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Mid-trimester cerclage outcomes in singleton and twin pregnancies: a single tertiary center experience

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Abstract

Objective: The aim of this study was to evaluate the maternal and neonatal outcomes of patients who underwent ultrasonography (USG) and emergency-indicated cerclage in the mid-trimester in singleton and twin pregnancies.

Methods: A total of 55 patients, 43 with singleton and 12 with twin pregnancies who underwent cerclage for short cervix (<25 mm) or cervical dilation between January 2015 and December 2021 were included in the study. The primary outcome was gestational age at birth, and secondary outcomes were neonatal birth weight, the status of admission to neonatal intensive care unit, neonatal survival, and the neonatal birth rates at <24 weeks, 24–27^{+6} weeks, 28–33^{+6} weeks, 34–36^{+6} weeks and >37 weeks.

Results: In singleton pregnancies, delivery interval was 15.05 (±2.9) weeks in the USG indication group and 2.8 (±2.5) weeks in the emergency indication group (p<0.001). The rate of pregnant women in the USG indication group who gave birth between 24–27^{+6} weeks of gestation was 4.9% (n=2), and the rate of pregnant women in the emergency indication group was 55.6% (n=5) (p<0.001). In total, in singleton pregnancies the rate of take-home baby was 85.7%, and neonatal mortality was 14.3%. In twin pregnancies, delivery interval was 12±1.41 weeks in the USG indication group, and it was 1.8±0.83 weeks in the emergency indication group (p<0.003). In twin pregnancies, the take-home baby rate was 94% and neonatal mortality was 6%.

Conclusion: Cervical cerclage reduces the possible risks of preterm delivery by prolonging the interval until delivery, especially in patients with singleton and twin pregnancies for whom USG is indicated, and promising neonatal outcomes are achieved.

Keywords: Preterm birth, cervical cerclage, twin pregnancy, emergency cerclage, ultrasound indicated cerclage.

Introduction

Preterm birth is defined as birth before 37 weeks of gestation and is one of the leading causes of perinatal morbidity and mortality. Morbidity is inversely related to the week of gestation at birth, and the most critical adverse outcomes occur in births below 32 weeks.[1] A cervical length screening is a proven method to identify patients at risk of spontaneous preterm delivery. Cervical length values of 25 mm or less measured with transvaginal USG (ultrasonography) in the mid-trimester of pregnancy are considered as short cervix.[2–4]

Cerclage procedure is performed in cases with a gynecological or obstetric history of preterm birth risk (history indication), short cervix determined after ultrasonographic evaluation (USG indication), and in cases with cervical dilation (rescue indication) after the vaginal examination.[5] History-indicated cerclage is applied prophylactically in the first trimester of pregnancy to patients with a previous history of 3 or more preterm births and/or second-trimester pregnancy loss. Ultrasound-indicated cerclage is recommended for patients with a previous history of one or more preterm births and/or mid-trimester pregnancy loss and a cervical length of <25 mm on USG and is applied up to the 24 weeks of gestation. Emergency or rescue cerclage is recommended for pregnancies below the 24 weeks of gestation in the absence of apparent infection, inflammation, and active labor and in the presence of membrane prolapse from the

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dilated cervical canal.[5] Although there is not enough evidence to support the use of USG or history-indicated cerclage for multiple pregnancies, it is widely believed that cerclage can be beneficial in cases where the cervical length is <15 mm.[5]

Although cervical cerclage is mainly performed with the transvaginal approach, it can be applied in the cervicoisthmic region via the transabdominal route in patients who have a previous unsuccessful cervical cerclage history vaginally or who cannot be performed cerclage vaginally due to anatomical limitations (e.g., history of trachelectomy).[6]

The present study aimed to evaluate the maternal and neonatal outcomes of patients who underwent USG- and emergency-indicated cerclage in the mid-trimester in singleton and twin pregnancies.

