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The Results of Cervical Cerclage Performed Between 2012-2016

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Abstract

Purpose/Aim: The aim of our study is to share the results of cerclage applied in our clinic and to define the factors affecting the success of cerclage.

Methods: Our study is a retrospective cohort study including 62 singleton pregnant women who underwent McDonald cerclage procedure in our clinic between January 2012 and December 2016. Cerclages were divided into two groups, as 'therapeutic cerclage' (TC) and 'prophylactic cerclage'(PC), and both of these groups were compared. Cerclage success was assessed at two separate endpoints: delivery after 28 gestational weeks and 37 gestational weeks.

Results: The gestational week of cerclage performed was found to be significantly lower in the 'TS' group than in the 'PS' group [TS: 20,29 ± 4,22 weeks, PS: 16,79 ± 4 , 04 weeks (p = 0.001)]. The length of the cervix was significantly shorter in the 'TS' group than in the 'PS' group [TS: 15,09 ± 4,89 mm, PS: 28,34 ± 6,78 (p <0,001)]. Cerclage-delivery interval found to be significantly longer in the 'PS' group than in the 'TS' group [PS: 18.45 ± 5.1 weeks, TS: 13.62 ± 5, 84 weeks, (p = 0.001)]. The gestational week of cerclage performed [Odds Ratio: 1,452 (1,287- 1,637), p=0,000{for 28th week} and Odds Ratio: 4,529 (2,413- 8,5), p= 0,000{for 37th week}] and the cervical length before surgery [Odds Ratio: 2.57 (1.589 - 5.678) *p* = 0.0041{for 28th week}] were determined as independent predictors of cerclage success.

Conclusion: There was no significant difference in cerclage success and pregnancy outcomes in the groups of TC and PC. The cervical length before surgery and the gestational week of cerclage are independent predictors for cerclage success.

Key words: Cervical Cerclage, Cervical Insufficiency, McDonalds Cerclage, Prophylactic Cerclage, Therapeutic Cerclage.

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Introduction

Cervical insufficiency (CI) is defined as the inability of the uterine cervix to protect pregnancy without clinical signs and/or symptoms (1-3). Cervical insufficiency causes recurrent, painless, second trimester losses and preterm labors (4). Although it appears in 0.1% to 1% of all pregnancies, this figure increases to 8% in patients with a history of recurrent second-trimester loss (5). Cervical insufficiency with recurrent pregnancy losses or preterm labor has an important place in maternal and neonatal mortality-morbidity (6-8). The most appropriate treatment option for this group of patients is cervical cerclage (CC) (9,10). The most commonly applied techniques today are modified Shirodkar and McDonalds Cerclage (McDC) methods (11-15). The success of these techniques in the treatment of CI has been demonstrated by many clinical studies and case series. Despite its effective use in laparoscopic and transabdominal techniques in addition to these techniques, which have been applied for many years, there are still reported cases of CI resulting in an unsuccessful cerclage procedure. In surgical procedures, the success of the procedure depends on the correct preoperative patient selection and the determination of the appropriate procedure for the patient, as well as the implementation of the effective intervention. Analyzing case series well, identification of risk factors affecting the success of the procedure and identifying or eliminating these risk factors or determining the surgical procedure according to risk factors will increase the chances of success of the procedure. In our center, 62 pregnant women who were diagnosed with CI between 2012-2016 and underwent a follow-up prophylactic or therapeutic McDC technique were evaluated within the scope of our study. In our study, our aim was to evaluate the results of cervical cerclage procedures applied in our center based on maternal risk factors, term delivery and live birth rates and neonatal health data.

Materıal And Method

Our study is a retrospective cohort study involving 62 singleton pregnancies at 16-24 gestational weeks who admitted to Medipol University Faculty of Medicine, Obstetrics and Gynecology Clinic between January 2012 and December 2016 and were diagnosed with cervical insufficiency and underwent McDonalds cerclage procedure.

Our study was conducted with the approval of Medipol University Non-Interventional

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Clinical Research Ethics Committee (Ethics committee approval date: October 6,2017 - Ethics Committee approval number: 10840098-604.01.01.E.35584).

File details and examination records were obtained from the archive records of the patients involved in our study. Data such as the age of patients, gravida and parity numbers, mode of delivery if they gave birth, abortion and preterm pregnancy loss were determined and noted. Thus, demographic data and transvaginal ultrasonogrophic (TVUSG) examination data obtained by analyzing retrospective examination information of patients were evaluated in our study. Cervical insufficiency diagnoses of the study patients were determined as a result of recorded history, physical examination and ultrasound examinations. All patients had transvaginal ultrasound evaluation using 8-11 mHz vaginal probe with General Electric Logiq brand ultrasound as TVUSG.

