



# Single-center 4-year outcomes of patients underwent cervical cerclage to prevent preterm labor

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## Abstract

**Objective:** Preterm labor is a significant health problem reason. Cervical insufficiency is one of the significant reasons of this condition. Therefore, we have reviewed the outcomes of patients that we applied cervical cerclage by comparing with the literature.

**Methods:** We retrospectively reviewed the medical files of 68 patients who referred to the Adana Application and Research Center of Başkent University between January 2010 and June 2014.

**Results:** Mean delivery time of the patients was 31 weeks and 6 days  $\pm$  7 weeks and 1 day, and mean birth weight was 2112 $\pm$ 1203 g. A total of 13 patients underwent emergency cerclage. Mean waiting period in patients who underwent emergency cerclage was 9 weeks and 4 days  $\pm$  6 weeks and 4 days. Administering progesterone in addition to the cerclage presented no effect on delivery time.

**Conclusion:** Cervical cerclage is a common obstetric procedure applied to prevent preterm labor due to cervical insufficiency. The most common procedure applied for that purpose is McDonald Cerclage. Delivery time can be delayed with cervical cerclage in selecting appropriate patient. While progesterone use only can be effective in preterm labor treatment, the synergic effect of progesterone with cerclage is not observed in concurrent use with cerclage.

**Keywords:** Cerclage, McDonald, progesterone.

## Özet: Preterm eylemin önlenmesi amacıyla servikal serklaj uygulanan hastaların 4 yıllık tek merkezli sonuçları

**Amaç:** Preterm eylem önemli bir sağlık problemi nedenidir. Servikal yetmezlik ise bunun en önemli nedenlerden biridir. Bu nedenle servikal serklaj uyguladığımız hastaların sonuçları literatür eşliğinde değerlendirilmiştir.

**Yöntem:** Başkent Üniversitesi Adana Uygulama ve Araştırma Merkezi'ne Ocak 2010 – Haziran 2014 tarihleri arası başvuran 68 hastanın dosya bilgileri retrospektif olarak taranmıştır.

**Bulgular:** Hastaların ortalama doğum haftası 31 hafta 6 gün  $\pm$  7 hafta 1 gün ve doğum kilosu 2112 $\pm$ 1203 g olarak bulunmuştur. Toplam 13 hastaya acil serklaj uygulanmıştır. Acil serklaj uygulanan hastalarda ortalama bekleme süresi 9 hafta 4 gün  $\pm$  6 hafta 4 gündür. Serklaja ek olarak progesteron verilmesinin ise doğum zamanına etkisi görülmemiştir.

**Sonuç:** Servikal serklaj, servikal yetersizlik nedeniyle olan preterm doğumu engellemek için sık uygulanan bir obstetrik prosedürdür. Bu amaçla en sık uygulanan prosedür ise McDonald serklajdır. Uygun hasta seçiminde servikal serklaj ile doğum zamanı ertelenebilmektedir. Preterm eylem tedavisinde sadece progesteron kullanımı etkin olmasına rağmen serklaj ile birlikte kullanımında serklaj ile progesteronun sinerjik etkisi gözlenmemektedir.

**Anahtar sözcükler:** Serklaj, progesteron, McDonald.

## Introduction

Preterm labor is a significant health problem and it is seen in 6–10% of all pregnancies.<sup>[1]</sup> The most significant reason of prenatal mortality is the premature birth and it constitutes 28.78% of the deaths.<sup>[2]</sup> Also, 50% of all perinatal mortality is preterm-based. Cervical insufficiency

is considered as one of the most significant preterm labor reasons.<sup>[3]</sup> The diagnosis of cervical insufficiency can be established usually on the basis of medical history and by ruling out other reasons. It is considered that a pregnant woman with painless cervical dilatation and delivery at second trimester (ruling out other reasons) has a structural cervical weakness which can be fixed sur-

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gically.<sup>[4]</sup> Three reasons usually cause cerclage indication. These are history-indicated cerclage (HIC), ultrasound-indicated cerclage (UIC) and physical examination-indicated cerclage (PEIC). Second trimester loss and/or preterm labor is screened in history-indicated cerclage while cervix length measurement below 25 mm and presence of previous early labor are screened in ultrasound-indicated cerclage and dilated cervix during manual and speculum examinations is screened in physical examination indicated cerclage.<sup>[4,5]</sup> In this study, we presented labor outcomes of the patients that we followed up after surgery in our clinic.

