A simplified pre-conceptional laparoscopic cervical cerclage for cervical insufficiency: a retrospective study from a single center

Ledi Kuang[1,2], GuoLin Luo[1,2], Xin Tan[1,2] and Hong Liao[1,2*]

Abstract

Background Cervical insufficiency is a pathological condition in obstetrics in which the cervix fails to retain the fetus before uterine contractions or labor (painless cervical dilatation). Patients usually have fetal loss in the mid-trimester or spontaneous pre-term birth due to painless cervical dilation. For non-pregnant women with cervical insufficiency, prophylactic laparoscopic abdominal cerclage (LAC) has been reported to improve pregnancy outcomes, such as live birth, neonatal survival, and full-term delivery rate. Conventional LAC involves opening the vesicular space and separating the anterior broad ligament leaves. In our surgical procedure, these two steps were omitted.

Methods An observational study was conducted retrospectively on patients who underwent a simplified pre-conceptional LAC between January 2015 and December 2022 at West China Second University Hospital, Sichuan University. Follow-ups for all the patients ended at the delivery of the fetus. Subsequently, clinical characteristics, perioperative data, and obstetric outcomes were recorded and analyzed.

Results In total, 108 patients were included in a pre-conception LAC group Mean operation time was 56.8 ± 22.8 min, and mean estimated blood loss was 21.4 ± 23.6 mL. Only one case of urinary retention was classified as a grade I postoperative complication, according to the Clavien–Dindo classification. No severe complications or sequelae were observed during the perioperative period. Obstetric outcomes from 98 patients were collected: three patients had miscarriages, and 95 had live births. Of the 95 live births, 4 were twins and 91 were singletons. Two patients had vaginal delivery, and 93 underwent Cesarean section; mean neonatal weight was 3310.2 ± 382.1 g.

Conclusion A simplified pre-conceptional LAC is a simple, safe, and effective method for women with cervical insufficiency. Thus, it is worthy of promotion to assist women with cervical insufficiency in achieving improved obstetric outcomes. Vaginal delivery after LAC is possible once the tape is removed before labor.

Keywords Pre-conceptional, Cervical insufficiency, Cervical cerclage, Laparoscopy

*Correspondence:
Hong Liao
liaohong520@outlook.com
[1]Obstetrics and Gynecology Department, West China Second University Hospital, Sichuan University, NO.20 Section 3, 17 Renmin South Road, Wuhou District, Chengdu, Sichuan Province 610041, China
[2]Key Laboratory of Birth Defects and Related Diseases of Women and Children, Sichuan University, Ministry of Education, Chengdu, Sichuan Province 610041, China

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Introduction

Cervical insufficiency is a pathological condition in obstetrics in which the cervix fails to retain the fetus before uterine contractions or labor (painless cervical dilatation) [1]. Patients usually have fetal loss in the mid-trimester or spontaneous pre-term birth due to painless cervical dilation [2]. Birth defects in the genital tract and hereditary connective tissue diseases are common congenital causes of cervical insufficiency [3]. Cervical insufficiency can also be acquired by cervical trauma, such as conization, trachelectomy, and repetitive cervical dilation [4]. So far, there is no consistent definition for cervical insufficiency; therefore, the incidence of 1% in the obstetric population could be inaccurate [5]. Clear diagnostic criteria and standard diagnostic tests for cervical insufficiency are lacking. It should be considered based on a history of painless cervical dilation in the second trimester or ultrasound evidence of cervical length < 25 mm before 24 weeks, or in patients with previous pre-term birth before 36 weeks of gestation [5, 6]. The diagnosis of cervical insufficiency in non-pregnant women is more challenging, and Hegar dilators are used to evaluate the patulous cervix, or a balloon elastance test is used to calculate the cervical resistance index [7, 8]. In China, the insertion of size 8 Hegar dilators through a non-pregnant cervix without resistance is widely accepted as an indication for cervical insufficiency [9].

