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Effectiveness of laparoscopic abdominal cerclage on pregnancy outcome in women with cervical incompetence: An observational cohort study

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ABSTRACT

Objective: To assess the successful pregnancy, preterm delivery and complications in patients with history of cervical insufficiency and failed vaginal cerclage who underwent laparoscopic abdominal cerclage (LAC).

Methods: In a mixed cohort study, the recorded data of 170 eligible patients in medical documents and hospital records were extracted at Arash Hospital, Tehran, Iran during the March 2022 to March 2025, retrospectively and the treatment outcomes gathered by medical history and telephone interview, prospectively. LAC approach was done after general anesthesia for all patients. Of all included patients, 94 cases got pregnant and during study and after follow up, pregnancy outcomes occurrence after cerclage, gestational age <35 weeks and ≥36 weeks, complications and failed pregnancies were recorded as primary study outcome. Data analysis performed with SPSS version 24 software, using descriptive and analytic statistics.

Results: 170 eligible women were included. Followed them during two years after operation, 94 women got pregnant. Of 94 pregnant women after LAC, 6 cases had unsuccessful pregnancy due to rupture of membranes, ectopic pregnancy, fetus heart abnormally, and intrauterine fetal death. Finally, from 81 mothers, 75 mothers had successful pregnancy and the LAC success rate of pregnancy was 92.6% and the incidence of delivery ≤35 weeks was 34%. Secondary infertility ($P=0.04$), lower maternal' age ($P=0.03$), and higher body mass index ($P=0.04$) were associated with successful pregnancy. Shorter interval from cerclage to conception was related to more term deliveries ($P=0.009$) and successful pregnancy ($P<0.001$).

Conclusions: LAC could be considered as an effective treatment to preserving pregnancy and preventing the preterm delivery, in patients with cervical incompetence.

KEYWORDS: Pregnancy; Abdominal cerclage; Insufficient cervical; Women; Child bring

Key Points

Question: What is the successful pregnancy rate and complications in patients with history of cervical insufficiency and failed vaginal cerclage who underwent laparoscopic abdominal cerclage (LAC)?

Findings: The successful pregnancy after LAC in women with failed cervical cerclage was 92.6% and the rate of delivery at 36 weeks and later was 66%. Secondary infertility, lower maternal' age, higher body mass index and lower time interval from cerclage to conception were associated with successful pregnancy and term delivery after LAC.

Meaning: LAC is an effective intervention to increase the chance of successful pregnancy and term delivery, especially in women with failed cervical cerclage. LAC could be suggested for patients with recurrent mid-trimester abortions or pregnancy loss due to cervical insufficiency.

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1. Introduction

Preterm birth is responsible for 15 million premature birth annually and is the direct cause of 35% of all neonatal deaths and the second cause of under-5 children' death after infection[1]. Cervical insufficiency is one of the factors that leads to preterm birth and late miscarriage, which typically presents as painless dilation of the cervix in the mid-trimester. It occurs in approximately 0.5%–1.0% of all pregnancies and accounts for 10%–25% of second-trimester pregnancy losses[2,3]. While transvaginal cervical cerclage (TVC) is considered as first-line treatment for cervical insufficiency, new studies recommended laparoscopic abdominal cerclage (LAC) as a highly effective procedure with minimum invasive option and neonatal outcomes, especially for failed cases by TVC[4]. The reported success rates ranged from approximately 71% to 100%[5,6].

Cervical cerclage has been the primary treatment for cervical insufficiency for more than 60 years[4]. Cerclage can be placed transvaginally or *via* laparotomy or laparoscopy[7,8] but in cases of failed vaginal cerclage or when the cervix is very short or deformed, abdominal cerclage may be used for treatment. This method has the advantage of a lower risk of ascending infection since there is no foreign body within the vagina[8,9]. Some researchers suggest that the benefits of abdominal cerclage go beyond its mechanical support, and there is increasing evidence that premature cervical dilation and effacement are the end result of an inflammatory process secondary to infection or changes in the microbiome[5,8,10]. The laparoscopic approach, with its improved visualization of pelvic anatomy, reduced blood loss, shorter hospital staying, and fewer complications compared with the open surgical approach and is preferred by many surgeons especially for women with failed/impossible vaginal cerclage[5,8]. High success rates in preventing second-trimester pregnancy loss and preterm birth have been reported with laparoscopic cerclage, which also offers the benefits of minimally invasive surgery[11]. However, the safety and efficacy of LAC during pregnancy or before conception remain controversial[12,13]. Therefore, this cohort study was designed to evaluate pregnancy outcomes after LAC in patients with cervical insufficiency who have a history of recurrent second trimester pregnancy loss and failed/impossible vaginal cerclage.

