



Primary, secondary, and tertiary preventions of preterm birth with cervical cerclage

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Abstract

Objective To evaluate the efficacy of cerclage in preventing preterm birth according to indication.

Study design Retrospective analysis of all women who underwent cerclage to prevent preterm birth in a university-affiliated medical-center (2007–2017). Multiple gestations were excluded. Cohort was divided to three subgroups according to cerclage indication: group A—primary prevention cerclage, performed during the first trimester, based on a history of cervical insufficiency; group B—secondary prevention cerclage, performed after sonographic visualization of asymptomatic cervical length shortening and previous preterm birth; and group C—tertiary prevention cerclage, performed at mid-trimester in women presenting with asymptomatic cervical dilatation. Primary outcome was gestational age at delivery. Secondary outcomes were maternal and neonatal complications.

Results During the study period 273 women underwent cervical cerclage: group A—215 (79%), group B—25 (9%), and group C—33 (12%). Patients in group C had significantly lower gravidity and parity. Gestational age at cerclage was highest in group C and lowest in group A (22 vs. 13 weeks $p < 0.001$). Median gestational age at delivery was 37 + 3 weeks in groups A and B and 34 + 3 in group C. This difference persisted after controlling for potential confounders ($p < 0.0001$). Preterm birth prior to 34 weeks of gestation were 10.7% in group A, 16% in group B, and 33.33% in group C ($p = 0.0021$). Neonatal complications including: respiratory distress syndrome, intraventricular hemorrhage, and necrotizing enterocolitis, were clmore prevalent in group C.

Conclusion Cerclage was shown to be an acceptable measure in cases of an anticipated increased risk of preterm birth with a low rate of procedure associated complications. However, the number-needed-to-treat cannot be determined from our data, because a control group was lacking.

Keywords Cerclage · Preterm birth · Cervical insufficiency · Prevention

Introduction

Preterm birth is the leading cause of neonatal morbidity and mortality worldwide, complicating up to 12% of pregnancies [1, 2]. Therefore, most health organizations and obstetric societies have declared that reduction or prevention of spontaneous preterm birth is a worldwide goal. Despite that,

many patients who are identified to be at high risk for preterm birth do not receive timely counseling and appropriate treatment [2, 3].

Cervical insufficiency, as defined by painless cervical dilatation, is an uncommon event complicating 0.3–1% of pregnancies [4]. It is a significant risk factor, associated with recurrent second-trimester pregnancy losses and preterm births of otherwise normal pregnancies. The three known interventions that are offered to patients identified with cervical insufficiency are progesterone treatment, pessary placement, and cervical cerclage.

There are several indications for cerclage placement, which can be divided grossly into 3 groups. History-based cerclage is indicated for patients with a history of two or more early preterm birth or mid-trimester pregnancy loss

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due to painless cervical dilatation regardless of current pregnancy characteristics. These procedures are usually carried out in late first trimester, as an elective procedure, preferably after confirmation of a viable intrauterine pregnancy. Ultrasound-based cerclage is indicated for asymptomatic patients with a short cervical length at mid-trimester, particularly with a prior history of preterm birth [5, 6]. Finally, a physical examination-based cerclage is indicated for patients presenting with cervical effacement and dilatation and no signs of other causes of pending pregnancy loss such as placental abruption, chorioamnionitis or contractions. This procedure is also referred to as "Emergency" or "Heroic" cerclage.

Studies evaluating the efficacy and complications of cerclage are limited. Needless to say that investigating the efficacy of each cerclage indication by conducting a properly designed randomized-control trial is both clinically and ethically challenging. This is especially true in the case of emergent cerclage, because these events may occur in the critical peri-viable period of pregnancy. However, data from cohort studies and case series demonstrated longer interval from presentation to delivery, and higher rates of neonatal survival in patients managed with cerclage compared to those managed expectantly [7–11].

In this study, we aimed to assess the efficacy of cerclage in preventing preterm birth and its complications according to indication.

Materials and methods

Study groups

A retrospective cohort study of all women carrying a singleton viable fetus, who underwent cerclage and delivered in a single university-affiliated tertiary medical center, between July 1st 2007 and December 31st 2017. We compared maternal and neonatal outcomes of pregnancies after three types of interventions: history-indicated cerclage (group A), ultrasound-indicated cerclage (group B), and physical examination-indicated cerclage (group C). Study was approved by our local institutional review board (Approval No, 0697-16-RMC).

