GENERAL GYNECOLOGY

Preconceptional laparoscopic abdominal cerclage: a multicenter cohort study

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OBJECTIVE: The purpose of this study was to evaluate the effectiveness of laparoscopic abdominal cerclage placement in the prevention of recurrent preterm birth.

STUDY DESIGN: We conducted a multicenter cohort study with retrospective Dutch (32 patients) and Boston (34 patients) cohorts who had undergone preconceptional laparoscopic abdominal cerclage placement. Eligible patients had at least 1 second/third trimester fetal loss or delivered at <34 weeks of gestation because of cervical insufficiency and/or a short or absent cervix. Primary outcome was delivery of an infant at ≥34 weeks of gestation with neonatal survival. Secondary outcome measures included surgical and pregnancy outcomes and patients' satisfaction (Dutch cohort).

RESULTS: Surgical outcomes of 66 patients were excellent, with 3 minor complications. After preconceptional laparoscopic abdominal cerclage, 35 pregnancies were evaluated. Twenty-five patients (71.4%) delivered at ≥34 weeks of gestation; 3 patients (8.6%) experienced a second-trimester fetal loss. The total fetal survival rate was 90.0%.

CONCLUSION: Preconceptional laparoscopic abdominal cerclage shows encouraging and favorable perinatal outcomes in patients with a poor obstetric history.

Key words: abdominal cerclage, cervical insufficiency, preconceptional laparoscopic abdominal cerclage

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Preterm birth (defined as the birth of an infant at <37 weeks of gestation) is an important determinant of perinatal morbidity and death. One predominant factor of preterm delivery is cervical insufficiency, which is estimated to complicate 0.1-1.0% of all pregnancies.[1] Cervical insufficiency is characterized by acute, painless cervical dilation in the absence of uterine activity. Without specialized treatment, cervical insufficiency has a high likelihood of reoccurrence in subsequent pregnancies. The traditional treatment for cervical insufficiency is placement of a vaginal cerclage.[2,3] In patients in whom a vaginal cerclage previously has failed or in whom a vaginal cerclage is technically not feasible because of an extremely short or absent cervix, an abdominally placed cerclage provides an alternative. The advances in minimally invasive surgery have led to the increasing use of the laparoscopic approach for abdominal cerclage placement, for which reports were first published in 1998.[4,5]

The aim of this study was to assess the effectiveness of preconceptional laparoscopic abdominal cerclage (LAC), in terms of surgical and pregnancy outcome and patient satisfaction.

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Materials and Methods

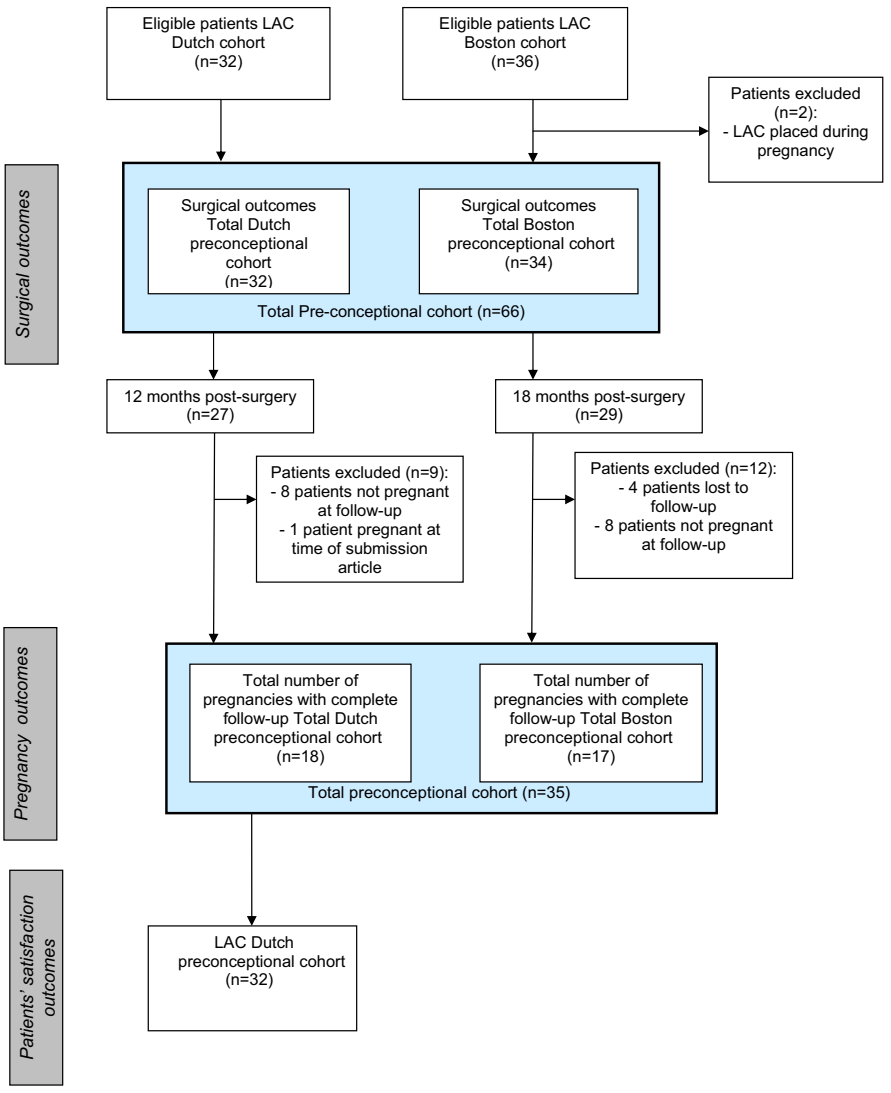
Study methods

Two separate cohort studies have been performed, both of which had a retrospective design. The Dutch cohort had consecutive inclusion of all patients who received an abdominal cerclage in the period of June 1997 to December 2011. After June 1997, all patients received LAC; before that date, laparotomy was performed. In the Boston cohort, all patients with LAC from May 2007 to December 2010 have been included. In this period, all patients in both the Dutch and the Boston cohort received a laparoscopic approach; LAC was not applied in the participating hospitals in this period. In both cohorts, patients were divided into 2 main indication groups for LAC: (1) previous failed vaginal cerclage (defined as a previous vaginal cerclage that resulted in a second- or third-trimester fetal loss, immature delivery, or premature delivery [delivery at <34 weeks of gestation]) and (2) previous cervical surgery (defined as recurrent loop electrosurgical excision procedure, (laser) conization of the cervix, or trachelectomy). A part of the latter group included patients with a previous immature or premature delivery.