2. Methods

2.1. Study design and setting

This study is a single arm mixed cohort study (retrospective and prospective) conducted at Arash Hospital, Tehran, Iran during the March 2022 to March 2025. Recorded data in medical documents were extracted from hospital records, retrospectively and the outcomes of treatment were gathered by in-person visits and telephone interviews, prospectively.

2.2. Participants and sampling

Inclusion criteria were all non-pregnant women in reproductive age with a documented history of cervical insufficiency, prior cervical surgery, very short cervix recurrent second trimester pregnancy loss, and prior failed vaginal cerclage who were candidates for LAC. Presence of malignancy, coagulopathy or systemic disease, cardiopathy and decline to participate or refusal of follow up contact were the exclusion criteria. Sample size calculation was estimated based on the success rate of pregnancy after LAC, equal 96% in another study[6] and type one error 5%. Therefore, the minimum sample size for this study projected 62 patients by considering precision ($d=0.05$). First, we assessed 170 eligible patients who underwent the LAC and followed them during two years after operation. Finally, from all recruited patients, 94 cases got pregnant and data of 94 pregnant women after LAC were assessed.

All eligible women were selected by census sampling and we enumerated all patients who meeting eligibility criteria during the study period. After ethics approval, patients were undergone LAC and followed for two years. The pregnancy occurrence was checked and all pregnant women were followed by in-person visit and telephone contact to reach the required data and pregnancy outcomes.

2.3. Exposure (Surgical technique)

General anesthesia was administered for all participants and the patients were placed in the lithotomy position. Then, standard aseptic surgical skin preparation and draping were performed and laparoscopic approach was used for surgery. First, a one 10 mm trocar placed at the umbilicus and three 5 mm trocars placed at right lateral, left lateral, and suprapubic locations. Then, the bladder was mobilized from the vesicouterine reflection to expose the cervix and uterine arteries bilaterally. A Mersilene tape (approximately 15 cm length, 5 mm width) was passed through the avascular medial plane lateral to the uterine artery at the level of the internal os on each side, traversing the lateral parametrium adjacent to the cervix. The tape ends were tied anterior to the cervix to create the abdominal cerclage. During the procedure, hemostasis was secured, position of the cerclage confirmed visually, needles removed, and the abdominal wall closed in standard fashion.

2.4. Study outcomes

The primary outcomes in this study were pregnancy occurrence after cerclage and gestational age <35 weeks and ≥ 36 weeks. The successful pregnancy after LAC is defined based on the neonatal survival after delivery[5] and preterm delivery defined based on gestational age lower 37 weeks[14], but we compared women with gestational age lower 35 weeks against women with gestational age 36 weeks and higher as preterm and term delivery. Our secondary

outcomes were intraoperative and postoperative complications as well as miscarriage (abortion) rate in women who got pregnant. Based on our categorization, 32 mothers with preterm delivery compared with 62 mothers in term category. In addition, data of 75 mothers with successful pregnancy compared with another group (19 cases) including unsuccessful pregnancy (6 cases) and patients who underwent abortion (13 cases).

2.5. Data collection

Data collection was conducted based on the hospital records, operative reports, inpatient charts, in-person visits and telephone interviews with patients to obtain study outcomes and verify missing data. Potential complications during the surgery and after surgery including uterine artery damage, intrauterine growth restriction (IUGR), gestational diabetes and the incidence of hematoma, transfusion requirement, preeclampsia anesthesia related complications were recorded. Demographics including age, height, weight, past medical history, past surgical history and reproductive variables such as gravidity, parity, and number of abortions was entered in a structured data collection form (checklist). In addition, outcomes of treatment including gestational ages at delivery, successful or abortion/failed pregnancy due to other factors and complications were recorded in the checklist.