Methods

Within the scope of this study, the records of a total of 67 singleton and twin pregnancies who underwent cerclage for short cervix (<25 mm) or cervical dilation between January 2015 and December 2021 in Necmettin Erbakan University Meram Medical Faculty Hospital Obstetrics and Gynecology Clinic were reviewed retrospectively. Ethics approval was obtained from the hospital ethics committee (2022/3637). Patients with preterm premature rupture of membranes (PPROM), vaginal bleeding, clinical chorioamnionitis, active uterine contraction, fetal anomaly or no fetal heartbeat, and patients with monochorionic monoamniotic twin pregnancy were not included. Twelve patients with ongoing pregnancies or whose neonatal results could not be reached were excluded. A total of 55 patients, 43 with singleton pregnancies and 12 with twin pregnancies, were included in the study. In the second trimester, patients with a history of preterm birth and/or second-trimester pregnancy loss and a cervical length of <25 mm by transvaginal USG were included in the USG-indicated group, and patients with a short cervix with accompanying cervical dilatation and/or membrane prolapse were included in the emergency (rescue) cerclage group.

Demographic (age, gravida, parity, previous abortion, preterm birth, previous cerclage history), obstetric (week of gestation at which cerclage was performed, presence of cervical length or cervical dilatation by transvaginal USG, complications such as chorioamnionitis or premature rupture of membranes occurring within three weeks after cerclage, the week of gestation at birth, type of delivery) and neonatal data (newborn birth weight, gender, Apgar score, neonatal intensive care unit (NICU) admission status) of the patients were accessed from the hospital's medical computer registry system. Neonatal outcomes were collected from the files registered in the hospital archive system and by contacting the patients by telephone. Gestational age (GA) was determined by first-trimester USG examination and measuring crown-rump length. Placental chorionicity in twin pregnancies was determined according to first-trimester USG records. PPROM was defined as the observation of active amniotic fluid on speculum examination or the positive detection of the AmniSure (QIAGEN Sciences, LLC, Germantown, MD, USA) test. The clinical diagnosis of chorioamnionitis was made based on the presence of at least one of the major criteria or at least two of the minor criteria. Major criteria: *(1)* Foul-smelling cervical discharge in speculum examination, *(2)* uterine tenderness. Minor criteria: *(1)* The maternal axillary temperature of ≥38ºC, *(2)* maternal tachycardia (≥100 bpm), *(3)* fetal tachycardia (≥160 bpm) and leukocytosis (≥15,000/mm^3).

The primary outcome was gestational age at birth, and secondary outcomes were neonatal birth weight, admission to NICU status, neonatal survival, and the neonatal birth rates at <24 weeks, 24–27^{+6} weeks, 28–33^{+6} weeks, 34–36^{+6} weeks, and >37 weeks. The cerclage procedure was performed vaginally in the lithotomy position under general anesthesia with the McDonald technique. No:5 Mersilene polyester tape (Ethicon, Inc., Raritan, NJ, USA) was used as the suture material. Before the procedure, the vagina was gently cleaned with povidone-iodine, and in the presence of prolapsed membrane, the membrane was pushed upwards from the cervical os with a sterile wet sponge or Foley catheter balloon (15–20 cc inflation). The Foley catheter was left in place until the end of the procedure to prevent membrane prolapse. A single dose of intravenous (iv) first-generation cephalosporin or clindamycin was administered to the patients before the procedure as a preoperative prophylactic in case of penicillin allergy. After the procedure, patients were given a single dose of 100 mg rectally and oral indomethacin 25 mg every 6 hours for 48 hours, and 200 mg/day of micronized progesterone vaginally until the 36th week of gestation. The patients were discharged 24–72 hours after the procedure. The patients were advised to rest and prohibited intercourse in the postoperative period. At the end of the first week

Table 1. Demographics of study population in singleton pregnancies.

Variable	USG indication cerclage group (n=34)	Emergency indication cerclage group (n=9)	p-value
Age (years)	33.2 (±6.2)	34.7 (±6.8)	0.394
Gravidity	3.88 (±1.8)	3.12 (±1.4)	0.153
Parity	1.58 (±0.9)	1.50 (±1.0)	0.604
Previous abortions	1.29 (±1.4)	0.62 (±0.7)	0.212

and first month postoperatively, a speculum examination was performed to exclude the presence of lower genital tract infection.