Indications

Our institute is a referral hospital for cervical cerclage placement. Women who are considered candidates for cerclage undergo consultation with maternal-fetal medicine specialists and are approved for the procedure only when a clear indication is diagnosed. Preventive, history-based cerclage was indicated by the following medical history: previous late abortions or preterm deliveries in the context of cervical insufficiency, significant cervical procedures such as

recurrent mechanical cervical dilatations, loop conization, or previous pregnancy complicated by cerclage. Cerclage could be indicated by the following ultrasound findings: visualization of asymptomatic cervical length shortening below 25 mm at mid-trimester pregnancies with a history of previous preterm delivery, late abortion or significant cervical procedures such as recurrent mechanical cervical dilatations, or loop conization. Finally, cerclage is also indicated in the case of a physical examination demonstrating mid-trimester asymptomatic cervical dilatation (at least 2 cm), significant effacement (above 60%), or membranes protrusion.

In cases of the following signs and symptoms: contractions, abdominal pain or tenderness, fever, membrane rupture, leukocytosis $> 15,000$, or vaginal bleeding; chorioamnionitis or placental abruption were ruled out before cerclage placement by amniocentesis or close follow-up until resolution of signs.

Procedure

Our institution is specialized in the McDonald cerclage procedure, done solely by trained experienced physicians. The procedure is done under general anesthesia or deep sedation in the operating room. The patient is placed in the lithotomy position; after the vagina is disinfected, the cervix is grasped in the anterior and posterior lips by ring forceps. Curved needle loaded with "Mersylon tape" is passed through the cervix as high above the external os as feasible. Three-to-four passes of the tape are taken circumferentially around the entire cervix avoiding entering the endocervix, bladder, rectum, and uterine vessels. The two ends of the suture are tied securely usually at six o'clock and cut, leaving the ends long enough for future removal. In cases of protruding membranes, the patient is placed in Trendelenburg's position. Observed membranes are gently irrigated with isotonic sterile water and ward off gently towards the uterus using soaked napkin or Foley catheter. Each patient is treated with preventive tocolysis with cyclooxygenase inhibitors. Women who underwent history-indicated cerclage were treated with a single 100 mg indomethacin suppository given per rectal (Aliviosin, Especialidades farmaceuticas centrum, Alicante Spain). Women who underwent ultrasound or physical examination-indicated cerclage were treated with two doses of 100 mg indomethacin suppository given per rectal 12 h apart during the first day (Aliviosin, Especialidades farmaceuticas centrum, Spain) followed by 25 mg indomethacin capsules given orally every 6 h for 2 days (Indovis, CTS chemical industries, Israel). After the procedure, the patient remains in hospital care for a few hours for observation to exclude immediate complication. Preterm premature rupture of membranes was related to cerclage placement if occurred within a week of the procedure.

Patients with mid trimester pregnancies were admitted for 24-h observation. After hospital discharge, patients were followed-up as an outpatient in our fetomaternal hospital clinic. Patients were instructed to avoid strenuous physical activity and sexual intercourse during pregnancy.

Data

Data were retrieved from our department comprehensive computerized perinatal database. The following demographic and obstetric parameters were recorded: indication for cerclage, maternal age, gravidity, parity, artificial reproductive techniques, previous cesarean delivery, hypertensive disorders, and diabetes mellitus during pregnancy and gestational age at cerclage. Intra-partum characteristics included: gestational age at delivery, mode of delivery, and indication for cesarean and regional anesthesia.

Neonatal outcome parameters were stratified to: respiratory composite outcome including any one of: respiratory distress syndrome (RDS), transient tachypnea of the newborn (TTN), mechanical ventilation and meconium aspiration syndrome, and general neonatal composite outcome including any one of: 5 min Apgar < 7, Umbilical blood pH < 7.1, neonatal intensive care unit admission, hypoglycemia, sepsis, hypoxic ischemic encephalopathy, respiratory distress syndrome, transient tachypnea of the newborn, mechanical ventilation, meconium aspiration syndrome, intraventricular hemorrhage, and necrotizing enterocolitis.

All outcomes were evaluated as independent outcomes or composites. Primary outcome was defined as

gestational age at delivery. Secondary outcomes were neonatal composites.

Statistical analysis

Data analysis was performed with the Statistical Analysis Software (SAS) version 9.4. Continuous variables were compared using General Linear Model (GLM). The Chi-square and Fisher's exact tests were used for categorical variables, as appropriate. Differences were considered significant when p value was less than 0.05. Following the bivariate analysis, linear regression analysis was utilized to adjust outcomes for potential confounders: gravidity, parity, and previous cesarean delivery.

