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Servikal Yetmezlikte Acil Serklaj Sonrası Gebelik Sonuçları: Retrospektif Çalışma**Pregnancy Outcomes After Emergency Cerclage For Cervical Insufficiency: A Retrospective Study**Emine KARABUK¹Pinar KADİROGULLARI²Nazlı ALBAYRAK¹Talat Umut KUTLU DİLEK³Ozlem PATA³

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¹Acibadem University School of Medicine, Department of Obstetrics and Gynecology, Istanbul/TURKEY²Acibadem University Atakent Hospital, Department of Obstetrics and Gynecology, Istanbul/TURKEY³Acibadem University School of Medicine, Department of Perinatology, Istanbul/TURKEY**ÖZ****Amaç :** Servikal yetmezlik nedeniyle acil serklaj yapılan hastaların maternal ve fetal sonuçlarını, serklajın etkinliğini ve güvenliğini değerlendirmek amaçlanmaktadır.**Gereçler ve yöntem :** Şubat 2010-Ocak 2019 tarihleri arasında, Acibadem Mehmet Ali Aydınlar Üniversitesi ve Mersin Üniversitesi Kadın Hastalıkları ve Doğum kliniğinde servikal yetmezlik nedeniyle acil serklaj uygulanan, canlı tekil gebeliği olan kadınlardan elde edilen veriler retrospektif olarak değerlendirildi.**Bulgular :** 29 hastaya McDonald tekniği ile acil serklaj uygulandı. Ortalama anne yaşı 31,82±4,449 yıl (21-38), Serklaj uygulanan hastaların operasyon sırasındaki ortalama gebelik haftası 22,17±2,071 hafta idi (18-28). Canlı gebelik oranı 79,3% (n=23) idi. Serklaj ve doğum arasındaki ortalama aralık 9,24±5,723 hafta (0-18), doğumda ortalama gebelik haftası 31,4±5,02 hafta (23-39) ve doğum ağırlığı 1873±903 g (650-3782) idi. Prosedürle ilgili komplikasyonlar görülmedi. 9 (30%) hasta sezaryen ile doğum yaptı.**Sonuç :** Acil servikal serklaj, servikal yetmezliği olan kadınlarda gebelik süresini uzatmakta ve yenidoğan sonuçlarını iyileştirmede etkilidir. Erken gebelik haftalarında servikal dilatasyonu olan kadınlar için uygun bir seçenek olarak düşünülmelidir.**Anahtar kelimeler :** Preterm doğum, servikal serklaj, servikal yetmezlik, servikal uzunluk**ABSTRACT****Aim:** Evaluation of maternal and fetal outcomes, effectiveness and reliability of the cerclage for the emergently cerclaged cases due to cervical insufficiency**Materials and Method:** Clinical data from live singleton pregnancies who were diagnosed cervical insufficiency were reviewed retrospectively between the Feb 2010-Jan 2019, at Acibadem University and Mersin University, Department of Obstetrics and Gynecology.**Results:** During the study period, total 29 cervical cerclage operation was performed by McDonald technique. Mean maternal age 31.82±4.449 years (21-38), mean gestational age at diagnosis and cerclage placement was 22.17±2.071 weeks (18-28). Take home baby rate was 79.3 % (n=23). Mean time interval between the cerclage and the birth is 9.24±5.723 weeks (0-18), mean pregnancy week during the birth is 31.4±5.02 weeks (23-39) and mean birth weight is 1873±903 g (650-3782). There was no surgical complication reported from the studied population. Thirty percent (9) of the patients were delivered by C-section.**Conclusion:** Emergency cerclage prolongs the pregnancy duration of the women with cervical insufficiency, and has marked effects on improving the neonatal outcomes. It is thought to be an appropriate choice for the women with cervical dilatation at the earlier pregnancy weeks.**Key words :** Preterm birth, cervical cerclage, cervical insufficiency, cervical length**INTRODUCTION**

One of the most important causes of the perinatal morbidity and mortality is the preterm delivery especially before the 34th weeks' of gestation (1, 2). Preterm birth rate in United States

is 11.3% of all the deliveries (3). Cervical insufficiency is one of the well-known reasons of the preterm delivery. Cervical insufficiency complicates 0.1%-1.0% of all deliveries (4) and accounts for 8 % of recurrent pregnancy losses at 2nd or 3rd trimester (5). In these cases, cervical cerclage procedure is

