Original Article

A Randomized Comparative Study between Second Trimester Cervical Cerclage and Observational Management on Duration of Pregnancy and Perinatal Outcome

Suzan Elsharkawy, Omar Khalil Elsayed, AbdelMonem Ali Fawzi, Ibrahim Mohamed Kamel El Makhzangi

Department of Obstetrics & Gynecology, Faculty of Medicine, Alexandria University, Egypt.

ABSTRACT

Background: Cervical cerclage is a commonly performed intervention in the care of women at risk of preterm birth or second-trimester fetal loss to prevent preterm cervical dilatation.

Aim: To compare the second trimester trans-vaginal cervical cerclage with conservative management on duration of pregnancy and perinatal outcome.

Materials and Methods: This was a randomized controlled clinical trial that included (40) pregnant females attending El-Shatby Maternity University Hospital antenatal care clinic. All cases of group A were subjected to planned cervical cerclage (McDonald) after the 14th week of gestation by the same surgeon. All cases of group B were subjected to observational management. Both groups did urinalysis and high vaginal swab to detect and treat infection. All cases were subjected to trans-vaginal ultrasound scans at 14, 16 and 18 weeks then every month till delivery to assess viability, internal os diameter, cervical dilatation and length of the cervical canal. Also the time of delivery, process of labor, complications, and fetal outcome were recorded.

Results: There was no statistically significant difference in cervical length measurements between the two groups at the gestational ages of 14, 16, 18 and 36 weeks, while at 24, 28 and 32 weeks gestation, the cervical length was longer in group A than group B and this was statistically significant. Also, no statistically significant difference was found between groups regarding timing, termination mode, specific complications observed during pregnancy and labor.

Conclusion: There is no evident role for a second trimester trans-vaginal cervical cerclage over conservative management on the duration of pregnancy and perinatal outcome.

Key Words: Cervical cerclage, cervical incompetence, perinatal outcome, preterm labor, recurrent abortion.

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Corresponding Author: Suzan Elsharkawy, Ph.D., Departmernt of Obstetrics & Gynecology, Faculty of Medicine, Alexandria University, Egypt. **Tel.:** 00201090052715, **E-mail:** s_abdelrahim00@alexmed.edu.eg

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INTRODUCTION

A miscarriage is the interruption of a pregnancy by removal or expulsion of a fetus/embryo before 20 weeks gestation from the uterus, resulting in or caused by its death.[1] An abortion can occur spontaneously due to complications during pregnancy or can be induced.[2-4] In the second trimester, a weak cervix can become a permanent problem. Such cervical incompetence leads to premature pregnancy loss resulting in miscarriages or preterm deliveries.[5]

Cervical incompetence is defined as a condition in which there is a painless dilatation of the internal os, which fails to retain the conceptus during pregnancy, with cervical length less than 25 mm.[6] Cervical incompetence affects about 1% of pregnant women.[6] Most common cases are Idiopathic, but there may be a cause; Congenital disorders (congenital mullerian duct abnormalities), diethylstilbsterol (DES) exposure in utero, Connective tissue disorder e.g:Ehlers-Danlos syndrome, or Surgical trauma (conization, large loop excision of the transformation zone (LLETZ), cone biopsy, cervical dilatation and obstructed labor).[6]

Funneling of the cervix with the changes in forms T, Y, V, U (correlation between the length of the cervix and the changes in the cervical internal os) could be best examined by trans-vaginal ultrasound.[7] Cervical stress test at 15-24 weeks (increasing transfundal intrauterine pressure while monitoring cervical length and the appearance of funneling) is recommended for the patients with a history of painless dilatation followed by fetal expulsion in the second trimester, conization, uterine malformations (uterus unicornis, uterus bicornis, uterus didelphys), cervical trauma, history of spontaneous or therapeutic abortions, preterm birth before 32 weeks.[7] Ultrasonography is the principal modality for the diagnosis of cervical incompetence during pregnancy (transabdominal, transperineal or transvaginal). Transvaginal assessment is the most accurate and more predictive than traditional

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digital cervical examinations. Magnetic Resonance Imaging (MRI) appearance of a cervical incompetence may demonstrate a higher degree of soft tissue contrast than ultrasonography[8].

