Outcome of Mid - Trimester Emergency Cervical Cerclage

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Abstract: Objective: To evaluate the role of emergency cervical cerclage in prolongation of pregnancy and its effect on pregnancy outcome. **Type of Study:** a prospective clinical trial. **Location:** Tertiary Center Hospital, during the period from March 2012 to May 2015. **Subjects and Method:** Twenty patients fulfilled the inclusion criteria (who presented with a dilated cervical or with or without bulging fetal membranes between 16 and 27 weeks) followed a set protocol of prophylactic antibiotics and tocolytics before and after application of the cerclage suture. In all procedures, the McDonald's technique was applied. **Results:** In general, Pregnancy was prolonged by 67.1± 38.1 days (ranged from 0 to 118 days). For the survivors it was 88.3 ± SD 15.8 days (ranged from 62to 118 days). In 75% of the patients (N=15) pregnancy was prolonged beyond 31 weeks gestation with seventeen survivors (two set of twins). The mean gestational age at delivery was 32.03 ±6.2 weeks (ranged from 20.2 to 39.5 weeks).For the survivors it was 35.5 ± 2.5weeks (ranged from 31 to 39.5 weeks). The mean birth weight at delivery 1879.2± 911.9gm (ranged from 390 to 3300gm). For the survivors it was 2333.3± 491gm (ranged from 1650 to 3300 gm). **Conclusion:** Emergency cervical cerclage is an effective obstetric procedure. Despite its associated potential complications, it is probably the only option for women presented with advanced cervical dilatation with or without prolapsed membranes. Nevertheless, it should be used judiciously and only after comprehensive patients evaluation and extensive counseling.

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1. Introduction

Cervical insufficiency is a well-known cause of second trimester pregnancy loss and is defined as the failure of the cervix to retain the foetus in utero till term due to a functional or structural defect of the cervix.[1] It is characterized by painless dilatation and effacement of the cervix, usually in the second trimester of the pregnancy, leading to bulging of foetal membranes through the uterine cervix and vagina, and, in severe cases through the external genitalia with resultant premature rupture of membranes and often, a pre-viable delivery.[2]It has been estimated that cervical incompetence is responsible for0.1-0.2% of all spontaneous abortions, contributes to 16-20% of all second trimester pregnancy losses,[3] 8-15% among women with prior history of recurrent spontaneous abortions[4]and 10% of preterm deliveries.[5] Cervical cerclage has been a common practice inobstetrics ever since it was first described by Shirodkar, and then McDonald in the 1950's. Indications for cerclage placement have included the patient's obstetric history, ultrasound findings, physical examination, or a combination of both. However most of the larger and randomized trials studying the effectiveness of cerclage were done for patients with a history of prior pregnancy loss or preterm birth (history-indicated cerclage) [6,7] or for the indication of a short cervix on ultrasound (ultrasound- indicated cerclage).[8,9]

Emergency cervical cerclage refers to the placement of a cerclage in the setting of significant cervical dilatation, and/or effacement with prolapsed or bulging membranes prior to 28 weeks of gestation in the absence of labour. ACOG supports the placement of a cervical cerclage up to 28 weeks of gestation.[10]However, many practitioners would not recommend emergency cervical cerclage beyond the period of foetal viability (i.e. ≥24 weeks gestation), because the potential harm likely outweighs the potential benefit.[11]The most challenging presentation of cervical incompetence, the woman with prolapsed membranes at or beyond a dilated cervical os has never been a subject of randomized trial. The published studies are either prospective on a small number of patients, or retrospective. Although these studies suggest that emergency cerclage is associated with prolonged gestation and reduced risk of preterm birth, due to certain limitations in these studies, the management of these patients remains controversial. The objectives of the present study are to evaluate my experience in emergency cervical cerclage and its impact on prolongation of pregnancy and pregnancy outcome.