Results

Overall, during the study period, 273 women that underwent cerclage delivered in our institute and met the inclusion criteria. Two hundred and fifteen (79%) women underwent preventive cerclage indicated by obstetric history; twenty-five (9%) women underwent mid-trimester, ultrasound indicated, cerclage; and 33 (12%) underwent physical examination indicated, heroic, cerclage. Baseline characteristics of women in the three groups are presented in Table 1. Women in the ultrasound-indicated and physical examination-indicated cerclage groups presented with lower gravidity and parity medians, and higher nulliparity rates compared to the history-indicated cerclage group ($p < 0.001$). Median gestational age at cerclage was 13 weeks in history-indicated cerclage group, 17 weeks in the ultrasound-indicated cerclage group and 22 weeks in physical examination-indicated

Table 1 Baseline characteristics for the study groups

	History-indicated cerclage ($N=215$)	Ultrasound-indicated cerclage ($N=25$)	Physical examination-indicated cerclage ($N=33$)	p value
Maternal age (years)	33 (20–51)	31 (27–39)	32 (22–45)	0.2691
Gravidity	4 (1–15)	3 (1–8)	2 (1–8)	0.0004
Parity	1 (0–8)	1 (0–3)	0 (0–4)	< 0.0001
Nulliparity	41 (19.07)	11 (44)	18 (54.55)	< 0.0001
Previous cesarean delivery	57 (26.51)	2 (8)	3 (9.09)	0.0155
Artificial reproductive technique	31 (14.42)	5 (20)	3 (9.09)	0.4973
Hypertensive disorders ^a	12 (5.58)	0 (0)	1 (3.03)	0.4093
Diabetes mellitus ^b	20 (9.3)	3 (12)	1 (3.03)	0.4154
Gestational age at cerclage (weeks)	13 (11–19)	17 (11–24)	22 (14–22)	< 0.0001
Placenta previa	2 (0.93)	0 (0)	0 (0)	0.7620

Values are presented as median (range) for continuous variable, and as n (%) for categorical variables

Statistically significant p values are in bold ($p < 0.05$)

^aHypertensive disorders—any of chronic hypertension (HTN), gestational HTN (PIH), preeclampsia or eclampsia;

^bDiabetes mellitus including: gestational and pre gestational diabetes mellitus

cerclage group ($p < 0.001$). The previous cesarean delivery frequencies were higher in the history-indicated cerclage group compared to ultrasound and physical examination-indicated cerclage groups (26.5% vs. 8 and 9.1%, respectively, $p = 0.0155$). Other demographic and obstetric characteristics such as diabetes mellitus and hypertensive disorders were similar between groups.

Preterm premature rupture of membranes rate associated with cerclage placement was very low. We identified a single case of preterm premature rupture of membranes related to physical examination-indicated cerclage, which resulted in preterm delivery at 22 weeks.

Birth characteristics of the study groups are presented in Table 2. Regarding primary outcome, women in the physical examination-indicated cerclage group delivered earlier compared to women in the history and ultrasound-indicated cerclage groups (34 + 3 weeks vs. 37 + 3 weeks, respectively, $p = 0.01$). This difference remained significant at the multivariate analysis after adjustment to potential confounders as elaborated in “Methods” ($p < 0.0001$). When stratified according to gestational week at delivery, we found only 2 cases of delivery before 24 weeks of gestation: one in the history-indicated cerclage and another

in the physical examination-indicated cerclage (0.47% and 3.03% of those groups, respectively, $p = 0.247$). Physical examination-indicated cerclage cases demonstrated high rates of preterm delivery before 28, 32, 34, and 37 weeks of gestation (21%, 33.33%, 33.3%, and 60.61%, respectively). For each of these gestational weeks, preterm delivery rates were significantly higher in the physical examination-indicated group compared to both history and ultrasound-indicated cerclage groups (Table 2). Figure 1 presents Kaplan–Meier survival curve for all three indications for cerclage, illustrating the lower rates of pregnancy prolongation in the physical examination-indicated cerclage at each gestational age. Birth weight was lower in the physical examination-indicated cerclage group, compared to history-indicated and ultrasound-indicated cerclage groups (2435 g in group C compared to 2880 g and 2842 g in groups A and B accordingly, $p < 0.001$). Mode of delivery and indication for cesarean delivery did not differ between groups. Nor were there differences in the rates of labor induction and epidural analgesia between the study groups. The cervical tear rate, a known complication of the cerclage procedure, was also similar between the groups.

