

Cervical length after cerclage: comparison between laparoscopic and vaginal approach

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Abstract

Purpose The aim of our study was to investigate the sonographic changes of the cervical length during pregnancy after the placement of a transvaginal cervical cerclage (TVC) or a laparoscopic abdominal cerclage (LAC) in patients with cervical insufficiency (CI).

Methods Between January 2008 and March 2015, a retrospective analysis of all women undergoing a prophylactic laparoscopic (LAC group) or transvaginal (TVC group) cerclage due to cervical insufficiency was conducted. Non-parametric variables were analysed with the Mann–Whitney (*U*) test, and categorical-type outcomes were analysed with the Fisher's exact test. A *p* value <0.05 was considered as significant. Data analysis was performed using Prism 5 for Mac OS X.

Results Thirty-eight patients were included. Of these, 18 and 20 underwent an LAC and a TVC, respectively. Mean gestational age at surgery in the LAC and TVC groups was 11.4 ± 1.6 and 17 ± 3 weeks, respectively ($p < 0.05$). The cervical length prior to surgery was similar among the two groups. After cerclage placement, the distance between the tape and the external cervical os differed

significantly between the two groups (LAC: 31.5 ± 8.8 mm vs TVC: 13.5 ± 4.9 mm; $p < 0.0001$) (Fig. 1). During pregnancy, the cervical length in the TVC group showed a significant shortening (from 26.6 ± 7 mm before surgery to 13.2 ± 7 mm at 33 weeks; $p < 0.0001$), while in the LAC group, the cervical length remained unchanged.

Conclusions In patients with CI, LAC is associated with a better preservation of the cervical length throughout pregnancy as compared to TVC.

Keywords Cervical insufficiency · Laparoscopic abdominal cerclage · Transvaginal cerclage · Prophylactic cerclage

Introduction

Preterm birth is a major cause of neonatal morbidity and mortality in industrialized countries. Preterm birth has multiple risk factors, including cervical insufficiency (CI). Its incidence varies between 0.05 and 2% and is classically defined as a painless cervical dilatation leading to recurrent second-trimester pregnancy losses and/or preterm birth under the 34th week of gestational age in the absence of other causes [1]. This is mainly related to a structural weakness of the cervix that can be congenital and/or acquired as a consequence of a cervical trauma or surgery causing a permanent inability to retain a pregnancy [2].

The diagnosis of CI is not simple and is traditionally based on medical history. In the last decade, different definitions have been suggested to diagnose a primary CI. Some authors proposed the combination of one or more pregnancy losses or preterm births with a cervical shortening of less than 25 mm at transvaginal ultrasound (TVS) prior to 24 weeks of gestation [3–5]. Independently of the

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definition used, the traditional surgical treatment for a CI is the vaginal placement of a cervical cerclage (TVC) [1]. In selected cases, where the vaginal approach has failed, a laparoscopic abdominal cerclage (LAC) can be considered [6]. Several studies have confirmed the high rate of successful pregnancies, the reliability, and the low risk of perioperative complications of the laparoscopic approach [7–9].

So far, the sonographic changes of the cervical length during pregnancy after the placement of a TVC or a laparoscopic abdominal cerclage LAC in patients with CI have not been investigated yet. The aim of our study was to investigate the cervical competence during pregnancy after prophylactic cerclage performed either transvaginally or laparoscopically in patients with classical CI.

Materials and methods

Between January 2008 and March 2015, a retrospective study, including all women who had a prophylactic LAC (LAC group) or TVC (TVC group) placement, was conducted. Ethical approval for the current study was obtained by the local institutional review board (Ethics Committee of the Canton of Bern, Switzerland).

Inclusion/exclusion criteria

Patients with a singleton pregnancy who had a prophylactic TVC with a McDonald suture due to a classical CI (TVC group) were included. Patients undergoing LAC during the first trimester of pregnancy or prior to pregnancy were included as well. Indication to LAC (LAC group) was a history of failed TVC. All patients had a history of more than two second-trimester pregnancy losses or preterm births prior the 34th week of gestation. Exclusion criteria were past pregnancy losses or preterm births due to an infection and multiple twin gestations.

Data collection

Data were collected from the patients' medical records and reviewed for patients' history, indication to cerclage, type of cerclage, intraoperative complications, sonographic cervical assessment, and delivery outcome. Cervical length was assessed sonographically until delivery in both groups of patients.