Routine transvaginal USG was not performed in the follow-ups. In case of active labor, chorioamnionitis, premature rupture of membranes, active vaginal bleeding, or intrauterine dead fetus, cerclage suture material was removed regardless of the week of gestation. In the absence of these conditions, the suture material was removed in the 36 weeks of gestation. In our clinic, dichorionic twin pregnancies are delivered at the 37–38 weeks of gestation and monochorionic twin pregnancies at the 36–37 weeks of gestation or earlier when indicated. All infants weighing over 500 g or 24 weeks of age (considered the limit of viability) were resuscitated by the neonatal team. Two doses of 12 mg betamethasone intramuscularly for fetal lung maturation for all pregnancies were considered viable 24 hours apart and for women with imminent preterm birth ($\leq 31^{+6}$ weeks), magnesium sulfate intravenous (IV) for fetal neuroprotection (4 g loading dose over 30 minutes, followed by 1 g/h maintenance infusion until birth) was applied.

The data were uploaded to SPSS v. 22 (Statistical Package for Social Sciences) (IBM Corp., Armonk, NY, USA) and analyzed in the computer environment. The conformity of the variables to the normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk tests). Comparison of groups was performed by Student's t-test for normally distributed numerical data and Mann-Whitney U test for non-normally distributed numerical data. Pearson's chi-square test and Fisher's exact test evaluated the categorical variables. A p-value <0.05 was considered statistically significant.

Ethics approval: For this study, permission was obtained from the ethics committee of Necmettin Erbakan University with the decision number 2022/3637 dated 04/02/2022.

Results

Of the 55 patients included in the study, 43 had singleton pregnancies, and 12 had twin pregnancies. Age, parity, gravida, and abortion histories of the patients who underwent cerclage with singleton pregnancies in the USG indication (n=34) and emergency indication (n=9) groups were similar, and there was no statistical difference between them (**Table 1**).

In singleton pregnancies, the week of gestation at cerclage was 19.05 (±2.9) weeks in the USG indication cerclage group and 21.8 (±2.4) weeks in the emergency indication cerclage group (p<0.001). The interval (time from cerclage week to delivery) was 15.05 (±2.9) weeks in the USG indication group and 2.88 (±2.5) weeks in the emergency indication group (p<0.001). The delivery types of the patients and the gender of the babies are summarized in **Table 2**. Week of birth, birth weight, and 1- and 5-minute APGAR scores were statistically significantly higher in the USG indication group, and the findings are presented in **Table 3**.

Considering the complications after the cerclage of the singleton pregnancies, complications occurred in

Table 2. Obstetric and neonatal outcomes in singleton pregnancies.

		n (%)
Mode of delivery (n=42)	Vaginal	27 (63)
	Cesarean section	15 (37)
Gender (n=42)	Male	20 (48)
	Female	22 (52)
Neonatal outcome (n=42)	Newborn with no illness	24 (57)
	NICU	16 (38)
	Stillbirth	2 (5)
Survival (n=56)	Take-home baby	36 (85.7)
	Neonatal death	6 (14.3)

All values are expressed as number (%). **NICU:** neonatal intensive care unit.

Table 3. Comparison of obstetric and neonatal outcomes in two groups in singleton pregnancies.

Variable	USG indication cerclage group (n=34)	Emergency indication cerclage group (n=9)	p-value
GA of cerclage (weeks)	19.05 (±2.9) (n=34)	21.88 (±2.4) (n=9)	0.012
Time interval between the cerclage and delivery (weeks)	15.05 (±5) (n=34)	2.88 (±2.5) (n=9)	0.000
GA at delivery (weeks)	34.11 (±4.9) (n=34)	24.55 (±1.8) (n=9)	0.000
Birth weight (gram)	2429 (±1000) (n=34)	801.2 (±155) (n=8)	0.000
1-minute Apgar score	6.1 (±1.8) (n=34)	2.5 (±1.6) (n=8)	0.000
5-minute Apgar score	7.8 (±2.1) (n=34)	4.2 (±2.3) (n=8)	0.003

The data are presented as mean± standard deviation. **GA:** gestational age.

