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COMPARISON OF PERINATAL OUTCOMES OF CERVICAL CERCLAGE PROCEDURES ACCORDING TO INDICATIONS, A RETROSPECTIVE COHORT STUDY

ENDİKASYONLARA GÖRE SERVİKAL SERKLAJ İŞLEMLERİNİN PERİNATAL SONUÇLARININ KARŞILAŞTIRILMASI: RETROSPEKTİF KOHORT ÇALIŞMASI

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ABSTRACT

Introduction: Cervical insufficiency and its complications of prematurity and fetal loss are still one of the major problems of obstetrics. Cerclage operation is an intervention with proven efficacy for the prevention of cervical insufficiency. The aim of this study was to compare the cerclage groups in terms of perinatal outcomes by forming homogeneous groups according to cerclage indication and duration of application and to develop new approaches for the prevention of prematurity and related complications in the light of the findings obtained.

Method: This was a retrospective cohort study in a single center. A total of 61 patients who underwent cervical cerclage operation between January 2021 and August were divided into three homogeneous groups according to the indications and timing of surgery: The history-indicated cerclage group was performed in the early midtrimester between 12-18 weeks and the ultrasound-indicated and the physical examination-indicated cerclage groups were performed in the late midtrimester between 18-27+6 weeks and these three groups were compared in terms of perinatal outcomes.

Results: As a result of our study, although adverse perinatal outcomes were observed more frequently as we progressed from the history-indicated cerclage group to the ultrasound-indicated and then to the physical examination-indicated cerclage groups, perinatal outcomes were statistically similar for all three groups.

Conclusion: Ultrasound and physical examination-indicated cerclages performed in the late midtrimester are efforts to prevent cervical insufficiency and its complications of pregnancy loss and prematurity, and in selected cases have the similar perinatal outcomes as history-indicated cerclage performed in the early midtrimester.

Keywords: Cervical insufficiency; Late midtrimester cerclage; Prematurity; Pregnancy loss.

ÖZET

Giriş: Servikal yetmezlik ve bunun erken doğum ve fetal kayıp gibi komplikasyonları, obstetrikte hala en önemli sorunlardan biridir. Serklaj operasyonu, servikal yetmezliğin önlenmesinde etkinliği kanıtlanmış bir müdahaledir. Bu çalışmanın amacı, serklaj endikasyonu ve uygulama süresine göre homojen gruplar oluşturarak serklaj gruplarını perinatal sonuçlar açısından karşılaştırmak ve elde edilen bulgular ışığında prematüre doğum ve ilgili komplikasyonların önlenmesine yönelik yeni yaklaşımlar geliştirmektir.

Yöntem: Bu çalışma, tek merkezli retrospektif bir kohort çalışmasıdır. Ocak 2021 ile Ağustos arasında servikal serklaj operasyonu geçiren toplam 61 hasta, endikasyon ve ameliyat zamanlamasına göre üç homojen gruba ayrılmıştır: Öyküye dayalı serklaj grubu 12-18. haftalar arasında erken orta trimesterde, ultrasona dayalı ve fizik muayeneye dayalı serklaj grupları ise 18-27+6. haftalar arasında geç orta trimesterde gerçekleştirildi ve bu üç grup perinatal sonuçlar açısından karşılaştırıldı.

Bulgular: Çalışmamızın sonucunda, öyküye dayalı serklaj grubundan ultrasona dayalı ve ardından fizik muayeneye dayalı serklaj gruplarına doğru ilerledikçe olumsuz perinatal sonuçlar daha sık gözlemlense de, perinatal sonuçlar üç grup için de istatistiksel olarak benzerdi.

Sonuç: Gebeliğin ikinci yarısının sonlarında yapılan ultrason ve fizik muayene ile belirlenen serklajlar, servikal yetmezliği ve bunun gebelik kaybı ve prematüre doğum gibi komplikasyonlarını önlemeye yönelik çabalar olup, seçilmiş vakalarda gebeliğin ikinci yarısının başlarında yapılan tıbbi öyküye dayalı serklajlarla benzer perinatal sonuçlar vermektedir.