2. Subjects and Method

This study is a prospective analysis of emergency cervical cerclage was conducted between first of March 2012 to 15th 0f May 2015 at our

department of obstetrics and Gynaecology, tertiary centre hospital. All women who underwent emergency cerclage in mid- trimester were included. We defined an emergency cerclage as a cerclage required when the membranes were bulging at or beyond the external os, with advanced cervical effacement and dilatation.

Inclusion Criteria:

All cases presented between 16 and 27 weeks gestation was fulfilled the following criteria:

1-Cervical dilatation between 1.5 and 4 cm.

2- Cervical effacement based on clinical diagnosis with or without herniation of the fetal membranes through the dilated cervix.

3-Absence of true labor pain.

4-Absence of clinical evidence of infection.

Exclusion Criteria:

Patients were considered not legible if they had any of the following findings:

1- Abnormal placental implantation or vaginal bleeding suggestive of placenta previa.

2-Clinical diagnosis of chorioamnionitis or muco-purulent vaginal discharge.

3-Ruptured fetal membranes.

4-Labor pain that did not respond to tocolytics.

Procedures:

Patients who fulfilled the criteria for emergency cerclage were counseled regarding the procedure, its chances of success and potential complications and were asked to sign a consent form.

In all cases ultrasonography was performed prior to admission to the procedure in order to confirm fetal viability, placental localization and screening for fetal congenital abnormalities. High vaginal swabs (HVS) were obtained from all patients for culture and sensitivity. Abortion was defined as spontaneous termination of pregnancy before 24weeks of gestation.

Surgical Procedure

In this study, the McDonald's technique of cervical cerclage was used in all cases. Briefly, patients were placed in a steep Trendelen burg position, under general anesthesia using Halothane, and a Sim's speculum was applied to expose the cervix. In order to facilitate the reduction of the herniating membranes the urinary bladder was filled with approximately 250-500 ml of 0.9% normal saline through a Foley catheter. The four quadrants of the cervix were grasped using sponge holding forceps. The cervix was then drawn downwards to help reducing the membranes to a higher level than the internal os. Wet surgical gauze on a sponge holding forceps was sometimes used to help replacing the membranes high beyond the internal os level. In some cases where the membranes were not fully reduced by this method, No. 22 Foley catheter was used. The catheter was gently inserted within the cervix and the balloon was inflated until the prolapsed membranes were displaced to a level higher than the internal os. The cerclage suture was then applied using Mersilene tape; the balloon was deflated and removed [24].

According to our policy in this hospital, all patients for cervical cerclage are given prophylactic antibiotics and tocolytics. The prophylactic antibiotics given is usually in the form of intravenous antibiotic (amoxicillin + clavulanic acid 1.5 g initial dose then 1.5 mg 12hourly) and administered 12-24 hours preoperatively and continued for three days. For the tocolytics, intravenous infusion of magnesium sulphate ($MgS0_4$) 2g per hour is administered prior to surgery and continued for 24 more hours. Postoperatively rectal progesterone suppositories 400 mg two times daily are often given as necessary.

3. Results

During the study period, initially twenty-five patients presented with features of cervical incompetence. Only twenty patients fulfilled the study inclusion criteria.

Eighteen patients had singleton pregnancies and two with twin pregnancies. The patients' characteristics are shown in (Table 1). Two patients had a history of cervical cerclage in a previous pregnancy. Eight patients were in their first pregnancies (primigravidas); six patients had previous mid-trimester miscarriages (cases No.2,6,8, 10, 13, and18) whereas two women had a history of preterm delivery. Fifteen of the patients were emergency cases who were directly admitted to the labor room as they presented with dilated cervices (3 to 4 cm) and a membrane prolapsed. The remaining five patients (cases No. 2, 6,8, 10, and18) were presented with a history of mid-trimester miscarriage. They were under follow up by ultrasonography for changes in cervical length, and latter referred for emergency cerclage because of shortening and dilatation, but the membranes were not prolapsed yet. In these five patients, pregnancy was prolonged beyond 37 weeks. Pregnancy was prolonged by 67.1 $\pm$ 38.1 days (ranged from 0 to 118 days). For the survivors it was 88.3 $\pm$ 15.8 days(ranged from 62to 118 days).The mean gestational age at the time of cerclage was 22.4 $\pm$ 2.1 weeks (ranged from 19.5 to 26.8 weeks), whereas the mean gestational age at delivery was 32.03± 6.2 weeks (ranged from 20.2 to 39.7 weeks). For the survivors it was 35.5 ± 2.5 weeks (ranged from 31 to 39.7 weeks).