Transvaginal and transabdominal cervical cerclage are the two main surgical approaches used to treat cervical insufficiency. Transvaginal cervical cerclage (TVC) involves inserting sutures around the cervical neck to prevent cervical dilation of cervix [10, 11]. However, the risks of traumatic rupture of membranes, vaginal bleeding, chorioamnionitis, and cervical lacerations increase after TVC [12]. An increase in vaginal discharge is also commonly observed. Abdominal cerclage involves placing a suture at the uterine isthmus to hold the uterine contents, and was first described in 1965 [13]. With the advantage of being minimally invasive, laparoscopic abdominal cerclage (LAC) is widely accepted as a safe method between 12 and 14 weeks gestation for preventing further fetal losses [14, 15]. For non-pregnant women with cervical insufficiency, prophylactic LAC has been reported to improve pregnancy outcomes, such as live birth, neonatal survival, and full-term delivery rate [16–18]. The traditional LAC procedure that includes dissection of the anterior leaves of the broad ligament to create an avascular space for needle placement, which is time-consuming and possibly increases the risk of postoperative adhesions.

Herein, we reported a simplified LAC in 108 non-pregnant women with previous fetal losses due to cervical insufficiency in this retrospective study. We described the perioperative data and followed-up the obstetric outcomes in this group.

Materials and methods

Participants

This retrospective observational study was conducted between January 2015 and December 2022 at West China Second University Hospital, Sichuan University. A total of 108 eligible women diagnosed with cervical insufficiency were included in this study.

This study was reviewed and approved by the ethics committee and the data inspectorate of West China Second University Hospital of Sichuan University and the methods were carried out in accordance with the relevant guidelines and regulations. Written informed consent was obtained from each participant after extensive evaluation prior to surgery. All women were informed of the possible need for elective cesarean section or transabdominal suture removal before vaginal delivery.

Inclusion criteria

All the participants were included by strictly following the inclusion criteria: 1) ≥ 2 mid-trimester pregnancy losses; 2) painless cervical dilation before miscarriage; 3) insertion of size 8 Hegar dilators through the cervix without resistance in non-pregnant status in a non-menstrual period; and 4) willingness to undergo prophylactic LAC after being informed of treatment options, such as TVC, LAC, and other non-surgical treatments. Endocervical swabs were sent for preoperative chlamydia and mycoplasma examinations to exclude cervical infections.

Exclusion criteria

Participants were excluded if they met the following criteria: (1) diagnosed diseases that were not suitable for reproduction; (2) genital malformation (uterus didelphys); (3) high suspicion of extensive pelvic adhesions by examination: (4) malignant diseases without treatment; and (5) diagnosed with diseases that were not suitable for laparoscopy.

Surgical procedures

Laparoscopic abdominal cerclage is usually performed during a non-menstrual period. The patients were administered general anesthesia and placed in the French position with both legs split. Instead of a traditional uterine manipulator, a uterine probe with a diameter of 5 mm was inserted into the uterine cavity to avoid cervical dilation and endometrial injury.

Three trocars were used during the entire procedure: a 10 mm optical trocar was placed in the navel, and a 30° scope was used; two 5-mm trocars were placed under direct visual control laterally in each lower quadrant. A 5 mm non-absorbable polyester tape with double-armed

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48 mm needles (RS-22; MERSILENE, Ethicon, Inc., Somerville, NJ, USA) was used. One needle was removed, and the remaining needle was straightened before use. The uterovesicle peritoneal reflection was used as an anatomical marker to identify the uterine isthmus. It was not necessary to open the vesicocervical space for the bladder flap or separate the anterior broad ligament leaves to identify the uterine arteries. First, the uterus was maintained in its natural position. The straight needle penetrated directly into the right parametrial tissue at the isthmus level. To avoid injury to the ascending branch of the uterine artery, the penetration point should be 2–3 mm away from the isthmus. The uterus was gently manipulated in an acutely ante-verted position, and the needle was pulled out from the other side until part of the MERSILENE tape passed. The needle penetrates in opposite directions at the symmetry point of the left parametrial tissue. The natural position of the uterus was restored, and the needle was pulled out until the MERSILENE tape passed the second penetration point. The tape was flattened and tightened around the isthmus using two forceps. After removing the needle, the MERSILENE tape was tied anteriorly at the isthmic surface with five throws of intracorporeal square knots. The tape was trimmed such that each end was approximately 3 cm in length. The steps of the simplified laparoscopic cervical cerclage were shown in Fig. 1.

