

ELECTIVE VERSUS ULTRASOUND-INDICATED CERVICAL CERCLAGE IN WOMEN AT RISK FOR CERVICAL INCOMPETENCE

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ABSTRACT

Background: To compare pregnancy outcomes in women at risk for cervical incompetence after elective versus ultrasound - indicated cerclage.

Methods: In a prospective randomized trial, singleton pregnancies with at least one previous spontaneous midtrimester loss or early preterm delivery (between 15 and 32 weeks' gestation) who met clinical criteria for the diagnosis of cervical incompetence were allocated to receive either an elective cerclage (elective cerclage group) or serial transvaginal cervical sonography at rest and after transfundal pressure every 2 weeks between 14 and 24 weeks' gestation, with cerclage only if indicated by cervical shortening (transvaginal sonography group). The Mann-Whitney U test, Chi-square and Fisher exact test were used for analysis of the data.

Results: A total of 97 patients were identified. Forty-five received elective cerclage and 52 were followed up with transvaginal sonography, of which 53.8% (28/52) required a cervical cerclage because of cervical changes. There were no significant differences in demographic characteristics and risk factors for cervical incompetence. The median gestational age at delivery [38 (range 17-40) vs. 38 (range 19-40) weeks; $p=0.90$], the early losses before 25 weeks' gestation (8.8% vs. 9.6%; $p=0.70$) and preterm deliveries before 37 weeks' (20% vs. 25%; $p=0.50$) were similar in the elective cerclage group and transvaginal sonography group respectively.

Conclusion: In women at risk for cervical incompetence, serial transvaginal cervical sonography, with cerclage only if indicated by cervical shortening, appears to be a safe alternative to traditional elective cerclage.

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INTRODUCTION

Cervical incompetence is a cause of mid-pregnancy loss and may be responsible for some cases of early spontaneous preterm birth. The cervix undergoes pain-

less dilation and effacement in the second-trimester. The amniotic membranes generally protrude into the cervical canal and the vagina, and their rupture is followed by a short and relatively pain-free preterm labor, and delivery of a live fetus.

This situation may lead to empirical use or overuse of cervical cerclage procedures. Transvaginal ultrasonography provides an objective method to assess the cervical length and the shape of the internal os.^{1,3} Cervical length is a marker for cervical competence, and

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cervical function is a continuous rather than a dichotomous variable.^{3,4} The earlier the gestational age at delivery, the shorter the cervix in the next pregnancy.⁴ Cervical length is related to the risk of recurrent preterm birth.^{5,9}

The risk of preterm birth increases as cervical length decreases.^{3,10} Some authors applied transfundal pressure during transvaginal sonography to evaluate the cervix and its internal os as a method which may assist in detecting asymptomatic cervical incompetence.^{11,13} However, two treatment methods have emerged in the management of pregnant patients at risk for cervical incompetence: an elective placement of cervical cerclage early in the second trimester, and transvaginal sonography of the cervix and placement of a suture in those patients with cervical changes suggestive of incompetence, either spontaneously or in response to transfundal pressure. The purpose of this study is to compare two management strategies in women at risk for cervical incompetence.

MATERIAL AND METHODS

This was a prospective randomized study comparing two management strategies in women at risk for cervical incompetence. The study population consisted of 97 women who were managed at Arash Maternity Hospital, Tehran University of Medical Sciences from January 2001 to September 2003.

Singleton pregnancies with an obstetric history of spontaneous midtrimester loss or early preterm delivery (between 15 and 32 weeks' gestation) accompanied by painless and progressive dilatation of the cervix and / or preterm rupture of the membranes without preceding contractions, in the absence of other possible causes of midtrimester loss or early preterm delivery were included. This midtrimester loss or early preterm delivery has generally occurred during the last ongoing pregnancy, or it may have happened during an earlier pregnancy, but only if all subsequent ongoing pregnancies were treated with either cervical cerclage or bed rest, or both. Exclusion criteria included multiple pregnancies, major fetal defects and intrauterine fetal death.

The study was conducted in accordance with the Declaration of Helsinki on human experimentation. The study was approved by the Institution, and an informed consent form was obtained from all women in the trial.

The primary outcome was gestational age at delivery with a significant change defined as a 2-week difference in gestational age at delivery, with the assumptions of type I error of 0.05 and a power of 80%, a total sample size of 97 women was needed to reach statistical significance.

Random assignment was performed immediately af-

ter inclusion in the trial, and women were allocated to receive either an elective cerclage (elective cerclage group) or serial transvaginal sonography of the cervix and cerclage only if indicated by cervical changes (transvaginal sonography group).

The patients in the elective cerclage group received cerclage placement at 12 to 15 weeks' gestation after sonographic examination of the fetus to confirm gestational age and exclude major defects.