Surgical techniques

TVC was placed in our hospital by experienced obstetricians, and the LAC was performed from a single gynecologist with an expertise in minimal invasive surgery. A

tocolytic treatment with indomethacin for 48 h after having performed the cerclage was performed.

TVC with a McDonald suture

The McDonald cerclage sutures were placed using a 5-mm Mersilene suture circumferentially around the cervix counterclockwise from 11 o'clock. The knot was tied at 12 o'clock.

LAC

A pneumoperitoneum was performed using the Verres technique. A 10-mm optic trocar was placed in the navel. Two ancillary 5-mm trocars were placed in each lower quadrant laterally and one 12-mm trocar suprapubically in the midline. The procedure started with the opening of the bladder peritoneum with a bipolar hook and the mobilization of the bladder to identify the vesico-cervical space. After identifying the uterine artery on both sides, a 5-mm Mersilene tape (Ethicon, Somerville, NJ) was introduced bluntly through the left broad ligament in the avascular space medially from the uterine artery. Then, a tunnel was made bluntly through the right broad ligament and the Mersilene tape was retracted backwards. The tape was knotted intra-corporally five times on the anterior cervico-isthmic segment. Then, the peritoneum was sutured to cover the knot.

Sonographic measurement of the cervix

A TVS was performed before and after the cerclage placement. Either a Voluson 730 (GE Ultrasound, Gattbrugg, Schweiz), a GE E8 (GE Ultrasound, Gattbrugg, Schweiz), or Acuson Sequoia (Siemens AG, Erlangen, Schweiz) ultrasound equipped with a 4–9 MHz endovaginal probe with color, and pulsed Doppler capabilities were used for each measurement.

The cervical length was measured with an empty bladder with the patient placed in dorsal lithotomy position. The vaginal probe was placed in the anterior fornix without pressure. The junction between the amniotic membrane and the cervical canal was considered as the internal os of the cervix. The lower end of the cervix was considered as the external os of the cervix. The cervical length was defined as the distance between the internal and the external os along the endocervical canal. If the cervical canal was curved, the cervical length was measured as a straight line between internal and external os. Prior to surgery, the entire cervical length was measured. After surgery, the cervical length was assessed from the internal to the external os of the cervix and from the tape to the external cervical os.

Statistical analysis: nonparametric variables were analysed with the Mann–Whitney (*U*) test. For categorical-type outcomes, the Fisher's exact test was used. A *p* value <0.05 was considered as significant. Data analysis was performed using Prism 5 for Mac OS X.

Results

A total of 38 cases were included. Mean gestational age at the time of cerclage placement in the LAC group and TVC group was 11.4 ± 1.6 and 17 ± 3 weeks, respectively. Of these patients, 18 (47.4%) underwent an LAC and 20 (52.6%) underwent a TVC. The clinical characteristics of the study population are summarized in Table 1. Surgical data are reported in Table 2. In the LAC group, six patients underwent the procedure prior to pregnancy. In the remaining cases, the procedure was performed during the first trimester of pregnancy. The mean time

interval between the LAC placement and the pregnancy in the patients being operated on prior to pregnancy was 2 ± 0.5 months. Prior to cerclage placement, cervical length was similar between the two groups (LAC group: 28.6 ± 11 mm; TVC group: 26.6 ± 7 mm; *p* = NS). After cerclage placement, the distance between the tape and the external cervical os was significantly shorter in the TVC group (LAC group: 31.5 ± 8.8 mm vs TVC group: 13.5 ± 4.9 mm; *p* < 0.0001) (Fig. 1). During pregnancy, the cervical length decreased significantly after cerclage placement in the TVC group (26.6 ± 7 mm before surgery; 13.2 ± 7 mm at delivery; *p* < 0.0001) but not in the LAC group (Figs. 2, 3). In each group, the cervix length shortened until the internal uterine os reached the tape, while the length from the tape to the external cervical os remained unchanged in both groups (Fig. 3). Seventeen out of 18 patients who underwent an LAC had an uncomplicated pregnancy course and delivered via caesarean section at 37.6 ± 2 weeks of gestation, with a