2.6. Statistical analysis

Data analysis was performed with SPSS version 24 software (IBM Corp., 2020). The normal distribution of data was assessed using Shapiro-Wilk and Kolmogorov-Smirnov tests and histogram. *Chi-square* test and independent *t*-test were used to compare groups

based on the qualitative and quantitative variables. Fisher exact test and continuity correction were used when it was necessary due to small number in cells. In addition, multivariate logistic regression analysis was used to remove the confounding variables. Wald stepwise method was used for entering variables into method. All significant variables and variables with *P* value less than 0.2 were included in the model and just significant variables of the model were reported in table. Descriptive statistics included mean, standard deviation, median, inter-quarter range (IQR) and percentage. *P* value lower than 0.05 was considered as significant.

2.7. Ethics statement

Ethical board of Tehran university of Medical Sciences approved the study protocol by IR.TUMS.IKHC.REC.1403.311 code at 2024.10.28 and the study was conducted after approval by the International Electrotechnical Commission (IEC). The written informed consent was obtained for participation in study and follow up. Moreover, all participants were informed of voluntary participation and assured of confidentiality and all data handling and interviews complied with institutional ethics requirements.

3. Results

3.1. Descriptive results

In this study, 170 cases who have the history of vaginal cerclage were recruited and they were underwent LAC. Figure 1 is the flowchart diagram showing the flow of participants throughout the study. Of all of recruited patients, 94 patients (55.29%) got pregnant

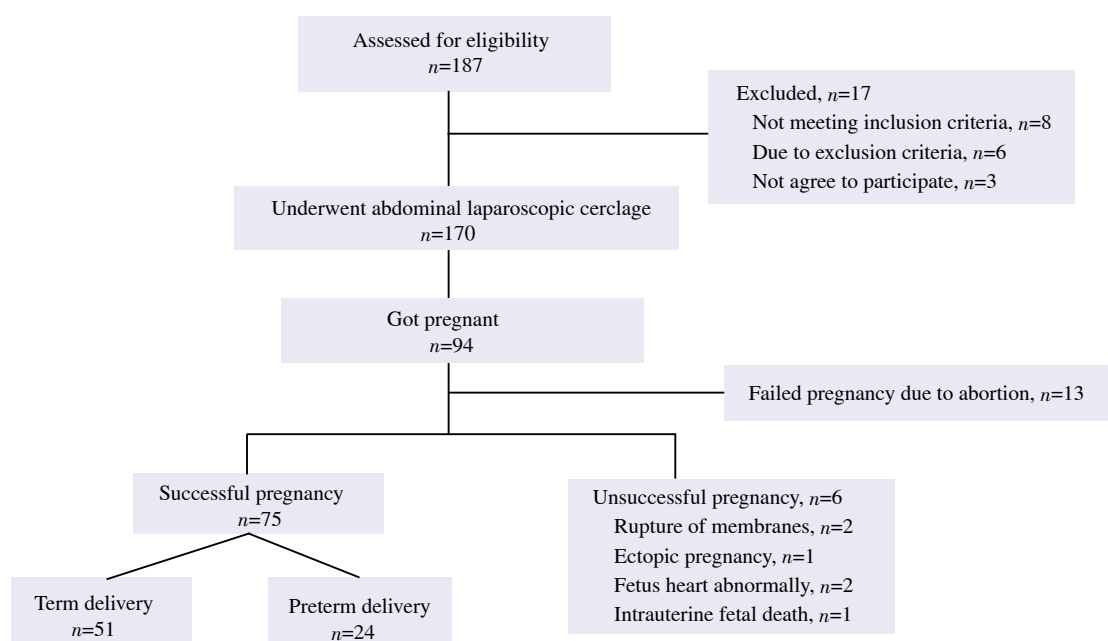


Figure 1. Flowchart diagram showing the flow of participants throughout the study.

and 13 women (13.82%) have experienced abortion before 20 weeks that was not related to the complications of the cerclage procedure. Nevertheless, from 81 remained cases, 6 cases had unsuccessful pregnancy owing to rupture of membranes (ROM) (2 cases), ectopic pregnancy (1 case), fetus heart abnormally (2 cases), and intrauterine fetal death (1 case). We followed these pregnant women to assess the success rate of pregnancy after LAC. The success rate of pregnancy after LAC was 92.59% (75/81). In addition, preterm delivery (<35 weeks) occurred in 24 cases (32.0%) of all mothers with successful pregnancy.