In all patients, the membranes were successfully reduced and reformation of the cervix occurred up to a length that ranged between 2 - 2.5 cm. In one case

the cervix was torn during the procedure, (case no 9).

Complete success was achieved in fifteen cases (75%) in that the cerclage was successfully applied after reducing the fetal membranes and pregnancy was prolonged beyond 31 weeks gestation with seventeen survivors (two set of twins) to result in a take home baby. The details of patients at presentation and pregnancies outcome are shown in (Table 2). In five patients, the cerclage suture was removed electively at 37 weeks gestation whereas in fourteen patients the cerclage stitch was removed prior to 37 weeks while they were in active preterm labor. The cervical dilatation was between 1.5 cm and 4 cm. In all cases, the results of the HVS culture showed no abnormal bacterial growth.

In one patient, we failed to perform the procedure (case No.9). Another patient (case No.4) aborted three days after the operation, another patient (case No.7) aborted four days after the operation, and another patient (case No.11) aborted twenty-three days after the operation. In one case, the pregnancy was prolonged for only 30 days, followed by spontaneous labor and delivery of very premature baby with neonatal death after two days (case No.15).

A comparison between past obstetric history and pregnancy outcome after emergency cervical cerclage is shown in (Table 3).

Table 1: Clinical characteristics of twenty patients

Maternal age(years)	26.8± 5.09 (19 -35)
Gravidity	2.1±1.09 (1 – 4)
Gestational age at cerclage(weeks)	22.4± 2.1 (19.5 – 26.8)
Extension of pregnancy(weeks)	9.5± 5.4 (0.0 -16.8)
Gestational age at delivery(weeks)	32.03±6.2 (20.2 - 39.5)
Birth weight at delivery (gm)	1879.2±911.9 (390 - 3300)
NO. of twins	2 (10%)
NO. of abortions	3 (15%)
NO. of preterm deliveries	11 (55%)
NO. of deliveries ≥ 37 weeks	5 (25%)

Data is reported as mean ±SD and range or Number and %.

Table 2: Details of 20 patients underwent emergency cervical cercelage.

Case No.	Obstetric History	Gestational age at cerclage	Cervical Dilatation (cm)	Extension Of pregnancy(days)	Gestational Age at delivery	Weight at birth (grams)	OUTCOME	Histopathology	Remarks
1	P.G	24w3D	4	9w2D	33w5D	2100	Survived	—	—
2	P0+1	23w2D	3	14w2D	37w4D	3000	Survived	—	GDM Class A1
3	P2+1	20w4D	4	13w5D	34w2D	2150	Survived	—	Previous Cervical cerclage
4	P1+0	19w6D	2	3D	20w2D	390	Abortion	Infection	—
5	P.G (twins)	22w3D	3	13w2D	35w5D	2000 2450	Both Survived	—	PIH
6	P0+2	25w5D	3	12w2D	38w	3300	Survived	—	Cervical tear during labor
7	P.G	21w2D	4	4D	21w6D	485	Abortion	—	—
8	Po+1	25w2D	2	14w3D	39w5D	2850	Survived		—
9	P2+0	23w5D	4	None	23w5D	550	Cancelled Due to Cervical tear	Infection	—
10	P1+2	20w3D	3	16w6D	37w2D	2500	Survived	—	—
11	P1+1	19w4D	4	W2D3	22w6D	480	Abortion	—	—
12	P.G	21w5D	1.5	14w4D	w2D36	2650	Survived	—	hypothyroidism
13	P0+1	22w3D	4	11w5D	34w1D	2150	Survived	—	
14	P0+1	20w3D	3	12w6D	33w2D	1750	Survived	—	GDM Class A2
15	P.G	22w1D	2	4w2D	26w3D	680	NND	—	—
16	P.G (twins)	20w3D	4	10w4D	W31	1650 1900	Both Survived	—	—
17	P1+o	23w4D	3	8w6D	32w3D	1850	Survived	—	Previous Cervical cerclage
18	P2+1	26w6D	1.5	11w2D	38w1D	2700	Survived	—	GDM Class A1
19	P.G	21W3D	3	14W5D	36W1D	2660	Survived	—	—
20	P.G	20W3D	4	12W6D	33W2D	1850	Survived	—	—