Table 1: Inclusion and exclusion criteria
Inclusion criteria:
1. Having a history of preterm birth
2. Being in the gestational week of 16.-24.
3. No congenital anomalies
4. Absence of vaginal bleeding (not accompanied by ablatio placenta, fetal distress, placenta previa)
5. No suspicion of chorioamnionitis
Exclusion criteria:
1. Multiple pregnancies, patients with preterm premature rupture of membrane or fetal anomaly
2. Patients with incomplete pregnancy outcomes
3. Pregnant women followed up with non-surgical procedures for cervical insufficiency

The inclusion and exclusion criteria of the study are presented in Table 1.

Cervical insufficiency risk group evaluation criteria: (i) Cervical canal measurements, (ii) Signs of funneling, if any, (iii) Surgical procedures to the cervix, (iv) A history of spontaneous preterm birth (35 weeks and below) at least 3 or more, which was previously determined to occur due to painless cervical insufficiency or unknown reasons, (v) and / or the history of second trimester pregnancy loss, previous pregnancies, if any, and their results were investigated.

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Technique: Cervical culture was taken from patients 1 week before the cerclage procedure (except in emergency cases) and culture-specific antibiotherapy was administered before the procedure if necessary. All patients were administered azithromycin 1000 mg prophylactically. Cervical cerclage was performed under spinal anesthesia or induction anesthesia in the dorsal lithotomy position, following proper site cleaning and covering. Double needle Mercilene polyester tape was attached to 3-6-9-12 o'clock levels, at os interna level, under the mucous membrane, and sutured. In the McDonald-Hofmeister modification, another suture is placed 1 cm distally of this first suture. Discharged patients were recommended to have at least 2 weeks of bed rest and no sexual intercourse (16). Except for the onset of spontaneous labor, membrane rupture or the need for premature birth, cerclage was performed at 37th week.

Patients were selected among the ones with age, gravida, parity, number of abortions, obstetric histories, cervical dilation and ultrasonographic measurements records. The gestational weeks of the patients included in the study were calculated according to their last menstrual dates and/or based on USG results in the first trimester.

Ultrasonographic cervical evaluation of the study patients was performed with a 5MHz, 120 degree convex angle vaginal probe while the bladder was empty in the lithotomy position. Cervical measurements were simultaneously made in the cross-section where the internal os, external os, cervical canal and endocervical mucosa could be displayed and enlarged to cover 3/4 of the screen. The measurement was made three times in each pregnant women and the shortest length with the best image quality was recorded (16-18).

As a result of ultrasonography measurements, the cerclage procedure applied to the patients with cervical length of 25 mm and below was defined as 'therapeutic cerclage' (TC). The cervical Insufficiency procedure applied to pregnant women with a cervical length above 25 mm and a history of abortion and preterm delivery with a previous diagnosis of cervical insufficiency was defined as 'prophylactic cerclage' (PC) (19-20).

Statistics: SPSS (Static Package of Social Sciences) 24.0 program was used to evaluate the data obtained. Kolmogrov-Smirnov and Shapiro-Wilk tests were used to test the normal distribution of the variables. Numerical variables with a normal distribution were expressed as mean ±standard deviation (SD), numerical variables without a normal distribution were expressed as median (Interquartile Range), and categorical variables were expressed as a percentage (%). Demographic and clinical characteristics that will create a risk factor for cervical failure were first analyzed using univariate analyses. Chi-square was used for categorical variables, and the t test was used for continuous variables. Cerclage success was evaluated with the delivery data after the 28th and 37th week of pregnancy. Cerclage success is the most important outcome of our study and group comparisons were made in this context. In light of the information obtained from the literature, birth after 28th gestational week was defined as our primary endpoint, and birth after 37th gestational week was defined as our secondary endpoint. Therapeutic (cervical length less than 25 mm) and prophylactic

(cervical length greater than 25 mm and patients with a history of cervical failure) pregnancy outcomes of cerclage groups were compared. Clinically significant data with a p value of less than 0.1 in univariate analyses were evaluated by multivariate analyses and independent predictors for cerclage success were investigated. The results were evaluated in a confidence interval of 95% and a level of significance of $p<0.05$.