Demographic characteristics of patients (Table 1) showed that 78.7% (74 cases) were housekeeper and more than 55% of women had college education. The rate of twin birth was 9.6% and the prevalence of primary and secondary infertility was 21.3% and 46.8%. Figure 2 shows that elective cesarean is the most common methods of pregnancy termination, and the abortion rate was occurred in 13 cases (21.3%) and the ectopic pregnancy was happened in on case. Descriptive data showed that the mean age of studied patients was (30.8±5.3) years old and it varied from 22 years to 49 years. The mean and median (IQR) of gravidity and abortion in studied mothers were 2(2-4) and 2(0-3), respectively (Table 1).

3.2. Univariate analytical results

We compared the data of mothers with successful pregnancy (75 cases) with other groups of mothers including abortions and unsuccessful pregnancies (24 cases) to assess the predictors of successful pregnancy in patients who underwent LAC. Moreover, based on gestational age, 32 mothers in preterm delivery (<35 weeks) and 62 mothers in term category (≥36 weeks) groups were compared. The difference between two groups was significantly different regarding to the methods of pregnancy termination ($P<0.001$).

Statistical tests showed a significant difference between two groups of mothers regarding to the age ($P=0.001$) and gestational age ($P<0.001$) (Table 2). Nevertheless, mothers with successful pregnancy and unsuccessful pregnancy were not significantly difference in body mass index (BMI), duration of infertility, gravidity, parity, death and abortion ($P>0.05$). Secondary infertility showed a significant relationship with successful pregnancy (OR 3.07, CI 95% 1.05-8.97; $P=0.04$). Nevertheless, there was no significant relationship between education, neonate gender, mother job, past medical history, primary infertility, secondary infertility, and complication ($P>0.05$). Our results showed that the preterm delivery is significantly higher in mothers with secondary infertility ($P=0.009$) (Table 3), and the duration time between cerclage to pregnancy ($P<0.001$) (Table 2) in preterm deliveries was significantly higher in mothers with term pregnancy in comparison to mothers with term deliveries.

The incidence rate of complication in women with successful pregnancy including IUGR, preeclampsia, and gestational diabetes was 1.3%, 6.3% and 7.5%, respectively.

Table 1. Baseline demographic information of the participants ($n=94$)

Demographic characteristics	Data
Mean age (±SD), years	30.8±5.3
Mean body mass index (BMI) (±SD), kg/m ²	26.9±3.1
Normal	27(28.7)
Overweight	52(55.3)
Obesity	15(16.0)
Education	
Diploma and lower	42 (44.7)
College	40(42.6)
Master and upper	12(12.8)
Job	
Housekeeper	74(78.7)
Employed	20(21.3)
Duration time between cerclage to pregnancy, months, median (IQR).	6(3-9)
Mean gestational age (±SD), weeks	31.7±10.3
Gravidity, number, median (IQR)	2(2-4)
Parity, number, median (IQR)	1(0-2)
Death, number, median (IQR)	1(0-2)
Abortion, number, median (IQR)	2(0-3)
Neonate sex	
Girl	38(40.5)
Boy	41(43.6)
Past medical history	
None	77(81.9)
Hypothyroid	12(12.8)
Diabetes mellitus	2(2.1)
Lupus	2(2.1)
Crone	1(1.1)
Past surgical history	
Curettage of pregnancy remnants	33(35.1)
Hysteroscopy	19(20.2)
Laparoscopy	10(10.6)
Twin pregnancy	9(9.6)
Primary infertility	20(21.3)
Secondary infertility	44(46.8)
Complication	
None	82(87.2)
Intrauterine growth restriction (IUGR)	1(1.1)
Preeclampsia	5(5.3)
Gestational diabetes	6(6.4)
Pregnancy outcome	
Yes	75(79.8)
Abortion	13(13.8)
Failed	6(6.4)
Gestational age (Preterm delivery)	
Lower 35 weeks	32(34.0)
36 weeks and higher	62(66.0)

Data are expressed as $n(\%)$ unless otherwise specified.