W= weeks D= days; PIH = pregnancy induced hypertension; GDM = gestational diabetes mellitus

Table 3: Comparison between past obstetric history and pregnancy outcome after emergency cervical cercelage

Variable	past obstetric history		Outcome after cercelage		*P-Value*
	NO.	%	NO.	%	
Abortion	5	25	4	20	0.49 NS
24-28 W	1	5	1	5	0.75 NS
29-31W	0	0	1	5	O.49 NS
32-36W	1	5	9	45	**0.02 S**
≥ 37W	4	20	5	25	0.49 NS

NS =not significant; S = significant

4. Discussion

Cervical cerclage is an intervention that is widely used to prevent miscarriage or delivery in the second trimester of pregnancy. It has been referred to as heroic cerclage or rescue cerclage in cases with advanced cervical dilation and bulging membranes due to its poor success rate.[12]

Emergency cervical cerclage in advanced cervical dilation with bulging membranes in the second trimester remains a controversial decision. The responsible obstetrician and the patient who presents with painless dilatation either have to wait for further events or to undertake a procedure that by itself carries its own risk of rupturing the membranes and thus ending the pregnancy. The outcome of these pregnancies is usually poor, but without a cerclage the loss of pregnancy is inevitable, reported survival rate following emergency cerclage varies from 12.5 % to 63 % in woman with advanced cervical dilatation.[11]

In this study a mean pregnancy prolongation time of 9.5 weeks and emergency cervical cercelage prolonged pregnancy beyond 31 weeks gestation in 75% of the studied group which means less special care for the survivors. These data, combined with other published data, suggest that emergency cervical cerclage under ideal circumstances with careful patients selection can significantly prolong pregnancy and increase the chance of viable pregnancy outcome. I believe that a meticulous and prudent surgical technique is the key for success. However, the rather encouraging results of the present study cannot be solely attributed to the surgical procedure per se, which has remained unchanged in the past decades. The treatment of the neonates that has changed dramatically over the years may also contribute to this success. It seems the current standard of neonatal treatment coupled with a very prudent and meticulous surgical technique of emergency placement of a cervical suture justifies today the performance of a cerclage procedure in these patients.

However, in counseling women about the therapeutic benefit of emergency cervical cerclage, the increase risk of membranes rupture and chorioamnionitis and its associated effects on both the mother and fetus as well as the risk of extending a pregnancy from viability to extreme prematurity should be discussed. It is generally accepted that cervical cerclage placement for cervical incompetence is best performed prior to the occurrence of significant cervical dilatation and effacement and this is clearly demonstrated in this study in cases No **1, 3, 13, 14 and 18.**

Cockwell *et al.,* 2005, presented 12 cases of emergency cerclage in which the mean prolongation of pregnancy was 7 weeks and one day, with a neonatal survival of over 70%.[13] **Thomas *et al.,*** 2013, presented 6 cases of emergency cerclage done for advanced cervical dilatation with bulging amniotic membranes between 24 to 26 weeks of gestational age in that four cases (66.7 %) carried on their pregnancies to term, and resulted in healthy live born babies.[14] **Matijewic *et al.,*** reported 66% of fetal survival in pregnancies with cervical dilatation and bulging membranes.[15] In our series, a live birth rate of 85.72 % was observed and all live born babies were healthy at the time of discharge.