Results

The age range of 62 singleton pregnant women who were diagnosed with cervical insufficiency was between 18 and 41, and the average age was 31.56±5. The median gravida value of the sample patients was calculated as 2 (IQR:0-4) and the median parity value was calculated as 1 (IQR:0-3). Data on demographic characteristics of the patients were presented in Table 2.

It was found that 48.4% of the study patients had gravida 1, 27.4% had gravida 2 and 24.2% had gravida 3 and above. It was observed that 62.9% of the patients had parity 0, 29% had parity 1 and 8.1% had parity 2 and above. It was found that 71% of the patients had no previous history of abortion, while 85.5% did not have a live birth.

As a result of descriptive analysis of the study patients according to previous pregnancy histories: 27.4% (n=17) had a history of preterm delivery, 37% (n=23) had a history of second trimester pregnancy loss, and 8% (n=5) had a previous history of cerclage (Table 2).

As a result of the descriptive analysis of the procedure: it was found that the week of pregnancy at the time of cerclage procedure was 18.4±4.3 weeks, the period of termination of pregnancy was 34.3±4.6 weeks, and the period of cerclage-delivery interval (the period from the week of pregnancy at the time of cerclage to the end of pregnancy) was 15.6±5.6 weeks. Of the patients, 54.8% underwent cerclage before the 20^{th} week of gestation. It was observed that 9.7% of the patients gave birth before the 28^{th} gestational week, 50% gave birth between the 28^{th} and 37^{th} gestation weeks, and 43.3% gave birth after the 37^{th} gestation week. Cervical length measured by USG before the procedure was found to be 21.29±8,842 mm on average.

The success of cerclage was defined as the delivery after the procedure in and after 28^{th} gestational week. Cerclage operation in 91.9% of patients was observed to be successful. The rate of achieving term after the cerclage procedure (delivery after 37^{th} gestational week) was 42.9%, while the live birth rate was 95.2% (Table 2).

Of the studied patients, 53.2% underwent 'therapeutic cerclage' (TC) and 46.8% underwent 'prophylactic cerclage' (PC) Study patients were examined in two groups: 'TC' and 'PC' according to the type of cerclage applied. No statistically significant difference was found between the groups in terms of demographic data, USG measurements, obstetric histories, and data before and after surgery (Table 2).

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Table 2: Demographic data of study patients and comparison of Therapeutic/ Prophylactic cerclage groups

Variables	**ALL (n:62) Mean± SD/ Median (IQR)**	**Therapeutic cerclage (n:33) Mean± SD/ Median (IQR)**	**Prophylactic cerclage (n:29) Mean± SD/ Median (IQR)**	***P value***
Age	31.56± 5	31.58± 4.33	31.55± 5.74	0.985
Gravida	2 (0-4)	1 (0-2)	2 (1-3)	0.234
Parity	1 (0-3)	1 (0-2)	1 (0-3)	0.603
Number of abortions	0 (0-3)	0 (0-3)	0 (0-2)	0.306
Number of live births	0 (0-2)	0 (0-2)	0 (0-2)	0.937
Preterm Delivery History, n (%)	17 (27.4%)	7 (21.2%)	10 (33.4%)	0.696
Second Trimester Pregnancy Loss Story, n (%)	23 (37%)	4 (12.2%)	19 (62.4%)	0.230
Cerclage Story, n (%)	5 (8%)	2 (6%)	3 (10.3%)	0.926
Gestational period of cerclage (Week)	18.4± 4.3	20.29± 4.22	16.79± 4.04	**0,001**
Cervix length before the procedure (mm)	21.29± 8.84	15.09± 4.89	28.34± 6.78	<**0,001**
Cerclage-Delivery Interval (Week)	15.6± 5.6	13.62± 5.84	18.45± 5.1	**0,001**
Pregnancy end period (Week)	34.3± 4.6	33.92± 5.41	35.24± 4.01	0.283
Baby Weight (gr)	2527.4± 961.01	2450± 1069	2615± 0.837	0.514
1st minute APGAR Score	7.69± 2.10	7.33± 2.36	8.1± 1.71	0.145

5th minute APGAR Score	8.69± 2.28	8.36± 2.56	9.07± 1.88	0.227
Normal Spontaneous Delivery, n (%)	7 (11.3%)	2 (6.1%)	5 (17.2%)	0.399
Cesarean Delivery, n (%)	52 (83.9%)	29 (87.9%)	23 (79.3%)	0.149
Abortion, n (%)	3 (4.8%)	2 (6.1%)	1 (3.4%)	0.309
Progesterone Use, n (%)	54 (87.1%)	4 (12.1%)	4 (13.8%)	0.570
Delivery after 28 weeks, n (%)	57 (91.9%)	29 (87.9%)	28 (96.6%)	0.360
Live Birth, n (%)	59 (95.2%)	31 (93.9%)	28 (96.6%)	0.549
Delivery at maturity (37th week), n (%)	26 (42.9%)	13 (39.4%)	13 (44.8%)	0.665

SD: Standart Deviation, IQR: Interquartile Range.