Table 1 Clinical characteristics of the study population

Characteristics	LAC group (no = 18)	TVC group (no = 20)	<i>p</i> values
Maternal age, years (median)	33	34	NS
Gravidity (median)	4	3	NS
Nullipara, no (%)	9 (50%)	5 (25%)	0.008
Patients with previous term pregnancy, no (%)	4 (22%)	10 (50%)	NS
Adverse obstetric history, no			
Early miscarriage	17	12	0.02
Late miscarriage	30	23	NS
Previous failed TV	6	5	NS
Previous cervical surgery (cone, LEEP)	2	3	NS
Ectopic pregnancies	2	0	NS
Preterm delivery	2	11	0.006
Cervical length before surgery, mm (mean \pm SD)	28.6 ± 11	26.6 ± 7	NS
Gestational age at intervention, weeks (mean \pm SD)	$11.4 \pm 1.6^*$	17.5 ± 3.2	0.005

LAC laparoscopic abdominal cerclage, TVC Trans vaginal cerclage, LEEP loop electrical excision procedure, BMI body mass index, SD standard deviation, NS not significant, no number

* The Gestational Age is referred to the 12/18 women who were pregnant at the time of cerclage

Table 2 Surgical data

	LAC group	TVC group
Antibiotic prophylaxis	Amoxicillin/clavulanate	Amoxicillin/clavulanate
Type of anesthesia	General	Neuraxial
Operative time (mean \pm SD)	55 ± 10	19 ± 6
Urinary catheter	Yes	No
Length of hospital stay	2.6 ± 0.9	2.9 ± 1.8
Surgical complications	0	0
Tocolytic agents	Indomethacin	Indomethacin

LAC laparoscopic abdominal cerclage, TVC transvaginal cerclage

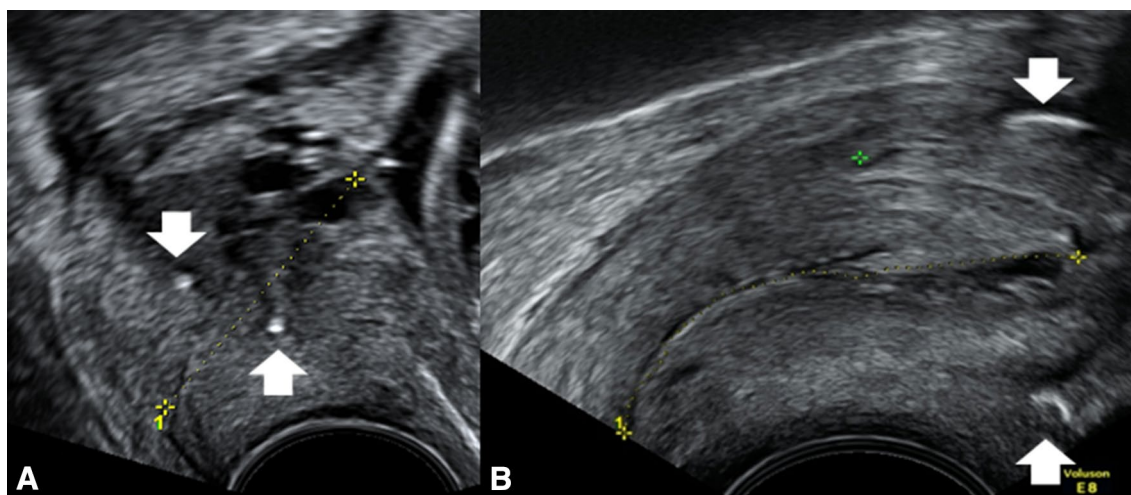


Fig. 1 Sonographic assessment of cervical length after vaginal (a) and laparoscopic cerclage (b). The cerclage tapes are marked with white arrows. In a, the yellow line represents the cervical length, while in b, it shows the cervical canal

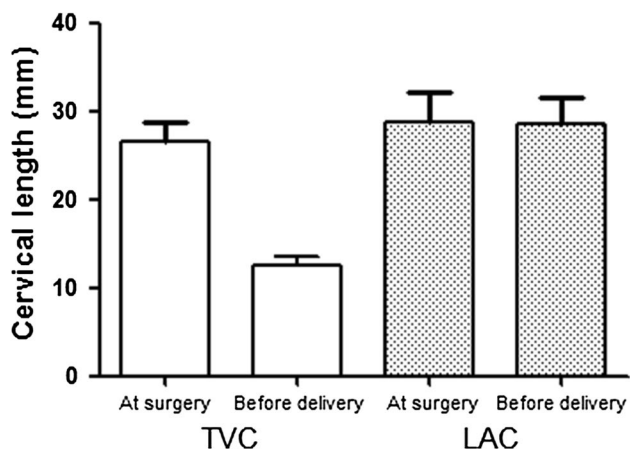


Fig. 2 Sonographic behaviour of cervical length after laparoscopic, vaginal cerclage. TVC transvaginal cerclage; LAC laparoscopic abdominal cerclage