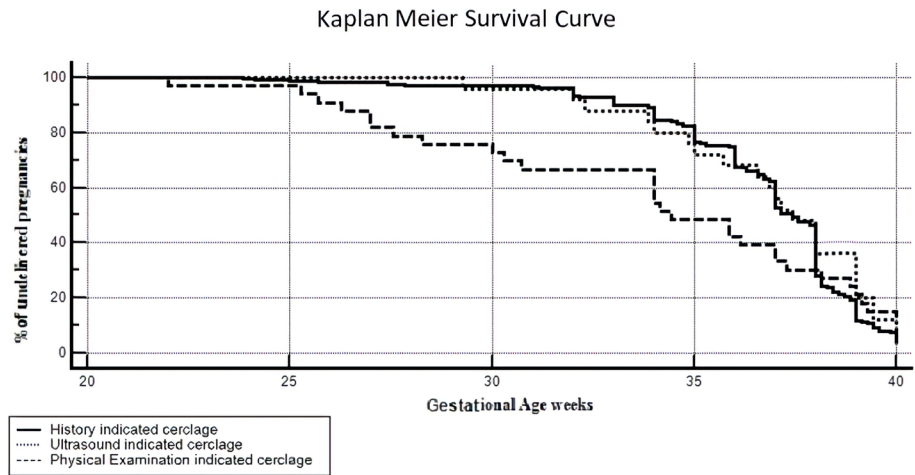
Table 2 Birth characteristics for the study groups

	History-indicated cerclage ($N = 215$)	Ultrasound-indicated cerclage ($N = 25$)	Physical examination- indicated cerclage ($N = 33$)	p value
Gestational age at delivery (weeks + days)	37 + 3 (23 + 6 – 41 + 5)	37 + 3 (29 + 2 – 41 + 0)	34 + 3 (22 + 0 – 40 + 3)	< 0.0001
Gestational age < 24 weeks	1 (0.47)	0 (0)	1 (3.03)	0.2476
Gestational age < 28 weeks	6 (2.79)	0 (0)	7 (21.21)	< 0.0001
Gestational age < 32 weeks	8 (3.72)	1 (4)	11 (33.33)	< 0.0001
Gestational age < 34 weeks	23 (10.7)	4 (16)	11 (33.33)	0.0021
Gestational age < 37 weeks	81 (37.67)	10 (40)	20 (60.61)	0.0442
Cesarean delivery	109 (50.70)	11 (44.00)	12 (36.36)	0.1554
Epidural analgesia	86 (40)	10 (40.00)	17 (51.52)	0.4525
Birth weight (g)	2880 (500–4250)	2842 (1040–3698)	2435 (502–3965)	0.0002
Male neonate	103 (47.91)	14 (56)	19 (57.58)	0.4746
Induction of labor	16 (7.44)	1 (4.00)	6 (18.18)	0.1991
Cervical tear	6 (2.79)	1 (4)	1 (3.03)	0.9434
Intrapartum fever	3 (1.4)	0 (0)	1 (3.03)	0.6253
Chorioamnionitis	2 (0.93)	0 (0)	0 (0)	0.7620
Placental abruption	3 (1.4)	1 (4)	2 (6.06)	0.1908
Rectovaginal group B streptococcus	5 (2.33)	0 (0)	0 (0)	0.5031
Indication for cesarean delivery				
Non reassuring fetal heart rate	5 (2.33)	1 (4.00)	2 (6.06)	0.6741
Other ^a	27 (12.56)	1 (4.00)	5 (15.15)	0.6741
Previous cesarean delivery	47 (21.86)	3 (12.00)	4 (12.12)	0.6741
Breech presentation	14 (6.51)	3 (12.00)	3 (9.09)	0.6741

Values are presented as median (range) for continuous variable, and as n (%) for categorical variables

Statistically significant p values are in bold ($p < 0.05$)

^aOther—any of: chorioamnionitis, placental abruption, fetal growth retardation, placenta previa

Fig. 1 Kaplan–Meier survival curve for all three indications**Table 3** Neonatal outcomes