Inclusion of patients and method of data collection

Eligible patients were women with a failed vaginal cerclage (defined as a previous vaginal cerclage that resulted in a second- or third-trimester fetal loss or immature or premature delivery [de-

FIGURE 1
Flowchart of included patients



LAC, laparoscopic abdominal cerclage.

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fined as delivery at <34 weeks of gestation]) and all patients in whom vaginal cerclage insertion was technically not possible because of an extremely short, scarred, or absent cervix because of recurrent loop electrosurgical excision procedure, (laser) conization of the cervix, or trachelectomy. Because some of these patients also had an immature or preterm delivery in their obstetric history, the judgment was made that the risk of an immature or premature delivery in a next pregnancy justified the placement of an abdominal cerclage (Supplementary Table provides details of obstetric history in the Appendix). All diagnoses of cervical insufficiency and the indication for placement of an LAC took place in the Dutch and the Boston clinics. All patients in whom LAC was placed during pregnancy were excluded. No patients had a previous successful vaginal cerclage (defined as delivery at ≥34 weeks of gestation). In the Dutch preconceptional cohort, all patients for whom LAC was planned were asked to participate consecutively; all of the patients agreed to participate (Figure 1). Approval was obtained from the Medical Ethical Exam Committee (trial no. 39306). Data were collected with the use of Case Report Forms and the local perinatal information network starting in September 2009. Additionally, telephone interviews were executed with all patients in the Dutch preconceptional cohort from September 2009 to December 2011, starting from at least 6 months after surgery and repeated every 6 months. These interviews included questionnaires on patient satisfaction and physical complaints after the procedure, duration of fertility wish, and pregnancy outcomes (Figure 2). In the Boston cohort, the records of all patients who had LAC inserted in a nonpregnant state in the Brigham and Women's Hospital (Boston, MA) from May 2007 to December 2010 were reviewed retrospectively after the approval of the appropriate institutional review board had been obtained.

The follow-up period of patients varied from 2-168 months in the Dutch cohort and from 12-48 months in the Boston cohort.

Surgical technique

All procedures were performed with general anesthesia as an interval procedure (ie, placed in nonpregnant patients) in the Dutch cohort (H.A.M.B. or J.A.F.H) and in the Boston cohort (J.I.E) according to a standard surgical and perioperative protocol.

Dutch preconceptional cohort

The laparoscopic instruments (one 12-mm umbilical trocar and 2 additional 5-mm trocars in the left lower quadrant and to the left of the umbilical trocar, respectively) and a small simple uterine mobilizer were inserted. The peritoneal surface of the bladder was incised to identify the appropriate position of the suture placement. The avascular space between the ascending and descending branch of the uterine artery was dissected at both sides. Precisely above the level of the sacrouterine ligaments at the cervicocorporal junction, a polyester suture (Braun cervix set, USP 6, 0.5 cm; B. Braun Melsungen AG, Melsungen, Germany) was directed through the paracercival tissue with a laparoscopic Deschamps needle. After placement, the suture was tension-free tied at the posterior site with 8 knots. Prophylactic antibiotic treatment was not applied.

Boston preconceptional cohort

Minor details differ from the Dutch technique. Instead of the use of a laparoscopic Deschamps needle, Mersilene tape (Ethicon, Somerville, NJ) with curved needles was used. The needles had to be straightened to fit through the trocar and to enable correct placement through the paracervical tissue at the cervicocorporal junction. A 5-mm wide Mersilene tape suture was placed medial to the uterine vessels. The needles were cut off and removed; 7 knots were placed anteriorly. The ends of the Mersilene tape were secured to the lower uterine segment with a 2-0 silk suture. The vesicouterine peritoneum was then closed with Monocryl suture (Ethicon) tied intracorporeally.

Participating centers

The following hospitals were included in the Dutch cohort: VU University Medical Center, Amsterdam, The Netherlands (n = 25); Haga Ziekenhuis, The Hague, The Netherlands (n = 1); Maxima Medisch Centrum, Veldhoven, The Netherlands (n = 1); University Medical Center Groningen, Groningen, The Netherlands (n = 1); Ziekenhuis Oost-Limburg, Genk, Belgium (n = 4). In the Boston cohort all patients (n = 34) were included in the Brigham and Women's Hospital, Boston, MA.

Outcome measures

The primary outcome measure was defined as delivery at ≥34 weeks of gestation with neonatal survival to hospital discharge.

Secondary outcome measures included surgical outcome parameters (eg, total operation time [defined as the total time in the operating room of LAC placement], excluding surgeries during which a laparoscopic myomectomy or cyst removal was also performed, total blood loss, hospitalization, and complications), pregnancy rate after surgery, and complications during pregnancy (eg, preterm contractions, use of tocolysis, preterm premature rupture of membranes). Deliveries at <34, <30, and <28 weeks of gestation were calculated for all pregnant patients, according to the most frequently used cutoff values in recent publications.[6]

FIGURE 2
Patient questionnaire

1) How did you experience the surgery (the placement of a tape around the cervix by laparoscopy): _____

2) Did you have any physical complaints after discharge from the hospital?
- ☐ Yes, namely _____
- ☐ No

3) Did you have a fertility wish after placement of the tape?
- ☐ Yes, _____ months after placement of the tape
- ☐ No

4) Did you get pregnant after the placement of the tape?
- ☐ Yes, _____ months after placement of the tape
- ☐ No, go to question number 6