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recommended (5). The novel definition of cervical insufficiency is the state when the fetus, placenta and membranes expelled without clinical contractions or labor between the 16th and 24th weeks' of gestation (5). The diagnosis of cervical insufficiency is usually made by a past medical history including any uterine or cervical interventions, painless cervical dilatation causing early preterm labor, gynecological exam and transvaginal ultrasound exam of uterine cervix. Cervical cerclage is used between the 16th and 24th weeks' of gestation at least for 50 years for to treat cervical insufficiency and prevent pregnancy losses. Cervical cerclage was described firstly described by Shirodkar (6) and later modified by McDonald (7). Emergency cervical cerclage is used to extend the pregnancy duration in the mid-trimester, and as a salvage procedure for the women with cervical dilatation and prolapsus of amniotic membranes. Besides, emergency cervical cerclage might increase the infection risk due to increased exposure time of fetal membranes to the vaginal flora, and effectiveness and the safety is controversial issue (8).

There are 3 proven indications by The American College Of Obstetrics And Gynecology (ACOG) that cervical cerclage could be effective: Current singleton pregnancy prior spontaneous preterm birth less than 34 weeks of gestation, and short cervical length (less than 25 mm) before 24 weeks of gestation, painless cervical dilatation in the second trimester, history of one or more second trimester pregnancy losses related to painless cervical dilatation and in the absence of labour or placental abruption and, prior cerclage due to painless cervical dilatation in the second trimester (9). Prophylactic or history indicated cerclage can be considered in case of previous history of unexplained second trimester delivery in the absence of labour or abruption and generally performed at 13th or 14th weeks of gestation. It is important to mention that there is no advantage of cervical cerclage for the multiple pregnancies, even there are various studies that showing the negative effects of the cerclage for multiple gestations (10). Emergency cerclage is performed in the second trimester, and its effectiveness is not still shown with the level of the cervical insufficiency (1).

In this study, we aimed to show the obstetric and neonatal results of emergency cervical cerclage in the women with cervical dilatation and/or prolapsus of fetal membranes.

MATERIALS AND METHODS

Between the February 2010-Jan 2019, data from two different centers were reviewed retrospectively (Acibadem University Atakent Hospital and Mersin University Hospital), Pregnant women who admitted with premature rupture of membranes, active

uterine contractions, clinical chorioamnionitis, vaginal bleeding, fetus with fatal anomalies and dead fetus were excluded. Incidentally detected short cervix (cervical length less than 25 mm by transvaginal ultrasound) with preterm birth history, short and ripened cervix with visible membranes, progressive shortened cervix without contractions were candidates for the emergency cervical cerclage. By the nature of retrospective study, there was no need of informed consent.

The medical records including demographic features (age, gravida, parity, prior abortus, prior cervical cerclage, pregnancy week at the time of cerclage procedure), complications (chorioamnionitis or amniotic membrane ruptures within the 3 weeks period cerclage placement), gestational age at the delivery and delivery outcomes (delivery method and newborn weight), transvaginal cervical length by ultrasound, prolapsus of amniotic membranes, leucocyte count (WBC), postoperative antibiotic, progesterone and tocolytic treatment following the procedure were recorded.

Emergency cervical cerclage was not performed to the pregnant women who have rupture of membrane, and heavy bleeding, with clinical and laboratory signs of infection (axillary temperature $>37.5^{\circ}\text{C}$, serum WBC $>14000/\text{mm}^3$, C-reactive protein (CRP) $>10\text{ mg/dL}$). Pregnancies with known fetal structural anomalies were not included in the study.

Under the general anesthesia, cervical cerclage sutures were placed by No:5 Mersilene polyester tape (Ethicone) with McDonald technique in the lithotomy position. In some cases of where the cervix was very thin, fragile or edematous, No:1 polypropylene (Prolene, Ethicon) sutures were used instead of the mersilene tape. Before procedure was started, vagina was cleaned by sterile saline, excess mucus and debris were removed gently. Membranes were gently pushed upward by sterile wet sponge or balloon Foley catheter for cases where membranes are visible or prolapsed from the uterin cervix. Foley catheter and filled balloon (with 15 cc sterile saline) remained in cervical canal to prevent prolapsus of membranes until the end of the procedure. Single dose intravenous first generation cephalosporins were administered during the surgical prophylaxis procedure. 17-hydroxyprogesterone caproate (500 mg i.m/weekly) or vaginal micronized progesterone (200 mg/night) was used until 34th weeks of gestation. Following the discharge, ampicillin + sulbactam 750 mg tablet p.o.twice a day and 2 % clindamycin phosphate cream vaginally 2 times a day were prescribed. In the postoperative period, bed rest, abstinence from sexual intercourse were advised. Speculum exam was

