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Elective cervical cerclage versus no treatment in women with the history of cervical insufficiency: retrospective analysis of pregnancy outcomes

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Summary

Purpose of investigation: To evaluate the effectiveness of elective cervical cerclage (CC) on the pregnancy outcome of patients with cervical insufficiency. *Material and Methods:* A retrospective cohort study was conducted on women with an obstetric history of cervical insufficiency on whom CC was applied or not. The two groups were compared for the main measure outcomes of mean gestational age at delivery, birth weight, Apgar scores at five minutes, number of premature and preterm deliveries, rate of preterm premature rupture of membranes, incidence of neonatal death, and admission to the neonatal intensive care unit (NICU). *Results:* A total of 183 women were eligible for the final analysis in the CC group and 183 were taken as the control group. There were significant differences in terms of the mean gestational age at delivery (37 ± 4.0 *vs.* 34±5 weeks, $p = 0.001$), the mean birth weight (3,000 ± 870 *vs.* 2,200 ± 860 grams, $p = 0.001$), the number of preterm deliveries (< 37 weeks) (40% *vs.* 63%, $p = 0.001$, OR: 0.4, 95% CI: 0.26–0.61) between CC and control groups, respectively. Median Apgar scores at five minutes were 9 in CC group and 8 in the control group ($p = 0.001$) and the percentages of admission to NICU were 14% in CC group and 34% in the control group ($p = 0.001$, OR: 0.30, 95% CI: 0.17–0.52). *Conclusion:* The placement of elective CC seemed to be effective in patients with a history of mid-trimester abortion or preterm delivery due to cervical insufficiency.

Key words: Cervical insufficiency; Cervical cerclage; Pregnancy outcome.

Introduction

Cervical insufficiency is characterized by painless dilation of the cervix in the second trimester. Cervical cerclage (CC) has been performed to prevent preterm delivery in order to decrease the adverse outcomes of cervical insufficiency. Transvaginal CC is applied either electively (prophylactic) depending on obstetric history or selectively (therapeutic) depending on ultrasonographic findings or emergently in the case of advanced cervical dilatation. Many clinicians use serial ultrasound assessment in the management of high-risk women to detect cervical changes prior to preterm delivery and then, selectively place cerclage to women with short cervix. A pregnancy is considered to be at high-risk for cervical insufficiency if the patient had a history of painless cervical dilatation. There are conflicting results whether women with a history of cervical insufficiency should be electively put on cerclage or if they should be followed by serial ultrasound for selective cerclage [1-5].

The aim of the present study was to evaluate the effectiveness of elective CC on the pregnancy outcome of patients with cervical insufficiency.

Materials and Methods

A retrospective cohort study was conducted on women with an obstetric history of cervical insufficiency with or without elective CC at Zeynep Kamil Women and Children Diseases Training and Research Hospital between March 2002 and July 2012. The study protocol was approved by the local Research and Ethics Committee of the present hospital. Women were identified through review of hospitalization diagnosis and operative schedules in the medical records. Once the patients were identified, the history of cervical insufficiency was confirmed by calling the patients and then, all hospital records' were abstracted. The history of cervical insufficiency was based on the patients' statement of a painless dilation of the cervix in the second trimester of their previous pregnancies. Women who could not be reached and whose obstetric outcomes were unknown were not included. Women with a history of mid-trimester abortion or preterm delivery due to uterine anomaly, previous history of cervical surgery, polyhydramnios, multiple pregnancy, abruption, iatrogenic early delivery or chorioamnionitis were also excluded from the study.

The CC group consisted of women at risk for pregnancy loss and/or early spontaneous preterm birth who were treated with an elective cerclage (n=183). The control group consisted of women who also had risk of pregnancy loss and/or early spontaneous preterm birth and were not treated with cerclage (n=183). The noted reasons for not performing CC to the control group were: non-compliance of patients (n=53), refusal of procedure (n=48), and unknown etiology (n=82). The two groups were compared