Anahtar kelimeler: Servikal yetmezlik; Geç orta trimester serklaj; Prematürite; Gebelik kaybı.

INTRODUCTION

Preterm birth, defined as delivery before 37+0 weeks of gestation, remains one of the leading causes of neonatal mortality and morbidity (1). Cervical insufficiency, the inability of the uterine cervix to maintain pregnancy during the second trimester, is a significant contributor to preterm labor (2). Cervical cerclage, a surgical suture technique applied to the cervix, is considered the most effective intervention for preventing preterm birth due to cervical insufficiency and is typically performed in select cases [1,3].

Indications for cervical cerclage in singleton pregnancies are divided into three groups: history-indicated cerclage, physical examination-indicated cerclage, and ultrasound-indicated cerclage (4).

History-indicated cerclage is performed in patients with a history of unexplained second-trimester pregnancy loss due to painless cervical dilatation, in the absence of predisposing factors such as labor or abruptio placentae. It is also indicated for patients with a previous pregnancy involving painless second-trimester cervical dilatation. This procedure is typically carried out between 12 and 14 weeks of gestation and is also referred to as prophylactic or elective cerclage (4-6).

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Physical examination-indicated cerclage is performed in cases of painless advanced cervical dilation in the absence of predisposing factors such as labor or placental abruption. Preoperative clinical examination should exclude uterine activity, intraamniotic infection, or both. When technically feasible, singleton pregnancies with internal cervical changes may benefit from cervical cerclage (4). This procedure, commonly referred to as emergency cerclage, is typically performed between 16 and 23 weeks of gestation (3) and can be considered up to 27 weeks and 6 days of gestation (1). Both history-indicated cerclage and physical examination-indicated cerclage meet the diagnostic criteria for cervical insufficiency (7).

Ultrasound-indicated cerclage is performed in singleton pregnancies with a cervical length of less than 25 mm before 24 weeks of gestation during the second trimester and a history of spontaneous preterm delivery before 34 weeks in a prior pregnancy (4). Although this condition does not meet the diagnostic criteria for cervical insufficiency, evidence suggests that cerclage reduces preterm delivery rates and improves neonatal morbidity and mortality (4,6). This procedure is typically performed between 16 and 23 weeks of gestation (3).

Although the choice of cerclage material and specific surgical technique is at the surgeon's discretion, the transvaginal McDonald and Shirodkar techniques are generally preferred and yield similar outcomes. Ease of application is the primary determining factor (8). Transabdominal cervicoisthmic cerclage is recommended in special cases, such as patients who have undergone trachelectomy or experienced previous failed transcervical cerclage procedures. This procedure may also be performed before pregnancy or laparoscopically, though no evidence suggests superiority in timing or technique (4). Cerclage removal is typically performed electively between 36 and 38 weeks of gestation unless adverse conditions, such as premature rupture of membranes, labor, or chorioamnionitis, arise (9,10).

The timing of cervical cerclage has been categorized in studies as early mid-trimester cerclage, performed between 12 and 18 weeks of gestation, and late mid-trimester cerclage, performed between 18 and 27 weeks of gestation. Late mid-trimester cerclage is less commonly performed in clinical practice, and its efficacy remains controversial. However, the morbidity and mortality associated with prematurity have prompted increased research into the use of late mid-trimester cerclage (5,7).

The aim of this study was to compare perinatal outcomes among cerclage groups by forming homogeneous groups based on the indication for cerclage and the timing of its application. The findings were used to propose new approaches for preventing prematurity and its associated complications.

METHODS:

This study was designed as a retrospective cohort study involving patients who underwent cerclage procedures at the Perinatology Clinic of Eskişehir City Hospital, Ministry of Health, Republic of Turkey, a tertiary care center, between January 2021 and August 2024. Informed consent was obtained from all patients before the procedure, and the cerclage operations were performed by two experienced maternal-fetal medicine specialists. The study included only singleton pregnancies, and cerclage procedures were performed between 12 and 27+6 weeks of gestation in accordance with the guidelines of RCOG (2022), ISUOG (2022), and ACOG (2014) (1,2,4).