## Methods

The demographic data, gestational follow-up and delivery information of 68 patients who admitted to Adana Application and Research Center of Başkent University between January 2010 and June 2014 were obtained retrospectively from the medical files of the patients and hospital database. The data were analyzed by using SPSS 20.0.0 (SPSS Inc., Chicago, IL, USA).

### Cervical Cerclage Procedure

The patients had dorsal lithotomy position. After applying Batticon on vulva-vagina area, McDonald cerclage was applied to all patients with Mersilen tape (MERSILENE® Polyester Fiber Suture, ETHICON; Johnson & Johnson, New Brunswick, NJ, USA) under sedation anesthesia. Patients were administered single-dose cefazolin before cerclage for prophylaxis purpose. After cerclage, single-dose rectal indomethacin (Endol® Suppository 100 mg) and single-dose intramuscular hydroxyprogesterone caproate (Proluton depot® 500 mg) were administered. Tocolytic treatment (indomethacin

4×25 mg per oral after 100 mg per rectal administration) and antibiotic treatment (ampicillin and azithromycin combination) were applied for 48 hours to all patients in addition to emergency cerclage. Ampicillin was completed to 10 days with oral preparations (amoxicilline 3×500 mg po) after 48-hour intravenous (ampicillin 4×2 g IV) administration. Azithromycin was administered as 3-day oral preparation (azithromycin 1×500 mg po 3-day). Cervical cerclage procedure was not applied to the patients who were suspected for chorioamnionitis, had membrane rupture and found to have elevated white blood cell count and C-reactive protein. The patients discharged were recommended bed rest. The cerclage was applied at 37 weeks except the onset of spontaneous labor, membrane rupture or the need for preterm labor.

## Results

We evaluated the cerclage results of 68 patients who admitted to our clinic between January 1, 2010 and June 2014. Mean age of 68 patients was 29.3 years. Mean cerclage week is 15 weeks and 6 days. Mean delivery time of all patients in the study was 31 weeks and 6 days, and mean birth weight was 2112 g. In the sub-groups, cerclage week was 14 weeks and 4 days, delivery week was 32 weeks and 3 days, and birth weight was 2215 g in patients who underwent history-indicated cerclage (HIC). In the patients who underwent ultrasound-indicated cerclage (UIC), mean cerclage week was 19 weeks and 6 days, delivery week was 33 weeks and 4 days, and birth weight was 2327 g. These mean values were 18 weeks and 5 days for cerclage week, 28 weeks and 3 days for delivery week, and 1570 g for birth weight in patients who were applied physical-indicated cerclage (PEIC) (Table 1). A total of 13 patients underwent emergency

**Table 1.** Cerclage week, delivery week and birth weight according to the indications.

	Indication											
	HIC*			UIC†			PEIC‡			Total		
	Mean	Number	Std. dev	Mean	Number	Std. dev	Mean	Number	Std. dev	Mean	Number	Std. dev
Age	29.8	46	5.01	30.6	9	5.47	27.0	13	6.19	29.3	68	5.36
Cerclage week	14w4d	46	1w6d	19w6d	9	2w3d	18w5d	13	3w	15w6d	68	3w1d
Delivery week	32w3d	40	7w1d	33w4d	9	5w6d	28w3d	11	7w5d	31w6d	60	7w1d
Birth weight (g)	2215	39	1175.87	2327	9	1064.2	1570	11	1356.45	2112	59	1203

\*History-indicated cerclage (HIC)

†Ultrasound-indicated cerclage (UIC)

‡Physical examination-indicated cerclage (PEIC)

**Table 2.** The effect of progesterone use on indications.

	HIC*		UIC†		PEIC‡		Total	
	Progesterone use							
	N/A	Available	N/A	Available	N/A	Available	N/A	Available
Delivery week	32w6d	32w2d	32w6d	34w4d	25w6d	29w3d	31w3d	31w6d
p	0.990		0.698		0.532		0.857	
Birth weight (g)	2196	2227	2190	2603	1366	1646	2095	2114
p	0.937		0.617		0.778		0.841	

\*History-indicated cerclage (HIC)

†Ultrasound-indicated cerclage (UIC)

‡Physical examination-indicated cerclage (PEIC)

cerclage (PEIC). Among them, the earliest was 13 weeks and the latest was 24 weeks. Mean period waited up to delivery was 9 weeks and 4 days in PEIC group. Mean delivery time was 31 weeks and 6 days in the group which was administered progesterone in addition to cerclage while it was 31 weeks and 3 days in the group not administered progesterone. However, this difference was not statistically significant ( $p=0.857$ ). In the groups administered progesterone and not administered, mean birth weight was 2124 and 2095, respectively, and this difference was also not statistically significant ( $p=0.841$ ) (Table 2). When administering and not administering progesterone according to the indications were compared, no statistically significant result was found in the analyses of sub-groups (Table 2). Similarly, the comparison of administering and not administering progesterone according to the sub-groups in the deliveries car-

ried out before and after 34 weeks showed no statistically significant result (Table 3).