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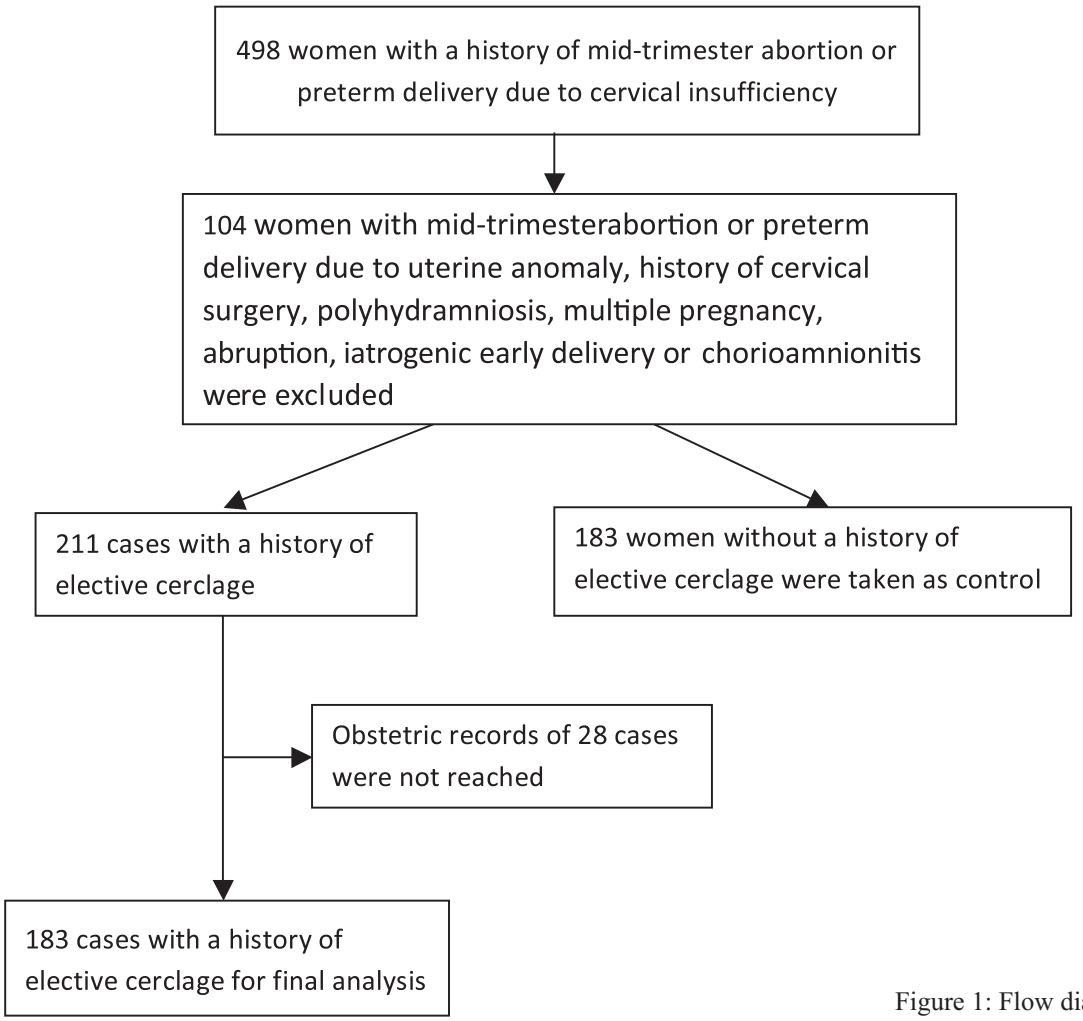

Figure 1: Flow diagram of the study.

for the main measure outcomes of maternal demographics and past obstetric history, mean gestational age at delivery, birth weight, Apgar score at five minutes, number of premature and preterm deliveries, preterm premature rupture of membranes (PPROM), neonatal death, and admission to the neonatal intensive care unit (NICU).

The CCs were performed by several senior obstetric specialists with McDonald technique at 13-15 weeks of gestation under general anesthesia unless contraindicated. The patients were discharged from the hospital on the following day. In the case of PPROM, the cerclage was removed based on gestational age. Those who had PPROM beyond 32 weeks of gestation or before 22 weeks of gestation, had their cerclages removed. Those who had PPROM between 22 and 32 weeks of gestation, the timing of cerclage removal were individualized. As standard procedure, CCs were removed at 36–37 weeks of gestation. Patients presenting with progressing premature labour prior to 36 weeks of gestation, had their cerclages removed at that time. In general, broad spectrum antibiotics and steroids were administered to the patients with PPROM.