A total of 61 cases underwent cerclage using the McDonald technique with prolene suture material (11). Patients were divided into three homogeneous groups based on the timing and indications for the cerclage. In this study, the indications for all cerclage operations performed between 12–18 weeks were history-indicated cerclage and the indications for all cerclage operations performed between 18–27 weeks were ultrasound-indicated cerclage and physical examination-indicated cerclage.

In all three groups, cerclage was not performed in the presence of clinical or laboratory signs of intrauterine infection, ultrasonographic signs of intrauterine inflammation (e.g., amniotic sludge or separation of membranes from the decidua), multiple gestation, uterine anomalies, fetal anomalies, bleeding, cervical dilation exceeding 4 cm, or active labor. In the history-indicated and ultrasound-indicated cerclage groups, the procedure was delayed until after the resolution of vaginitis or cervicitis if such infections were present. Before undergoing the cerclage procedure, all patients were observed for 24 hours to rule out preterm labor, preterm prelabor rupture of membranes (PPROM), occult placental abruption, and intraamniotic infection. All patients received prophylactic antibiotics (ampicillin 1 g intravenously every 6 hours for 24 hours, followed by oral amoxicillin 500 mg every 8 hours for 5 days) and indomethacin tocolysis (25 mg orally every 8 hours for 48 hours) according to our institutional protocol, consistent with current guideline recommendations. In addition, daily vaginal progesterone support was administered preoperatively and postoperatively in all cases.

One week postoperatively, the cervix was evaluated for necrosis. Maternal and fetal well-being were closely monitored throughout the pregnancy, and in the absence of obstetric complications such as PPROM or preterm labor, cerclage removal was scheduled at 37 weeks of gestation.

Maternal general, demographic, and obstetric information, along with fetal and neonatal data, were retrieved from the medical records maintained by the data processing center of the Turkish Republic Ministry of Health Eskişehir City Hospital. The history-indicated, ultrasound-indicated, and physical examination-indicated cerclage groups were compared in terms of maternal age, body mass index (BMI), gravidity, parity, number of previous miscarriages, gestational age at the time of cerclage, cervical length, cervical dilation, gestational age at cerclage removal, gestational age at birth, neonatal birth weight, 1-minute and 5-minute Apgar scores, latency period (time between cerclage placement and delivery), history of previous live births, post-cerclage miscarriage, delivery before 37 weeks, delivery before 34 weeks, cesarean section rate, neonatal intensive care unit (NICU) admission, and incidence of chorioamnionitis.

Data analysis was conducted using IBM SPSS Statistics (Version 22). The Kolmogorov-Smirnov test and visual inspection of histograms were used to assess the normality of data distribution. Since the data were not normally distributed, continuous variables were presented as medians and interquartile ranges (IQR), while categorical variables were expressed as numbers and percentages. The Kruskal-Wallis test was employed to compare median values across groups, with pairwise comparisons conducted using the Mann-Whitney U test. Categorical variables were compared using the chi-square test. A multivariate logistic

Table 1: Comparison of demographic features, clinical characteristics and perinatal outcomes between the study groups.