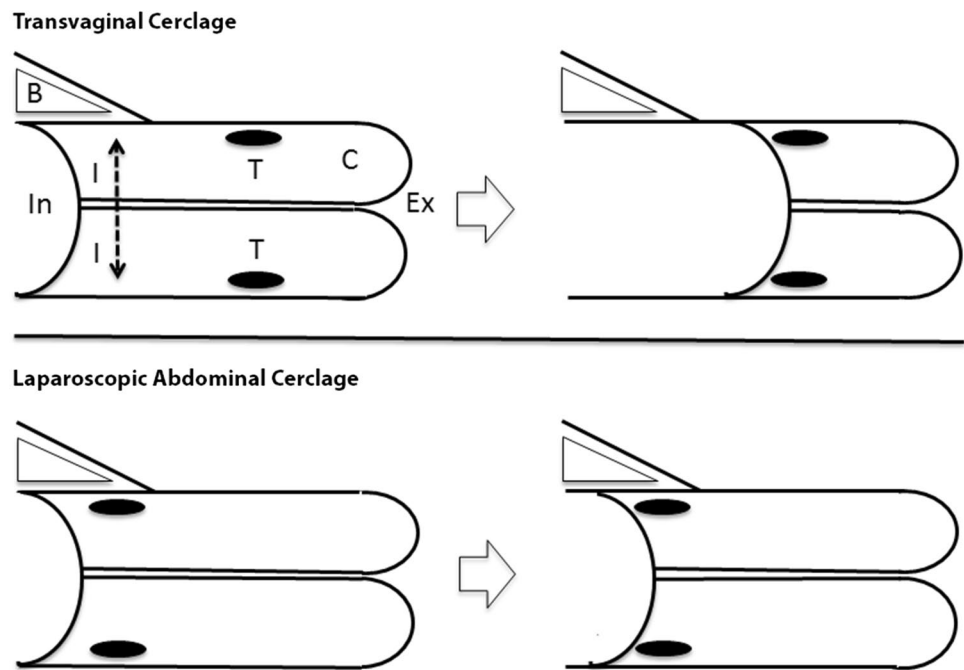
good neonatal outcome. In one case, an additional TVC was performed because of bulging of the membranes through the cervical canal after the LAC placement, probably due to an insufficient tightening of the tape. Unfortunately, this pregnancy ended in a miscarriage at 12 weeks of gestation. Eighteen out of 20 patients who underwent a TVC had an uncomplicated pregnancy course and delivered spontaneously (56%) or by a caesarean section (44%) at 37.2 ± 4 weeks of gestation with good neonatal outcomes. In two cases, a preterm delivery occurred due to an insufficient tightening of the tape. In both cases, the neonatal outcome was good.

Discussion

Based on the results of the previous studies and meta-analysis showing that the placement of a cervical cerclage may be effective in reducing preterm birth in selected patients [10], our results focus on which surgical approach is more effective in maintaining the cervical length. We focused on the sonographic changes of the cervical length in relation to technique used and not on the pregnancy outcome. We were able to show that the position of the tape within the cervix can play an important role in the cervical competence during pregnancy (Fig. 3). Between the two groups, a significant difference in cervical length at 33 weeks was found. In the LAC group, in which the cerclage was positioned in the cervico-isthmic area and, therefore, in a more proximal position as compared to the TVC group (Fig. 1), the cervical length did not change throughout the pregnancy (Figs. 2, 3). On the contrary, in the TVC group, in which the tape was placed more distal as compared to the LAC group, we observed a significant shortening of the cervical length during pregnancy.