All statistical analysis was performed with the Number Cruncher Statistical System (NCSS) 2007. Normally distributed variables were compared with Student *t*-test and Mann Whitney U test were used for variables not distributed normally. Qualitative data were analyzed by using Pearson Chi-square test, Fisher's Exact test, and Yates Continuity Correction test. A p-value of < 0.05 was accepted as statistically significant.

Results

A total of 498 patients, 183 women in the CC group and 183 women in the control group were included in the final analysis (Figure 1). No significant differences were observed between the groups in terms of the mean maternal age, gravidity, parity, body-mass index, the number of previous mid-trimester loss, preterm deliveries (< 37 weeks), term delivery, and alive baby (Table 1).

There were significant differences in terms of the mean gestational age at delivery (37 ± 4.0 *vs.* 34 ± 5 weeks, $p = 0.001$), the mean birth weight (3.000 ± 870 *vs.* 2,200 ± 860 grams, $p = 0.001$), the number of preterm deliveries (< 37 weeks) (40% *vs.* 63%, $p = 0.001$, OR: 0.4, 95% CI: 0.26–0.61), median Apgar scores at five minutes (9 *vs.* 8, $p = 0.001$) between CC and control group, respectively (Table 2). No statistically significant differences were found bet-

Table 1. — *Demographic characteristics and past obstetric history of the patients in CC and control group.*

	CC group (n=183)	Control group (n=183)	*p* value
Maternal age (years, mean±sd)	30±6	29±6	0.13
Gravidity (mean±sd)	4±2	4±2	0.74
Parity (mean±sd)	3±1	2±1	0.10
BMI (kg/m², mean±sd)	24±3	23±3	0.12
Mid-trimester abortion (≥1) (%)	79%	87%	0.10
Preterm delivery < 37 w (≥1) (%)	46%	50%	0.56
Term delivery (≥1) (%)	18%	26%	0.18
Alive baby (≥1) (%)	96%	91%	0.13

CC: cervical cerclage; BMI: body mass index; sd:standard deviation; w:weeks.
$p < 0.05$ is considered statistically significant.

Table 2. — *Comparison of pregnancy outcomes of the patients in the CC and control group.*

	CC group (n=183)	Control group (n=183)	*p* value
Gestational age at delivery (week, mean±sd)	37±4	34±5	0.001
Birth weight (gr,mean±sd)	3000±870	2200±860	0.001
Apgar scores at five minutes (median)	9	8	0.001
PPROM (n, %)	24 (13%)	39 (21%)	0.10
Neonatal death (n,%)	11 (6%)	20 (11%)	0.13
NICU (n,%)	25 (14%)	63 (34%)	0.001
Number of deliveries at (n,%)			
<20w or <500gr	14 (8%)	11 (6%)	0.68
20-23+6w	4 (2%)	5 (3%)	1.00
24-27+6w	7 (4%)	8 (4%)	1.00
28-31+6w	9 (5%)	25 (14%)	0.007
32-36+6w	40 (22%)	66 (36%)	0.003
≥37w	109 (60%)	68 (37%)	0.001

CC: cervical cerclage; NICU: neonatal intensive care unit;
sd: standard deviation; gr: gram; w: weeks.
p<0.05 is considered statistically significant.

ween CC and control group in the number of early (< 25 weeks) losses (11% *vs.* %10, $p = 0.86$, OR: 1.12, 95% CI: 0.54–2.34), the percentage of PPROM (13% and 21%, respectively, $p = 0.11$), and neonatal death (6 % and 11%, respectively, $p = 0.1$). The rate of admission to the NICU was 14% in the CC group and 34% in the control group ($p = 0.001$, OR: 0.30, 95% CI: 0.17–0.52).

Discussion

In the present study the outcomes of patients with or without elective CC were compared. The results showed significantly better pregnancy outcomes in the elective cerclage group than the control group. The likelihood of developing preterm delivery (< 37 weeks) was lower following the elective cerclage placement (OR: 0.4, 95% CI: 0.26 –0.61) and also, higher mean weight was observed in CC group. Median Apgar scores at five minutes were statistically higher in the cerclage group but this did not mean clinical significance because the median of Apgar scores were eight and nine. The authors also found lower rate of attending to the NICU in the cerclage group which may be related to the lower rate of preterm birth after elective cerclage placement (OR: 0.30, 95% CI: 0.17 - 0.52).

