

# Does amnioreduction increase success of emergency cervical cerclage in cases with advanced cervical dilatation and protruding membranes?

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## Summary

**Objective:** To investigate whether amnioreduction has any impact on emergency cervical cerclage outcome. **Materials and Methods:** Data of women who underwent emergency cervical cerclage for advanced cervical dilatation and protruding membranes were analyzed retrospectively. **Results:** During the study interval, a total of 56 women who were underwent amnioreduction (n=26) and who did not (n=30) were eligible for analysis of the study. Gestational age at cerclage, delivery, and prolongation of pregnancy interval were comparable between the groups ( $21.3 \pm 3.3$  vs.  $20.6 \pm 3.1$  weeks;  $p = 0.44$ ;  $28.3 \pm 6.1$  vs.  $28.1 \pm 5.6$  weeks;  $p = 0.74$ ;  $53.7 \pm 46.1$  vs.  $47.3 \pm 36.7$  days;  $p = 0.56$  respectively). Number of live birth rates and perinatal mortality rates were also not statistically significantly different between the groups (73.1% vs. 70.0%;  $p = 0.80$ ; 15.4% vs. 13.3%;  $p = 0.83$ ). **Conclusions:** Emergency cerclage yields live take home baby rates in more than half of the patients. The decision to perform amnioreduction should be based on suspicion of chorioamnionitis and patient's motivation to know exactly what is the risk of chorioamnionitis.

**Key words:** Emergency cerclage; Pregnancy outcome, Neonatal outcome; Amnioreduction.

## Introduction

Preterm birth is still the leading cause of neonatal morbidity and mortality besides advancement in prenatal care [1]. The etiology of preterm birth is not exactly known, but there are possible factors that may result in it like maternal infection, inflammation, multiple gestation, and placental insufficiency. Independent from the etiological factors, once the pathway begins, the final stage results in a shortened and a dilated cervix. In cases with a shortened and a dilated cervix, mechanical closure of the cervix may be the only hope for delay of delivery to a viable fetal period.

Cervical cerclage procedure has been introduced to prolong pregnancy for a period of time for the newborn to survive [2]. Cerclage procedure can be performed mainly due to three indications: 1) elective cerclage, 2) ultrasound indicated, and 3) emergency cerclage [3].

One of the main pitfalls during emergency cerclage procedure is the difficulty to perform it with protruding membranes. In order to decrease the pressure exerted upon the external cervical ostium, amnioreduction has been discussed in the literature [4-6].

In the present study, the authors aimed to investigate whether amnioreduction has any impact on emergency cervical cerclage outcome.

## Materials and Methods

This retrospective study examined the data of women who underwent emergency cervical cerclage for advanced cervical dilatation and protruding membranes and delivered in an obstetric unit of a tertiary center at Kocaeli University School of Medicine, Kocaeli, Turkey, between June 2008 and February 2013. The local ethics committee approved the study.

In this study, the primary outcome measure was to determine whether amnioreduction has any impact on emergency cervical cerclage outcome. Secondary outcomes were gestational weeks at delivery and neonatal outcomes.

Criteria for enrollment included all the pregnant women with a single live fetus who underwent an emergency cervical cerclage procedure performed for advanced cervical dilatation and protruding intact membranes between 12-28 weeks of gestation. Advanced cervical dilatation and protruding membranes were defined according to sterile speculum examination and transabdominal ultrasound investigation. A dilatation  $\geq$  three cm with visible protrusion of intact fetal membranes at or below the external cervical os was considered as advanced cervical dilatation. The cases with amniotic membranes prolapsing until or beyond the level of bladder outlet on sagittal transabdominal ultrasound examination were considered to be advanced ultrasonographically. Gestational age was determined by the last menstrual period and/or by first trimester ultrasonography if the patient was unsure of the date of her last menstrual period.

Exclusion criteria included fetus with multiple gestations, multiple anomalies, uterine abnormality, preterm premature rupture of

membranes (PPROM), and clinical signs of chorioamnionitis (uterine tenderness, maternal temperature  $>38^{\circ}\text{C}$ , fetal tachycardia, WBC count  $>16,000$ , CRP  $>1.5$  mg/dl, and foul vaginal smell).

The study population consisted of a total of 84 consecutive pregnant women with advanced cervical dilatation and protruding membranes who had been offered amnioreduction procedure. After patients were evaluated according to inclusion and exclusion criteria, 61 of the 84 patients were analyzed. Among 61 patients who underwent emergency cerclage procedure, 30 patients who accepted amnioreduction formed group 1 and 31 patients who did not accept amnioreduction formed group 2.

