

Outcomes of prophylactic and emergency cerclage versus expectant management for cervical insufficiency: a single-center retrospective, comparative study

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Summary

Aim: To compare the outcomes after prophylactic cerclage, emergency cerclage, and expectant management in women with cervical insufficiency. **Materials and Methods:** From 2011 to 2015, Eulji University Hospital's database was retrospectively analyzed to identify women with cervical insufficiency without premature rupture of membranes (PROM), clinical chorioamnionitis, or labor pain from 12 to 26 weeks of gestation. Gestational age at delivery, term delivery rate, after-34-weeks-of-gestation delivery rate, intensive-care-unit admission rate, neonatal sepsis, and neonatal mortality rate were compared between each group. **Results:** Forty-eight women underwent prophylactic cerclage: 56 emergency cerclage and 21, expectant management. Prolongation of pregnancy was longer in the prophylactic cerclage group than in the emergency group (22.8 ± 2.7 weeks vs. 13.3 ± 6.1 weeks, $p < 0.001$). Preterm delivery rate < 34 gestational weeks was significantly higher in the emergency cerclage group than the prophylactic group (37.5% vs. 14.6%, $p = 0.009$). Elevated pre-cerclage C-reactive protein (CRP) was associated with delivery before 34 weeks in the emergency cerclage group [odds ratio (OR): 15.849; 95% confidence interval (CI): 1.289-194.898, $p = 0.031$]. Comparing the emergency cerclage and expectant groups, prolongation of pregnancy was higher in the emergency group than the expectant group (13 ± 6.1 weeks vs. 8 ± 5.7 weeks, $p = 0.002$). However, there were no significant differences between the two groups regarding preterm delivery < 34 weeks and perinatal outcomes. **Conclusions:** Preterm delivery rate < 34 gestational weeks was higher in the emergency cerclage group than the prophylactic group. There were no significant differences between the emergency cerclage and the expectant groups in pregnancy and perinatal outcomes.

Key words: Cervical insufficiency; Emergency cerclage; Expectant management.

Introduction

Cervical insufficiency is defined as the inability of the uterine cervix to retain a pregnancy in the absence of the signs and symptoms of uterine contraction or pain, regardless of chorioamnionitis, premature rupture of membranes (PROM), or placenta abruptio in the second trimester. The pathophysiology of cervical insufficiency is still poorly understood. Risk factors associated with cervical insufficiency include conization, mechanical dilation of the cervix, obstetric lacerations, congenital Müllerian anomalies, and deficiencies in cervical collagen and elastin. Diagnosis is based on a previous history of painless cervical dilatation in the second trimester. Prophylactic cerclage may be indicated in patients with a previous history of cervical insufficiency. History-indicated cerclages typically are performed at approximately 13-14 weeks of gestation. However, more recently, women with no previous history of cervical insufficiency can be diagnosed in the mid-second trimester based on ultrasonographically short cervical length or amniotic membrane bulging. Emergency cerclage in women with bulging amniotic membrane is associated with more severe complications, such as chorioamnionitis,

PROM, cervical laceration or bleeding, and even more fetal loss than that associated with prophylactic cerclage. Although several studies show greater benefits of emergency cerclage when compared with expectant management [1-3], there is still considerable controversy regarding its effectiveness. Other studies show that conservative management followed by progesterone or expectant management also are effective in women with ultrasonographically short cervical length [4-6]. Therefore, many clinicians are choosing conservative management instead of emergency cerclage in patients with amniotic membrane bulging in an effort to avoid severe complications. Moreover, some randomized controlled clinical trials have reported that even history-indicated prophylactic cerclage demonstrates no evidence that cervical cerclage will prolong gestation or improve survival [7, 8]. In the present study, the authors retrospectively compared the outcomes of two groups: patients with prophylactic cerclage and emergency cerclage. Additionally, they compared each group between emergency cerclage and expectant management in women diagnosed with cervical insufficiency with or without amniotic membrane bulging. They ana-

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Table 1. — *Characteristics and pregnancy outcomes between prophylactic cerclage and emergency cerclage groups.*