Variables	**History-indicated cerclage (n=28)**	**Ultrasound- indicated cerclage (n=21)**	**Physical examination-indicated cerclage (n=12)**	***P-value***
Maternal age (years) (median, IQR)	29 (7.75)	28 (9)	27.5 (6.5)	0.17
BMI (median, IQR)	26.9 (5.4)	27.4 (7.6)	26.9 (9.1)	0.61
Gravidity (median, IQR)	3 (2)	2 (2)	1 (1.75)	**0.02**
Parity (median, IQR)	0.5 (1)	1 (1)	0 (0)	**0.003**
Number of previous miscarriages (median, IQR)	1 (1)	0 (0.5)	0 (1.75)	0.42
Gestational age at cerclage operation (weeks)(median, IQR)	14 (2.75)	22 (6.75)	22.5 (5.5)	**<0.001**
Cx length(mm),(median,IQR)	36 (2)	19 (14)	5 (4.75)	**<0.001**
Cervical dilatation (cm) (median, IQR)	0 (0)	0 (1)	3 (1)	**<0.001**
Gestational age at cerclage extraction (weeks) (median, IQR)	37 (0.75)	37 (1.5)	37 (7.25)	0.47
Gestational age at birth (weeks) (median, IQR)	38 (1)	37 (2)	37 (8.25)	0.25
Birthweight (g) (median, IQR)	3100 (745)	2950 (805)	2735 (1816.25)	0.09
Apgar 1st minute (median, IQR)	8 (1)	8 (1)	8 (2.5)	0.07
Apgar 5th minute (median, IQR)	9 (1)	9 (1)	9 (2.25)	**0.01**
Latency period (weeks) (median, IQR)	23 (3)	13 (6)	11.5 (5.5)	**<0.001**
Preivous livebirth (n, %)				**0.001**
None	10 (35.7%)	12 (57.1%)	12 (100%)	
Vaginal delivery	7 (25%)	7 (33.3%)	0 (0%)	
Cesarean section	11 (39.3%)	2 (9.5%)	0 (0%)	
Post-cerclage miscarriage (n, %)	0 (0%)	1 (4.8%)	1 (8.3%)	0.35
Delivery <37th weeks of gestation (n,%)	6 (21.4%)	8 (38.1%)	5 (41.7%)	0.31
Delivery <34th weeks of gestation (n,%)	2 (7.1%)	3 (14.3%)	4 (33.3%)	0.10
Cesarean section rate (n, %)	19 (67.9%)	10 (47.6%)	5 (41.7%)	0.20
NICU admission (n,%)	4 (14.3%)	3 (14.3%)	5 (41.7%)	0.10

Abb. BMI: Body mass index, IQR: Inter quartile range, NICU: Neonatal intensive care unit

Table 2: Multivariate regression analysis evaluating the independant determinants of delivery >34th weeks of gestation.

Variable	OR	95% CI	P-value
Maternal age	0.99	0.82 – 1.19	0.93
Parity	0.45	0.06 – 3.30	0.43
Previous live birth	3.53*	0.94 – 6.10*	0.06
Gestational age at cerclage	0.61	0.38 – 0.98	0.04
Cerclage group	15.36	0.33 – 71.33	0.16
Cervical length	0.85	0.64 – 1.14	0.28
Cervical dilatation	0.49	0.13 – 1.81	0.29
BMI	1.06	0.88 – 1.27	0.49

Abb. BMI: Body mass index, CI: Confidence interval, OR: Odds ratio

regression analysis was performed to identify independent determinants of delivery before 34 weeks of gestation. Statistical significance was set at p<0.05.

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Committee of the Republic of Turkey Ministry of Health, Eskişehir City Hospital (approval date: October 22, 2024; decision number: ESH/BAEK 2024/62).

RESULTS:

A comparison of demographic features, clinical characteristics and perinatal outcomes between the study groups is presented in Table 1.

Of the 12 patients who underwent physical examination-indicated cerclage, 11 were nulliparous, while the remaining patient had a history of early abortion but no previous live births. Consequently, gravida and parity were significantly lower in the physical examination-indicated cerclage group compared to the other two groups (P = 0.002 and P = 0.003, respectively). Cerclage was performed at significantly later gestational ages in the ultrasound-indicated and physical examination-indicated cerclage groups compared to the history-indicated cerclage group (P < 0.001).

As we moved from the history-indicated cerclage group to the ultrasound-indicated and physical examination-indicated cerclage groups, cervical length was significantly shorter (P < 0.001), while cervical dilation was significantly greater (P < 0.001). The median gestational age at cerclage removal was 37 weeks across all three groups, with no significant difference (P = 0.47). Regarding gestational age at birth, the median value was 38 weeks in the history-indicated cerclage group and 37 weeks in both the ultrasound-indicated and physical examination-indicated cerclage groups, with no statistically significant difference (P = 0.25).