5) First pregnancy after the surgery:
- Did you have a miscarriage?
  - ☐ Yes, at _____ weeks/months of gestational age (go to question number 5)
  - ☐ No
- Did you have an ectopic pregnancy?
  - ☐ Yes, at _____ weeks/months of gestational age (go to question number 5)
  - ☐ No
- Were you hospitalized during your pregnancy?
  - ☐ Yes, at _____ through _____ weeks of gestational age, because of _____
  - ☐ No
- Did you have any infection during your pregnancy?
  - ☐ Yes, namely _____
  - ☐ No
- Did your membranes rupture too early?
  - ☐ Yes, at _____ weeks of gestational age
  - ☐ No
- Did you take any medication during your pregnancy to suppress premature womb contractions?
  - ☐ Yes, from _____ until _____ weeks of gestational age
  - ☐ No
- Were there any problems with the tape during your pregnancy?
  - ☐ Yes, namely _____
  - ☐ No
- Was the tape removed during your pregnancy?
  - ☐ Yes, at _____ weeks
  - ☐ No
- At what gestational age was your delivery?
  - ☐ _____ weeks
- Did you have a cesarean delivery?
  - ☐ Yes
  - ☐ No, I gave birth vaginally after the tape was removed
  - ☐ No, I gave birth vaginally without removal of the tape
- Were there any problems during delivery or cesarean delivery?
  - ☐ No, go to question number 5
  - ☐ Yes, namely _____

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FIGURE 2
Patient questionnaire

- Can you describe the first 5 minutes after birth, were there any direct postpartum problems with your child?
  - ☐ No
  - ☐ Yes, namely _____
  - ☐ Don't know/remember
- Was your child admitted to the neonatal intensive care/neonatal ward after the delivery?
  - ☐ Yes, _____ weeks in total
  - ☐ No

6) Presently, what is the condition of your child?

* Healthy	Y/N
* Mentally disabled: _____	Y/N
* Physically disabled: _____	Y/N

7) Are you content about your surgery? Y/N
- if no: _____

8) Would you recommend this surgery to other patients if they were in your position?

_____

_____

9) Do you have any additional comments regarding your surgery?

_____

_____

10) Do you have any additional comments regarding this questionnaire?

_____

_____

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In the Dutch cohort, secondary outcome measures also included patient satisfaction and experiences regarding surgery and pregnancy (Figure 2).

Definitions

Early pregnancy was defined as a positive (urine or blood) pregnancy test. *Ongoing pregnancy* was defined as a vital intrauterine pregnancy at 12 weeks of gestation.[7] *Cutoff values for first-, second-, and third-trimester loss* were defined as fetal loss at ≤13 weeks of gestation, fetal loss at 14-22 weeks of gestation, and fetal loss at ≥23 weeks of gestation, respectively, because these cut-off values have been used most frequently in the recent literature.[6] *Fetal survival rate per pregnancy* was defined as the total number of live born infants who survived the neonatal period (to hospital discharge) divided by the total number of all pregnancies. *Fetal survival rate per ongoing pregnancy* was defined as the total number of live born infants who survived the neonatal period divided by the total number of all ongoing pregnancies (excluding first-trimester losses).

Statistical analysis

Results of both cohorts are presented separately and combined (total preconceptional cohort). Outcomes of both preconceptional cohorts were compared with the use of the Student *t* test for continuous data in case the parameter was distributed normally; otherwise the Mann-Whitney *U* test was applied. Categoric variables were compared with the use of the Fisher exact test. We compared the outcome between the Dutch and Boston cohort using logistic regression analysis with respect to delivery at ≥34 weeks of gestation and second-trimester fetal losses. Linear regression analysis was performed to compare the outcome of both cohorts with respect to gestational age at cesarean delivery. In these 3 regression analyses, previous failed vaginal cerclage and maternal age were included as covariables (Table 1). All tests were 2-sided; a probability value of $< .05$ was considered significant. For the analyses of pregnancy outcome, we used only the results of the first pregnancy (miscarriage or delivery) after preconceptional LAC.

RESULTS

Demographic results

Sixty-six patients had a preconceptional LAC placed (Figure 1). Patients in the Dutch cohort were significantly younger than patients in the Boston cohort (33.3 vs 36.1 years; $P < .01$). At least 60% of all patients had 1 previous second- or third-trimester pregnancy loss. In the group with indication of a previous failed vaginal cerclage, all patients had experienced a previous delivery at 14-34 weeks of gestation, despite their vaginal cerclage. More than one-half of all patients had a previously failed vaginal cerclage. Apart from age, demographic characteristics were not significantly different between the Dutch and Boston cohorts. Details are presented in Table 2.

Surgical outcomes

Surgical outcomes report on complications that occurred to 2 weeks after surgery (Table 3).[6] Mean total operation time (the total time in the operating room) in the Dutch and the Boston cohorts was 88.8 vs 96.6 min ($P = .29$), respectively. Mean blood loss in all patients was <40 mL. Severe hemorrhage (defined as blood loss of >400 mL) did not occur in any case. In 3 of 66 patients (4.5%) with a preconceptional LAC, minor perioperative complications occurred (perforation of the uterus and a pelvic infection). According to the protocol, all patients went home 1 day after the surgical procedure in the Dutch cohort and on the day of the procedure in the Boston cohort. No additional antibiotics or medication were used in the

perioperative period. LAC could be placed without major problems in all patients and without conversion to a laparotomy.