8.8% of the patients with the USG indication, while it was 33.3% in the patients with the emergency indication (p<0.001). PPROM developed in 2 (22.2%) patients and spontaneous abortion in 1 (11.1%) patient who underwent cerclage for emergency indication (p<0.001). In the USG indication group, 3 (8.8%) chorioamnionitis cases were detected.

When the birth week was classified categorically in singleton pregnancies, the rate of delivery below 24 weeks was 5.9% (n=2) in the USG indication group, while it was 33.3% (n=2) in the emergency indication group (p<0.001). Again, the rate of pregnant women in the USG indication group who gave birth between 24–27^{+6} weeks of gestation was 4.9% (n=2), and this rate was 55.6% (n=5) in the emergency indication group (p<0.001). While the rate of patients who delivered over 37 weeks of gestation was 47.1% (n=16) in the USG indication group, this rate was 0% (n=0) in the emergency indication group (p<0.001). There was no statistically significant difference between the patients who gave birth at 28–33^{+6} and 34–36^{+6} weeks of gestation (**Table 4**).

Table 4. Complications and neonatal outcomes according to the groups in singleton pregnancies.

		USG indication cerclage group (n=34)	Emergency indication cerclage group (n=9)	p-value
Procedure related complications	No complication	31^{a} (91.2%)	6^{b} (66.7%)	<0.001
	Ruptured membranes	0^{a} (0%)	2^{b} (22.2%)	
	Spontaneous abortion	0^{a} (0%)	1^{b} (11.1%)	
	Chorioamnionitis	3^{a} (8.8%)	0^{a} (0%)	
Delivery weeks	<24 weeks	2^{a} (5.9%)	2^{b} (33.3%)	<0.001
	24–27^{+6} weeks	2^{a} (4.9%)	5^{b} (55.6%)	
	28–33^{+6} weeks	5^{a} (14.7%)	0^{a} (0%)	
	34–36^{+6} weeks	9^{a} (26.5%)	0^{a} (0%)	
	>37 weeks	16^{a} (47.1%)	0^{b} (0%)	
Birth weight (gram)	<1500	6^{a} (17.6%)	8^{b} (100%)	<0.001
	1500–2500	8^{a} (23.5%)	0^{b} (0%)	
	>2500	20^{a} (58.8%)	0^{b} (0%)	
Neonatal outcome	Newborn with no illness	24^{a} (70.6%)	0^{b} (0%)	0.001
	NICU admission	9^{a} (26.5%)	7^{b} (87.5%)	
	Stillbirth	1^{a} (2.9%)	1^{a} (12.5%)	
Survival	Take-home baby	31^{a} (91.2%)	5^{b} (62.5%)	0.037
	Neonatal death	3^{a} (8.8%)	3^{b} (37.5%)	

All values are expressed as number (%). The same letters on the same line indicate that there is no statistical difference between the two groups, and different letters indicate that there is a significant difference. **NICU:** neonatal intensive care unit.

Table 5. Obstetric outcomes of twin pregnancies.

Variable	USG indication cerclage group (n=7)	Emergency indication cerclage group (n=5)	p-value
GA of cerclage (weeks)	20.57±2.14	19.8±2.48	0.876
GA at delivery (weeks)	32.5±1.98	25.0±0.0	0.012
Time interval between the cerclage and delivery (weeks)	12±1.41	1.8±0.83	0.003

The data are presented as mean± standard deviation. **GA:** gestational age.

Considering their birth weight in singleton pregnancies, all newborns (n=8, 100%) born in the emergency indication group were <1500 g, and the rate of newborns (n=6) in this category in the USG indication group was 17.6% (p<0.001). There were 23.5% newborns in the 1500–2500 g category and 58.8% in the >2500 g category in the USG indication group, and the rate of newborns in these categories in the emergency indication group was 0% (p<0.001) (**Table 4**).