Although the median neonatal birth weight decreased as we progressed from the history-indicated to the ultrasound-indicated and physical examination-indicated cerclage groups, this decrease was not statistically significant (P = 0.09). The latency period (time from cerclage to delivery) was significantly longer in the history-indicated cerclage group compared to the ultrasound-indicated and physical examination-indicated cerclage groups (P < 0.001).

There were no significant differences in post-cerclage pregnancy loss, delivery before 37 weeks of gestation, or delivery before 34 weeks of gestation among the three groups (P = 0.35, P = 0.31, P = 0.1, respectively). However, in percentage terms, of the 28 patients in the history-indicated cerclage group, none (0%) experienced miscarriage, 2 (7.1%) delivered before 34 weeks, and 6 (21.4%) delivered before 37 weeks. In the ultrasound-indicated cerclage group, consisting of 21 patients, 1 (4.8%) experienced miscarriage, 3 (14.3%) delivered before 34 weeks, and 8 (38.1%) delivered before 37 weeks. In the physical examination-indicated cerclage group, comprising 12 patients, 1 (8.3%) experienced miscarriage, 4 (33.3%) delivered before 34 weeks, and 5 (41.7%) delivered before 37 weeks. Results related to 1st and 5th minute Apgar scores, cesarean section rates, and neonatal intensive care unit (NICU) admission rates were similar across all three groups. However, in terms of percentage, 4 out of 28 cases (14.3%) in the history-indicated cerclage group, 3 out of 21 cases (14.3%) in the ultrasound-indicated cerclage group, and 5 out of 12 cases (41.7%) in the physical examination-indicated cerclage group required NICU admission.

Infectious complications did not develop during follow-up in all three groups and no intraoperative or postoperative surgical complications were observed in any of the cases.

Multivariate regression analysis identified the independent main determinants of delivery after 34 weeks, as presented in Table 2. It was observed that only the timing of cerclage application was a significant determinant of delivery after 34 weeks. Maternal age, parity, previous live birth, cerclage group, cervical length, cervical dilation, and BMI did not significantly affect the timing of delivery beyond 34 weeks.

DISCUSSION

Results from this study indicate that, although adverse perinatal outcomes were more frequently observed as we progressed from the history-indicated cerclage group to the ultrasound-indicated and physical examination-indicated cerclage groups, perinatal outcomes were statistically similar across all three groups. We also found a longer latency period in the history-indicated cerclage group, suggesting that performing a cerclage operation in the absence of cervical involvement may prolong this period.

True cervical insufficiency affects 0.05–2% of the obstetric population and is a leading cause of midtrimester pregnancy loss and prematurity-related complications (9,12). Although cervical pessary has been suggested as a non-surgical option for managing cervical insufficiency, its effectiveness remains inconclusive due to limited and conflicting data. Further research is needed to establish the role of cervical pessaries in clinical guidelines for cervical insufficiency management (9,13).

Regarding the use of progesterone in the treatment of non-surgical cervical insufficiency, its role in preventing second-trimester pregnancy loss due to cervical insufficiency remains unclear. Therefore, routine use of progesterone is not recommended, and additional studies

are required (9,14). In contrast, cerclage is a surgical intervention with well-established efficacy in the treatment of cervical insufficiency (9,14).

Beyond 24 weeks, the use of emergency cerclage is limited due to technical challenges, the risk of concomitant chorioamnionitis, and the potential for iatrogenic preterm premature rupture of membranes (PPROM). Cervical dilation greater than 4 cm or prolapse of membranes is associated with a high risk of cerclage failure (1,4,6,15-17].