3.3. Multivariate analytical results

The multivariate regression analyses showed that duration time between cerclage to conception, mother age and BMI were the related factors of successful pregnancy, and BMI and gravidity were the significant determinants of preterm delivery. Nevertheless, by increasing the duration time between cerclage to conception ($P=0.04$) and mother age ($P<0.05$), the chance of successful pregnancy will decreased, but by increasing the BMI ($P=0.03$) the probability of having successful pregnancy enhanced. Moreover, the multivariate

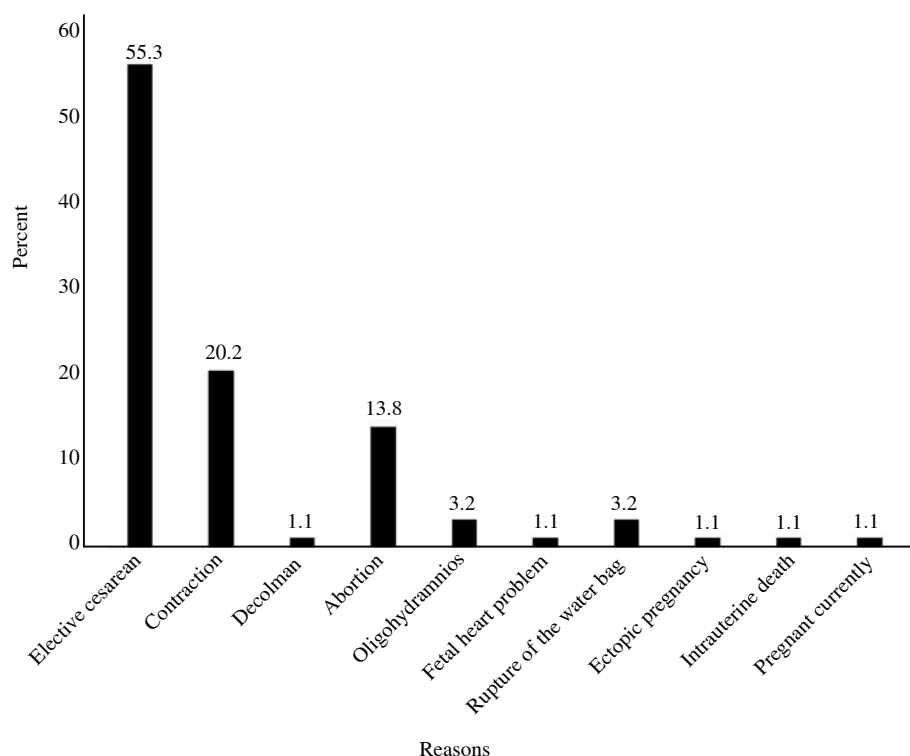


Figure 2. Reasons of pregnancy termination after laparoscopic abdominal cerclage (LAC) in the studied women.

Table 2. The relationship between successful pregnancy with age, body mass index and reproductive history variables of the studied women.

Variables	Successful pregnancy <i>n</i> =75	Unsuccessful pregnancy <i>n</i> =19	<i>P</i> value	Term pregnancy <i>n</i> =62	Preterm pregnancy <i>n</i> =32	<i>P</i> value
Body mass index (BMI), kg/m ²	27.26±2.86	25.51± 3.48	0.03	27.33±2.84	26.09±3.34	0.06
Age, years	30.2±4.5	33.1±7.4	0.04	30.3±4.7	31.8±6.3	0.20
Gestational age, weeks	36.6±1.3	10(6-18)	<0.001	37.1±0.8	22(8-34)	0.25
Duration time between cerclage to conception, months	5(3-9)	6(4-12)	0.04	5.0(3.0-9.3)	6.0(4.0-11.2)	<0.001
Gravidity, number	2(2-4)	2(2-4)	0.86	2(2-3)	3(2-4)	0.11
Parity, number	1(0-2)	1(0-2)	0.67	1(0-2)	1(0-2)	0.29
Death, number	1(0-2)	1(0-2)	0.57	1(0-2)	1(0-2)	0.54
Abortion, number	2(0-3)	1(0-2)	0.69	2(0-2)	2(0-3)	0.38

Data are expressed as mean±SD or median (IQR).

regression showed similar effect for BMI and by increasing BMI, the rate of preterm delivery decreased ($P=0.03$). In addition, by increasing the number of gravidities, the chance of preterm delivery will increase ($P<0.05$) (Table 4).