	Prophylactic cerclage, n=48		Emergency cerclage, n=56		p-value
	Mean	SD	Mean	SD	
Maternal age (years)	33.1	4.2	32.9	4.4	0.958
Parity	1.18	1.04	0.69	0.65	0.016
Cervical length (cm)	3.1	0.63	1.36	0.97	<0.001
Pre-cerclage CRP (mg/dL)	0.58	0.7	0.67	1.03	0.924
Post-cerclage CRP (mg/dL)	0.81	0.97	0.83	1.01	0.904
Gestational age at cerclage (weeks)	14.3	1	21.2	4	<0.001
Gestational age at delivery (weeks)	36.7	3.4	34.3	4.6	0.005
Prolongation of pregnancy (weeks)	22.8	2.7	13.3	6.1	<0.001
Term delivery (n, %)	27	56.3	25	44.6	0.238
Preterm delivery (n, %)					
< 37 weeks	21	43.8	31	55.4	0.238
< 34 weeks	7	14.6	21	37.5	0.009
Birth weight (kg)	2.8	0.58	2.32	0.9	0.007
Apgar score 1 min	6.9	1.7	5.6	2.4	0.003
Apgar score 5 min	8.2	1.5	7.5	1.9	0.093

Data are presented as mean, SD, number, and percentage. SD = standard deviation; p value of < 0.05 is considered significant. CRP = C-reactive protein.

Table 2. — *Odds ratios (using a logistic regression model) for potential associations for outcomes of pregnancy after emergency cerclage.*

	Delivery < 34 weeks		
	OR	95% CI	p-value
Cervical length	1.329	0.343-5.148	0.681
Funneling	2.093	0.278-15.768	0.473
Membrane bulging	9.225	0.536-158.649	0.126
Pre-cerclage CRP	15.849	1.289-194.898	0.031
Post-cerclage CRP	1.365	0.402-4.632	0.618

p value of < 0.05 is considered significant. OR = odds ratio; CI = confidence interval; CRP = C-reactive protein

lyzed pregnancy and perinatal outcomes in each group.

Materials and Methods

This study was approved by the institutional review board of Eulji university hospital (2017-11-003). Data was retrospectively analyzed using the medical records of women who were diagnosed with cervical insufficiency between January 2011 and December 2015 at Eulji University Hospital in Daejeon, South Korea. Inclusion criteria were: (i) singleton pregnancies between 12 and 26+6 weeks, (ii) ultrasonographically short cervical length (less than 25 mm), (iii) amniotic membranes bulging, (iv) prior mid-trimester fetal loss history, (v) no labor pain, (vi) no PROM, (vii) no clinically discernible chorioamnionitis, and (viii) no significant vaginal bleeding. Amniotic membrane bulging was diagnosed to be present when an amniotic sac was visible under speculum examination, with cervical external os dilatation. Cervical funneling means the dilatation of the internal os of the cervix, but with an intact external os of the cervix. One hundred seventy-nine women met these criteria. One hundred fifty-one women underwent prophylactic or emergency cerclage, while 28 women received expectant management. Out of the 151 cerclage patients, 104 were delivered at Eulji University Hospital: 47 of 151 were loss to follow-up. Out of the 28 expectant management patients, 21 were delivered at Eulji University Hospital: 7 out of 28 were loss to follow-up.

Cerclage was performed under spinal anesthesia in the lithotomy position. The McDonald cerclage was the first choice for

this procedure and the Shirodkar cerclage was only performed for prophylactic cerclage in a few cases. The McDonald procedure was used by mersilene sutures. Expectant management involved the administration of progesterone and/or tocolytics if uterine contraction was detected after the cerclage operation, and patients were observed for pain, contraction, or other complications. Cefazidone was administered as a prophylactic antibiotic intravenously (I.V.) for at least four days in the prophylactic cerclage group and for seven days in the emergency cerclage group. The suture was removed at 36-37 weeks of gestation or whenever labor was established.

In the expectant management group, I.V. tocolytics, antibiotics, and/or intramuscular progesterone were administered in addition to bedrest. The decision as to whether emergency cerclage or expectant management would be implemented was made on an individual basis, according to cervical dilatation, gestational week, C-reactive protein (CRP) level, or new-onset uterine contraction. Basic patient characteristics (age, parity, history of prior mid-trimester fetal loss, previous spontaneous preterm delivery, cerclage in previous pregnancy), pregnancy outcomes (duration of pregnancy prolongation, gestational age at delivery, delivery mode, cerclage operation weeks, post-cerclage expectant use), and perinatal outcomes (Apgar scores at 1 and 5 minutes, birth weight, intensive care unit (ICU) admission, neonatal sepsis, neonatal mortality, take-home-baby status) were compared between the prophylactic cerclage group and the emergency cerclage group, between the emergency cerclage group and the expectant management group, and between women with amniotic membrane bulging and women without this condition. The duration of pregnancy prolongation was defined as the number of weeks from the week of the cerclage operation until delivery in the cerclage group and as the number of weeks from admission until delivery in the expectant management group.

