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Effectiveness of cervical encerclage and its perinatal outcome-A cohort study

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ABSTRACT

Introduction: Cervical incompetence is the inability of cervix to support a full term pregnancy. The patient presents with a partially dilated cervix, with or without a history of recurrent mid trimester losses or preterm births. It is believed that the forced mechanical closure of an 'incompetent' cervix with a suture maintains the cervical length, thus preventing preterm labor.

Objectives: To evaluate effectiveness of cervical encerclage in women with cervical incompetence and its perinatal outcomes.

Materials and Methods: This ambispective cohort study was conducted in the department of Obstetrics and Gynecology, Amala Institute of Medical Sciences, Thrissur. Medical records were reviewed during the period of 2008-201. 79 cases were included in this study.

Clinical data, gestational age, cervical dilatation at the time of cerclage, cerclage-delivery interval, gestational age at the time of delivery, birth weight and maternal complications, were collected.

Results: Mean gestational age at the time of cerclage is 18.686 ±4.0200 weeks. Mean cerclage - delivery interval is18.510 ±6.3026 weeks. Cerclage delivery interval in prophylactic cases is 20.13 ±3.79 weeks and in rescue cerclages it is 9.487± 2.73 weeks. Prophylactic cerclage is more effective than rescue cerclages (p=0.0002). Mean gestational age at delivery is 36.666 ±5.3354 weeks. 23cases (29%) had low birth weight babies (<2500 gm). No maternal complications were noted in the study. 12 cases(14%) showed preterm complications. 8cases (10%) resulted in fetal demise.

Conclusion: Based on this study we conclude that cerclage is beneficial in prolonging pregnancy with a consequent reduction of fetal losses and neonatal deaths.

1. Introduction

Cervical incompetence is associated with a history of passive painless dilatation of cervix, which leads to preterm birth and second trimester pregnancy loss. It is defined as the inability to support a full term pregnancy. Etiology behind it may be traumatic injury (previous trauma to the cervix such as repeated dilatation and curettage or surgical procedures affecting the integrity of the cervix), congenital abnormalities (diethylstilbestrol exposure or malformed cervix) or a structural defect of the cervix (cases with collagen defect/deficiency such as Ehler danlos syndrome). It has been proposed that these risk factors may change the threshold by which the mechanical barrier of the cervix can be breached, thus leading to colonisation of cervix by vaginal bacteria and up-regulation of the pro-inflammatory pathways initiating cervical changes and preterm labour.[1]

Preterm birth is the most common cause of fetal and neonatal mortality and morbidity. Premature dilatation of cervix due to incompetence is one of the reason for second trimester miscarriage and preterm delivery. Belief in cervical insufficiency is the basis for cervical cerclage.

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The first description of cervical incompetence was reported back in 1658 by Cole, Culpetter and Rowland, quoted " the second fault in women which hindered conception is when the seed is not retained or the orifice of the womb is so slack that it cannot rightly contract itself to keep in the seed. The fibers of the womb are broken in pieces, one from another and the inner orifice of the womb overmuch slackened ". Despite the description of this condition, a surgical approach for treatment emerged nearly 300 years later.[2]

In 1955, Shirodkar introduced cervical cerclage as a surgical technique to restore cervical function. In 1957, McDonald developed a simpler procedure, a surgical intervention which rapidly became the gold-standard for the treatment of patients with cervical insufficiency, in women with a suggestive history of cervical incompetence, so as to provide a degree of structural support to a weak cervix with the help of sutures or synthetic tape to reinforce the cervix and thus to prolong pregnancy till term. Both of them described surgical procedures with similar success rates (approximately 85 to 90 percent) when either technique is performed prophylactically.

The Shirodkar suture is a transvaginal purse string suture inserted after bladder mobilization above the level of the cardinal ligament, while the McDonald suture is inserted lower at the cervicovaginal junction, but without bladder mobilization (Shirodkar, 1955; McDonald, 1957).[3,4] Cervical cerclage was initially introduced for two main indications: the prevention of second trimester losses for pregnant patients with painless shortening or advanced dilatation (rescue cerclage) and for the treatment of recurrent second trimester late miscarriages or preterm deliveries (prophylactic cerclage).[3,4]

Cervical insufficiency is the term that has now replaced the phrase, cervical incompetence. Incidence of incompetence is believed to be less in our population. However, the most recent estimate from the Centers for Disease Control and Prevention's National Center for Health Statistics indicates that 14,000 discharges from acute care hospitals included the diagnosis, "cervical incompetence."[5]

While cervical insufficiency is known to involve a progressive dilatation and shortening of the cervix, the pathogenesis of this condition is not clearly understood. Cervical incompetence occurs along a spectrum of severity, a higher degree incompetence leading to mid trimester miscarriages and lesser degree causing some cases of preterm delivery. Typically, the patient presents with a partially dilated cervix, in the absence of uterine contractions or intrauterine infections, with or without a history of recurrent mid trimester losses or preterm births.