	History-indicated cerclage (N=215)	Ultrasound-indicated cerclage (N=25)	Physical examination-indicated cerclage (N=33)	p value
5 min Apgar score <7	5 (2.33)	1 (4)	2 (6.06)	0.4279
Umbilical cord pH	7.37 (7.08–7.47)	7.35 (7.3–7.4)	7.35 (7.16–7.62)	0.9872
Neonatal intensive care unit	36 (16.74)	4 (16)	10 (30.30)	0.1641
Hyperbilirubinemia	31 (14.42)	4 (16)	7 (21.21)	0.5998
Phototherapy	15 (6.98)	2 (8)	4 (12.12)	0.5857
Intra ventricular hemorrhage	3 (1.40)	2 (8)	3 (9.09)	0.0147
Transient tachypnea of the newborn	5 (2.33)	0 (0)	0 (0)	0.5031
Respiratory distress syndrome	10 (4.65)	2 (8)	4 (12.12)	0.2100
Sepsis	13 (6.05)	0 (0)	4 (12.12)	0.1624
Necrotizing entero-colitis	1 (0.47)	1 (4)	3 (9.09)	0.0019
Retinopathy	0 (0)	0 (0)	2 (6.06)	0.0007
Hypoglycemia	2 (0.93)	0 (0)	0 (0)	0.7620
Respiratory Composite outcome ^a	19 (8.84)	2 (8)	6 (18.18)	0.2330
Neonatal composite outcome ^b	15 (19)	1.8 (20)	4.4 (36.4)	0.0921

Values are presented as median (range) for continuous variable, and as *n* (%) for categorical variables

Statistically significant *p* values are in bold ($p < 0.05$)

^aRespiratory composite outcome—any of: Transient tachypnea of the newborn, Respiratory distress syndrome, Mechanical ventilation, Meco-nium aspiration syndrome

^bNeonatal composite outcome—any of: Apgar at 5 min <7, Umbilical cord pH <7.1, Neonatal intensive care unit admission, Respiratory composite outcome, Hypoglycemia, Sepsis, Acidosis, Hypoxic ischemic encephalopathy, Intra ventricular hemorrhage, and Necrotizing entero-colitis

Bivariate analysis of individual and composite neonatal outcomes is presented in Table 3.

Regarding secondary outcome, the main differences in neonatal outcomes between the three groups were higher rates of intra ventricular hemorrhage (9.1% in group C vs. 1.4% and 8% in groups A and B, respectively, $p=0.015$); necrotizing enterocolitis (9.1% in group C vs. 0.5% and 4% in groups A and B, respectively, $p=0.002$); and retinopathy (6.1% in group C vs. none in groups A and B, $p<0.001$) in the physical examination-indicated cerclage subgroup. Both respiratory and neonatal composite outcomes were more

frequent in the physical examination-indicated cerclage, but failed to reach statistical significance when compared to others (Table 3).

Discussion

In the current study, we aimed to investigate obstetric and neonatal outcome in pregnancies requiring cervical cerclage, stratified according to cerclage indication. Our results demonstrate that in pregnancies complicated by physical

examination-indicated cerclage, the procedures prolong gestation to a median of 34 + 3 weeks. Women who underwent physical examination-indicated cerclage demonstrated significantly higher rates of preterm delivery all over and in specific gestational age at delivery increments (< 28, < 32, < 34 and < 37 weeks of gestation) when compared to history or ultrasound-indicated cerclage. Moreover, physical examination-indicated cerclage cases were associated with higher frequencies of neonatal complications (i.e., respiratory morbidity, intraventricular hemorrhage, necrotizing enterocolitis, and retinopathy).

The indications for cerclage can be regarded as primary, secondary, and tertiary preventions of preterm births. Primary prevention aims to reduce the incidence of the disease by intervening before it occurs. History-indicated cerclage is analogous to primary prevention, as it means identifying pregnancies that are at high risk for cervical insufficiency and intervening to prevent that injury before it even occurs during early pregnancy stages. Secondary prevention aims to detect and intervene, while the disease is present in its early stages, before it fully develops. Ultrasound-indicated cerclage is analogous to secondary prevention, as it aims to reduce the impact of the cervical shortening that has already occurred and to halt its progress. Finally, tertiary prevention aims to reduce the long-term effects of the disease. Physical examination-indicated cerclage is analogous to tertiary prevention, as it aims to soften the impact of an ongoing injury, thus enabling an improved neonatal outcome compared to non-intervention.

The median gestational age at cerclage indicated by history in our study was 13 weeks, as it was done for primary prevention on early pregnancy stage. As expected, other indications for cerclage resulted in placement later during pregnancy: 17 weeks in ultrasound-indicated cerclage group and 22 weeks in physical examination-indicated cerclage group.