Postoperative care

The patients were encouraged to get off the bed to regain activity 2 h postoperatively, and they were discharged on the second postoperative day. The patients were followed-up for one week after discharge by telephone regarding their physical status.

Data collection

Patients characteristics (age, body mass index [BMI] reproductive history, previous cervical and uterine surgeries or injuries, and comorbidities) were carefully recorded. Perioperative parameters (additional procedures, operation duration, estimated total blood loss, and complications) were also recorded. Outpatient visits were arranged one month postoperatively, and conception was encouraged at one menstrual cycle later if there were no positive findings at the last visit. Obstetric outcomes (conception time, delivery mode, gestation weeks, and infant's health status) were collected via telephone.

Results

Study population

In total, 108 patients diagnosed with cervical insufficiency underwent prophylactic LAC during the study period. Most of the patients (105/108) had second trimester fetal loss, and the other three had early third trimester fetal loss. The mean age of these group was 31.1±3.9 years (range, 23–42 years), with a mean BMI of 23.7±3.2 kg/m2 (range, 17.9–33.3 kg/m2). Twenty-three of the patients had given birth previously, but the remaining 85 were nulliparous. Among the 108 patients, 39 of them had one pregnancy loss, 42 patients had two pregnancy loss, 20 patients had three pregnancy loss and the last 7 patients had four and above pregnancy loss. Previous cervical or uterine procedures were recorded, including conization, loop electrosurgical excision, transvaginal cerclage, hysteroscopy and artificial abortion in the first trimester. In total, 24 patients had one procedures, 23 patients had two procedures, 9 patients had three procedures and 10 patients had four and above procedures. Patient characteristics, reproductive histories and previous cervical or uterine procedures are listed in Table 1.

Perioperative outcomes

Among the 108 patients, 44 underwent only LAC, and 64 underwent additional procedures at the same time. Details of the patients' perioperative outcomes are shown in Table 2. Regarding additional procedures, enterolysis accounted for the most (41/108), followed by hysteroscopy (24/108), which was performed in patients with
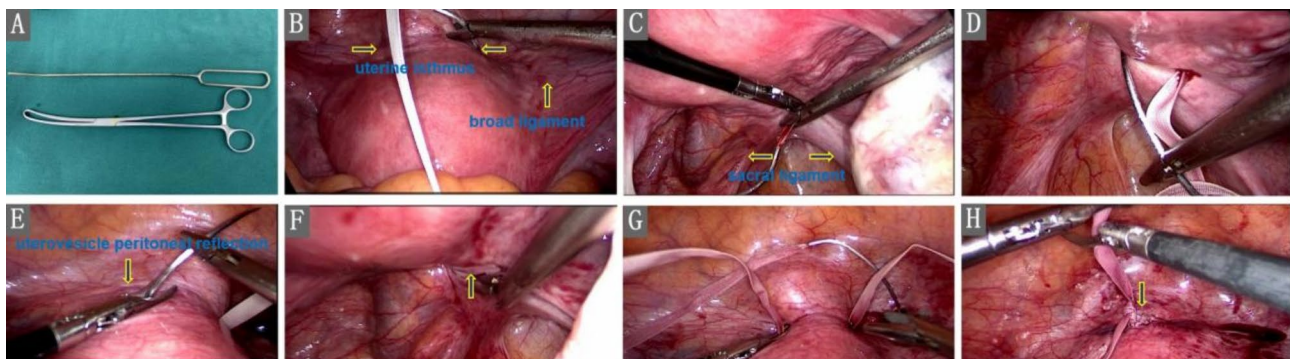
Fig. 1 Steps of the simplified pre-conceptional laparoscopic cervical cerclage. A uterine probe and a forceps were used to manipulate the uterus (**A**). The needle was penetrated into the right parametrial tissue at the isthmus level (**B**) (**C**). The needle was penetrated into the left parametrial tissue at the isthmus level (**D**) (**E**). The tape was flattened and tightened around the isthmus(**F**). The MERSILENE tape was tied anteriorly at the isthmic surface (**G**) (**H**)