The data are represented as medians (range) or frequencies (percentage). Statistical analysis was performed using SPSS version 18.0. The authors applied the Mann-Whitney test for determining continuous variables. Fisher's exact test was used to detect differences in categorical data by group. Potential associations with delivery < 34 gestational weeks after emergency cerclage were explored using a logistic regression analysis and reported as odds ratio (OR) and 95% confidence interval (CI). A p value of < 0.05 (two-tailed) was considered statistically significant.

Table 3. — Perinatal outcomes between prophylactic cerclage and emergency cerclage groups.

	Prophylactic cerclage, n=48		Emergency cerclage, n=56		p-value
	Number	%	Number	%	
Intensive care unit admission	11	22.9	27	48.2	0.008
Neonatal sepsis	5	10.4	8	14.3	0.552
Neonatal mortality	0	0	2	3.6	0.498
Take home baby	21	43.8	14	25	0.044

Data are presented as number and percentage. *p* value of < 0.05 is considered significant

Table 4. — Comparison of characteristics, pregnancy outcomes, and perinatal outcomes between women with amniotic membrane bulging group and those without.

	Membrane bulging(-), n=90		Membrane bulging (+), n=13		p-value
	Mean	SD	Mean	SD	
Maternal age (years)	33.1	4.38	32.7	4.0	0.804
Parity	0.97	0.9	0.69	0.75	0.30
Pre-cerclage CRP (mg/dL)	0.61	0.95	0.78	0.92	0.282
Post-cerclage CRP (mg/dL)	0.69	0.85	1.56	1.42	0.005
Gestational age at cerclage (weeks)	17	4.1	23.8	3.3	<0.001
Gestational age at delivery (weeks)	36	3.7	30.6	4.8	0.001
Prolongation of pregnancy (weeks)	19.1	5.6	7	5.1	<0.001
Birth weight (kg)	2.6	0.72	1.76	0.94	0.002
Apgar score 1 min	6.5	1.8	3.6	2.6	<0.001
Apgar score 5 min	8.1	1.5	5.9	2.2	0.005
Intensive care unit admission (n, %)	28	31.1	10	76.9	0.004
Neonatal sepsis (n, %)	8	8.9	5	38.5	0.011
Neonatal mortality (n, %)	2	2.2	0	0	1.0
Take home baby (n, %)	35	38.9	0	0	0.004

Data are presented as mean, SD, number, and percentage. SD = standard deviation; *p* value of <0.05 is considered significant. CRP = C-reactive protein.

Results

Of the 104 women who were delivered at Eulji University Hospital, 48 underwent prophylactic cerclage and 56 underwent emergency cerclage. Table 1 shows the characteristics, pregnancy outcomes, and perinatal outcomes of our patients. In the prophylactic cerclage group, mean cervical length was 3.1 cm, but in the emergency cerclage group, mean cervical length was 1.36 cm. There was a significant difference in cervical length between the two groups. Prolongation of pregnancy are significantly longer in the prophylactic cerclage group than in the emergency cerclage group (22.8 ± 2.7 weeks vs. 13.3 ± 6.1 weeks, $p < 0.001$). Preterm delivery rate < 34 gestational weeks was significantly higher in the emergency cerclage group than in the prophylactic cerclage group (37.5% vs. 14.6%, $p = 0.009$). Elevated pre-cerclage CRP level was significantly associated with delivery before 34 weeks in the emergency cerclage group (OR: 15.849; 95% CI: 1.289-194.898, $p = 0.031$) (Table 2).

Table 3 shows perinatal outcomes between the prophylactic and the emergency cerclage groups. ICU admission rate was significantly higher in the emergency cerclage group than in the prophylactic cerclage group (48.2% vs. 22.9%, $p = 0.008$). However, there were no significant differences in neonatal sepsis and mortality between the two groups.

