±6.57	26.56±5.70	<0.001
Postoperative WBC counts ($\times 10^9$/L)	10.75±2.27	9.99±2.27	0.03
Postoperative CRP (mg/L)	13.62±5.69	11.52±4.31	0.01
Suture to delivery interval (days)	43.72±24.44	61.99±25.82	<0.001
Survival (%)	75.29% (64/85)	90.41% (66/73)	0.01
Birth weight (g)	1791.56±545.74	2073.49±563.25	0.004
	(n=64)	(n=66)	

P value of <0.05 was considered significant.

cervical cerclage [10–13]. However, only a very few informative randomized controlled trials (RCT) with large sample size have been conducted for evaluating the use of emergency cerclage [14], and the effectiveness and safety remain controversial.

The effectiveness of emergency cerclage

Some obstetricians believe that once cervical dilatation has occurred, infections, uterine contractions, or rupture of the membranes often follow, leading to a poor outcome after emergency cerclage [15,16]. In some developed countries, it is not recommended to perform emergent cervical cerclage beyond the limit of fetal viability (≥24 weeks), because the potential for harm probably outweighs the potential benefit [1]. Although the treatment of neonates in China had improved dramatically over the past few years [17], infants born before 28 weeks of gestation only have a survival rate of <50%, and more than half of the surviving infants are moderately to severely handicapped [18–20]. In the urgent situation of bulging membranes, emergency cervical cerclage may be the only hope for prolonging gestation until fetal viability is reached.

In this study we illustrate that emergency cerclage can lead to the delivery of a live infant with a success rate of 82.28%. The mean procedure-to-delivery interval was 52.16±26.62 days. We believe that achieving 82.28% live births can be considered a good result for mid-trimester emergency cerclage in the presence of protruding membranes. Our results are mostly in agreement with previous reports. Recently, some studies found that emergency cervical cerclage was a favorable approach to cervical dilatation in the mid-trimester and can lead to delivery of a more viable infant [21–24]. Aoki et al. (2014) compared the role of bed rest with emergency cervical cerclage and the results indicate significant increase in median duration of pregnancy prolongation (44 days *vs*. 12.5 days, P<0.01). The numbers of deliveries after 28 and 32 weeks were also significantly higher in the cerclage group than in the bed rest group (P<0.05) [25]. Evidence shows a significant increase in live birth rate (72% *vs*. 25%) in the emergency cervical cerclage group [26]. Abo-Yaqoub et al. (2012) also reported a significant increase in pregnancy duration at the time of delivery and neonatal birth weight in women with emergency cervical cerclage after 20 weeks [27]. Althusius et al. (2003)

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reported that without cerclage, the mean cerclage-delivery interval was 20 days, and the mean gestational age at time of delivery was less than 26 weeks, with 80% of women delivering before 28 weeks. They also suggested that the significant reduction in neonatal morbidity is an added benefit of emergency cervical cerclage [28].

The safety of emergency cerclage

Exposure of the fetal membranes to vaginal bacteria may increase the risk of chorioamnionitis, intraamniotic infection, hematosepsis of mother, or even maternal death because of severe infection. In our study, no severe maternal complications such as hematosepsis or maternal death occurred after emergency cerclage. Prophylactic broad-spectrum antibiotics given before, during, and after the cerclage and regularly monitoring inflammatory markers may reduce the incidence of infection.

Bulging membranes into the cervix, avoiding inadequate placement of the cerclage in a superficial portion of the cervix, and the risk of iatrogenic rupture of the membranes during the operative procedure make emergency cerclage difficult for surgeons and poses challenges such as uterine contraction, laceration of the cervix, or even hysterorrhexis after cerclage. In our study, two patients developed laceration of the cervix but no hysterorrhexis occurred after cerclage. Our experience allowed us to improve the operative technique and use aggressive tocolysis. However, aggressive tocolysis may lead to another problem. Atosiban, an oxytocin antagonist, has been shown to inhibit preterm uterine contractions effectively in placebo-controlled clinical trials without causing any significant cardiovascular, pulmonary, or central nervous system adverse effects [29]. Nevertheless, it is too expensive in China to be a first- choice medicine. Ritodrine hydrochloride, the main traditional drug in China, is a beta-2 adrenoceptor agonistic that may cause maternal adverse effects, especially cardiovascular problems [30]. One woman suffered pulmonary edema in our study, which might have been related to long-term and large-dose usage of ritodrine hydrochloride. However, the prognosis of this case was good because of early detection and timely treatment. Therefore, tocolytic therapy, especially ritodrine hydrochloride therapy, should be carefully administered and monitored appropriately.