Although it has become the basic management tool for cervical incompetence, cervical cerclage - especially emergent cerclage- remains a procedure with well-defined risks and questionable benefits. Thus, it should be used judiciously.[9] The only generally accepted indication for elective cerclage placement is a history suggestive of cervical incompetence.[9] Asymptomatic women with a history of mid-trimester delivery and sonographic evidence of cervical shortening or funneling also may benefit from a cerclage placement.[9] Absolute contraindications to cervical cerclage include uterine contractions or labor, unexplained vaginal bleeding, intrauterine or vaginal infection, rupture of fetal membranes, intrauterine fetal demise, major fetal anomaly, and a gestational age beyond 28 weeks.[9]

There is lack of consensus on the optimal cerclage technique, timing of suture placement, and optimal care following insertion. Complications are not well documented and often difficult to separate from risks inherent to the underlying condition. The aim of this work was to compare the second trimester trans-vaginal cervical cerclage with conservative management on duration of pregnancy and perinatal outcome.

PATIENTS AND METHODS

This was a randomized controlled clinical trial that included forty (40) pregnant females attending El-Shatby Maternity University Hospital antenatal care clinic. The patient recruitment started on January 2009 and ended on January 2010. Data preparation, statistical analysis, manuscript writing and revision were completed by the end of 2010. All patients signed a well-informed written consent to declare their agreement to be enrolled in this study as agreed upon by the ethical committee. Inclusion criteria were; any pregnant female at risk with gestational age from 14 to 26 weeks, maternal age 20- 35 years old, singleton living pregnancy, History of preterm delivery < 34 weeks or history of two or more repeated 2nd trimester spontaneous abortions. Exclusion criteria were; multiple gestations, Diabetes mellitus, gestational diabetes or essential hypertension, Hematological and coagulative disorders, any systemic diseases as collagenic and autoimmune disorders, fetal congenital anomalies and rupture of membranes.

A computer generated randomized division of the forty patients into 2 main groups namely A & B was done. Group A included Twenty (20) pregnant females whom were subjected to elective trans-vaginal cervical cerclage (Mc Donald's operation). Group B included Twenty (20) pregnant females whom were subjected to observational management.

All patients were subjected to thorough history taking and clinical examination, routine laboratory investigations including midstream urine analysis with culture & sensitivity and high vaginal swab. Complete ultra-sonographic scanning was done to assess fetal viability, biometry, and estimated date of delivery, exclude fetal anomalies, or multiple gestation. Cervical length measurement and diameter of the internal os was assessed by trans-vaginal ultrasound and the conditions of the membranes was noticed and recorded.

All cases of group A were subjected to planned cervical cerclage (McDonald) after 14th week of gestation by the same surgeon. All cases of group B were subjected to observational management. All cases were subjected to trans-vaginal ultrasound at 14, 16 and 18 weeks then every month till delivery to assess viability, internal os diameter, cervical dilatation and length of the cervical canal. Also recording of the time of delivery, process of labor, complications, and fetal outcome were done. During the follow up of both groups, any patient detected by ultrasound to have a dilated cervix, was considered as a part of failure rate.

Data were fed into the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp). Qualitative data were described using numbers and percent. The chi-square tests, Fisher exact test, and independent T-test were used to determine the relationship between variables. Significance of the obtained results was judged at the 5% level.

RESULTS

The age distribution, duration of marriage, gravidity and parity were comparable among the two groups as shown in (Table 1). No statistical significance was found between group A and group B regarding urine analysis, that was evaluated by measuring white Cell count / high power field (Mean ± SD= 32.78 ± 37.75 and 48.75 ± 45.25 c/ hpf, $p= 0.556$) respectively. Also, No statistically significant difference was found between the two studied groups regarding the type of organisms detected in vaginal swabs shown in (Table 2).

Table 1: Comparison between the two studied groups regarding age, duration of marriage, gravidities and parities.

	Group A		Group B		Test of sig.
	No.	%	No.	%	
Age (years)					
<25	5	25.0	3	15.0	χ^2= 0.630 *p = 0.730*
25-30	9	45.0	10	50.0	
>30	6	30.0	7	35.0	
Range	20.00-33.00		20.00-35.00		t= 0.873 *p= 0.388*
Mean ± SD	27.55 ± 3.98		28.70 ± 4.34		
Married since (years)					
<5	8	40.0	5	25.0	χ^2= 1.026 p= 0.311
5+	12	60.0	15	75.0	
Range	3.00-8.00		3.00-10.00		t= 2.316* *p= 0.027*
Mean ± SD	5.10 ± 1.48		6.50 ± 2.26		
Gravidity					
<5	14	70.0	12	60.0	χ^2= 440.0 *p= 0.507*
5+	6	30.0	8	40.0	
Range	3.00-6.00		3.00-6.00		t= 0.557 *p= 0.581*
Mean ± SD	4.10 ± 0.85		4.25 ± 0.85		
Parities					
0	8	40.0	8	40.0	χ^2= 0.168 *p= 0.920*
1	7	35.0	6	30.0	
2	5	25.0	6	30.0	
Range	0.00-2.00		0.00-2.00		t= 0.190 *p= 0.850*
Mean ± SD	0.85 ± 0.81		0.90 ± 0.85		