Table 1 Patients' characteristics and histories of reproduction and surgeries

Patient characteristics (*n* = 108)	Values/No. of patients
Mean age (y)	31.1 ± 3.9
Body mass index (BMI)	23.7 ± 3.2
Multipara	23
Nullipara	85
Number of pregnancy loss	
One	39
Two	42
Three	20
Four and above	7
Previous cervical or uterine procedures	
One	24
Two	23
Three	9
Four and above	10

Table 2 A summary of the patients' perioperative outcomes

Procedural outcomes (*n* = 108)	Values/No. of patients
Laparoscopic abdominal cerclage only	44
Additional procedures	64
Hysteromyomectomy	14
Oophorocystectomy	10
Electrosurgery for endometriosis	7
Enterolysis	41
Hysteroscope	24
Diagnostic curettage	6
Conization	1
Fallopian tube repairment	6
Ovarian drilling	1
Hydrotubation	10
Mean operation time (min)	
All cases	56.8 ± 22.8 min
No additional procedures	45.3 ± 14.5 min
Mean estimated blood loss (mL)	
All cases	21.4 ± 23.6 mL
No additional procedures	13.9 ± 10.4 mL
Perioperative complications	1 (urinary retention)
Transfusion volume	1084.3 ± 355.8 mL
Postoperative activities of daily living	
Day 0	41.5 ± 9
Day 1	65.5 ± 11
Numerical rating scale of pain intensity	
Day 0	2.7 ± 0.5
Day 1	1.7 ± 0.8
Day 2	0.5 ± 0.7

Table 3 Obstetric outcomes of patients after pre-conceptional laparoscopic cervical cerclage

Obstetric outcomes (*n* = 98)	Values/No. of patients
Spontaneous conception	74
In vitro fertilization	24
Time of pregnancy post-operation (months)	8.9 ± 7.6
Delivery mode	
Vaginal delivery	5
Cesarean section	93
Mersilene tape reservation	64
Mersilene tape removal	29
Termination at < 26 weeks (*n* = 3)	
First-trimester loss	0
Second-trimester loss	2
Termination due to anomaly	1
Delivered at ≥ 26 weeks (*n* = 95)	95
Twins	4
Singletons	91
Preterm delivery (< 37 weeks)	10
Full-term delivery	85
Premature rupture of membranes	2
Median gestational weeks at delivery	38^{+3} weeks
Mean neonatal weight (g)	
All newborns	3310.2 ± 382.1 g
Without twins	3347.2 ± 338.9 g
Number of low birth weight (< 2500 g)	2
Requiring neonatal intensive care units	4
Neonatal death	0

and the tubes were all removed the first day after surgery, with a mean drainage volume of 34.2 ± 5.7 mL. There was one report of urinary retention, which was classified as grade I postoperative complication according to the Clavien–Dindo classification [19]. No injuries to vessels, intestines, bladders, or ureter during surgery.

The Barthel scale was used to evaluate patients' basic activities of daily living on the day before the surgery, the day of surgery, and the first day after surgery [20]. The mean score of activities of daily living was 65.5 ± 11 on the first day after surgery, suggesting patients regained their physical function on the first day after surgery. At the same time, the numerical rating scale (range, 0–10 score)was used to measure pain intensity. Patients felt mild pain on the surgery day and first day after the surgery, and nearly no pain on the second day after the surgery. The mean score of activities of daily living and mean score of pain intensity in dfferent time point were all listed in Table 2.