The impact of history-indicated cerclage on pregnancy outcome and neonatal complications has been previously studied. Several studies have shown its efficacy in prevention of preterm births and reduction in perinatal morbidity and mortality [12–14]. The largest randomized trial has shown a reduction in preterm births < 33 weeks only in a very high-risk group with at least three prior preterm births [15]. Other case series have shown an increase in the mean perinatal survival rate from 27% before and 74% after McDonald cerclage [16]. Our study demonstrated good pregnancy outcome in women who underwent history-indicated cerclage. Our protocol for placing this suture is somewhat less strict than in the above-mentioned trials, but in accordance with international guidelines [17], women in this subgroup had naturally higher gravidity, parity and delivered at a median gestational age of 37 + 3 weeks, neonatal outcomes were overall satisfactory.

Vast variation regarding outcomes of pregnancies complicated by ultrasound-indicated cerclage exists in the literature [18–22]. Good body of evidence shows that in women who had one prior preterm birth in addition to cervical shortening on ultrasound examination, there was a significant decrease in pre-viable births before 24 weeks, perinatal mortality, and births before 37 weeks, following cerclage placement [22]. In our study, we presented a small group of women treated with cerclage indicated by ultrasound. These women were chosen both for cerclage placement and study inclusion by strict criteria of both cervical shortening and prior preterm birth or late abortion as elaborated in “[Material and methods](#)”. In this selected group of women, we found good pregnancy outcomes comparable to available literature. Our findings add power to the previous studies and conclude that in a selected group of patients ultrasound-indicated cerclage should be considered as a treatment for preterm birth prevention associated with good outcomes.

Physical examination-indicated cerclage, also referred as emergent or heroic cerclage, is an uncommon intervention, which resides far from current clinical consensus. The main concern of those opposing this procedure is that it may cause prolongation of gestation only to result in an extremely premature delivery. In a historical cohort comprised of 225 women between 14 and 25 + 6 weeks of gestation, 152 received a physical examination-indicated cerclage and 73 were managed expectantly. Physical examination based cerclage was associated with longer interval from presentation until delivery, improved neonatal survival, birth weight greater than 1500 g and preterm birth less than 28 weeks compared with expectant management [10]. A recent meta-analysis reviewing small studies of women who underwent physical examination-indicated cerclage during mid-trimester demonstrated a significant increase in pregnancy prolongation: 57 days latency from cerclage to delivery. The mean gestational age at delivery was 30.6 weeks with cerclage and 25.2 weeks with expectant management [23]. In our study, we found a longer pregnancy prolongation of 87 days latency from cerclage placement to delivery and a median gestational age at delivery of 34 + 3 weeks.

The higher neonatal complication rate found in this group of women can be explained by the lower gestational age at delivery. Our findings empower the legitimacy of cerclage in women with mid-trimester cervical dilatation and demonstrate surprisingly good outcomes given meticulous patient selection and very well trained destined personnel. Moreover, we suggest that timely placement of cerclage, in elective or sonographic circumstances, is a better option than expectant management if there is possibility of “deterioration” to heroic circumstances.

The limitations of this study derive mainly from its retrospective nature. The sample size of the study group was relatively small due to the rarity of these events. We lacked

appropriate control group of expectant management and thus were unable to determine the number-needed-to-treat to prevent preterm birth with either cerclage indication. Moreover, by comparing the three discussed types for cerclage, we not only compare the different indications that present different anticipated risk of preterm birth, but impose an inherent bias, since the intervention was taken in different gestational week. Having said that existing literature show improved outcome with cerclage in the correct indications; hence, it might be ethically challenging to match control groups of conservative management for each of the subgroups that we investigated.

In conclusion, our study provides important information that may help caregivers counsel patients about expected pregnancy outcome in candidates for such procedure. Data from our present study indicate that in a selected group of women with cervical insufficiency treated with cervical cerclage, pregnancy outcomes were reassuring. Physical examination indicated cerclage in a specific and selected population conducted by well-trained physicians is associated with good pregnancy outcomes.

Author contributions EK and EH contributed to all process of submission from the preliminary hypothesis, data collection, data analysis, and manuscript writing. SD-G and AG contributed to data collection and analysis. KT-G and AW took part in the project development and manuscript writing and drafts editing.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Human and animal rights This article does not contain any studies with animals performed by any of the authors. The Rabin Medical Center institutional review board approved the study (0697–16-RMC), with waiver of informed consent due to the retrospective, observational design of the study.

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