Pregnancy week at the time of the cerclage procedure in the 'Therapeutic Cerclage (TC)' group was found to be statistically significantly more advanced than the 'Prophylactic Cerclage (PC)' group [TC:20.29±4.22 weeks PC:16.79±4.04 weeks (p= 0.001)]. Cervical length before the procedure was significantly shorter in the' TC' group than in the ' PC' group [TC:15.09±4.89 mm, PC:28.34±6.78 (p< 0.001)]. Cerclage-Delivery interval was found to be significantly longer in the PC group compared to the TC group [PC:18.45±5.1 weeks, TC:13.62±5.84 weeks, (p= 0.001)].

A history of premature birth was significantly higher in the 'PC' group and a history of cervical failure was significantly higher in the 'TC' group (p= 0.001). It was found that other demographic data did not differ between groups. No significant difference was found between the TC and PC groups in terms of postpartum outcomes (newborn weight, APGAR scores). No significant difference was observed between the groups in terms of the rates of cesarean delivery, normal spontaneous delivery, live delivery and abortion.

In our study, in light of information obtained from the literature in evaluating cervical cerclage success, births after the 28th gestational week were evaluated as the primary endpoint, while births after the 37th gestational week were evaluated as the secondary endpoint. No significant difference was found between the TC and PC groups in terms of cerclage success. Independent risk factors affecting cerclage success were analyzed according to primary and secondary endpoints.

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Factors that may affect cervical cerclage success were evaluated primarily by univariate analyses (Table 3). Variables with a P value less than 0.1 and clinically significant variables were placed in the multivariate analysis model [chi square:68.23 for the model evaluated by the Omnibus test, and (p< 0.001)].

Table 3: Independent risk factors affecting delivery after 28 weeks and 37 weeks.

	Univariate			**Multivariate**					
				Model 1			**Model 2**		
Variables	HR	95% CI	P value	HR	95% CI	P value	HR	95% CI	P value
Age	0.98	0.92- 1.03	0.508						
Gestational period of cerclage	1.41	1.27- 1.57	<0,001	1.45	1.28- 1.63	<0,001	4.52	2.41- 8.50	<0,001
Cervix length before the procedure	0.96	0.92- 1	0.047	2.57	1.58- 5.67	0.004	1	0.86- 1.16	0.963
Pregnancy end period	0.86	0.78- 0.93	0.001	0.88	0.67- 0.94	0.102			
Cerclage Type	0.47	0.27- 0.83	0.009	1.85	0.78- 4.35	0.157	1.06	0.22- 4.98	0.940
Delivery Type	1.76	0.79- 3.92	0.165						
Preterm Delivery History, n (%)	1.28	0.50- 3.25	0.595						
Second Trimester Pregnancy Loss Story, n (%)	2.05	1.05- 4.03	0.035	0.84	0.40- 1.74	0.645	1.63	0.53-4.98	0.388

Model 1: *Independent risk factors affecting delivery after 28 weeks,* ***Model 2:*** *Independent risk factors affecting delivery after 37 weeks*

As a result of the multivariate analysis, it was found that week of pregnancy at the time of cerclage procedure [Odds Ratio: 1.452 (1.287-1.637), (p< 0.001)] and cervical length before the cerclage [Odds Ratio: 2.57 (1.589 - 5.678), (p = 0.0041)], and deliveries after the 28th gestational week was found to be independent risk factors that affect the success of cervical cerclage (Table 3).

Variables were placed in a multivariate analysis model to determine the independent risk factors affecting term delivery (birth after 37th week of gestation), which is our secondary endpoint in evaluating cervical cerclage success [chi square:60.022 for the model evaluated

by the Omnibus test, (p<0.001)]. As a result of a multivariate analysis the gestational period of cervical cerclage was found the independent risk factor of delivery after 37th weeks of gestation and the cervical serclage success [Odds Ratio:4.529 (2.413-8.50), (p< 0.001)] (Table 3).