4. Discussion

In this cohort study, 94 women who underwent LAC following prior failed vaginal cerclage, got pregnant and 81 reached a pregnancy beyond the early losses considered unsuccessful for the procedure and 75 had successful pregnancy outcomes attributable to LAC, yielding an LAC success rate of 92.59%. We applied LAC on pre-conceptional period, and other studies showed that this method does not delay achieving pregnancy without a negative impact on the chances of conception[6]. Transabdominal cerclage leads to

92% of deliveries ≥ 34 weeks as a successful method for preventing preterm delivery and increases the gestational age at delivery to 37.3 weeks[7].

However, our cohort consisted exclusively of women with prior failed vaginal cerclage, an extremely high risk population for mid trimester loss. In such patients, the relative benefit of LAC can be large, explaining the high success proportion among those achieving pregnancy. Moreover, high success and low serious complication rates in our series may reflect experienced surgeons and standardized operative technique.

The observed procedural success rate in our study (92%) was consistent with previously published series of LAC which was reported in other studies and ranged from 70%–90%[6,15–17]. Nevertheless, the high success could be as a result of specific group of patients who had prior failed vaginal cerclage and the

Table 3. The relationship between demographic variables and medical history of patients with successful pregnancy after cerclage operation.

Demographic variables	Successful pregnancy n=75	Unsuccessful pregnancy n=19	P value	Term pregnancy n=62	Preterm pregnancy n=32	P value
Education						
Diploma and lower	34(45.3)	8(42.1)	0.88 [§]	26(41.9)	16(50.0)	0.68 [§]
College (Associate and bachelor degrees)	31(41.3)	9(47.4)		27(43.5)	13(40.6)	
Master and higher	10(13.3)	2(10.5)		9(14.5)	3(9.4)	
Neonate gender						
Girl	36(48.6)	2(40.0)	0.71 [*]	26(42.6)	12(66.7)	0.06 [§]
Boy	38(51.4)	3(60.0)		35(57.4)	6(33.3)	
Job						
Housekeeper	59(78.7)	15(78.9)	0.98 [§]	47(75.8)	27(84.4)	0.34 [§]
Employed	16(21.3)	4(21.1)		15(24.2)	5(15.6)	
Past medical history						
Yes	14(18.7)	3(15.8)	0.53 [*]	11(17.7)	6(18.8)	0.90 [*]
No	61(81.3)	16(84.2)		51(82.3)	26(81.2)	
Primary Infertility						
Yes	14(18.7)	6(31.6)	0.22 [§]	11(17.7)	9(28.1)	0.24 [§]
No	61(81.3)	13(68.4)		51(82.3)	23(71.9)	
Secondary Infertility						
Yes	31(41.3)	13(68.4)	0.04 [§]	23(37.1)	21(65.6)	0.009 [§]
No	44(58.7)	6(31.6)		39(62.9)	11(34.4)	
Complication						
Yes	12(16.0)	0(0.0)	0.14 ^{§§}	10(16.1)	2(6.2)	0.15 [*]
No	63(84.0)	19(100.0)		52(83.9)	30(93.8)	
Past surgical history						
No	23(30.7)	9(47.4)	0.49 ^{§§}	19(30.6)	13(40.6)	0.34 [§]
Curettage	27(36)	6(31.6)		23(37.1)	10(31.2)	
Hysteroscopy	17(22.7)	2(10.5)		15(24.2)	4(12.5)	
Laparoscopy	8(10.7)	2(10.5)		5(8.1)	5(15.6)	

Data are expressed as n(%). *: Fisher Exact test is used; §: Chi square test is used; §§: continuity correction of Chi square test.

Table 4. The multivariate regression results of related factors of successful pregnancy and preterm delivery.