At least two studies [16,17] have reported a lower success rate (50% and 59%) with emergency cervical cerclage as compared with prophylactic cerclage (86% and 81%). I suggest that in emergency cervical cerclage a lower success rate could be because either the cervical cerclage was applied too late or that some prophylactic cervical cercelages are placed in women who do not need them. To reduce the number of unnecessary cervical cercelages, there is a growing tendency towards following ***Althuisius and coworkers***[18] which aims at delaying elective cervical cerclage until evident cervical changes at ultrasonography appear. This observation was applied for the high-risk patients in this study and five of them were detected. From the present study and previous publications [19,20] predictors of successful emergency cervical cerclage include absence of placental separation, absence of infection, and absence of true labor and successful replacement of the prolapsed fetal membranes. We observed patients for sufficient time to exclude placental abruption or labor and clinical infection. The main

difficulty lies in the diagnosis of subclinical infection.

In a study carried by ***Abdullah and associates***[20], histopathology of the placenta revealed evidence of placental and chorioamniotic infection in all unsuccessful cases. This was evident in cases No **4&9** in this study. This reflects that the standard methods of detecting subclinical infection (only with HVS) failed to detect infections. C-reactive protein and amniotic fluid for microbiology culture and sensitivity failed also to detect subclinical infections. The underlying subclinical infection can`t be excluded in one case that ended up in abortion who had increased WBC count prior to the cerclage. **Purnima et al.,** 2011, evaluated a retrospective analysis of 20 cases of emergency cerclage, which reveals a significant association between initial white cell count and perinatal outcome. This information is helpful in decision making and counselling the patients regarding likely outcome.[21] If silent membrane prolapsed to or past the external os occurs at 22 weeks or before, the incidence of intrauterine bacterial colonization is 20% to 50% as reported by **Romero et al**., 1992.[22] By replacing the membranes and closing the cervix, the risk of exposure to vaginal infection is reduced. Therefore, the inflammatory-like process, which is responsible for cervical ripening and onset of contraction, is also reduced. This causes the cervix to close, lengthen, and prolong the pregnancy. Because of these difficulties, it is better to consider starting a combination of antibiotics to cover aerobes and anaerobes (e.g. metronidazole in addition to a cefalosporine, erythromycin or (amoxycillin+ clavulanic acid).

For the successful reduction of the fetal membranes, we feel that overfilling of the urinary bladder with normal saline is a safe and easy procedure. It is now recommended to use balloons of the type used for endoscopic proportional dissection [(23)]. In women with advanced cervical dilatation in the second trimester with or without membranes prolapsed emergency cervical cerclage -despite its associated risk at the short and long term- may be the only hope for prolonging pregnancy. There has not been any randomized study addressing the issue of emergency cervical cercelage versus an approach of bed rest and expectant management [(24)]. In the absence of inconclusive evidences to demonstrate clear benefits, emergency cervical cerclage should be used judiciously and only after comprehensive patients' assessment and extensive counseling.

Conclusion:

Emergency cervical cercelage remains an important part of the obstetric procedure for the management of cervical incompetence. However, it is a surgical procedure with well-defined operative risks. As such and until adequate clinical trials are available demonstrating a clear benefit, emergency cervical cerclage is a treatment option which could be the only hope for women presented with advanced dilatation of the cervix with or without membranes prolapsed. It should be used judiciously and only after comprehensive patients' evaluation and selection as well as after extensive counseling.

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