Dıscussıon

Our study patients were evaluated in two groups: TC and PC groups. In their clinical research with 205 patients, Korb D et al. divided their patients into high and low-risk of CI groups and compared them according to risk factors such as a history of preterm birth, second trimester loss, and cerclage history (21). The mean gestational week for the cerclage procedure, the gestational week of delivery, and postpartum outcomes (infant birth weight, 1st and 5th minute APGAR scores) of the sample, which was similar to our prophylactic group that underwent McDonald cerclage, were in line with our study data.

In their study of 116 patients, Sun X et al. defined the delivery of patients after 28 weeks as a successful cerclage (22). Gestational week results of therapeutic and prophylactic cerclage groups were found earlier in prophylactic group, in accordance with the data of our study. Live birth rates did not make a significant difference between the groups and are consistent with our results. Although birth rates reaching term after cerclage were higher in the prophylactic group in the study by Sun X et al., birth rates after the 28th and 37th weeks were similar between the two groups (22).

Similar to our evaluation, in their study with 41 pregnant women, Hançerlioğlu N et al. applied McDC technique, and divided the patients into therapeutic, prophylactic and emergency cerclage groups for evaluation (23). The results of researchers who determined the birth rate reached term in the PC group as 54.54%, which assert higher success rate for PC, contradict the data of our study. In our study, the number of groups was determined as n=33 for therapeutic cerclage and n=29 for prophylactic cerclage compared to the data of the researchers who evaluated 6 patient data in the therapeutic group in their studies. The rates of term delivery were 39.4% in the therapeutic group, and 44.8% in the prophylactic group. The difference between the groups was not statistically significant.

In our study, therapeutic and prophylactic cerclage groups were compared in terms of live birth rates, baby birth weight, 1st and 5th min Apgar scores. No significant differences were found between the groups. Karaca İ et al. also supports our study with the data obtained in their clinical research (24).

We observed a negative linear relationship between the cerclage-delivery interval and the cerclage performed gestational week in our study patients. Data obtained by Benifla JL et al. in their study evaluating 34 pregnant women who underwent emergency surgery after 20 weeks also supports this observation (25).

In their study with 47 patients, In Jalal EM et al. evaluated the outcome points according to deliveries after 28th weeks and 37th weeks. In their study, 44.6% of the patients

gave birth before the 28th week. In our study, although our outcome points were common, the birth rate before the 28th week was 8.1% and the birth rate before the 37th week was 57.1%. As a result of their study, Jalal EM et al. reported that vaginal membrane appearance in USG and early membrane rupture after cerclage were associated with cerclage failure, in other words, birth before 28th weeks. In our study, data other than the length of the cervix could not be analyzed, and similarly predictors for cerclage failure were determined as cerclage performed gestational week and the length of the cervix before the procedure (26).

Conclusıon

As a result, early USG monitoring in pregnant women with 2nd trimester pregnancy loss or a history of preterm delivery is vital for fetal mortality, morbidity and smooth pregnancy process both for the mother and fetus. In pregnant women with a history of cervical insufficiency or pregnant women with a recent CI diagnosis, carrying out TC and PC procedures in the most appropriate period, following frequent follow-ups, increases both the success of the procedure and the chances of continuity of pregnancy. In our study, we found that PC was quantitatively superior to TC in achieving term, but this difference was not statistically significant. Many studies have identified independent predictors for cerclage success. The independent predictors we identified in our study were determined as cerclage performed gestational week and the length of the cervix before the procedure. The insight that cerclage at an early period reduces to chance to term delivery in CI-diagnosed pregnant women will be a valuable information in making a decision about the timing of cerclage procedure through careful follow-ups in patients with CI history (pregnant women with a history of preterm delivery or 2nd trimester loss).

No differences were found between therapeutic and prophylactic cerclage groups in terms of cerclage success, live birth rates, and postpartum data.

Cerclage-Delivery interval' was shorter in the TC group compared to the PC group. It is believed that this statistically significant difference may be associated with the application of cercglage in the PC group earlier in pregnancy. On the other hand, it is also possible to interpret this difference in favor of a higher rate of pregnancy continuity in the PC Group.

Lımıtatıons

The used of single-center and single-cerclage-technique are the limitations of our study. The low number of samples and the problem of homogeneity make it necessary to evaluate these analyses in larger patient groups and with randomized design studies.

Conflıct Of Interest

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We declare that we do not have any actual or potential conflicts of interest, including any financial, personal or other relationships with other people or organizations, within three years from the commencement of the business that could inappropriately affect or be perceived to affect our study.

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