The patients in the second group had serial transvaginal sonography of the cervix performed every 2 weeks, beginning at 14 weeks' gestation, and were offered an emergency cerclage placement only if the endocervical canal length shortened to 20 mm or less, either spontaneously or in response to transfundal pressure before 24 weeks' gestation. At transvaginal cervical evaluation, the patient was placed in the dorsal lithotomy position and the vaginal probe was introduced into the anterior vaginal fornix. A 6.5 MHz vaginal transducer (Dynamic Imaging Co; Livingston, Scotland, UK) was used. The appropriate sagittal view of the cervix was obtained by simultaneous imaging of its external and internal os. Once orientation was achieved, the vaginal probe was pulled back to avoid compression of the upper cervix. The length of the cervix was measured from the internal os to the external os, measuring the furthest points at which the cervical walls were juxtaposed. All patients had cervical measurements obtained with and without transfundal pressure as described by Guzman et al.¹¹ Patients with a cervical length of more than 20 mm were managed expectantly. This did not include the use of prophylactic tocolytics, routine antibiotics, hospitalization or home uterine monitoring. All cerclage procedures either elective or ultrasound-indicated were performed in the absence of uterine contractions, uterine bleeding, preterm rupture of the membranes or chorioamnionitis. All cerclage procedures were of the McDonald type, using a Mersilene band (Ethicon, Brussels, Belgium). In all patients undergoing cerclage, prophylactic antibiotics were given intraoperatively; none were given chronic prophylactic tocolytics. Home uterine monitoring was not used, nor was prophylactic inpatient bed rest. All patients were discharged from hospital on the first postoperative day. Statistical analysis was performed with the use of Mann-Whitney-U test for the continuous variables (maternal age, body mass index, gestation at cerclage, gestation at delivery) and Chi-Square or Fisher exact test for categorical variables (obstetric history, cigarette smoking, percentage of preterm deliveries). A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 97 patients were identified. Forty-five patients were treated with an elective cerclage at 12-15 weeks (median 14, mean 14.2, SD 0.8). In the serial transvaginal sonography group, there were 52 patients and 28 (53.8 %) of these were found to have a cervix of 0-20 mm spontaneously or in response to transfundal pressure, (median 15, mean 12.6, SD 5.7) and had cervical cerclage at 16-23 weeks (median 20, mean 20.1, SD 1.8). As expected, gestational age at placement of cerclage was significantly earlier in the elective group (14.0 versus 20.0 weeks, $p < 0.0001$). Demographic analysis demonstrated no significant differences in mean maternal age (28.2 years versus 27.4 years), mean body mass index (27 kg/m² versus 26 kg/m²), incidence of cigarette smoking (3% versus 5%) or multiparity 39 (86.6%) versus 43 (82.6 %) in the elective cerclage group and transvaginal sonography group respectively. Analysis of the two groups for historical risk factors for cervical incom-

petence demonstrated no significant difference in the rates of previous preterm delivery, mid-trimester loss, dilatation and curettage procedure, mullerian anomaly, history of cone biopsy or prior cerclage (Table I).

The median gestational age at delivery of those who had elective cerclage was 38 weeks (mean 35.8, range 17-40) and those who underwent ultrasound assessment was 38 weeks (mean 35.5, range 19-40); these were not significantly different ($p = 0.90$). The early losses before 25 weeks' gestation occurred in 8.8% (4/45) of the elective cerclage group and in 9.6% (5/52) of the transvaginal sonography group ($p = 0.70$). Spontaneous delivery before 37 weeks' gestation occurred in 20% (9/45) of the elective cerclage group and in 25% (13/52) of the transvaginal sonography group ($p = 0.50$). In the 52 patients who were followed up with serial transvaginal sonography, there were 24 (46.1%) with a cervical length of more than 20 mm and 3 (12.5%) of these delivered before 37 weeks (Table II). However, there was no significant difference in pregnancy outcome in the elective cer-

Table I. Risk factors for cervical incompetence.*

Historic risk factor	Elective cerclage group (n= 45)	Transvaginal sonography group (n= 52)
One prior second - trimester loss	19 (42.2)	23 (44.2)
Two prior second trimester losses	10 (22.2)	13 (25)
>3 second trimester losses	6 (13.3)	8 (15.3)
Early third trimester preterm delivery (26-32) weeks' gestation	12 (26.6)	15 (28.8)
Cone biopsy	1 (2.2)	2 (3.8)
Mullerian anomaly	3 (6.6)	3 (5.7)
Prior cerclage	6 (13.3)	5 (9.6)
One prior dilatation and curettage procedure	4 (8.8)	6 (11.5)
>Two prior dilatation and curettage procedures	3 (6.6)	4 (7.6)

Data are presented as n (%)

*p= not significant

Table II. Gestation at delivery of the two groups of women at risk for cervical incompetence; elective cerclage group, and serial transvaginal sonography group.