Previsible delivery (delivery at <24 weeks) occurred in 7 out of 46 patients in HIC group, in 1 out of 9 patients in UIC group, and in 3 out of 13 patients in PEIC group.

## Discussion

Cervical insufficiency is defined as the condition where cervix cannot bear fetus until the term depending on the structural or functional weakness of cervix.<sup>[1]</sup> It is characterized with painless cervical dilatation causing premature rupture of membranes and the birth of fetus usually in the second trimester.<sup>[1]</sup> It is responsible for 0.2% of spontaneous abortions, 16–20% of pregnancy loss cases during second trimester and 8–15% of recurrent abortions.<sup>[2,3]</sup> Cervical insufficiency is responsible for about

**Table 3.** Distribution of before and after 34 weeks according to indication and progesterone use.

	Indication											
	HIC* N (%)			UIC† N (%)			PEIC‡ N (%)			Total N (%)		
	Delivery		Total	Delivery		Total	Delivery		Toplam	Delivery		Total
	<34 weeks	>34 weeks		<34 weeks	>34 weeks		<34 weeks	>34 weeks		<34 weeks	>34 weeks	
Progesterone is not available	6 (37.5)	10 (62.5)	16 (100)	2 (33.3)	4 (66.6)	6 (100)	2 (66.6)	1 (33.3)	3 (100)	10 (40)	15 (60)	25 (100)
Progesterone administered	9 (37.5)	15 (62.5)	24 (100)	1 (33.3)	2 (66.6)	3 (100)	6 (75)	2 (25)	8 (100)	16 (45)	19 (55)	35 (100)
Total	15	25	40	3	6	9	8	3	11	26	34	60

\*History-indicated cerclage (HIC)

†Ultrasound-indicated cerclage (UIC)

‡Physical examination-indicated cerclage (PEIC)

10% of preterm labors.<sup>[4]</sup> In the treatment, cervical cerclage, progesterone, passer and bed rest are used either alone or in combination.<sup>[6-10]</sup> One of the standard approaches in the treatment of cervical insufficiency is cervical cerclage application. Preterm labor risk decreases significantly with the application of cervical cerclage in singleton pregnancies (RR 0.80; 95% CI 0.69–0.95). However, no decrease has been observed in perinatal death (8.4% vs. 10.7%) and neonatal morbidity (9.6% vs. 10.2%).<sup>[11]</sup> Clinical benefit of cervical cerclage application in multiple pregnancies was not shown.<sup>[12]</sup> There are studies showing that the use of progesterone only or cervical passer only as an alternative to cerclage is as much effective as cerclage.<sup>[13-15]</sup> Today, the techniques of Shirodkar and McDonald are the most common applications. In McDonald technique, purse-string suture is applied on cervix-fornix junction.<sup>[16]</sup> In Shirodkar technique, the most important points are the application of suture onto the closest location to the level of internal os, dissecting cervix from bladder and rectum, and covering suture with mucosa. Frequently, polyester and polypropylene suture materials are used. Success rates up to 85–90% were reported with both McDonald and modified Shirodkar techniques.<sup>[17]</sup> Modified Shirodkar application is preferred mostly in those whose McDonald cerclage fails and have structural cervical abnormality. Prophylactic cerclage is applied in case of live fetus between 13 and 16 weeks without any abnormality.<sup>[18]</sup> In this study, McDonald cerclage technique was used on all patients who had cerclage.

In the compilation of Shuag et al., preterm labor rate decreased from 17% to 13% (<33 weeks of gestation), and neonatal mortality decreased from 17% to 9% in patients who underwent prophylactic cerclage based on their histories. In the same study, 30% decrease in preterm labor (<35 weeks of gestation) and 36% decrease in mortality were reported in UIC patient group.<sup>[4]</sup> Although our study was not a randomized controlled study, we found that mean delivery time was over 32 weeks and mean birth weight was over 2000 g in both HIC and UIC groups (HIC: 32 weeks and 3 days, and 2215 g; UIC: 33 weeks and 4 days, and 2327 g). Previaible delivery (delivery at <24 weeks) occurred in 7 out of 46 patients in HIC group, in 1 out of 9 patients in UIC group, and in 3 out of 13 patients in PEIC group. There were only two patients whose delivery was after 39 weeks, and they were both from PEIC group. Cerclage was applied at week 17 to

the first patient and at week 24 to the second patient. In both patients, cervical dilatation was observed during speculum examination and amniotic membranes in direct examination.