Pregnancy outcomes

With the exception of mean gestational age at cesarean delivery, pregnancy outcomes were not significantly different between the Dutch and Boston cohorts (Table 4); results have been combined in the total preconceptional cohort. A total of 56 patients (84.8%) had a complete follow-up examination after preconceptional surgery. Four patients were lost to follow up, and 36 of 52 patients (69.2%) became pregnant after LAC placement. One patient was in her second trimester of pregnancy at submission of this article and therefore could not be included in all analyses (Figure 1). Three of 35 patients (8.6%) had a second-trimester miscarriage; all 3 patients had a LAC based on a previous failed vaginal cerclage. The first patient had bulging membranes (without uterine contractions) through the cerclage on a routine checkup in the hospital at 16 weeks + 4 days of gestation and signs of intrauterine infection, given elevated C-reactive protein plasma levels. After counseling, the pregnancy was evacuated by curettage. The second patient was admitted to the hospital at 15 weeks + 6 days of gestation for abdominal pain. On ultrasound scanning, bulging membranes were visible. Despite immobilization and intravenous adminstration of antibiotics, the uterine contractions persisted, and membranes were bulging into the introitus. After counseling, she chose for termination of the pregnancy, and the fetus (consistent with 12 weeks of gestation) was evacuated by curettage. Both procedures were complicated with a total blood loss of 1000 mL. The third patient had bulging membranes at 21 weeks of gestation without uterine contractions and was admitted to the hospital. Because of progressive cervical dilation in the following 2 days of hospitalization, the fetus was evacuated by uncomplicated dilation and extraction. No third-trimester losses occurred.

Premature contractions, defined as uterine contractions at <37 weeks of gestation occurred in 5 of 35 patients (14.3%), who were treated with temporary tocolysis, although no cervical changes were observed. Two of these patients received tocolysis from 18-28 weeks of gestation. Because both patients were treated in Greece, no detailed information on the indication was available. Both patients delivered a healthy neonate by an uncomplicated cesarean delivery at 38 + 1 weeks of gestation, respectively. No detailed information of the use and duration of tocolysis was reported for the third and fourth patient. The fifth patient received 3 doses of indomethacin (50 mg) 3 times on 1 day only at 16 + 3 weeks of gestation. This treatment was given because of uterine contractions based on intestinal problems. At 35 + 6 weeks of gestation, preterm premature rupture of the outer membrane occurred without signs of chorioamniotitis. The patient underwent a cesarean delivery at 36 + 1 weeks of gestation, and a healthy infant was delivered.

A total of 35 pregnancies with complete follow-up evaluation of the pregnancy were included in our study. Twenty-five of these 35 patients (71.4%) delivered a viable infant at ≥34 weeks of gestation, and 2 patients (5.7%) delivered at <34 weeks of gestation. Twenty-seven of the 35 pregnant patients (77.1%) reached the third trimester; in all these patients, a cesarean delivery was performed with a mean gestational age of 37.2 ± 1.7 weeks. Because of differences in intuitional protocol, the mean gestational age at cesarean delivery was 2 weeks lower in the Boston cohort ($P < .001$) where no patients were allowed to proceed in gestation to >37 weeks. In 5 of 27 patients (18.5%), the cesarean delivery was complicated by hemorrhagia, placenta accreta, and uterine rupture. Uterine rupture occurred in 1 patient (5.9%) with complete dehiscence of the previous cesarean delivery scar below the level of the cerclage; the abdominal cerclage was removed. Fetal survival rate in the total preconceptional cohort was 77.1% if the first trimester losses were included and was 90.0% if only ongoing pregnancies were analyzed.

There were no differences between the Dutch and Boston cohorts in total number of deliveries at ≥34 weeks of gestation or second-trimester fetal losses that were based on our logistic regression analyses in which previous failed vaginal cerclage and maternal age where included as covariables. Linear regression analysis with the same covariables showed that gestational age at cesarean delivery in the Boston cohort was significantly lower than in the Dutch cohort (Table 1).

TABLE 1
Regression analysis

Variable	Regression coefficient (B)	SE	*P* value
Logistic regression analysis for delivery at ≥34 weeks of gestation			
Dutch-Boston cohort	1.29	0.81	.11
Dutch-Boston cohort[a]	1.16	0.83	.16
Dutch-Boston cohort[b]	0.81	0.93	.38
Logistic regression analysis for 2nd-trimester fetal loss			
Dutch-Boston cohort	0.63	1.28	.62
Dutch-Boston cohort[a]	0.98	1.30	.45
Dutch-Boston cohort[b]	–0.11	1.57	.94
Linear regression analysis for gestational age at cesarean delivery			
Dutch-Boston cohort	–2.34	0.51	< .01
Dutch-Boston cohort[a]	–2.28	0.50	< .01
Dutch-Boston cohort[b]	–2.05	0.56	< .01

[a] Covariable: previous failed vaginal cerclage; [b] Covariable: failed vaginal cerclage and maternal age.

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TABLE 2
Baseline characteristics

Variable	Preconceptional cohort							
	Dutch			Boston				
	Previous failed vaginal cerclage (n = 16)[a]	Previous cervical surgery (n = 10)[a]	Total Dutch cohort (n = 32)[b]	Previous failed vaginal cerclage (n = 23)[a]	Previous cervical surgery (n = 2)[a]	Total Boston cohort (n = 34)[c]	Total (n = 66)	*P* value[d]
Demographic data								
Study group, n	16	10	32	23	2	34	66	
Mean age ± SD, y[e]	32.7 ± 4.0	34.9 ± 2.8	33.3 ± 4.2	36.3 ± 3.3	40.5 ± NA	36.1 ± 3.8	34.8 ± 4.2	.006
Ethnicity								.13
White, %	76.9	100	84.0	65.0	100	92.0	88.1	
Non-white, %	23.1	0	16.0	35.0	0	8.0	11.9	
Body mass index, kg/m^2[f,g]	26.5 ± 8.3	26.6 ± 15.2	26.3 ± 7.0	23.7 ± 11.3	NR	23.8 ± 10.7	25.2 ± 9.3	.98
Gravidity, n[g]	3.0 ± 3.0	0.5 ± 1.3	2.0 ± 2.5	3.0 ± 2.0	NA	3.0 ± 2.0	2.0 ± 2.0	.58
Parity, n[g]	2.0 ± 2.0	0.5 ± 2.0	2.0 ± 2.0	2.0 ± 1.0	NA	1.0 ± 1.0	1.0 ± 1.0	.91
Obstetric history								
Patients with ≥1 pregnancy loss during 2nd/3rd trimester, %	66.7	50.0	64.3	69.6	50.0	60.6	62.3	.80
Patients with delivery at 14-34 weeks of gestation, %[h]	100	50.0	75.9	100	50.0	72.7	74.2	.88
1st trimester losses, n[g]	0.0 ± 1.0	0.0 ± 0.3	0.0 ± 0.8	0.0 ± 1.0	NA	0.0 ± 1.0	0.0 ± 1.0	.39
2nd and 3rd trimester losses, n[g]	2.0 ± 2.0	0.5 ± 1.3	1.0 ± 2.0	1.0 ± 2.0	NA	0.9 ± 0.9	1.0 ± 2.0	.34
Indication cerclage								
Patients with a previous failed vaginal cerclage, %[i]	100	0	50.0	100	0	67.6	61.3	.19
Patients with surgical (cervical) history, %[j]	31.3	100	46.4	30.4	100	27.3	36.1	.18

NA, not available; *NR,* not reported.