According to exclusion criteria, six women with multiple gestations, one fetus with multiple anomalies, one woman with an uterine abnormality, six women with PPROM, and nine fetuses with clinical signs of chorioamnionitis (uterine tenderness, maternal temperature  $>38^{\circ}\text{C}$ , fetal tachycardia, WBC count  $>16,000$ , CRP  $>1.5$  mg/dl and foul vaginal smell) were excluded from the study.

For the patients who accepted amnioreduction procedure, an ultrasound guided abdominal amnioreduction (ten ml/week) was performed with a 16-gauge amniocentesis needle after adequate sterilization one hour before the operation. After the procedure, intraamniotic infusion of one gram sulbactam-ampicillin was applied. Besides laboratory examinations performed for both of the groups in order to rule out chorioamnionitis, the amniotic material obtained in group 1 was also investigated for gram's stain, glucose measurement, and microbial culture. Bacterial visualization during gram stain and glucose concentration of  $<10$  mg/dl were accepted as evidence of chorioamnionitis and were not performed cerclage procedure. Three patients in group 1 did not undergo cerclage procedure after diagnosis of chorioamnionitis in the amniocentesis material.

All cerclage procedures were of the McDonald type by the same operator (EC) with Mersilene tape was used as suture placed at the most distal part of the cervix as previously described [7]. All patients were treated according to the same protocol in the post-operative period: hospitalization was maintained and the women were restricted to bed rest for 48 hours. They were discharged at least one week after the operation from the hospital whenever they do not have regular uterine contractions. Daily ultrasound follow-up of amniotic fluid level and vaginal speculum examination for amniotic fluid flow were performed until the patients were discharged from the hospital. Patients had transvaginal ultrasonography performed weekly after discharge and bed rest was advised until delivery. All the patients received sulbactam and ampicillin (three g/day for seven days, po), amikacin (1.5 g/day for seven days, i.v.), metronidazole (1,000 mg/day for seven days, i.v.), povidone iodine (0.2 g/day for seven days, intravaginal), indomethacin (300 mg/day for three days, rectally) and progesterone (50 mg/day i.m. for ten days).

The statistical analysis of the data was performed using the Statistical Package for Social Sciences. Results were reported as mean  $\pm$  standard deviation and percentages. Differences between the groups were assessed using chi-square test for categorical data. In order to detect the differences of continuous variables between the groups, Chi-square test was used. For all comparisons  $p < 0.05$  was considered statistically significant.

## Results

During the study interval, a total of 56 women were eligible for analysis of the study (in one patient from each group, the membranes ruptured during the operation). Se-

Table 1. — Maternal variables according to data of cerclage procedure women who underwent (group 1) and who did not undergo amnioreduction (group 2) [values are n, mean ( $\pm$ standard deviation) or n/N (%)].

Variable	Group 1 (n=26)	Group 2 (n=30)	p
Gestational age at admission (weeks+days)	21.3 $\pm$ 3.3	20.6 $\pm$ 3.1	0.44
Maternal age (years)	28.2 $\pm$ 5.3	29.3 $\pm$ 5.1	0.42
Primigravidity	14 (53.8)	15 (50.0)	0.79
Previous abortion $\geq 1$	3 (11.5)	3 (10.0)	1.00
First trimester miscarriage	6 (23.1)	5 (16.7)	0.54
Second trimester miscarriage	3 (11.5)	4 (13.3)	0.84
Previous preterm delivery at 24-34 weeks $\geq 1$ (n)	2 (7.7)	2 (6.7)	0.54
Cervical dilatation at admission (cm)	5.0 $\pm$ 2.8	4.0 $\pm$ 2.2	0.18
CRP <sup>a</sup> on admission (mg/dl)	2.2 $\pm$ 3.2	1.5 $\pm$ 1.6	0.33
WBC <sup>b</sup> count on admission (/ $\mu$ l)	13903 $\pm$ 3297	13103 $\pm$ 3772	0.40

<sup>a</sup> C-reactive protein; <sup>b</sup> white blood cell count.

Table 2. — Pregnancy outcome among women who underwent (group 1) and who did not undergo amnioreduction (group 2) [values are n, mean ( $\pm$ standard deviation) or n/N (%)].