Table 4 shows the comparison of characteristics, pregnancy outcomes, and perinatal outcomes between women with and without amniotic membrane bulging. Gestational age at delivery was significantly higher in women without amniotic membrane bulging than in those with amniotic membrane bulging (36 ± 3.7 weeks vs. 30.6 ± 4.8 weeks, $p = 0.001$). Prolongation of pregnancy was significantly higher in women without amniotic membrane bulging than in those with amniotic membrane bulging (19.1 ± 5.6 weeks vs. 7 ± 5.1 weeks, $p < 0.001$). In perinatal outcomes, ICU admission rate and neonatal sepsis were significantly higher in women with amniotic membrane bulging than in those without amniotic membrane bulging [(76.9% vs. 31.1%, $p = 0.004$), (38.5% vs. 8.9%, $p = 0.011$), respectively].

Table 5 shows the comparison of characteristics, pregnancy outcomes, and perinatal outcomes between the emergency cerclage group and the expectant management group. Gestational age at diagnosis was significantly higher in the expectant group than in the emergency cerclage group (24.2 ± 2.9 weeks vs. 21 ± 3.7 weeks, $p < 0.001$). Prolongation of pregnancy was significantly higher in the emergency cerclage group than in the expectant group (13 ± 6.1 weeks vs. 8 ± 5.7 weeks, $p = 0.002$). However, there were no significant differences between the two groups regarding preterm delivery < 34 weeks and perinatal outcomes.

Table 5. — Comparison of characteristics, pregnancy outcomes, and perinatal outcomes between emergency cerclage group and expectant groups.

	Emergency cerclage, n=56		Expectant group, n=21		p-value
	Mean	SD	Mean	SD	
Maternal age (years)	32.9	4.41	31.9	5.18	0.421
Parity	0.69	0.65	0.42	0.5	0.096
Cervical length (cm)	1.36	0.97	0.81	0.82	0.024
CRP (mg/dL)	0.67	1.03	0.44	0.52	0.331
Gestational age at diagnosis (weeks)	21	3.7	24.2	2.9	<0.001
Gestational age at delivery (weeks)	34	4.6	32	5.8	0.183
Prolongation of pregnancy (weeks)	13	6.1	8	5.7	0.002
Amniotic membrane bulging (n, %)	13	23.6	8	38.1	0.207
Term delivery (n, %)	25	44.6	6	28.6	0.2
Preterm delivery (n, %)					
< 37 weeks	31	55.4	15	71.4	0.2
< 34 weeks	21	37.5	11	52.4	0.238
Birth weight (kg)	2.32	0.9	2.29	1.05	0.901
Apgar score 1 minute	5.6	2.37	5.45	2.54	0.782
Apgar score 5 minutes	7.5	1.9	7.25	2.02	0.568
Intensive care unit admission (n, %)	27	48.2	13	54	0.197
Neonatal sepsis (n, %)	8	14.3	2	10	1.0
Neonatal mortality (n, %)	2	3.5	2	9.5	0.298
Take home baby (n, %)	14	25	4	20	0.766

Data are presented as mean, SD, number, and percentage. SD = standard deviation; p value of <0.05 is considered significant. CRP = C-reactive protein.

Discussion

In the present study, the authors found significant prolongation of pregnancy duration in the prophylactic cerclage group when compared with the emergency cerclage group. Two randomized controlled trials concluded that there was no evidence that prophylactic cerclage prolonged gestation or improved survival [7, 8]. However, an intent-to-treat study of 1,292 women at risk of preterm delivery found that there were fewer deliveries before 33 weeks of gestation in the prophylactic cerclage group [9]. In Feb 2014, the American College of Obstetricians and Gynecologists (ACOG) concluded that cerclage placement may be indicated based on a history of cervical insufficiency, such as history of one or more second-trimester pregnancy losses related to painless cervical dilation, and in the absence of labor or abruptio placenta, or prior cerclage due to painless cervical dilation in the second trimester [10].

Emergency cerclage resulted in successful pregnancy and perinatal outcomes in this study. Term delivery rate was 44.6%, and perinatal mortality was only 3.6%. According to a retrospective study reported by Gundabattula *et al.* [11], in 74 women who were found to have premature cervical dilatation who underwent emergency cerclage at a mean of 21.9 weeks of gestation, term delivery rate was 8.8% and perinatal mortality was 7.2%. There were greater pregnancy and perinatal outcomes in this study when compared with those of previous studies [11]. The authors also analyzed factors related to poor outcomes after emergency cerclage. For example, the present results suggested that elevated pre-cerclage CRP level was significantly related to delivery rate before 34 weeks of gestation. In a retrospective study,