The major clinical importance of cervical insufficiency is the difficulty in differentiating this condition from other causes of early preterm delivery and miscarriages. Physicians always tend to exclude other causes of preterm delivery before confirming diagnosis of cervical insufficiency. For this reason, a diagnostic criteria and rational treatment algorithms are essential for the appropriate management of these pregnancies.

Due to difficulties in making a confident diagnosis of cervical incompetence there are wide variations in the use of cervical cerclage. This variation also reflects the lack of evidence (studies and trials) concerning the efficacy of cervical cerclage (Grant 1989). There is no agreed definition of cervical insufficiency by absolute measurable criteria and the diagnosis is usually a retrospective one based on clinical symptoms and history. It is important that before incompetence is diagnosed, appropriate diagnostic criteria are applied and other causes of preterm labor are excluded, because treatment is invasive and has got potential complications affecting both mother and fetus. It was mentioned in recent trials that overuse of prophylactic cerclage is because of the inability to diagnose cervical incompetence with any degree of reliability on the basis of history and clinical picture alone.

Past authors have suggested widening of the cervical canal demonstrated by hysterosalpingogram, ease of insertion of cervical dilators (hegar s dilator number 8), force required to withdraw a Foley catheter with its bulb inflated through the internal os and several different methods to measure the force required to stretch the cervix (for example, using an intracervical balloon) as a measurable diagnostic method for cervical incompetence. These methods have significant flaws, including their requirement that they should be performed when the subject is not pregnant, ignoring the known effects of pregnancy on the cervix, and the effect of hormones during the menstrual cycle. At present, there is no reliable preoperative test confirming the presence of cervical insufficiency in women with historical risk factors. With the advent of transvaginal ultrasound measurements of cervical length and the description of "funneling" in the 1990s, new criteria have been proposed for establishing the diagnosis of cervical insufficiency. In this new paradigm, the diagnosis is not a dichotomy, where the cervix is proclaimed either "incompetent" or competent. Rather, the cervix is viewed as a dynamic component of the lower uterine segment, varying in its ability to remain closed and uneffaced in the presence of uterine contractions as well as different biochemical, bacteriological, and immunological stimuli.[6]

In our clinical practice, the decision to insert a cervical suture is most commonly based on past obstetric history and, to a lesser extent, clinical assessment of the cervix during pregnancy by vaginal examination or measurement of cervical length by ultrasound examination. Cerclage is said to be prophylactic, if it is performed in asymptomatic women and normally inserted electively at 12-14 weeks of gestation. Unless effectively treated, the incompetence

related risk of miscarriages may repeat in future pregnancies with subsequent losses occurring at progressively earlier gestational ages.

The real incidence of cervical insufficiency is unknown because diagnosis is essentially clinical and it is not possible to reliably diagnose women with cervical weakness in non pregnant state. Epidemiological studies suggest an approximate incidence of 0.5% in the general obstetric population and 8% in women with a history of previous mid trimester miscarriages.[2]

According to available data from previous studies, in cases where cervical incompetence was diagnosed in a previous pregnancy or if there are known risk factors, a prophylactic cervical encerclage could be a reasonable management option. Other prophylactic cases include those apparently asymptomatic women with clinically detected shortening of cervix or with minimal cervical dilatation which is detected during routine clinical visits. But in cases where patient presents with an advanced cervical dilatation and a bulging bag of membranes, an emergency or rescue encerclage may be indicated, which is considered to be a salvage measure to prevent preterm deliveries. Rescue encerclage has long been the subject of controversy. Royal college of obstetricians and gynaecologists (RCOG) states that the insertion of rescue encerclage may delay the delivery by a further 5 weeks on average as compared to bed rest and expectant management alone.[7]

The main goal of the study is to review and evaluate the efficacy of cervical encerclages (both prophylactic and emergency/rescue encerclages) among women with cervical incompetence and to find out the maternal and neonatal outcomes.