[a] Indication placement of laparoscopic abdominal cerclage; [b] Includes 6 patients with "other" indication: 4 patients with previous immature or premature delivery and/or instrumental termination of pregnancy that lead to clinical assessment of a technically unfeasible cervix to insert a vaginal cerclage and 2 patients with no reported data of indication of laparoscopic abdominal cerclage placement; [c] Includes 9 patients with "other" indication: 8 patients with previous immature or premature delivery and/or instrumental termination of pregnancy that lead to clinical assessment of a technically unfeasible cervix to insert a vaginal cerclage and 1 patient with no reported data of indication of laparoscopic abdominal cerclage placement; [d] Preconceptional total Dutch/total Boston cohort; [e] Data are given as mean ± SD; [f] Prepregnancy; [g] Data are given as median ± interquartile range; [h] Includes all 2nd- and 3rd-trimester fetal losses and all (immature and premature) deliveries at 14-34 weeks of gestation (excluding 1st trimester losses); [i] Defined as a previous 2nd or 3rd trimester fetal loss, immature or premature delivery (defined as delivery at 14-34 weeks of gestation) with a vaginal cerclage in situ; the higher percentage of failed vaginal cerclage compared with previous 2nd/3rd trimester losses in the Boston preconceptional cohort can be clarified by the fact that not all failed vaginal cerclage resulted in a pregnancy loss, but other complications, such as prematurity (defined as delivery at 34 weeks of gestation or less), instead; [j] Surgical cervical history includes recurrent loop electrosurgical excision procedure, (laser) conisation of the cervix, and trachelectomy.

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TABLE 3
Surgical outcomes

	Preconceptional cohort			
Outcome	**Total Dutch (n = 32)**	**Total Boston (n = 34)**	**TOTAL (n = 66)**	***P* value[a]**
Total operation time, min[b,c]	88.8 ± 22.7	96.6 ± 23.3	93.1 ± 23.1	.29
Blood loss during surgery, mL	26.1 ± 22.1	35.5 ± 21.8	31.6 ± 22.2	.12
Severe hemorrhage >400 mL, n[c]	0	0	0	NA
Blood transfusion required,[d] n	0	0	0	NA
Additional complications, n (%)[d,e]	2 (7.7)	1 (3.0)	3 (4.5)	.58
Median nights of admission to hospital after surgery	0	0	0	.23

NA, not available.

[a] Preconceptional total Dutch/total Boston cohort; [b] Total time in the operating room; all surgeries in which a laparoscopic myomectomy or cyst removal was performed were excluded from operation time analysis; [c] Data are given as mean ± SD; [d] During surgery or until 2 weeks after surgery; [e] Other than severe hemorrhage (>400 mL), for example, uterine perforation, pelvic infection, fever.

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Patient satisfaction

All patients in the Dutch cohort (n = 32) consented to participate and completed the questionnaire. All patients were very satisfied with the results of the surgery, regardless of their fertility or pregnancy result. No adverse effects of the surgery were reported; subjective reported recovery was fast. All patients had the wish to conceive after LAC placement; the onset of active fertility wish varied from 1-24 months after surgery. Seven of 8 nonpregnant patients (87.5%) currently are receiving fertility treatment (Table 5).

COMMENT

LAC leads to acceptable perinatal outcomes in patients with a poor obstetric history. This is a large study of LAC placement before pregnancy, with a differentiation of indication for LAC that describes follow-up evaluation of subsequent, consecutive inclusion of patients that includes patient satisfaction and experience regarding surgery and pregnancy. We also presented baseline characteristics and obstetric outcomes for the 2 main indication groups (1) previous failed vaginal cerclage (defined as a previous vaginal cerclage that resulted in a second- or third-trimester fetal loss, immature delivery, or premature delivery [defined as delivery at <34 weeks of gestation]) and (2) previous cervical surgery (defined as recurrent looped electrosurgical excision procedure, (laser) conization of the cervix, or trachelectomy). To our knowledge, no randomized controlled trial is available. The largest study to report on LAC placement describes 61 patients: 34 patients with a preconceptionally placed LAC and 31 patients with a LAC that had been inserted during pregnancy.[8]

Apart from age, which was 2.8 years higher in the Boston group compared with the Dutch population, all demographic data were not significantly different. The higher age might be an explanation for the higher number of reported first-trimester losses in the Boston cohort (23.5%) compared with the Dutch cohort (5.6%), although we cannot exclude other inherent differences in the underlying populations.

Despite the poor obstetric history of patients in the total preconceptional cohort, favorable pregnancy results are presented after interval LAC. Fetal survival rates per pregnancy were encouraging: 83.3% in the Dutch cohort and 70.6% in the Boston cohort. Fetal survival rates per ongoing pregnancies were high, from 88.2% in the Dutch cohort to 92.3% in the Boston cohort. Percentages in the previous reported systematic review are slightly higher,[6] which described 95.8% fetal survival rate per ongoing pregnancy.

Most of the patients delivered a viable infant at ≥34 weeks of gestation. In the current literature delivery at ≥34 weeks of gestation is reported in 90.9-100%[6,8-11]; however, it is likely that methodologic differences exist in these studies and that not all first-trimester miscarriages were reported similarly.