Although there is no prospective study about administering progesterone until delivery in addition to cervical cerclage, there are some retrospective and observational cohort studies. Contrary to expectations, adding progesterone to cerclage application did not create any synergic effect in these studies. Hospitalization and uterine contraction were less in patients who took progesterone only. This may be caused by the anti-inflammatory effect, oxytocin inhibition and immune modulatory effect of progesterone. 17- $\alpha$ OHPC was used intramuscularly in all studies containing progesterone in addition to cerclage.<sup>[19-22]</sup> Unfortunately, there is no study on other progesterone preparations. A synergic effect may appear later in the use of other preparations.<sup>[23]</sup> It was seen in our study that delivery time and birth weight are not affected in patients by administering progesterone (intramuscular 17- $\alpha$ OHPC) in addition to the cerclage in line with the literature. In our study, mean birth time was found as 31 weeks and 6 days  $\pm$  7 weeks in patients administered progesterone in addition to the cerclage, and 31 weeks and 3 days  $\pm$  7 weeks and 4 days in patients who were not administered progesterone. Birth weight was 2124 $\pm$ 1139 g in patients administered progesterone, and 2095 $\pm$ 1310 g in patients not administered progesterone. These values were not statistically significant.

The activity of emergency cerclage is quite high in a patient group selected well. It is very efficient in patients who are below 22 weeks, have cervical dilatation under 3 cm and who are negative for inflammatory indicators. In the literature compilation of Namouz et al., mean waiting time after cerclage was 8 weeks and 5 days, mean birth weight was 1766 g, and mean delivery time was 30 weeks and 30 weeks and 4 days.<sup>[24]</sup> In our study, we found mean waiting time as 9 weeks and 4 days  $\pm$  6 weeks and 4 days in PEIC group, and these values were consistent with the literature. In our study, we found mean delivery time as 28 weeks and 3 days, and mean birth weight as 1570 g in patients who had emergency cerclage. Considering the contribution of one-week delay of delivery on mortality between 24 and 32 weeks of gestation, the significance of delaying preterm labor becomes more prominent. In the compilation of Shuag et al., neonatal mortality decreased from 71% to 31% in PEIC group.<sup>[4]</sup>

## Conclusion

Cervical cerclage is an obstetric procedure to prevent preterm labor. The most common procedure applied for that purpose is McDonald Cerclage. The efficiency in selecting appropriate patient has been supported by the literature in each indication. Although progesterone use is very effective in the treatment of preterm labor, no synergic effect has been observed by its concurrent use with cerclage. Prospective randomized studies focused on that purpose and further studies using progesterone other than 17- $\alpha$ OHPC are required. The disadvantage of this study is being retrospective and limited in terms of population. However, conducting similar procedures and follow-up through a standard intervention in a single clinic is the advantageous aspect of the study.