2. Relevance

Delivery prior to 37 weeks of gestation (preterm) occurs in 10% of pregnancies and accounts for 75% of neonatal deaths. Delivery is iatrogenic in about a third of cases and spontaneous in the rest, with cervical incompetence being one of the most common causes. This study reviews the available evidence and assess the effectiveness of the use of cervical cerclage in the management of cervical incompetence. Aspects covered in this study include the diagnosis of cervical incompetence, an assessment of relevant research publications and trials on the use of cervical cerclage in the prevention of preterm birth, and its role as an emergency treatment in pregnant women presenting with painless cervical dilatation.[8]

The 3–12% incidence of preterm labor and preterm delivery varies widely with different populations, including risk factors such as low maternal pre-pregnancy weight, low socioeconomic status, racial and ethnic factors, maternal education, maternal work patterns, physical effort during pregnancy especially during the third trimester, maternal sexual activity, tobacco use, interval between pregnancies, bacterial vaginosis, and other types of bacterial colonization of vagina, uterine abnormalities, number of fetuses, and more. The incidence of cervical insufficiency is very difficult to determine because there are no clear clinical criteria for the diagnosis. Rather, the diagnosis is made by exclusion of other causes of preterm delivery, but the many retrospective studies of cervical cerclage have at least given us the frequency of cerclage operations in some large cohorts around the world.[5,9–11]

Preterm birth complications are the leading cause of perinatal mortality and morbidity. Almost 1 million children die each year due to complications of preterm birth (2013 data). Approximately 13 million preterm births occur annually worldwide with an incidence ranging from approximately 5 to 12%.[5] One of the major contributing factor of preterm births and mid trimester abortions is cervical incompetence. Cerclage remains a commonly performed intervention which is believed to be useful in tackling cervical incompetence. However, in singleton pregnancies of women who have had a previous preterm birth or second trimester loss, cerclage appears to be associated with a significant reduction in preterm birth.[12]

In this background, the efficacy of cervical encerclage is analysed in this study, to determine whether this procedure is feasible, taking into account the associated maternal as well as fetal complications and outcomes.

3. Aim

To evaluate effectiveness of cervical encerclage in women with cervical incompetence and preterm labor and to find out its perinatal outcomes.

4. Objectives

1. To determine the time from cervical encerclage to delivery in terms of number of weeks of gestation and gestational age at delivery.
2. To find out neonatal outcome in terms of term birth, birth weight, preterm birth and complications.
3. To find out maternal outcomes and complications in terms of sepsis, lacerations of cervix.
4. To find out the effectiveness of rescue encerclage in prolonging pregnancy in preterm labour.

5. Materials and Methods

This ambispective cohort study was carried out in the Department of Obstetrics and Gynaecology, Amala Institute of Medical Sciences, Thrissur during the period from December 2017 to October 2019. This medical college is providing medical service to a mixed population of Thrissur. Seventy nine patients undergoing cervical encerclage, fulfilling the selection criteria were the subjects of the study.

5.1. Study design

Ambispective cohort study - was used.

5.2. Study setting

The study was conducted in the Department of Obstetrics and Gynaecology, Amala Institute of Medical Sciences.

5.3. Study period

The study was conducted during December 2017- October 2019, however patients who has undergone cerclage among inclusion criteria, from 2008 to 2017 were also included.

5.4. Sample size calculation

Sample size was calculated from the study by Dr. Sheng Wang, done in Tonji Hospital Wuhan, China during January 1, 2010-July 31, 2015. Of 166 patients who underwent encerclage, after exclusion of patients with missed abortions, 121 singelton pregnancies were included in the analysis. Mean gestational weeks at delivery was 34.22 ±5.77 and mean suture to delivery interval was 15.72 ±7.15 which was taken for sample calculation, which showed a sample size of 79 cases in total to be included in the study.[17]-α/2 x Sd

Where,
α = 0.05 (1.96)
Sd =7.15
Mean =15.72
d =Absolute error (10% of mean) n = 79

5.5. Study population

Patients presenting in Gynaecology opd of Amala institute of medical sciences, Thrissur.

5.6. Inclusion criteria

Singleton viable pregnancies, who had undergone cervical encerclage in the current pregnancy or pregnancy under consideration(in case of retrospective analysis), and presented with

1. Preterm labour
2. Previous history of encerclages
3. Previous history of preterm births or midtrimester losses
4. Sonologically detected short cervix

5.7. Exclusion criteria

1. Patients with undiagnosed uterine bleeding.
2. Patients with sonographically detected fetal anomalies, intrauterine death.
3. Patients with intrauterine infections.(clinical evidence of chorioamnionitis).
4. Patients with premature rupture of membranes.
5. Patients with chronic hypertension, diabetes mellitus, severe pre eclampsia.
6. Patients with multiple pregnancy.