	Group 1 (n=26)	Group 2 (n=30)	p
Gestational age at cerclage placement (weeks+days)	21.3 $\pm$ 3.3	20.6 $\pm$ 3.1	0.44
Operation time (min.)	80.2 $\pm$ 16.9	78.3 $\pm$ 14.9	0.66
Gestational age at delivery	28.3 $\pm$ 6.1	28.1 $\pm$ 5.6	0.74
Prolongation of pregnancy (days)	53.7 $\pm$ 46.1	47.3 $\pm$ 36.7	0.56
Miscarriage (n)	7 (26.9)	9 (30.0)	0.80
Delivery at 24-28 weeks of gestation (n)	6 (26.7)	5 (23.1)	0.54
Delivery at 28-32 weeks of gestation (n)	3 (26.7)	5 (26.9)	0.58
Delivery at 32-34 weeks of gestation (n)	3 (16.7)	7 (11.5)	0.25
Delivery at 34-37 weeks of gestation (n)	5 (10.0)	3 (15.4)	0.33
Delivery at $>37$ weeks of gestation (n)	2 (3.3)	1 (7.7)	0.47
Mode of delivery			
Vaginal	11 (42.3)	13 (43.3)	0.94
Cesarean section	15 (57.7)	17 (56.7)	0.94

lected maternal variables according to the groups are presented in Table 1. Maternal age, primigravidity, previous abortion  $\geq 1$ , number of first and second trimester miscarriages, and number of previous preterm deliveries at 24-34 weeks of gestation were similar between the groups. Gestational age and cervical dilatation at admission were also similar (21.3  $\pm$  3.3 vs. 20.6  $\pm$  3.1 weeks;  $p = 0.44$ ). Mean white blood cell counts and C-reactive protein levels were not statistically significantly different in between the

Table 3. — Neonatal outcomes according to the groups [values are n, mean ( $\pm$ standard deviation) or n/N (%)].

	Group 1 (n=26)	Group 2 (n=30)	p
Live birth (n)	19 (73.1)	21 (70.0)	0.80
NICU admission <sup>a</sup>	10 (38.5)	12 (40)	0.91
Neonatal birthweight (g)	1593 $\pm$ 1089	1445 $\pm$ 1015	0.60
Neonatal birthweight <1000 g	12 (46.2)	12 (40.0)	0.64
Neonatal birthweight in between 1000-2500 g	4 (15.4)	11 (36.7)	0.07
Neonatal birthweight >2500 g	10 (38.5)	7 (23.3)	0.22
Apgar score 1 minute	3.5 $\pm$ 2.7	3.9 $\pm$ 3.3	0.63
Apgar score 5 minute	4.3 $\pm$ 3.2	4.6 $\pm$ 3.7	0.73
Perinatal mortality <sup>b</sup>	4 (15.4)	4 (13.3)	0.83
Neonatal death within 7 days after postpartum	0	0	-
Discharged alive	15 (57.7)	17 (56.7)	0.94

<sup>a</sup> Live-born neonates died within seven days in the post-partum period.

<sup>b</sup> Neonatal intensive care unit admission.

groups.

Pregnancy outcomes among women who were and were not performed amnioreduction according to the groups are demonstrated in Table 2. Gestational age at cerclage, delivery, and prolongation of pregnancy interval were comparable between the groups (21.3  $\pm$  3.3 vs. 20.6  $\pm$  3.1 weeks;  $p$  = 0.44; 28.3  $\pm$  6.1 vs. 28.1  $\pm$  5.6 weeks;  $p$  = 0.74; 53.7  $\pm$  46.1 vs. 47.3  $\pm$  36.7 days;  $p$  = 0.56, respectively). Also, when the operation time was compared, there was no difference (80.2  $\pm$  16.9 vs. 78.3  $\pm$  14.9;  $p$  = 0.66). Miscarriage rates, delivery rates between 24-28 weeks, 28-32 weeks, 32-34 weeks, 34-37 weeks, and >37 weeks were not statistically significantly different between the groups. Mode of delivery was also similar according to the analysis.

Data of newborns according to groups are presented in Table 3. Mean birthweight, neonatal intensive care unit admission (NICU), number of fetuses with birthweight <1,000 grams, 1,000–2,500 grams, and >2,500 grams were similar between the groups. One and five minute Apgar scores were also similar when comparing the groups. Number of live birth rates and perinatal mortality rates were not statistically significantly different between the groups (73.1% vs. 70.0%;  $p$  = 0.80; 15.4% vs. 13.3%;  $p$  = 0.83). Number of fetuses discharged alive were also comparable in groups one and two (57.7% vs. 56.7%;  $p$  = 0.94).

## Discussion

Today, cervical cerclage procedure is still debatable although it being a relatively common operation. The most common accepted indication for cervical cerclage procedure is cervical insufficiency [8]. Protruding membranes usually occur as a consequence of cervical insufficiency. The incidence of cervical insufficiency has been reported

to be between 0.05-1% of all pregnancies [9]. Although management of cervical insufficiency is usually problematic, early detection and intervention are more important. However, there is no way to detect insufficiency earlier besides ultrasound findings of cervical length measurements. Therefore, there remains only two choices to manage a patient with protruding membranes during direct visualization: either wait and apply palliative strategies or perform an intervention without detriment to the mother and fetus. In this study, the present results indicated that in almost half of the patients- either with or without amnioreduction- discharge with a healthy fetus could be possible.