**Conflicts of Interest:** No conflicts declared.

## References

- Lumley J. Defining the problem: the epidemiology of preterm birth. *BJOG* 2003;110 Suppl 20:3–7.
- Ngoc NT, Merialdi M, Abdel-Aleem H, Carroli G, Purwar M, Zavaleta N, et al. Causes of stillbirths and early neonatal deaths: data from 7993 pregnancies in six developing countries. *Bull World Health Organ* 2006;84:699–705.
- Abdel-Aleem H, Shaaban OM, Abdel-Aleem MA. Cervical pessary for preventing preterm birth. *Cochrane Database Syst Rev* 2013;5:CD007873.
- Suhag A, Berghella V. Cervical cerclage. *Clin Obstet Gynecol* 2014;57:557–67.
- Kuon R-J, Hudalla H, Seitz C, Hertler S, Gawlik S, Fluhr H, et al. Impaired neonatal outcome after emergency cerclage adds controversy to prolongation of pregnancy. *PLoS One* 2015;10:e0129104.
- Göğşen M, Önalın SK, Yanık FF, Mülayim B, Zeyneloğlu HB. Our case series of the emergency McDonald cerclage and the review of the literature. *Turkish Journal of Obstetrics and Gynecology* 2010;7:202–5.
- Debby A, Sadan O, Glezerman M, Golan A. Favorable outcome following emergency second trimester cerclage. *Int J Gynaecol Obstet* 2007;96:16–9.
- Stromme WB, Haywa EW. Intrauterine fetal death in the second trimester. *Am J Obstet Gynecol* 1963;85:223–33.
- Jewelewicz R. Incompetent cervix: pathogenesis, diagnosis and treatment. *Semin Perinatol* 1991;15:156–61.
- Iams JD, Johnson FF, Sonek J, Sachs L, Gebauer C, Samuels P. Cervical competence as a continuum: a study of ultrasonographic cervical length and obstetric performance. *Am J Obstet Gynecol* 1995; 172(4 Pt 1):1097–103; discussion 104–6.
- Alfirevic Z, Stampalija T, Roberts D, Jorgensen AL. Cervical stitch (cerclage) for preventing preterm birth in singleton pregnancy. *Cochrane Database Syst Rev* 2012;4:CD008991.
- Rafael TJ, Berghella V, Alfirevic Z. Cervical stitch (cerclage) for preventing preterm birth in multiple pregnancy. *The Cochrane database of systematic reviews* 2014;9:CD009166.
- Conde-Agudelo A, Romero R, Nicolaidis K, Chaiworapongsa T, O'Brien JM, Cetingoz E, et al. Vaginal progesterone vs. cervical cerclage for the prevention of preterm birth in women with a sonographic short cervix, previous preterm birth, and singleton gestation: a systematic review and indirect comparison metaanalysis. *Am J Obstet Gynecol* 2013;208:42.e1–42.e18.
- Alfirevic Z, Owen J, Carreras Moratonas E, Sharp AN, Szychowski JM, Goya M. Vaginal progesterone, cerclage or cervical pessary for preventing preterm birth in asymptomatic singleton pregnant women with a history of preterm birth and a sonographic short cervix. *Ultrasound Obstet Gynecol* 2013;41:145–51.
- Society for Maternal-Fetal Medicine Publications Committee, with assistance of Vincenzo Berghella. Progesterone and preterm birth prevention: translating clinical trials data into clinical practice. *Am J Obstet Gynecol* 2012;206:376–86.
- Odibo AO, Berghella V, To MS, Rust OA, Althuisius SM, Nicolaidis KH. Shirodkar versus McDonald cerclage for the prevention of preterm birth in women with short cervical length. *Am J Perinatol* 2007;24:55–60.
- Caspi E, Schneider DF, Mor Z, Langer R, Weinraub Z, Bukovsky I. Cervical internal os cerclage: description of a new technique and comparison with Shirodkar operation. *Am J Perinatol* 1990;7:347–9.
- İsaoğlu Ü, Yılmaz M, Kadanalı S. The results of cervical cerclage in a single center during a five-year period. *Journal of Clinical and Experimental Investigations* 2010;1:104–7.
- Zakut H, Lanciano A. The influence of progesterone treatment on the course and outcome of pregnancies following suture of the cervix for cervical incompetence. *Clin Exp Obstet Gynecol* 1981;8:1–5.
- Berghella V, Figueroa D, Szychowski JM, Owen J, Hankins GD, Iams JD, et al.; Vaginal Ultrasound Trial Consortium. 17-alpha-hydroxyprogesterone caproate for the prevention of preterm birth in women with prior preterm birth and a short cervical length. *Am J Obstet Gynecol* 2010;202:351.e1–6.
- Rafael TJ, Mackeen AD, Berghella V. The effect of 17alpha-hydroxyprogesterone caproate on preterm birth in women with an ultrasound-indicated cerclage. *Am J Perinatol* 2011;28: 389–94.
- Rebarber A, Cleary-Goldman J, Istwan NB, Rhea DJ, Desch C, Russo-Stieglitz K, et al. The use of 17 alpha-hydroxyprogesterone caproate (17p) in women with cervical cerclage. *Am J Perinatol* 2008;25:271–5.
- Defranco EA, Valent AM, Newman T, Regan J, Smith J, Muglia LJ. Adjunctive therapies to cerclage for the prevention of preterm birth: a systematic review. *Obstet Gynecol Int* 2013;2013:528158.
- Namouz S, Porat S, Okun N, Windrim R, Farine D. Emergency cerclage: literature review. *Obstet Gynecol Surv* 2013;68:379–88.