Zhu *et al.* [12] reported that factors related to poor pregnancy outcomes were presenting symptoms, cervical dilatation, postoperative white blood cell (WBC) count, and postoperative CRP level. However, they did not evaluate preoperative CRP level. In the present study, post-cerclage CRP was a slightly elevated after the cerclage operation. As antibiotics were used for at least seven days postoperatively after emergency cerclage, post-cerclage CRP was not significantly elevated when compared with pre-cerclage CRP. In a retrospective study reported by Fuches *et al.* [13], 134 women who underwent an emergency cerclage procedure at 15-26 weeks of gestation tended to develop early preterm delivery before 32 weeks of gestation when they were multigravid with a history of spontaneous preterm labor, cervical dilatation > 2 cm, amniotic membrane bulging, and pre-cerclage CRP > 1.5 mg/dL or WBC $\geq 13,600 \text{ mm}^{-3}$. These results are generally consistent with the present observations.

The period of pregnancy prolongation tended to be shorter in the amniotic membrane bulging group than in those without amniotic membrane bulging. There are a few studies assessing factors associated with pregnancy outcomes in women with amniotic membrane bulging for emergency cerclage [1, 13]. In these studies, it was found that women with a protruding amniotic sac had poorer outcomes than those in women without an amniotic sac present at the external os. In the present study, women with membrane bulging tended to have a shorter gestational age at delivery, greater prolongation of pregnancy, and more frequent neonatal sepsis than those without amniotic membrane bulging.

There were studies on whether emergency cerclage or ex-

pectant management could be helpful for women with cervical insufficiency discovered in the late second trimester because of poorer prognosis, comparing patients with membrane bulging to those without membrane bulging. Althuisius *et al.* [14] randomized 23 women who had membrane bulging before 27 weeks of gestation: 13 women were randomly assigned to the emergency cerclage and indomethacin group and ten women were assigned to the bed rest-only group. Preterm delivery before 34 weeks of gestation was significantly lower in the emergency cerclage and indomethacin group. However, there was no difference in perinatal survival. In the present study, 21 women in the expectant management group were treated with antibiotics, tocolytics, and progesterone, along with bed rest. Therefore, regarding preterm delivery before 34 and 37 weeks of gestation, there was no significant difference between the emergency cerclage group and the expectant group. Also, there was no significant difference in perinatal outcome between the two groups.

The present authors found no randomized controlled trial study that compared the treatments of cervical cerclage and vaginal progesterone directly for the prevention of preterm birth in women with cervical insufficiency in the mid-trimester. One indirect meta-analysis of randomized controlled trials reported outcomes for vaginal progesterone versus cervical cerclage for the prevention of preterm birth in women with a sonographic short cervix, previous preterm birth, and singleton gestation [6]. They concluded that either vaginal progesterone or cerclage are equally efficacious in the prevention of preterm birth. These results are generally consistent with the present observations. Another retrospective observational study reported that cervical cerclage and vaginal progesterone therapies in women without a history of preterm birth showed similar effectiveness for term delivery and perinatal outcomes [15]. However, there were differences between previous studies and the present study. In the previous studies, the cervical cerclage groups were not prescribed any progesterone or tocolytics. However, in the present study, the emergency cerclage group was prescribed progesterone and/or tocolytics if they experienced uterine contraction after a cerclage operation. Nevertheless, there were no differences regarding delivery and perinatal outcomes between the two groups. However, because this was a retrospective study, it is possible that the reasons why some women did not receive a cerclage confounded the outcomes of the study. The present authors selected expectant management over emergency cerclage when they had shorter cervical length (< 1 cm) and fetal viability (> 24 weeks of gestation).

The present study is limited by the fact that it is a retrospective study, and the lack of randomization. However, the authors found that preterm delivery rate < 34 weeks of gestation was significantly higher in the emergency cerclage group than in the prophylactic cerclage group. Elevated pre-cerclage CRP level was significantly associated with

delivery before 34 weeks in the emergency cerclage group. Additionally, there were no significant differences between the emergency cerclage group and the expectant management group in both pregnancy and perinatal outcomes.

The present results suggest that in women with a history of painless cervical dilation after the first trimester, prophylactic cerclage has good pregnancy outcomes. However, in women with painless cervical dilation without previous second trimester preterm delivery, there were no differences in pregnancy outcomes between the emergency cerclage and expectant management groups.

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