Deep venous thrombosis (DVT), a blood clot forming in a deep vein, is another maternal complication after emergency cerclage. The factors that increase risk for DVT on cerclage patients are hypercoagulable state of pregnancy and prolonged bed rest. In our study, 2 women developed DVT. We suggest reducing the incidence by teaching patients to turn often if bed rest is to be maintained, encouraging ambulation as early as possible if allowed, and telling patients to report any pain or dull ache in the calves.

Several factors related to pregnancy outcomes

In this study we also found that several factors were closely related to pregnancy outcomes. Namouz and Gupta [31,32] reported that predictors of poor outcome were prolapsed membranes, evidence of intra-amniotic or systemic infection, symptomatic presentation, and cervical dilatation greater than 3 cm. Our results also suggest that the degree of cervical dilatation, the postoperative CRP value and WBC count, and any clinical symptoms before the operation are the major predictors of success or failure of emergency cerclage.

Fortner et al. [33] reported that women who receive an emergency cerclage are more likely to deliver at an earlier gestational age when the cervical dilation is ≥2 cm at the time of procedure. This may be due to the increased exposure of fetal membranes to vaginal bacteria and because women with bulging membranes are more susceptible to infection. Moreover, the procedure is associated with more challenges as the degree of cervical dilation becomes greater. It is reported that women with cervical dilation of ≥2 cm at cerclage placement were more likely to have an intracervical Foley balloon catheter utilized for membrane reduction during the procedure. Our present study revealed that patients with cervical dilation ≥3 cm tend to have longer operation duration, and higher WBC count and CRP levels after the operation. Neonatal outcomes were better in patients with cervical dilation <3 cm.

Pregnancy is unlikely to be prolonged in the presence of infection. Although none of the women in our current study had any evidence of infection before the operation, we detected significantly higher postoperative CRP value and WBC count in the failure group than patients in the success group. We speculate that women without evidence of infection at the time of the procedure may have subsequently developed chorioamnionitis, which usually results from infection by microorganisms. The CRP value and WBC count can reflect subclinical or clinical chorioamnionitis with greater sensitivity. Thus, postoperative CRP and WBC count are accurate predictors of poor outcome of cerclage and have immense clinical value as post-cerclage monitoring indicators.

It has been reported that in women with emergency cerclage, delivery <32 weeks was significantly more common in women with symptoms (vaginal bleeding, discharge, or pelvic pressure sensation) [34]. Our results also indicate that pregnancy outcome of the women without symptoms are better than in women with any presenting symptoms. We speculate that patients with symptoms were more likely to develop infection and contraction after operation, leading to poor outcome of cerclage.

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Conclusions

Our present study demonstrates a favorable prolongation of pregnancy and neonatal outcome in emergency cerclage placement in women with advanced cervical dilatation and bulging of fetal membranes. In addition, our results indicate that several factors, including the degree of cervical dilatation, postoperative CRP value and WBC count, and any clinical symptoms, are closely related to the pregnancy outcomes. However, the study is limited by its retrospective nature and two limitations warrant consideration. First, we only included women followed-up and giving birth in our setting after the operations and had no data about those who were not followed-up. Second, operations were not conduct by the same doctor during the 10-years study period, which may induce statistical bias. More robust RCTs are recommended to clarify the fundamental concerns in this complex subject area.

Details of ethics approval

The study was approved by the Ethics Committee of Sun Yat-sen Memorial Hospital of Sun Yat-sen University.

Declaration of conflict of interest

None. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript

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