performed to evaluate suture security and lower genital tract infection at postoperative 7th day and end of first month. Transvaginal ultrasound exam was not performed routinely especially after 26th weeks of gestation. Sutures were removed in case of active labor, rupture of membranes, fetal death and profuse bleeding. In case this problems are not occurred, cerclage sutures were removed from the pregnant women after 37th weeks of gestation.

Analysis of the data is made by Medcalc 7.4. In order to determine the distribution of data Kolmogorov-Smirnov test was used. As the definition, for the quantitative variables mean \pm standard deviation; for qualitative variables number of patient (percentage) are given. Student's- t test was used to compare normally distributed data. $p < 0,05$ was accepted statistically significant.

RESULTS

During the study period, total 29 cervical cerclage operation was performed by McDonald technique. Mean maternal age 31.82 ± 4.49 years (21–38), mean gestational age at diagnosis and cerclage placement was 22.17 ± 2.071 weeks (18–28). Clinical and demographic findings, postoperative C-reactive protein (CRP), white cell (WBC) and newborn results are shown at Table1.

Table 1. Pregnancy outcomes and maternal characteristics of the patients who underwent emergency cerclage

	Study Group
	n : 29
	Mean \pm SD
	Mean (min-max)
Maternal age, years	31.82 ± 4.49 (21-38)
Gravida	2.54 ± 1.45 (0-4)
Parity	0.27 ± 0.62 (0-2)
Pregnancy week during the cerclage	22.17 ± 2.07 (18-28)
Time interval between the cerclage and delivery (weeks)	$9.24 \pm 5,72$ (0-18)
Pregnancy week during the labor	
27 ⁺	6 (21.7%)
28	23 (78.2%)
34	9 (47.8%)
37	6 (21.7%)
Birth weight, g	1873 ± 903 (650-3782)
C-section	9 (30 %)
Postoperative WBC (Å~109/L)	10.20 ± 2.26
Postoperative CRP (mg/L)	13.88 ± 6.29

During postoperative pregnancy follow-ups, no intrauterine exitus fetus was observed and all pregnancies were resulted with live birth. In total, 7 babies were dead because of extreme pre-

maturity or other prematurity related complications. Take home rate for babies was 79.3 % (n=23). Mean time interval between the cerclage and the birth is 9.24 ± 5.723 weeks (0-18), mean pregnancy week during the birth is 31.4 ± 5.02 weeks (23-39) and mean birth weight is 1873 ± 903 g (650-3782). For the women with preoperative transvaginal cervical length less than 15 mm, mean pregnancy duration was 29.3 ± 5.75 weeks, and for women with cervical length more than 15 mm it was 32.52 ± 4.35 weeks ($p=0.101$). The mean period from intervention to delivery was 7.30 ± 6.09 weeks in women with the cervical length less than 15 mm, while it was 10.26 ± 5.40 weeks in the group cervical length with more than 15 mm ($p=0.19$).

There was no surgical complication reported for the studied population. 30% (n:9) of the patients were delivered by cesarean section. Newborn outcomes were poor for the women with cervical length less than 15 mm. Neonatal mortality rate was higher in this group.

DISCUSSION

There are several studies in recent years criticising the clinical and perinatal outcomes and complications of emergency cervical cerclage (11,12,13). There are a few randomised controlled trials (RCT) with large samples in order to evaluate the reliability and efficiency of emergency cerclage (14). The emergency cerclage has poor outcomes if cervical dilatation occurs with prolonged heavy uterine bleeding, infections, uterine contractions and rupture of membranes (15,16). In some countries, emergency cervical cerclage is not recommended earlier than the fetal viability limits (generally less than 23 weeks), because of the fact that possible risks outweigh the benefits (17).