5.8. Details of the study

This ambispective cohort study was conducted in the Department of Obstetrics and Gynaecology, Amala institute of medical sciences, Thrissur. Medical records was reviewed for patients who underwent cervical encerclage either prophylactic or emergency, during the period of 2008-2017 for retrospective analysis of cases. 79 cases who has undergone prophylactic cerclage and emergency cerclage during the study period were included in this study.

Diagnosis of cervical incompetence was made in patients who presented with complaints of pelvic pressure sensation or increased vaginal discharge by physical examination using speculum. patients who had a past history of mid trimester losses or preterm births were also included. Another method of diagnosis is ultrasonologically detected cases of short cervix. The criteria for cerclage were that there must be no rupture of membranes, significant uterine contractions vaginal bleeding, intrauterine infections (axillary temperature <98.6 ∘F, serum WBC <14x10 9).

Features of chorioamnionitis was clinically excluded.[13,14] All subjects had undergone ultrasound examination by an experienced operator to determine fetal number and viability, fetal abnormalities, and cervical length. Clinical management was individualized following an informed discussion between a senior obstetrician and the patient.

Mc Donald procedure was performed for all patients, under spinal anaesthesia. Ethibond is used to suture the cervix, while an inflated foleys bulb was used with gentle pressure to replace the membranes to allow suturing in cases with bulging fetal membranes All subjects were discharged with advice to avoid strenuous activities and standing for long durations. Sutures were removed in all women who went into labour, ruptured their membranes, developed infection or on reaching 37 weeks of gestation.

5.9. Outcome

The following data were collected from medical records-clinical data, gestational age, cervical dilatationat the time of cerclage, cerclage-delivery interval, gestational age at time of delivery, fetal survival, neonatal birth weight and maternal complications. Neonatal outcomes and maternal outcomes were measured from above mentioned data.

5.10. Study tools and data collection

Informed consent was taken from all patients. All data obtained were kept confidential. Detailed history and physical examination (speculum examination) was followed

by obstetric ultrasound for analyzing cervical length in elective cases. All the necessary preoperative investigations which are already done were reviewed and all women satisfying the inclusion criteria were recruited into the study after signing a written informed consent. The patients, after discussing the pros and cons of cervical encerclage were given the choice to enter the study.

The data required for the study were obtained after careful and thorough analysis of the case sheets and investigations and operative notes maintained at the hospital.

The following would be the characteristics studied:-

1. Demographic characteristics: Age, obstetric score, previous history of mid trimester abortions and preterm births
2. Cervical dilatation at time of cerclage
3. Gestational age at time of cerclage (weeks
4. Cerclage-delivery interval (weeks
5. Gestational age at delivery (weeks
6. Neonatal survival
7. Preterm complications
8. Birth weight
9. Maternal complications (maternal death, sepsis, laceration of cervix

5.11. Statistical considerations

The data obtained were coded and entered in Microsoft excel sheet and analysed using SPSS. Descriptive statistics was used for data analysis.

5.12. Ethical considerations

1. Institutional research committee and ethical committee clearance was obtained.
2. Informed consent was taken from each subject.
3. Detailed subject information was provided to the subjects to read before taking consent.
4. Confidentiality of the subject was maintained.

6. Results

This ambispective cohort study was undertaken in the Amala Institutes of Medical Sciences Thrissur, during the period from December 2017 to October 2019.

Seventy nine cases of cervical encerclage, which met the inclusion criteria, were studied with respect to the variables cited in the objectives.

Of the 79 women in the study population, 67 cases (85%) underwent elective cerclage while 12 cases (15%) underwent emergency cerclage. Of the elective cases, 39 (49%) underwent history indicated cerclage and 28(35%) had ultrasound indicated/ Therapeutic cerclage (Table 1)

In total, 67 elective cases were studied and 12 cases were emergency cerclage. (Table 2)

Table 1:

	Frequency	Percent
History Indicated	39	49
USG Indicated/ Therapeutic	28	35
Rescue encerclage	12	15
Total	79	100

Table 2:

History indicated (Rescue/Elective)	Frequency	Percent
Elective	67	85
Rescue	12	15
Total	79	100

6.1. Study parameters and outcomes

6.1.1. Age

The mean age of women included in the study was 26.506 ± 4.6378 years.

Majority of the patients belong to the 21-25 age group.