Postoperative obstetric outcomes

At the time of data collection, 98 patients became pregnant after the surgery. The postoperative obstetric outcomes including conception modes, delivery modes and the time of termination were fully list in Table 3. There were two cases of second trimester loss and one case of

irregular vaginal bleeding or suspicious endometrial polyps. The patients' perioperative outcomes including mean operation time, mean estimated blood loss, mean intraoperative transfusion volume for patients with or without additional procedures were listed in Table 2. Most of the patients were placed on a pelvic drainage tube for better observation of abdominal hemorrhage postoperatively,

termination due to fetal anomalies. The two second-trimester losses resulted in uncontrolled uterine contractions during mid-trimester. They underwent another laparoscopy to remove the cervical tape, and finally, they underwent vaginal abortion at 20 and 23 gestational weeks separately. One fetus was diagnosed with tetralogy of Fallot at 24 weeks of gestation. The women also chose to remove the cervical tape under laparoscopy, followed by vaginal abortion after fatally induced labor. There were 95 live births, of which there were 4 twins and 91 singletons. Of the 95 live births, 94 were delivered by Cesarean section. Sixty-four (64/98) women chose to keep the Mersilene tape for future pregnancy during Cesarean section, and 29 women had the tape removed during surgery. Notably, two women underwent open surgery to remove the Mersilene tape at 37 gestational weeks, and then completed vaginal delivery at 38+5 and 37+6 gestational weeks.

Mean neonatal weight was 3310.2±382.1 g, and only two neonates from different twins weighted<2500 g. Four infants who were deliveried less than 34 gestational weeks were sent to neonatal intensive care units, and no neonatal deaths were reported.

Discussion

According to a large prospective register-based study, the incidence of miscarriage was estimated to be 21.1% before 20 weeks of gestation, whereas the incidence of stillbirth was estimated to be 17.5% [21]. The definition of pre-term birth has shifted from the gestational age at birth to a more complex functional taxonomy according to the known etiologic factors, which is crucial for interventions, prevention, and overall clinical management to be effective [22]. The cervical insufficiency is one of those etiologic factors which would cause mid-trimester miscarriages. However, a history of miscarriage or pre-term delivery increases the risk of cervical insufficiency, which, in turn, increases the risk of miscarriage [23]. To break the vicious circle, prevention of cervical insufficiency could be a breakthrough to break this vicious circle. Cervical insufficiency can be congenital or acquired, and the prevention strategy should concentrate on acquired cervical insufficiency.

Damage to the structural integrity due to trauma or surgery may be responsible for cervical insufficiency. Conization increases the risk of mid-trimester fetal loss due to impairment of the intact cervix, specifically when cone heights are more than 2 cm [24–26]. A history of abortion and specifically induced abortions were also associated with cervical insufficiency [27]. A history of a spontaneous or induced abortion increases the risk for cervical insufficiency by up to 2.71 times at the next pregnancy. Moreover, operative hysteroscopy may be a risk factor for cervical insufficiency development. In a small retrospective study, the incidence of cervical insufficiency was significantly higher (13.7%) in a group that underwent operative hysteroscopy, while it was 3.4% in a control group (13.7% vs. 3.4%) [28]. These procedures destroy the intact cervix or over-dilate the cervix, thereby impairing the mechanical support of cervix during pregnancy. In our study, 24.1% (26/108) of the patients underwent cervical surgery, and more than half of the patients (53.7%, 58/108) underwent uterine surgery. Recurrent dilation and extension of the cervix are non-negligible factors in cervical tissue injury.