Emergency cerclage failure is higher in the patients with cervical dilatation larger than 4cm or patients with prolapsus of membranes (18). In another retrospective study evaluating the efficiency of emergency cerclage has reported similar outcomes to our data regarding the time interval between the suture and delivery (13). Mean time interval between the cervical suture and the delivery was 9.24 ± 5.723 weeks in our study, and comparable with literature. Zhu et.al, reported (19) that emergency cerclage can result with 82.28 % success of live births. In this study, mean time interval between the procedure and the delivery was 52.16 ± 26.62 days (19). Pang et al (20) reported that time interval between cerclage and delivery was 11.2 ± 7.1 weeks and mean gestational age at delivery was 34,1 weeks in cases where cerclage procedure is applied for prolapsed amniotic membranes.

Aoki et.al (21), compared the bed rest with emergency cercla-

ge, and it is reported that cerclage is a better choice in terms of delivery interval (respectively 12,5 days vs 44 days). Increased in-utero time for the fetus provides better perinatal outcomes. This relationship is more evident before 30th week of gestation. Also, Stupin et al reported (4), in case of prolapsed amniotic membrane before 27th week of gestation, emergency cervical cerclage increase the live birth rate in comparison with bed rest (72 % vs 25%). Abo-Yaqoub et.al (22), reported a significant increase in newborn weight for the women with emergency cervical cerclage applied after the 20th pregnancy week. Althusius et.al (23), mentioned that the distinct fall in the morbidity of the newborns is an additional benefit of the emergency cervical cerclage (23). In a study comparing emergency and elective cerclage, cesarean section rate in the emergency cerclage group was 27% where it was 48% in the elective cerclage. The emergency cerclage does not affect the way of the delivery and it is concordant with the recent literature (13,24,25). In our study, 30% of the patients with cerclage are underwent cesarean section, and the rate is comparable with the previous literature.

Patients who underwent emergency cerclage and having symptoms (such as vaginal discharge, pelvic pressure, vaginal bleeding) have higher preterm birth rate before 32nd week of gestation (26). The outcomes of the asymptomatic women are better than the women with symptoms. Several retrospective series reported that complication rates following cervical cerclage were higher (12,19). Although we did not report any postoperative complications in our study group, the low number of cases in our study should be considered as a limitation.

Several studies showed that membranes exceeding to the external os and/or cervical dilatation more than 15 mm might be an independent determinant for failure of cerclage (18,25). In a recent study, emergency cervical cerclage is not considered as a rationale approach for the patients with an advanced cervical dilation (>4 cm) together with protruding membranes in early second trimester (27). Also Wang et al (24) reported that an inverse relation with the degree of cervical length shortening and pregnancy outcomes was observed; women with a cervical length between 25 and 30 mm had the best outcomes. In our study, 10 patients had cervical length less than 15 mm or amniotic membranes extending to the external os before the cervical cerclage procedure and most of these patients had worse outcomes than the others. We think that regardless of cervical length, pregnant women with firm cervix have better perinatal outcome than dilated and soft cervix.

To perform cervical cerclage, there is no specific cut-off for cervical length by transvaginal ultrasound in asymptomatic patient. Owen et al (28) suggested that cervical cerclage could be performed to the women who have a previous preterm birth before 34th weeks of gestation with the cervical length shorter than 15 mm. However in a meta-analysis (29), it is reported that cerclage should be performed for patients with the history of preterm labor or shortening of the cervical length (cervical length \leq 25mm). This study showed that pregnancy duration is shorter in women with cervical length less than 15mm compared to the women with cervical length more than 15mm, even though it is not statistically significant. If the length of cervix is sonographically less than 25mm, then cerclage can be suggested (29). Our study shows that in cases with cervical length <15mm, the time interval between cerclage and the labor is shorter.

The limitation of the study is having small number of cases and a retrospective structure. Regarding to the ethical issues, it would not be possible to work on the control group for a prospective study, because of the fact that consents of the patient should be taken for the procedures. There should be more reliable RCTs in the literature in order to minimize the concerns on this specific area.

CONCLUSION

Our study showed that as a rescue procedure, emergency cervical cerclage for the women with cervical dilatation and fetal membrane prolapsus provides better perinatal outcomes. Extensive counselling is necessary prior to cervical cerclage procedure with a detailed discussion on the risks and benefits of cerclage versus conservative management as a rescue or salvage procedure.

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