Gestation delivery (Weeks)	Elective cerclage (n= 45)	Transvaginal sonography group		
		Total (n= 52)	Cerclage (n= 28)	No cerclage (n= 24)
12-24	4 (8.8)	5 (9.6) $p = 0.70$	3 (10.7)	2 (8.3)
25-37	5 (11.1)	8 (15.3)	7 (25)	1 (4.1)
>37	36 (80)	39 (75)	18 (64.2)	21 (87.5)
Total <37	9 (20)	13 (25) $p = 0.50$	10 (35.7)	3 (12.5)

Data are presented as n (%)

clage group compared with the ultrasound assessment group.

DISCUSSION

The true efficacy of cervical cerclage in preventing second-trimester pregnancy loss and early preterm labor and increasing fetal survival has not been clearly demonstrated. Neither of two randomized trials of elective cervical cerclage, compared with no cerclage, in singleton pregnancies found statistically significant benefit of cerclage placement for prevention of preterm delivery.^{14,15} There are some studies comparing management by elective cerclage versus serial transvaginal cervical sonography in women at risk for cervical incompetence. Althuisius et al.¹⁶ randomly assigned women with a prior preterm delivery caused by possible cervical incompetence to either prophylactic cerclage ($n = 23$) or serial transvaginal sonogram ($n = 44$). This last group was further randomly assigned to therapeutic cerclage if transvaginal cervical length was $<25\text{ mm}$ at <27 weeks' gestation. No difference in preterm delivery or neonatal outcome was found between the prophylactic cerclage and serial transvaginal sonography groups. They demonstrated that ultrasound-indicated cerclage is a safe alternative to the prophylactic cerclage and may reduce the incidence of preterm delivery at <34 weeks' gestation among high risk patients.

Kelly et al.¹⁷ identified patients with an unclear history of incompetent cervix, of which 45 received early cerclage and 61 were followed up with serial vaginal sonography. No significant difference was demonstrated between the two groups in any measure of pregnancy outcome.

Berghella et al.¹⁸ retrospectively reviewed 177 patients with singleton

pregnancies who had prior second-trimester loss, 66 of these received prophylactic cerclage and 111 were followed up with transvaginal sonography. Forty of these 111 (36%) had therapeutic cerclage because of cervical change. The two management groups of prophylactic cerclage versus transvaginal sonography of the cervix did not differ in any measure of obstetric outcome. They found that for patients at high risk of preterm delivery, serial transvaginal sonography of the cervix, and limiting cerclage only to patients who show early sonographic changes, may have two potential benefits: preventing complications of cerclage in patients who do not need it and uncovering the possible true value of this procedure in those patients who can benefit the most. But they included only patients with a prior second-trimester loss and excluded patients whose last delivery occurred at term without obstetric inter-

vention.

The findings of our study suggest that in women at high risk for mid-trimester loss or early preterm delivery, serial transvaginal cervical sonography followed by cervical cerclage in those with a short cervix is an acceptable alternative to the traditional elective cerclage and avoids unnecessary surgical intervention without a significant increase in adverse outcome. In the transvaginal sonography group of this study 46% (24/52) did not require the cerclage procedure because the endocervical length remained above 20 mm. In our study, no significant difference in obstetric outcome was found when comparison was made between the entire transvaginal sonography and elective cerclage groups (Table II). When we performed a comparison of patients who received elective and ultrasound-indicated cerclage we found that the patients who received ultrasound-indicated cerclage, had a higher incidence of preterm delivery before 37 weeks' gestation, [35.7% (10/28) versus 20% (9/45); $p = <0.05$] than patients who had elective cerclage. This finding is not an unexpected one, because the risk of preterm birth increases as cervical length decreases.

However, serial transvaginal ultrasonographic assessment of the cervix in women at risk for cervical incompetence and placement of a suture in those patients with cervical changes suggestive of incompetence appears to be a safe alternative to the traditional cerclage and can prevent unnecessary surgical intervention. This fact is even more important when we consider the possible complications associated with the cerclage procedure. Furthermore, serial transvaginal sonography has been helpful in making early diagnoses and avoiding the complications that accompany advanced dilatation and effacement of the cervix. In a study comparing early versus clinically indicated late cerclage, women who had late cerclage did significantly worse than who had elective early cerclage.¹⁹

Nevertheless, ultrasound-indicated cerclage has not been proven to be beneficial in randomized controlled studies.²⁰ We think more and larger randomized prospective trials of ultrasonographic diagnosis of incompetent cervix and of ultrasonographically indicated cerclage, compared with elective cerclage, is needed.

At present, our results suggest that management of women with risk factors for cervical incompetence with serial transvaginal sonography of the cervix every 2 weeks between 14 to 24 weeks' gestation, and placement of a therapeutic cerclage only if indicated by cervical changes is a reasonable alternative to the use of elective cerclage in the early second-trimester and reduces the need for unnecessary surgical intervention without significant increase in adverse outcome.

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