In terms of neonatal outcome in singleton pregnancies, more NICU admission rates (87.5% vs. 26.5%) were detected in the emergency indication group compared to the USG indication group, and the newborn with no illness ratio was higher in the USG group than in the emergency group (70.6% vs. 0%) (p<0.001).

The neonatal mortality rate in singleton pregnancies was 37.5% in the emergency indication group, which was 8.8% in the USG indication group (p=0.037). In total, the rate of take-home baby was 85.7%, and neonatal mortality was 14.3% (**Table 2**).

Considering the subgroup analysis of twin pregnancies, cerclage was performed in 58% (n=7) with USG indication and 42% (n=5) with emergency indication. The rate of spontaneous abortion as a complication was 33% (n=4), and all were in the emergency indication group. There was no difference between the groups in terms of cerclage week, and the week of delivery was higher in the USG indication group (32.5±1.8) than in the emergency indication group (25.0±0) (p<0.012). While the interval was 12±1.41 weeks in the USG indication group, it was 1.8±0.83 weeks in the emergency indication group (p<0.003). When the week of birth was examined categorically, 50% (n=4) of the deliveries were at 28–33^{+6} weeks, 38% (n=3) at 34–36^{+6} weeks, and 12% (n=1) at 24–27^{+6} weeks. As birth weight, 69% (n=11) of newborn twins were 1500–2500 g, 18% (n=3) were <1500 g, and only 13% (n=2) were >2500 g (**Tables 5** and **6**).

In twin pregnancies, there was NICU admission in 81%, and newborn with no illness rate was 19%. We determined the take-home baby rate as 94% and neonatal mortality as 6% (**Table 6**).

Discussion

The present study revealed that cervical cerclage applied in patients with a history of preterm birth or second-trimester abortion in a previous pregnancy and short cervical length in transvaginal ultrasonography (TvUSG) was more successful in prolonging the gestational period compared to the group in which cervical dilation was detected and then cerclage was applied. Likewise, perinatal and neonatal outcomes in the group with a short cervix in twin pregnancies were more satisfactory than in the emergency cerclage group.

Table 6. Perinatal and neonatal outcomes of twin pregnancies.

		n (%)
Cerclage indication	USG	7 (58%)
	Emergency	5 (42%)
Procedure related complication	Spontaneous abortions	4 (33%)
Delivery (n=8)	24–27^{+6} weeks	1 (12%)
	28–33^{+6} weeks	4 (50%)
	34–36^{+6} weeks	3 (38%)
Birth weight (g) (n=16)	<1500	3 (18%)
	1500–2500	11 (69%)
	>2500	2 (13%)
Neonatal outcome (n=16)	Newborn with no illness	3 (19%)
	NICU admission	13 (81%)
	Stillbirth	0 (0%)
Survival	Take-home baby	15 (94%)
	Neonatal death	1 (6%)

All values are expressed as number (%). **NICU:** neonatal intensive care unit.

Wang et al., in their study on singleton pregnancies, indicated that the degree of cervical length and perinatal outcomes were inversely related, and especially those with a cervical length of 25–30 mm had better results.[7] Many studies have been published in recent years evaluating the efficacy, perinatal outcomes, and complications of cerclage with emergency and USG indications.[4,8–11] However, the number of randomized controlled studies with large samples evaluating the effectiveness of emergency cerclage in singleton and especially twin pregnancies is limited.[12–14] Ciavattini et al. reported that emergency cerclage had worse pregnancy outcomes than elective cerclage performed in early pregnancy, but it was superior to the conservative method alone. The results were better, especially in the group with cervical dilatation of less than 5 cm.[15] Emergency cerclage is associated with a poor outcome, especially if cervical dilatation is 4 cm or more and a bulging membrane.[16] In our study, the delivery interval in singleton pregnancies was 15 weeks in the USG-indicated group and 2.8 weeks in the emergency-indicated group, and we found the mean delivery week 34 weeks in the USG-indicated group and 24.5 weeks in the emergency-indicated group. Our study determined the take-home baby rate in singleton pregnancies 91.2% in the USG-indicated group, 62.5% in the emergency-indicated group and 83.7% overall.