Effectiveness of emergency cervical cerclage has been investigated in the literature with regards to interval between delivery and neonatal outcomes [10-12]. Celen *et al.* have investigated 75 pregnant women with cervical dilatation in the second trimester [10]. They have reported fetal survival rates as high as 89.1% without any complications. Cavus *et al.* discussed pregnancy outcomes in 20 patients treated with emergency cervical cerclage [11]. They reported 55% of patients with delivery at 36 weeks. Khan *et al.* compared outcomes of elective, urgent, and emergency cerclage procedures [12]. Their results revealed a mean of 11 weeks of prolongation of pregnancy. The present results indicated 30.0% and 33.6% of deliveries after 32 weeks in each group.

Amnioreduction has been introduced for two main purposes in the literature: 1) to lower the pressure exerted upon the membranes and 2) to obtain amniotic sample for investigation of intra-amniotic infections [4-6, 13-15]. In 1979, Goodlin introduced amniocentesis in cases with cervical incompetence [4]. Afterwards, Locatelli *et al.* performed amnioreduction of amniotic fluid followed by amnioinfusion and reported higher delivery rates after 32 weeks of gestation [5]. Mays *et al.* also performed amnioreduction, but this time they investigated amniotic fluid for the presence of chorioamnionitis [6]. Cerqui *et al.* reported three cases of cervical cerclage with the assistance of amnioreduction [13]. Locatelli *et al.* compared in another study intracervical Foley catheter with amnioreduction and suggested lower rates of extreme prematurity with amnioreduction [14]. Finally, Makino *et al.* categorized bulging membranes as type 1 or type 2 according to protrusion beyond the inlet or completely occupying the vagina [15]. In their study, they also reported similar results in both groups that underwent amnioreduction and cerclage procedure. In the present study, the authors also compared the outcomes in cases with and without amnioreduction. Delivery weeks, birthweights, perinatal mortality rates, and number of discharged alive fetuses were similar in between the groups. In three patients cervical cerclage procedure was going to be performed unless amniocentesis materials revealed chorioamnionitis. Hence, although the obstetrical out-



comes are comparable to the patients who did not undergo amnioreduction, the latter may provide investigation of chorioamnionitis from the amniocentesis material.

Main concern regarding the decision to perform emergency cerclage procedure is the possible complications. Kahn *et al.* reported 17.7% premature rupture of membranes (PROM) and 29.4% uterine contractions until delivery [12]. Liddiard *et al.* compared elective and emergency cervical cerclage [16]. Opposite to the previous studies, they reported higher complication rates (ruptured membranes in 33% of patients) and lower mean gestation at delivery (26 weeks). The present results indicate a higher gestational age at delivery (28 weeks in both of the groups) with almost no complications including PPROM.

Emergency cerclage was compared with expectant management or bed rest for prolapsed fetal membranes in the literature. Aoki *et al.* reported comparable prolonged pregnancy duration with emergency cerclage in the absences of signs of infection or painful uterine contractions [17]. Similarly, Stupin *et al.* compared 89 cerclage cases with 72 conservative procedures retrospectively [18]. In their study, they reported significantly higher live births in the cerclage group (72% vs. 25%;  $p < 0.001$ ). Daskalakis *et al.* also compared emergency cervical cerclage with bed rest [19]. Neonatal survival rate was reported as 31% and 94.1%, respectively, between the groups.

Success of emergency cerclage procedure have raised the question of whether outcomes could be predicted. Deb *et al.* and Guducu *et al.* analyzed the predictors of success in cases with protruding membranes [20, 21]. In both studies, they concluded that presence of membrane prolapse was a strong predictor factor. Also, Deb *et al.* made an analysis related with initial WBC and stated a significant association with WBC counts. Gupta *et al.* also analyzed predictors of success in their study on 45 emergency cerclage patients [22]. They defined chorioamnionitis as predictor of poor outcome. Although not consistent enough, prolapsed membranes, advanced cervical dilatation, maternal symptoms, and equivocal markers of infection have been accepted as associated poor outcome markers. Cervical dilatation has been compared in the literature as a predictor of pregnancy outcome. While Fortner *et al.* defined  $\geq$  two cm dilatation for delivery at an earlier gestation, Abo-Yaqoub *et al.* defined  $\geq$  three cm for cerclage failure [23, 24]. Debby *et al.* compared emergency second trimester cerclage outcomes in patients with and without bulging membranes into the vagina [25]. They reported favorable outcomes even in cases with bulging membranes.

In conclusion, emergency cerclage yields live take home baby rates in more than half of the patients. The decision to perform amnioreduction should be based on suspicion of chorioamnionitis and patient's motivation to know exactly what is the risk of chorioamnionitis.

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