Of the 35 pregnant patients with a preconceptionally placed LAC and a complete pregnancy follow-up evaluation, 3 of the LACs that were placed may be considered as failures, given the 3 second-trimester losses that occurred. Two losses probably were due to cervical insufficiency, and one loss was due to infection possibly also related to cervical insufficiency. In the systematic review, only 1 failure was reported of the 44 cases with a preconceptional LAC[6]; however, as discussed previously, underreporting of failures in the systematic review cannot be excluded. The surgical outcomes after LAC are also encouraging. The surgical procedure is technically easy and quick to perform with minimal perioperative complications (4.5%). This is comparable with 2.3% reported perioperative complications in the recent systematic review.[6] Because this procedure has been performed since 1998, the surgical learning curve of the procedure has not yet been completed; therefore, better surgical outcomes (eg, shorter operation time) may be expected in future procedures. In this study, only total operation time could be used because skin-to-skin operation time was not reported in the Dutch cohort.

This study has several limitations. One of the limitations is the retrospective study design. Another limitation is the rather wide indication for LAC that included both patients with previous failure of a vaginal cerclage and patients in whom a high risk of a premature or immature pregnancy was expected. The latter indication is a matter of debate and it can be questioned if progesterone would have been beneficial in some of these patients. Also, patients were included in different hospitals; however, all diagnoses of cervical insufficiency and the indication for placement of an LAC took place in the Dutch and the Boston clinics. Because of the different local protocols, the risk of variation in ob-

TABLE 4
Pregnancy outcomes

Outcome	Preconceptional cohort							
	Dutch			Boston				
	Previous failed vaginal cerclage[a] (n = 12)	Previous cervical surgery[a] (n = 8)	Total[b] (n = 27)	Previous failed vaginal cerclage[a] (n = 21)	Previous cervical surgery[a] (n = 2)	Total[c] (n = 29)	Total (n = 56)	*P* value[d]
Patients lost to follow up, n	0	0	0	0	0	4	4	
Pregnant patients after interval procedure, n/N (%)[e]	12/16 (80.0)	4/8 (50.0)	19/27 (70.4)	13/21 (61.9)	2/2 (100.0)	17/25 (68.0)	36/52 (69.2)	.75
Complications during pregnancy								
Total pregnant patients, n	12[f]	4	19[f]	13	2	17	36	
Total fetal loss per trimester, n/N (%)	2/11 (18.2)	0	3/18 (16.7)	5/13 (38.5)	0	5/17 (29.4)	8/35 (22.9)	.44
1st	0	0	1/19 (5.3)[d]	4/13 (30.8)	0	4/17 (23.5)	5/36 (13.9)	.17
2nd	2/11 (18.2)	0	2/18 (11.1)	1/13 (7.7)	0	1/17 (5.9)	3/35 (8.6)	.52
3rd	0	0	0	0	0	0	0	NA
Premature preterm rupture of membranes[g]	1/11 (9.1)	0	1/18 (5.6)	0	0	0	1/35 (2.9)	.58
Chorioamnionitis	0	0	0	0	0	0	0	NA
Premature contractions at <37 wk of gestation, n/N (%)[h]	3/11 (27.3)	0	3/18 (16.7)	2/13 (15.4)	0	2/17 (11.8)	5/35 (14.3)	.64
Medication[i]	3/11 (27.3)	0	3/18 (16.7)	1/13 (7.7)	0	2/17 (11.8)	5/35 (14.3)	.63
Immobilization[j]	2/11 (18.2)	1/4 (25.0)	3/18 (16.7)	3/13 (23.1)	0	4/17 (23.5)	7/35 (20.0)	.67
Other complications[k]	0	1/4 (25.0)	2/18 (11.1)	1/13 (7.7)	0	1/17 (5.9)	3/35 (8.6)	.61
Pregnancy outcome								
Total pregnancies with complete follow up, n[l]	11	4	18	13	1	17	35	
Total deliveries[m]								
Gestational age ≥34 wk, n/N (%)	9/11 (81.8)	4/4 (100)	15/18 (83.3)	6/13 (46.2)	1/1 (100.0)	10/17 (58.8)	25/35 (71.4)	.15
Gestational age <34 wk, n/N (%)	0	0	0	2/13 (15.4)	0	2/17 (11.8)	2/35 (5.7)	.23
Gestational age <30, n/N	0	0	0	0	0	0	0	NA
Gestational age <28 wk, n/N	0	0	0	0	0	0	0	NA
Patients with cesarean delivery, n	9	4	15	8	1	12	27	
Mean gestation at cesarean delivery, wk[n]	37.9 ± 0.9	38.5 ± 1.0	38.2 ± 0.9	35.5 ± 1.8	37.0 ± NA	35.9 ± 1.6	37.2 ± 1.7	< .001
Complications during cesarean delivery, n/N (%)[o]	2/9 (22.2)	0	2/15 (13.3)	2/8 (25.0)	0	3/12 (25.0)	5/27 (18.5)	.63
Fetal outcome: survival rate, %								
Pregnancy[p]	81.8	100	83.3	88.	100	70.6	77.1	.38
Ongoing pregnancy[q]	81.8	100	88.2	61.5	100	92.3	90.0	.72

In the Dutch preconceptional cohort, 1 patient is currently pregnant.
NA, not available.