Some studies have supported the idea that cervical insufficiency is a subtle form of collagenopathy. From the analysis of next-generation sequencing results in 21 patients, Volozonoka et al. identified several genes (*COL1A1*, *COL3A1*, *FBN1*, *HIF1A*, *LMNA*, and *MATR3*) whose products participate in collagen biosynthesis and cell-extracellular matrix communication are also associated with cervical insufficiency [23]. In a comparison of cervical collagen between non-pregnant women with congenital cervical insufficiency and normal parous women, the median cervical hydroxyproline concentration was significantly lower in patients with cervical insufficiency [29]. Notably, pregnancy or parturition could lead to a decrease in cervical hydroxyproline concentration, which is in accordance with the finding that the number of miscarriages or deliveries increases the risk of cervical insufficiency [21]. Changes in cervical collagen concentration also alter the contractility of cervical smooth muscle. Decreased rigidity of the cervical extracellular matrix leads to a compromise in cervical smooth muscle cell contractile tone and a predisposition to sphincter laxity, which contributes to premature cervical failure [30].

Cervical cerclage is an option for preventing fetal loss caused by cervical insufficiency. However, the diagnosis of cervical insufficiency should be made prudently when miscarriage or pre-term birth occurred, because the cervical cerclage may only benefit those patients with real cervical insufficiency. Cervical cerclage is usually performed via the transvaginal route during pregnancy. It is indicated for pregnancy at high risk of pre-term births, mid-trimester fetal losses, or transvaginal ultrasound cervical length of <25 mm before 24 weeks [9, 31]. The suture should be placed as high as possible, close to the internal os, hopefully attaining a cerclage height>2 cm [32]. Thus, the cervical length should not be short enough to allow sufficient room for suturing. Generally, TVC is regarded as a safe method, but there is still a risk of perioperative complications, such as hemorrhage, cervical lacerations, lesions or trauma of the cervix, pyrexia, severe maternal infections (amnionitis or chorioamnionitis), or direct pre-term premature rupture of membranes [33–36]. Combining data from 44 studies, Van Dijk et al.

reported that most perioperative complications of TVC were hemorrhage (0.9–2.3%) and pre-term premature rupture of membranes (0.0–2.5%) [36]. Notably, the incidence of complications varied between prophylactic and emergency TVC. Complications were lowest in a prophylactic TVC group, which was performed in the first trimester for women who have had ≥3 pre-term deliveries and/or mid-trimester losses.

Transabdominal cerclage is another option, especially for women in whom cerclage has failed (delivery before 28 weeks after a history- or ultrasound-indicated [but not rescue] cerclage) [37]. Transabdominal cerclage can be performed during laparotomy or laparoscopy, either preconceptually or after conception [38]. Laparoscopy has been proven to be safe for both mother and fetus, with no increase in adverse obstetric outcomes [39]. Owing to the inherent advantages of laparoscopy over laparotomy, LAC is more recommended [38]. Several retrospective studies reported that pre-gestational LAC was more effective in reducing spontaneous pre-term birth at ˂34 weeks than mid-term TVC [17, 40]. In a multicenter randomized controlled trial aimed at women with previous failed cerclage, a LAC group had significantly fewer fetal losses than a TVC group (3% [1/39] vs. 21% [7/33]) [41].

Another advantage of preconceptual LAC, which could be underestimated, is the reduced anxiety caused by surgery. Anxiety and stress are common during pregnancy. However, obstetric complications and unplanned surgeries can significantly increase maternal state anxiety [42, 43]. Maternal state anxiety is associated with adverse pregnancy outcomes, such as miscarriage, pre-eclampsia, pre-term delivery, and low birth weight, with particularly strong evidence for an increased risk of pre-term birth and low birth weight [44, 45]. Thus, prophylactic preconceptual LAC instead of TVC during pregnancy could be a more appropriate candidate for relieving maternal state anxiety in women with cervical insufficiency.