χ^2: Chi square test **t:** Student t-test ***:** Statistically significant at $p \leq 0.05$

Table 2: Comparison between the two studied groups according to vaginal swab

	Group A		Group B		Test of sig.
	No.	%	No.	%	
Lactobacilli	8	40.0	9	45.0	χ^2= 0.102, *p= 0.749*
Trichomoniasis	4	20.0	6	30.0	FEp= 0.716
Gardnerella vaginalis	4	20.0	3	15.0	FEp= 1.000
Candida	12	60.0	11	55.0	χ^2= 0.102, *p= 0.749*
B streptococci	2	10.0	1	5.0	FEp= 1.000
Only one	10	50.0	10	50.0	χ^2= 0.000, *p= 1.000*
Two or more	10	50.0	10	50.0	

χ^2: Chi square test

Comparison between group A&B according to cervical length in (cm) measured by trans-vaginal ultrasound during different stages of follow up showed no statistical significance in cervical length between two groups in gestational age of 14, 16, 18 and 36 weeks, while in 24, 28 and 32 weeks cervical length was statistically significant longer in group A than group B. As regards cervical internal os diameter in (mm) measured by trans-vaginal ultrasound during same stages of follow up, it showed no statistical significance between the two studied groups in all gestational ages except at 32 weeks, as it was statistically significant narrower in group A than group B, as shown in (Table 3).

Table 3: Comparison between the two studied groups according to cervical length (cm) and internal os diameter (mm).

		14 wks	16 wks	18 wks	24 wks	28 wks	32 wks	36 wks
cervical length (cm)								
Group A	Mean	3.48	3.41	3.39	3.22	3.24	3.34	3.32
	SD	0.44	0.47	0.59	1.04	1.39	0.70	0.35
Group B	Mean	3.50	3.26	2.85	2.56	2.09	2.06	2.84
	SD	0.45	0.55	0.91	1.13	1.33	1.35	0.85
Z (p)		0.195 (0.845)	0.832 (0.405)	1.805 (0.071)	2.203* (0.028)	2.406* (0.016)	3.239* (0.001)	1.109 (0.268)
Internal os diameter (mm)								
Group A	Mean	1.90	2.05	2.00	2.31	2.14	1.18	2.50
	SD	1.48	1.79	1.73	1.99	1.99	1.47	1.69
Group B	Mean	1.75	2.00	2.47	3.44	3.50	4.13	4.20
	SD	1.55	1.81	1.71	1.63	1.62	1.36	1.92
Z (p)		0.319 (0.750)	0.071 (0.943)	0.951 (0.341)	1.539 (0.124)	1.840 (0.066)	3.130* (0.002)	1.347 (0.178)

Z: Z for Mann Whitney test between the two studied groups ***:** Statistically significant at $p \leq 0.05$

No statistical significance was found between the two studied groups regarding timing, termination mode, specific complications observed during pregnancy and labor, while number of pregnancies ended in abortions were considered as failure rate, as shown in (Table 4).

Table 4: Comparison between the two studied groups according to time, mode of termination, and complication of pregnancy & labor.

	Group A		Group B		Test of sig.
	No.	%	No.	%	
Labor time/weeks					
<28	6	30.0	8	40.0	χ^2= 1.055
28-	6	30.0	7	35.0	*p = 0.590*
>36	8	40.0	5	25.0	
Range	16.00-40.00		15.00-38.00		t= 0.866
Mean ± SD	30.20 ± 7.71		28.20 ± 6.88		*p= 0.392*
Mode of delivery or abortions (AB)					
SVD	6	30.0	4	20.0	χ^2= 0.686
CS	8	40.0	8	40.0	*p= 0.710*
AB(failure rate)	6	30.0	8	40.0	
Complications					
Preterm rupture of membranes	6	40.0	3	37.5	MCp=0.351
Precipitate labor	1	6.7	0	0.0	
Preterm	3	20.0	3	37.5	
Cervical trauma	4	26.7	0	0.0	
Intrauterine fetal death	1	6.7	2	25.0	

χ^2: Chi square test **t:** Student t-test **MCp:** p for Monte Carlo test

In addition, there was no statistical significant difference found between the two studied groups regarding fetal outcome, incubated infants and incubation time, as shown in (Table 5).