A previous report stated that USG-indicated cerclage emerged to avoid unnecessary history-indicated cerclage.[17] The retrospective study on a large sample by Seyama et al. demonstrated that cerclage with history and USG indications did not prevent preterm birth compared to the control group. In contrast, cerclage with physical examination indication significantly reduced the risk of preterm birth in each pregnancy period. They even stated that USG-indicated cerclage might contribute to preterm deliveries under 31 weeks. The reason for the result being this way in the study of Seyama et al. can be explained by both the sample size and the non-cerclage group nature of the control groups.[11] Our study revealed a significant increase in deliveries under 24 and 28 weeks in the emergency indication group in singleton pregnancies compared to the USG-indicated group (33.3% vs. 5.9%, 55.6% vs. 4.9%, respectively). The rate of deliveries over 37 weeks was higher in the USG-indicated group than in the emergency-indicated group (47.1% vs. 0%).

Mid-trimester cervical cerclage application remains the subject of discussion in twin pregnancies. Although previous studies could not prove the superiority of cerclage over the conservative method,[18] the studies performed in recent years have reported successful results in mid-trimester cerclage in twin pregnancies.[19] In a meta-analysis examining mid-trimester cerclage in twin pregnancies with a short cervical length (<25 mm), the benefit of cerclage could not be proven.[20] Pan et al. concluded that the week of gestation at birth was higher in the cerclage group compared to the control group in their retrospective cohort study in which they applied physical examination-indicated cerclage in twin pregnancies (32.5 vs. 27.5 weeks), and they found a significant decrease in the incidence of spontaneous preterm births at <24 weeks, <28 weeks, <32 weeks and <34 weeks in the cerclage group compared to the control group.[21] Our study determined that the mean delivery week was 32.5 in the USG-indicated group and 25 in the emergency group in twin pregnancies. We observed that 50% of the deliveries were between 28 and 33^{+6} weeks and 38% were between 34 and 36^{+6} weeks.

Cilingir et al. reported in their study where they applied emergency cerclage and included twins with both short cervix and cervical dilation that the delivery interval was 6.4 weeks on average, 4.1 weeks in the group with bulging membrane patients, and 10 weeks in the group with a short cervix.[22] This result shows that the group with cervical dilation and bulging membranes in twin pregnancies has a poorer prognosis than those with a short cervix, similar to a singleton pregnancy.

In a randomized controlled multicenter study published in 2020, the authors compared 17 patients who underwent physical examination indicated cerclage in twin pregnancies with 13 patients who did not.[14] The Data and Safety Monitoring Board advised ending the experiment after an interim analysis was conducted due to a significant drop in perinatal mortality in the cerclage group. Comparing the cerclage group to the group that did not have a cerclage, the rate of preterm birth drastically dropped as seen below: 70% vs. 100% in births that occur at <34 weeks of gestation, 64.7% vs. 100% at <32 weeks, and 41% vs. 84% <28 weeks. Mean gestational age at delivery was 29 vs. 22.5, and mean delivery interval was 8.3 vs. 2.9. Perinatal mortality rate decreased from 77% to 17.6%.[14]

The limitations of our study are the retrospective, single-center design of the study and the absence of a control group. However, we believe that it is unethical to compare the results with the control group, as current studies have proven the superiority of cerclage over the conservative wait-and-see approach. Another issue is the study's small sample size and the lack of a sufficient number of patients to categorize the degree of cervical dilation, especially in the emergency cerclage group.

Conclusion

In conclusion, the cervical cerclage reduces the possible risks of preterm delivery by prolonging the interval until delivery, especially in patients with singleton and twin pregnancies for whom USG is indicated, and promising neonatal outcomes are achieved.

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Compliance with Ethical Standards: The authors stated that the standards regarding research and publication ethics, the Personal Data Protection Law and the copyright regulations applicable to intellectual and artistic works are complied with and there is no conflict of interest.

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