In terms of prophylactic pre-conceptual LAC, conventional LAC involves opening the vesicular space and separating the anterior broad ligament leaves. These procedures help identify the uterine artery and prevent injury. However, these would also prolong surgery time, extend the surgical area, and increase tissue injury, leading to postoperative pelvic and abdominal adhesion [46]. Serious postoperative adhesions may cause small bowel obstruction and increase the risk of hemorrhage, perforation, reduced surgical exposure, and prolonged operation time in repeat surgeries [47]. In our surgical procedure, these two steps were omitted, and no perioperative complications were reported. The main concern with our simplified LAC was injury to the bladder and uterine vessels. From our eight years of experience, the key point of the procedure was to recognize the uterovesicle peritoneal reflection, which could be an anatomical marker

for identifying the uterine isthmus. The second key point was to keep the needle vertically penetrating the parametrial tissue in close proximity to the isthmus, which could evade the uterine vessels. From a report about the conventional LAC, mean operation time for single LAC was 51 ± 27 min, and mean estimated blood loss was 18 ± 12 mL [14]. While for our simplified LAC, the mean operation time was 45.3 ± 14.5 min, and mean estimated blood loss was 13.9 ± 10.4 mL. There was another report about the experience of simplified LAC, mean operation time $(26\pm4.7$ min), and mean estimated blood loss (11.9 mL) [18]. These data support the idea that simplified LAC is safe, with less operation time and blood loss.

Another advantage of our simplified LAC is that we avoided the use of a conventional uterine manipulator to position the uterus. Complications of uterine manipulation include uterine perforation, cervical laceration, and cervical bleeding [48, 49]. Additionally, the use of a vaginal cup overdraws the cervical tissue. As discussed previously, cervical injury and dilation increase the risk of cervical insufficiency. Thus, we chose to use a uterine probe together with a cervical tenaculum rather than a uterine manipulator or vaginal cup to minimize cervical injury. The uterine probe is much smaller than the rod of the uterine manipulator, and there are no concerns regarding the longitudinal tension of the cervix caused by lifting the vaginal cup. We also performed LAC in pregnant women (data not shown), and no probe or cervical tenaculum was used. We had another Forceps inserted through an additional 5 mm port in the left lower abdomen to manipulate the uterus. During the procedure, the tape was tied either anteriorly or posteriorly to the isthmus. In our patient, the knots were tied anteriorly to the isthmic surface. For patients undergoing vaginal delivery, the knots can be easily removed with a 5 cm long open cut superior to the pubis symphysis under local anesthesia. Each patient was informed that they still had a chance to undergo vaginal delivery once the tape had been removed before surgery. However, two patients chose to undergo vaginal delivery after tape removal at 37 gestational weeks. One baby was delivered at 38^{+5} gestational weeks, with a total labor duration of 8 h and 40 min. The other one was delivered at 37^{+6} gestational weeks with a total labor duration of 6 h and 20 min. The remaining patients underwent cesarean delivery; 64 of them chose to keep the tape for future pregnancy, and the others chose to remove the tape.

In conclusion, we reported a series of patients who were diagnosed with cervical insufficiency and underwent pre-conceptual LAC. We demonstrated that preconceptual LAC is an effective option for preventing mid-terminal fetal loss in women with cervical insufficiency. Notably, the simplified LAC is a simple, safe, and effective method that is worthy of promotion. Finally,

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vaginal delivery after LAC is still possible once the tape is removed before labor. However, the limitations of this report mainly came from two aspects: one was the small cohort of patients, and the second was the experience drawn from a single center, which could be the cause for the deviation in the final conclusions. We hope that more centers will opt for a simplified pre-conceptual LAC to help more women with cervical insufficiency.

Abbreviations
LAC   Laparoscopic abdominal cerclage
TVC   Transvaginal cervical cerclage
BMI   Body mass index

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 reviewed and approved by the ethics committee and the data inspectorate of West China Second University Hospital of Sichuan University. All experimental protocols were approved by the ethics committee and the data inspectorate of West China Second University Hospital of Sichuan University. Informed consent was obtained from all subjects and/or their legal guardian(s). All methods were carried out in accordance with the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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