Table 5: Comparison between the two studied groups according to fetal outcome and incubated infants

	Group A		Group B		Test of sig.
	No.	%	No.	%	
Outcome					
Good	5	25.0	3	15.0	χ^2=1.865
Died	5	25.0	9	45.5	*p= 0.394*
Incubated then:	10	50.0	8	40.0	
Good	6	60.0	4	50.0	FEp=
Died	4	40.0	4	50.0	1.000
Incubation time					
Range	1.00-21.00		1.00-21.00		Z=1.128
Mean	6.00 ± 6.65		9.63 ± 7.15		*p= 0.259*
Median	2.50		10.50		

χ^2: Chi square test **t:** Student t-test

DISCUSSION

Cervical incompetence is a common cause of mid-trimester abortion and preterm birth. Classically, dilation and effacement of the cervix occur without uterine contractions or pain. These events happen because of weakness in the cervix, which opens under increasing pressure of the uterine contents as pregnancy progresses. If the changes are not stopped, rupture of the membranes and delivery of a premature baby can eventually result.[10] Trans-vaginal cervical cerclage was introduced as a treatment of cervical incompetence in 1951. Over the years and with accumulating evidence, our understanding of this clinical entity has changed so much.[11]

In the current study, we randomized 40 pregnant women at risk into two groups, with elective cerclage in one group or observation in the other. Comparing the two groups, although there was a statistical significant difference in cervical length measurements during some follow up visits, that indicated a longer cervix with a cerclage in group A,these differences resulted in no statistical significant difference in the duration of pregnancy or perinatal outcome. Noteworthy, women with prophylactic cerclage have had a slightly higher risk for complications as cervical trauma (26.7% in group A & 0% in group B, *P=0.351*).

Several clinical trials of cerclage placement versus observational management in the general obstetric population reported conflicting results. For example, Heath *et al*. in 1998 studied a low-risk obstetric population in Great Britain that underwent trans-vaginal measurements of cervical length. Women with lengths of 15 mm or less were managed expectantly (n=21) or had a Shirodkar cerclage placed (n=22). Only 5% in the cerclage group delivered prior to 32 weeks' gestation, compared with 52% in the expectantly managed group.[12]

Another observational study in which data were collected prospectively from a general obstetric population, Hibbard *et al*. in 2000 also found an increase in the duration of pregnancy (2 weeks) among women who underwent cerclage placement for a cervical length less than 26 mm (n=43), compared with those who had no cerclage placed (n=42).[13]

Althusius *et al*. in 2001[14] studied a high-risk population in the Cervical Incompetence Prevention Randomized Cervical Trial (CIPRACT), which involved primary randomization to determine the effects of prophylactic cerclage, and secondary randomization to determine the effects of therapeutic cerclage. Women with a history of preterm delivery before 34 weeks who had a "classic" history of cervical incompetence were allocated to prophylactic cerclage or no cerclage in the late first or early second trimester. Thus, these gravidas already met the diagnosis of cervical incompetence. Both groups were then followed with serial measurements of cervical length. A second randomization to therapeutic cerclage or bed rest occurred if a cervical length less than 25 mm was found before 27 weeks' gestation. This trial showed a statistically significant greater mean gestational age and improved pregnancy outcomes among women in both groups who received a cerclage, suggesting that therapeutic cerclage is a valuable management option in at-risk women with cervical shortening. Moreover, the study design of primary and secondary randomization offers a sound strategy for management.[14]

On the other hand, others reported contradicting results. In a retrospective review of an obstetric population with cervical lengths of 15 mm or less, Hassan *et al*. in 2001 compared women whom had a cervical cerclage (n=25) with those who did not (n=45). In contrast to the two trials just mentioned, cervical cerclage failed to decrease the rate of abortion and spontaneous preterm delivery. Moreover, patients with a cerclage had an increased incidence of premature rupture of membranes.[15]