[a] Indication placement of laparoscopic abdominal cerclage; [b] Includes 4 patients with "other" indication: previous immature or premature delivery and/or instrumental termination of pregnancy that lead to clinical assessment of a technically unfeasible cervix to insert a vaginal cerclage; [c] Includes 6 patients with "other" indication: previous immature or premature delivery and/or instrumental termination of pregnancy that lead to clinical assessment of a technically unfeasible cervix to insert a vaginal cerclage; [d] Preconceptional total Dutch/total Boston cohort; [e] After 12 months in the Dutch cohort vs 18 months in the Boston cohort; [f] 1 patient was in the second trimester of pregnancy during submission of the article; she was not included in the analyses of pregnancy outcome parameters; [g] Occurred at 35 + 6 weeks of gestation; [h] All patients with premature contractions received tocolyse therapy; [i] Proluton, antibiotic, 17-hydroxyprogesterone therapy; [j] defined as hospitalization and bed rest for at least 1 day; [k] For example, urinary tract infection, vaginal blood loss; [l] Does not include the patient who was pregnant during submission of the article; [m] Does not include patients with a curettage in the first or second trimester of pregnancy; [n] Data are given as mean ± SD; [o] Severe hemorrhage (≥1000 mL), uterine rupture (in 1 patient at 35 + 4 weeks of gestation); [p] Defined as the total number of live born infants who survived the neonatal period (to hospital discharge) divided by all pregnant patients, including early pregnancy losses; [q] Defined as the total number of live born infants who survived the neonatal period (to hospital discharge) divided by all patients with an ongoing pregnancy (ie, a vital intrauterine pregnancy at 12 weeks of gestation, exclusion of first-trimester miscarriages).

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TABLE 5
Patient satisfaction results

Variable	Dutch preconceptional cohort (n = 32)
Patient satisfaction results	
Patients included, n	32
Physical complaints after discharge from surgery, n/N	0/32
Satisfied patients regarding surgery, n/N (%)	32/32 (100)
Recommendation of surgery to other patients, n/N (%)	32/32 (100)
Fertility wish after surgery, n/N (%)	32/32 (100)
Interval fertility wish after surgery, mo[a]	32 (1-24)
Time of surgery to conception, mo[b,c]	10.8 ± 9.5
Patients with no pregnancy at 12 mo after laparoscopic abdominal cerclage	
Patients, n	8
Age, y[c]	39.2 ± 2.7
Treatment in fertility center, n/N (%)	7/8 (87.5)

[a] Data are given as median (range); [b] Data reported in 12/32 patients; [c] Data are given as mean ± SD.

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stetric care, such as immobilization and the standardized cesarean delivery at 37 weeks of gestation in the Boston cohort, could affect pregnancy outcomes.

The optimal gestational age for cesarean delivery in these patients is undefined. According to the protocol a cesarean delivery was planned in the Boston cohort at 37 weeks of gestation and in the Dutch cohort at 39 weeks of gestation. In the Boston cohort, 1 uterine rupture occurred after uterine contractions that started at 35 + 4 weeks of gestation. Routine cesarean delivery at 37 weeks of gestation would not have prevented this serious complication. It is remarkable that all patients in the Dutch cohort reported high satisfaction with the procedure, despite the fact that a considerable percentage of the patients did not become pregnant and that 2 failures were reported. Based on the questionnaire in the Dutch population, a considerable percentage of patients delayed their pregnancy wish, even after successful surgery. This might relate to their poor obstetric history and the fear of miscarriage. In this study, the pregnancy rates were comparable, 68.0 and 70.4% in the Boston and the Dutch cohorts, respectively. In recent literature, the pregnancy rate after preconceptional LAC varies from 42.9-90.9%.[6,8-11] Yet, 87.5% of the nonpregnant patients within 12 months of follow up are still undergoing fertility treatment. Furthermore, increasing maternal age and previous extensive cervical surgery, such as conization or trachelectomy, might affect reproduction. Although it cannot be excluded, it seems unlikely that LAC would impair conception or implantation of the embryo.

The presented results of LAC are hopeful. However, larger studies with a prospective design and appropriate registration of baseline characteristics, standardized indications for the application of LAC, and clear instructions on pregnancy-related interventions (including repeated cervical length measurements, medication, immobilization, and gestational age at cesarean delivery) are required to study the effect of LAC on pregnancy outcome, including safety aspects. The placement of LAC in patients with previous cervical surgery in whom the cervix is too short to enable eventual emergency cerclages is a matter of debate, given the positive effect of progesterone in patients with previous cervical surgery.[12] A randomized controlled trial is considered to be the most optimal design to answer this question. However, a large, prospective cohort study may be considered to be the most ideal study design in patients with a previous failed vaginal cerclage. Given the poor obstetric history, it will be hard to include these patients in a randomized controlled trial in which the alternative therapy does not include LAC.

In conclusion, LAC is associated with excellent perioperative results and favorable perinatal outcomes in patients with a poor obstetric history. Patient satisfaction and personal experience are rated high. ■

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APPENDIX

SUPPLEMENTARY TABLE

Obstetric history prior to laparoscopic abdominal cerclage

Cohort	Week of delivery	Therapy	Clinical presentation	Cervical length at 18 wk, mm	Birthweight, g	Placental pathology
DUTCH						
Patient no.- pregnancy, no.						
1-1	Term	N	NA	NR	NR	N
1-2	17	N	CI	—	NR	NR
2-1	38	N	NA	NR	2440	N
2-2	21 + 3	N	CI	NR	400	N
2-3	26	N	CI	NR	NR	NR
3-1	24	N	CI	NR	NR	NR
3-2	23	Vaginal cerclage	CI	NR	NR	NR
4-1	Term	Vaginal cerclage	Intrauterine fetal death	NR	NR	N
5-1	NR	Vaginal cerclage	NR	NR	NR	NR
6-1	24	N	CI	NR	750	N
6-2	16	N	Intrauterine fetal death	NR	NR	N
6-3	32	Vaginal cerclage	NA	NR	2040	N
6-4	22	Vaginal cerclage	CI	NR	516	N
7-1	19+3	N	CI	NR	NR	N
8-1	Twins (interval): 21 + 3 and 22 + 2	Vaginal cerclage	CI	53	NR	N
9-1	23	N	CI	33	645	N
10-1	17	N	Immature rupture of membranes	NR	NR	N
10-2	19 + 1	N	CI	NR	NR	N
11-1	36 + 2	N	NA	NR	NR	N
11-2	25 + 3	Vaginal cerclage	Gastroenteritis	NR	769 and 866	Chorioamnionitis
12-1	NA	Vaginal cerclage	Failed vaginal cerclage	NA	NA	NA
13-1	NA	NA	NA	NA	NA	NA
14-1	16 + 4	N	NR	NR	NR	NR
14-2	14 + 1	N	NR	NA	NR	NR
14-3	23 + 6	Vaginal cerclage	CI	NR	655	N
15-1	21 + 4	N	Preterm premature rupture of membranes	NR	437	N
16-1	17	N	NR	NA	119	N
16-2	24 + 5	Vaginal cerclage	Intrauterine infection	NR	730	Chorioamnionitis
17-1	23 + 2 (Twins)	N	CI	NR	NR	NR
18-1	20 + 4	Vaginal cerclage	CI	NR	400	Chorioamnionitis