Options for the clinical management of the patients with a history of mid-trimester fetal loss or early preterm delivery are elective cerclage in early second trimester or close cervical surveillance and placement of a CC selectively only if there are cervical changes demonstrated by ultrasonography. There are conflicting results about the management of these patients in the current literature [1, 2, 3-5]. Some authors reported that many elective cerclages have been performed unnecessarily and awaiting ultrasound finding of cervical insufficiency prior to placement of a cerclage will result in a decrease in the number of unnecessary elective cerclages [6]. In To *et al.* study, with the policy of sonographic surveillance followed by CC in women at increased risk of spontaneous mid-trimester or early preterm delivery, the expectant management results in a decrease in the requirement of the cerclage with a rate of 40% but in the elective group the preterm delivery rate was lower than the ultrasound indicated group (15% *vs.* 31%) [7]. In the present study, the preterm delivery rate was significantly lower in the cerclage group than the control group (40% *vs.* 63%, respectively), but the early pregnancy loss rates were similar (11% vs. %10). Guzman *et al.* reported that patients with shortened cervix demonstrated by ultrasound, benefited from the placement of a selective cerclage and they found no significant difference in pregnancy outcomes between elective and selective cerclages [8]. Conversely, Nelson *et al.* found that selective cerclage placement might have helped prolonging pregnancy and reducing premature birth, but higher rate of obstetrics morbidities such as a higher frequency of PPROM (64.7%) and chorioamnionitis (42.9%) were noted in selective cerclage group [3]. Similarly, Kurup *et al.* reported that patients who had selective cerclage placement after ultrasound findings of cervical insufficiency had poorer obstetric outcomes than those who had cerclages placed electively [2]. In order to consider sonographic surveillance followed by CC as an alternative to the elective cerclage, pregnancy outcome should be compromised when the selective cerclage is placed after the detection of cervical shortening.

Women with a history of spontaneous mid-trimester abortion and preterm delivery have an increased risk of recurrence in the subsequent pregnancies. According to meta-analysis results of Berghella *et al.,* cerclage does not prevent preterm birth in all women with short cervix, but in the subgroup of women with prior preterm birth, cerclage may reduce premature birth [9]. The recent ACOG Practice Bulletin was published in the favor of elective cerclage that recommends the placement of cerclage at ap-

proximately 13-14 weeks of gestation in women with the history of one or more second-trimester pregnancy losses related to painless cervical dilation and in the absence of labor or abruptio placentae [10]. This recommendation supports the effectiveness of elective cerclage and the present study results. In expectant management, it is not easy to follow up the patients closely and to detect high-risk patients early. Guzman *et al.* described how an incompetent cervix may shorten at a rate of four to eight mm per week between 15 and 24 weeks of gestation [8]. They suggest following high-risk patients with scans every two weeks that allow performing more timely intervention. As described previously, To *et al.* performed transvaginal sonography in women with a history of one or more mid-trimester miscarriage or early preterm delivery at 12–15+6, 16–19+6 and 20–23+6 weeks [7]. Missing the high-risk patients during the screening of cervical length may cause advanced cervical dilatation and need for emergent cerclage which is associated with a high risk of adverse outcome [11]. Also, improper selection of the patients for the cerclage may lower the benefit. In the present study, there were no statistically significant difference between the groups with regards to adverse outcomes as PPROM and neonatal death, but the incidence of preterm delivery was significantly higher in the control group.

The present results show that the placement of elective CC may be effective in patients with an obstetric history of mid-trimester abortion or preterm delivery due to cervical insufficiency. Although the present results were in the favor of elective cerclage, these findings should be interpreted cautiously. However, these results were the consequence of retrospective analysis. The present study was not randomized, but the similarity in the baseline characteristics of the groups can make it possible to compare the outcomes and control known confounders. The small sample size, the presence of possible bias in the selection of the control group, and possible adverse outcome of the patients whose obstetric outcomes were not reached in the CC group are the limitations of this study.

In conclusion, the placement of elective CC seemed to be effective in patients with the history of mid-trimester abortion or preterm delivery due to cervical insufficiency.

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