Furthermore, in a nonrandomized prospective observational trial of women at high risk for repeated abortions and/or preterm delivery, Berghella *et al*. in 1999 reported that those undergoing cerclage (n=39) for cervical length less than 25 mm and/or for 25% funneling fared no better than women who did not undergo cerclage placement (n=24).[16]

To address the value of therapeutic cerclage, Rust *et al*. in 2001[17] designed a prospective, randomized trial of both high-risk and low-risk women with second-trimester shortened cervical measurements with funneling and a total cervical length less than 25 mm. These women were allocated to therapeutic cerclage or bed rest. Prior to randomization, all women underwent cervical and urinary cultures and amniotic fluid analysis to exclude underlying intra-amniotic infection. Both groups then were followed

with weekly trans-vaginal cervical measurements. A rescue cerclage was placed if prolapsing membranes occurred in either group.[17]

Although decreasing cervical length was associated with poorer pregnancy outcomes, cervical cerclage did not result in a statistically significant greater mean gestational age or improved perinatal outcome, contradicting the results reported in the CIPRACT trial. Furthermore, patients who needed rescue cerclage had the worst outcomes. One explanation may be that the CIPRACT trial included only patients with a history of cervical incompetence, whereas Rust *et al*. included low-risk and high-risk women unexpectedly noted to have a shortened cervix.[17]

These terminologies (prophylactic, planned, emergency, urgent, rescue) of cervical sutures/cerclage can be ambiguous. More appropriate nomenclature based on indication for cervical suture is recommended recently.[18] For instance, a history-indicated cerclage is performed as a prophylactic measure in asymptomatic women and usually inserted as a planned procedure at 11–14 weeks of gestation as a result of factors in a woman's obstetric or gynaecological history, which increase the risk of spontaneous second trimester loss or preterm birth. An Ultrasound-indicated cerclage is performed on asymptomatic women as a therapeutic measure in cases of cervical length shortening seen on trans-vaginal ultrasound performed between 14 and 24 weeks of gestation. On the other hand, Emergency cerclage is inserted as a salvage measure in the case of premature cervical dilatation with exposed fetal membranes in the vagina.[19]

Cochrane review concluded that, in women with a singleton pregnancy at high risk of pregnancy loss based on woman's history and/or ultrasound finding of 'short cervix', there was a significant reduction in preterm births compared to controls before 37, 34 and 28 weeks of gestation in women who had cerclage compared to no cerclage (average risk ratio [RR] 0.77, 95% confidence interval [CI] 0.66–0.89, incorporating nine studies with 2415 women).[19]

A pre-specified subgroup analysis of an international multicentre trial, which recruited 1292 women to cerclage or no cerclage, coordinated by the Medical Research Council (MRC) /Royal College of Obstetricians and Gynaecologists (RCOG), found that only women with a history of three or more pregnancies ending before 37 weeks of gestation (n = 104) benefitted from cerclage, which halved the incidence of preterm birth before 33 weeks of gestation (15% versus 32% $P > 0.05$). No effect was observed in those with only one (birth before 33 weeks of gestation in the cerclage group 14% versus 17% in the expectant group) or two previous early births (birth before 33 weeks of gestation in the cerclage group 12% versus 14% in the expectant group.[20]

Regarding ultrasound-indicated cerclage, a meta-analysis that included 607 pregnancies from four RCTs reported that in the subgroup of women with singleton pregnancies with a history of preterm second trimester loss (16+0–23+0 weeks of gestation) or birth before 36 weeks of gestation, cerclage resulted in a significant reduction in birth before 35 weeks of gestation (RR 0.57; 95% CI 0.33–0.99 and RR 0.61; 95% CI 0.40–0.92, respectively) when compared with expectant management.[21]

Noteworthy, Berghella V. *et al*. (2011) concluded that, Women with a history of spontaneous second trimester loss or preterm birth who have not undergone a history-indicated cerclage may be offered serial sonographic surveillance, as those who experience cervical shortening (less than 25mm) may benefit from ultrasound-indicated cerclage.[22] On 2013, Berghella V. *et al*. published an interesting Cochrane Database Systemic Review: "for women with a singleton pregnancy and no other risk factors for preterm birth, insertion of cervical cerclage is not recommended in whom have a short cervix incidentally identified on a late second trimester ultrasound scan".[23]

CONCLUSION

This study concluded that; there is no benefit for a second trimester trans-vaginal cervical cerclage in at risk women over conservative management on the duration of pregnancy and perinatal outcome.

CONFLICT OF INTEREST

There are no conflicts of interests.

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