There are several strengths of the current study. A 2017 meta-analysis reported that the emergency cerclage group had a lower gestational age and birth weight at delivery, as well as more frequent occurrences of preterm premature rupture of membranes (PPROM), compared to the elective cerclage group. However, there was no difference between the two groups in terms of successful vaginal deliveries (18). In a study conducted by Chen et al., patients were divided into elective and emergency cerclage groups, which were then compared. However, we hypothesized that the ultrasound-indicated cerclage group and the physical examination-indicated cerclage group represented heterogeneous subgroups within the emergency cerclage category. To address this, we divided the emergency cerclage group into two more homogeneous groups: the ultrasound-indicated cerclage group and the physical examination-indicated cerclage group. As a result, we created three homogeneous groups: the history-indicated cerclage group, the ultrasound-indicated cerclage group, and the physical examination-indicated cerclage group.

Upon retrospectively analyzing our cases after categorizing the groups, we found that the history-indicated cerclage group was applied during the early midtrimester (12–18 weeks), whereas the ultrasound-indicated and physical examination-indicated cerclage groups were applied in the late midtrimester (18–27+6 weeks). We then compared these three groups in terms of perinatal outcomes. While perinatal outcomes worsened in percentage terms as we progressed from the history-indicated cerclage group to the ultrasound-indicated and physical examination-indicated cerclage groups, no statistically significant differences were observed.

The fact that this study was conducted at a single center, with patients divided into three homogeneous groups, may have influenced the differences observed compared to the study by Chen et al. Additionally, all cerclage procedures were performed by two experienced maternal-fetal medicine specialists. The history-indicated cerclage cases were performed between 12–18 weeks of gestation, while the ultrasound-indicated and physical examination-indicated cerclage cases were performed between 18–27+6 weeks. Furthermore, as detailed in the Materials and Methods section, we were highly selective in choosing patients for cerclage, which could have contributed to the observed differences.

In a 2018 study on late second-trimester cerclage involving a total of 30 cases, it was reported that this procedure was safe, with 90% of cases successfully delivering vaginally, and that it might be effective in prolonging pregnancy (5). However, unlike our study, Hagit et al. did not create an early cerclage group, did not categorize the late midtrimester cerclage groups based on their indications, nor did they compare these groups with each other.

We believe that the timing of cerclage in our study, performed between 12–18 weeks of gestation for patients with a history-indicated cerclage, aligns closely with existing literature. This may be due to obstetricians referring patients to us early, supported by thorough anamnesis (4). The fact that 11 of the 12 cases in the physical examination-indicated cerclage group had a gravida of 0 and only 1 case had a history of early abortion (indicating that no cases of missed history-indicated or ultrasound-indicated cerclage occurred) supports this assumption. Similarly, cerclage was performed between 18–27+6 weeks in the ultrasound-indicated and physical examination-indicated cerclage groups, which aligns with the literature (1). However, we believe that the ultrasound-indicated cerclage group could potentially be diagnosed and treated earlier. Our internal training in this regard is ongoing.

Despite these strengths, the retrospective design of our study and the small sample size are limitations. As such, future studies using a prospective design with increased sample sizes should be conducted to build on the results from this study.

CONCLUSION

Ultrasound and physical examination-indicated cerclages performed in the late midtrimester aim to prevent cervical insufficiency and its associated complications, such as pregnancy loss and prematurity. In select cases, these procedures yield perinatal outcomes similar to those of history-indicated cerclage performed in the early midtrimester. However, further research should be conducted to confirm these results, specifically utilizing prospective studies with larger sample sizes.

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Ethics Committee Approval: This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study protocol was approved by the Ethics Committee of the Republic of Turkey Ministry of Health, Eskişehir City Hospital (approval date: October 22, 2024; decision number: ESH/BAEK 2024/62).

Informed Consent: Informed consent was obtained from all patients before the procedure.

Authorship Contributions: MCK, ZB and EA collaborated on designing the study, collecting and analyzing the data, and writing the manuscript. MCK, ZB, BDY, EA, MS, EAS, HK contributed to designing the study, collecting data, and editing the manuscript. MCK, ZB and AT assisted with data analysis and interpretation. MCK, ZB, EA, BDY and AT provided critical feedback and made revisions to the manuscript. All authors reviewed and approved the final version of the manuscript for submission.

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