The pathophysiological process of CI is still poorly understood. Various theories have been postulated to explain a primary CI, including surgical traumas to the cervix, altered biomechanical properties, and in utero exposure to diethylstilboestrol [1]. New strategies to assess the pathophysiology underlying CI have been developed and are giving promising preliminary results [2, 11, 12]. A multicentre study to evaluate the usefulness of a novel method based on a cervical aspiration technique in pregnant women to predict preterm delivery is ongoing [13]. However, independently of the postulated etiology, the key component of CI is a structural cervical weakness. In our

Fig. 3 Graphical representation of cervical length after vaginal, laparoscopic cerclage insertion and before delivery. *B* bladder, *In* internal cervical ostium, *Ex* external cervical ostium, *T* tape, *C* cervix, *I* cervico-isthmic area



study, a sonographic shortening of the cervix between the internal cervical os and the tape occurred both in patients who underwent LAC as in patients who underwent TVC. This shortening was more pronounced in the patients who underwent a TVC, in whom the tape is placed more caudal as compared to the patients who underwent an LAC. Moreover, no difference was found within the two groups in cervical length when this was measured from the tape to the external cervical os. These findings are of particular interest, because they underline how the position of the tape plays an important role in supporting the pregnancy and at the same time shows how the cervico-isthmic area plays a role in maintaining the cervical length.

A randomized study has demonstrated that the cerclage placement in patients with a CI is an effective intervention as compared to an expectant management to prevent preterm delivery in appropriately selected cases [10].

In our study population, two preterm deliveries (with good neonatal outcomes) and one miscarriage at the 12th week of gestational age were recorded in the TVC and LAC groups, respectively. The focus of our study is the sonographic changes of cervical length after TVC vs LAC and not the reduction of preterm birth rate in pregnant women with CI. Nevertheless, the unsuccessful events recorded in our cohort of patients might arouse speculations with regard to which the most effective procedure might be. However, the small number of negative outcomes and the small size of our patient cohort do not allow a clinically meaningful comparison between the two procedures in terms of preterm delivery rates. Further prospective studies may be helpful in identifying which the most effective

strategy is in preventing preterm deliveries. Based on our results, we can only speculate that a better maintenance of the cervical length may lead to a better outcome. On the other hand, it has to be noted that patients who undergo an LAC will have to deliver via caesarean section. In an era of increased maternal morbidity and mortality in developed countries, mainly associated with increased caesarean sections [14], it is mandatory to try keep the caesarean section rate as low as possible through a rigorous obstetrical management [15].

Studies analysing the effectiveness of the use of the obstetrical history to indicate the placement of a cervical cerclage have shown conflicting results [16–19]. Only women with three or more spontaneous preterm births or second-trimester losses have shown to benefit from a cerclage [16]. However, the low predictive value of the obstetrical history in defining a CI (often incomplete or not available), and the understandable reluctance to wait three or more spontaneous preterm births or second-trimester losses before recommending a cerclage complicate this issue. However, the placement of a cerclage is a surgical procedure that is not free from risks and in certain cases may even lead to an increase in preterm birth rates [20]. The sonographic evaluation of the cervical length seems to be a useful tool for diagnosing a CI. A meta-analysis of five randomized trials demonstrated that in cases with obstetrical risk factors, the placement of a cervical cerclage, when based on cervical length measured ultrasonographically, decreased the rate of preterm birth (<35 weeks of gestation) by 30%, with a substantial decrease in perinatal mortality and morbidity [21]. On the other hand,

recent studies demonstrated that the majority of women in whom an ultrasound-indicated cerclage was placed did not need an intervention in the following pregnancy [22, 23]. Despite the controversies regarding the usefulness of the ultrasonographic evaluation of the cervix in diagnosing a CI, the sonographic shortening of the cervix from the internal uterine os to the tape showed in our study may be a useful method in monitoring patients after a cerclage placement, irrespective of the surgical approach. The limitation of the present study is its retrospective design and the small sample size which is related to the strict indication to a cervical cerclage placement at our institution. Nonetheless, this is the first study that analyses the sonographic changes of the cervix in patients diagnosed with CI who undergo a TVC or an LAC. Since all patients included in this study were at high risk for CI, we do not know which cervical modifications can be expected in a not so strictly defined group of women. Hypothetically, it could be postulated that, if after the placement of a cervical cerclage, a shortening of the isthmus part of the cervix does not occur, a CI can be ruled out. These observations may be of relevance in a subsequent pregnancy to select the patients that will benefit from a prophylactic cerclage. Prospective trials are needed to investigate this hypothesis on its clinical relevance.

Compliance with ethical standards

Conflict of interest This study was not founded. The authors (Daniela Bolla, Maria Luisa Gasparri, Sabrina Badir, Michael Bajka, Michael D Mueller, Andrea Papadia, and Luigi Raio) declare to have no conflict of interest. Animal were not involved in the study. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All patients signed an informed consent, prior to surgical procedures.

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