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SUPPLEMENTARY TABLE

Obstetric history prior to laparoscopic abdominal cerclage *(continued)*

Cohort	Week of delivery	Therapy	Clinical presentation	Cervical length at 18 wk, mm	Birthweight, g	Placental pathology
19-1	NA	NA	NA	NA	NA	NA
20-1	38	N	NA	NR	2840	N
20-2	40	N	NA	NR	3220	N
20-3	18 + 3	Vaginal cerclage	CI	NR	176	Chorioamnionitis
21-1	19	Vaginal cerclage	NR	NR	NR	NR
21-2	21	Vaginal cerclage	NR	NR	NR	NR
22-1	NA	NA	NA	NA	NA	NA
23-1	18	N	NR	NR	NR	NR
23-2	25	Vaginal cerclage	NR	NR	NR	NR
23-3	25	Vaginal cerclage	NR	NR	NR	NR
24-1	Term	Vaginal cerclage	NA	NR	NR	N
25-1	NA	NA	NA	NA	NA	NA
26-1	19	Vaginal cerclage	NR	NR	NR	NR
26-2	12	Vaginal cerclage	NR	NR	NR	NR
27-1	17-25	N	NR	NR	NR	NR
27-2	17-25	Vaginal cerclage	NR	NR	NR	NR
27-3	17-25	Vaginal cerclage	NR	NR	NR	NR
BOSTON						
Patient no.- pregnancy, no.						
1-1	22	Vaginal cerclage	CI	NR	NR	NR
2-1	27	Vaginal cerclage	CI	NR	NR	N
3-1	NA	NA	NA	NA	NA	NA
4-1	21	N	CI	NR	NR	Chorioamnionitis
5-1	Term	N	NA	NR	2495	N
5-2	16 (Twins)	N	CI	NA	NR	NR
5-3	21	N	CI	NR	NR	NR
5-4	16	Vaginal cerclage	CI	NA	NR	NR
6-1	Term	N	NA	NR	3232	N
6-2	22	N	CI	NR	NR	N
6-3	24	Vaginal cerclage	CI	NR	NR	N
7-1	16-17	N	CI	NA	NR	N
7-2	21	Vaginal cerclage	CI	NR	NR	NR
8-1	29 + 2	Vaginal cerclage	CI	NR	NR	N
9-1	17	N	CI	NA	NR	N
9-2	26 + 3	Vaginal cerclage	CI	NR	NR	N
11-1	19 + 5	N	CI	NR	NR	N
11-2	19 + 2 (Twins)	Vaginal cerclage	CI	NR	NR	Chorioamnionitis
12-1	26 + 1	N	CI	NR	NR	N
13-1	NA	NA	NA	NA	NA	NA

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SUPPLEMENTARY TABLE

Obstetric history prior to laparoscopic abdominal cerclage *(continued)*

Cohort	Week of delivery	Therapy	Clinical presentation	Cervical length at 18 wk, mm	Birthweight, g	Placental pathology
14-1	23 + 3 (Twins)	N	CI	NR	NR	N
14-2	20	Vaginal cerclage	CI	NR	NR	N
15-1	30	Vaginal cerclage	CI	NR	1590	N
16-1	NR	NR	NR	NR	NR	NR
17-1	30 + 6	Vaginal cerclage	CI	NR	1680	N
18-1	24 + 0	Vaginal cerclage	CI	NR	708	N
19-1	Term	N	NA	NR	NR	N
19-2	16	N	NA	NR	NR	N
19-3	16	N	NA	NR	NR	N
19-4	21	Vaginal cerclage	CI	NR	NR	N
20-1	18 (Twins)	N	CI	NR	NR	N
20-2	19 (Twins)	Vaginal cerclage	Preterm premature rupture of membranes	NR	NR	Chorioamnionitis
21-1	24 + 1	Vaginal cerclage	CI	NR	490 and 670	N
22-1	19	N	CI	NR	NR	N
22-2	17	Vaginal cerclage	CI	NR	NR	N
23-1	37	Vaginal cerclage	NA	NR	NR	N
24-1	37	N	NA	NR	2440	N
24-2	34 (Twins)	Vaginal cerclage	NR	NR	1630 and 1890	N
24-3	19 + 1	Vaginal cerclage	CI	NR	NR	Chorioamnionitis
25-1	23	N	CI	NR	NR	N
25-2	31 + 2	Vaginal cerclage	CI	NR	NR	N
26-1	22 + 4	N	CI	NR	NR	N
26-2	36 + 4	Vaginal cerclage	CI	NR	3155	N
26-3	21 + 3 (Twins)	N	CI	NR	NR	N
27-1	NA	NA	NA	NA	NA	NA
28-1	2nd trimester (NR)	N	NR	NR	NR	NR
28-2	19	Vaginal cerclage	CI	NR	NR	NR
29-1	18	N	CI	NR	NR	NR
29-2	19	N	CI	NR	NR	NR
30-1	23	N	CI	NR	NR	NR
31-1	19 + 3 (Twins baby A loss at 12 wk)	Vaginal cerclage	CI	NR	NR	N
33-1	26	N	CI	NR	860	N
34-1	21 + 6 (Triplets)	N	CI	NR	NR	N
35-1	38	Vaginal cerclage	NA	NR	NR	N
37-1	24 + 1	N	CI	NR	NR	N

Exclusion of first-trimester losses, extra-uterine pregnancies, and elective abortions.
CI, cervical insufficiency; *N,* none; *NA,* not applicable; *NR,* not reported.

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