Factors	B	S.E.	P value	Exp(B)	95% CI for EXP(B)	
					Lower	Upper
Successful pregnancy						
Duration time between cerclage to conception	0.092	0.045	0.04	1.096	1.050	1.197
Mother age	0.098	0.050	<0.05	1.103	1.010	1.217
BMI	-0.200	0.094	0.03	0.818	0.681	0.983
Preterm delivery						
BMI	-0.169	0.079	0.03	0.844	0.723	0.986
Gravidity	0.321	0.167	<0.05	1.378	0.993	1.914

CI: confidential interval. BMI: body mass index.

laparoscopic approach. Different studies showed that the LAC is more effective than other methods of cerclage for preserving pregnancy[5,15,16]. Age and time between LAC and conception was significantly lower in mothers with successful *versus* unsuccessful pregnancies. The finding that secondary infertility predicted higher odds of successful pregnancy after LAC (*OR* 3.07) is noteworthy. Prior studies have variably reported infertility type as a factor owing to the fact that women with secondary infertility may have had at least one prior successful pregnancy indicating a potentially more favorable uterine environment or differences in underlying causes of infertility[18,19]. This contrasts with expectations that primary infertility might reflect better cervical anatomy[18,20,21]. However, it is considerable that women with primary or secondary infertility were treated for their problems and routine treatment for

infertility such as *in vitro* fertilization (IVF) was used for them to have successful pregnancy. High strength of relationship between successful pregnancy after LAC might be related with infertility treatment methods.

Preterm delivery was significantly associated with secondary infertility and with a shorter interval between cerclage and conception. Marchand *et al*'s study showed that laparoscopic cerclage is an effective method for prevention of deliveries <34 weeks and preserving the pregnancy[15]. The preterm delivery rate of 32.0% among successful pregnancies is higher than population averages and was higher than the reported in other studies[22] but it was similar the results of Hall *et al*'s study that the rate of births ≥27 to 33 weeks were 37.2%. In addition, our results was in consistent with cohorts of women with prior cervical insufficiency as an inherently high

risk group[23]. However, the target women in different studies were different. Some reviews also showed that LAC could decrease the mid trimester loss and increase term birth rates, but residual preterm delivery remained an issue, particularly in patients with additional obstetric risk factors[11,15,16]. Our data showed associations between interval from cerclage to conception and preterm delivery and suggested that the shorter interval is associated with lower rate of term delivery in our cohort. These results are in line with idea that preconception cerclage allows uterine and local tissue recovery before pregnancy stresses occur[24,25]. Several studies indicated that preconceptional abdominal cerclage is associated with fewer intra pregnancy complications and possibly improves pregnancy durability compared with cerclage placed during pregnancy[25–27].

There are some study's limitations. The complete enumeration of all patients meeting eligibility criteria reduced the selection bias inherent to sampling and using the combination of existing data and interview with patients were the strength of this study. However, some obstetric complications including IUGR, preeclampsia, and gestational diabetes were reported in our study that were infrequent and should be care about them in women with LAC. In addition, absence of a concurrent control group was a limitation of this study and could reduce the causal inference and comparability of outcomes to alternative management strategies.

In conclusion, our results showed that LAC could be considered as an effective treatment to preserving pregnancy and preventing the preterm delivery, in patients with cervical incompetence. Therefore, our results are important to inform clinical decision making in patients with recurrent mid-trimester abortions or pregnancy loss due to cervical insufficiency. However, due to the fact that comparative data are sparse, our finding for the effect of infertility on preterm delivery need more cautious in interpretation and further studies are recommended.

Conflict of interest statement

The authors declare that they have no competing interests.

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Availability of data and materials

Due to privacy and ethical restrictions, the data are not publicly available. However, the data sets used and/or analyzed during this study are available from the corresponding author on reasonable request.

Authors' contributions

Reihaneh Hosseini and Zahra Asgari contributed to designing the study. Zahra Yazdi, Shirin Farhodi, and Sarasadat Mollasaedi conducted the study and cooperated in data collection and following patients. Aynaz Boostan and Bahareh Khakifirouz analyzed the data and wrote the results. Reihaneh Hosseini and Zahra Yazdi prepared the manuscript draft and finally all authors read and approved the final manuscript.

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