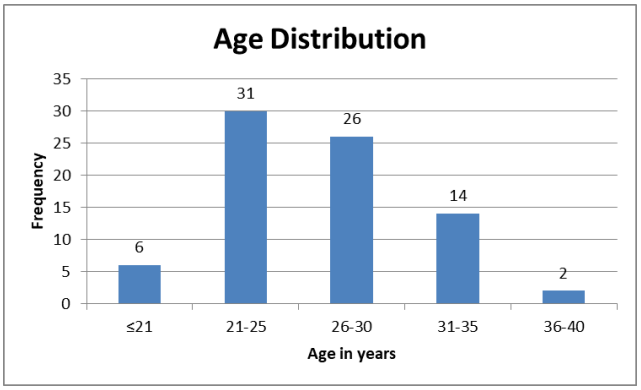

Fig. 1:

6.1.2. Parity

In the study population, 29 patients (36%) were primigravida and 50 patients (64%) were multigravida.

6.1.3. History of preterm births and mid trimester abortions

Among 79 women, 39 patients had history indicated cerclages. Of these 32 patients (41%)had history of mid trimester abortions and 7 patients (9%) had history of preterm births.

Table 3:

Previous h/o Preterm delivery	Frequency	Percent
No history	30	50.0
H/o mid trimester abortions	32	41.0
H/o preterm births	7	9.0
Total	79	100.0

6.1.4. Cervical dilatation at time of cerclage

In 24 cases, cervical dilatation of ≤ 1 cm is noted. These patients had incidentally detected cervical dilatation during routine vaginal examination.10 cases had advanced cervical dilatation ≥1 cm.

Table 4:

Cervical Dilatation at time of cerclage	Frequency	Percent
0	45	57
1.0	24	30
2.0	10	13
Total	79	100.0

6.1.5. Gestational age at the time of cerclage

Majority of the cerclages were done during gestational age 15-20 weeks. Mean gestational age at the time of cerclage is 18.686±4.0200 weeks.

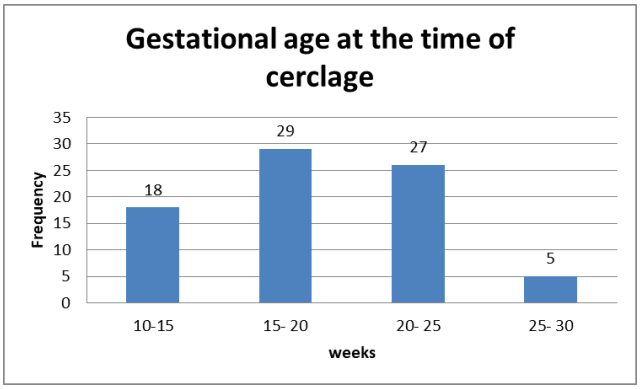

Fig. 2:

6.1.6. Gestational age at time of delivery

Mean gestational age at the time of delivery in the study was 36.666± 5.3354 weeks. Most of the pregnancies (69) under consideration reached near term.

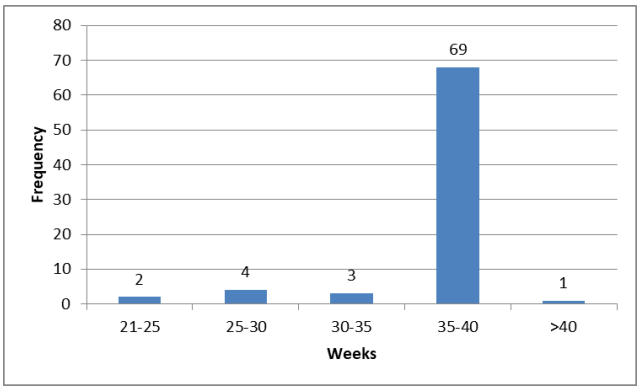

Fig. 3:

6.1.7. Cerclage –Delivery interval

Mean cerclage delivery interval in the study was 18.510 ±6.3026 weeks. Mean cerclage delivery interval.for elective cerclages was 20.131 ± 3.79 weeks and 9.487 ± 2.73 weeks for emergency cerclages.

Table 5:

Cerclage delivery interval	Frequency	Percent
<1	4	5
1-5	2	3
5-10	10	13
10-15	25	32
15-20	32	40
>20	6	7
Total	79	100.0

Pregnancy prolongation of <5 weeks was found in 6 cases.

Cerclage delivery interval is a direct measure of pregnancy prolongation which in turn shows the effectiveness of the procedure. Comparing this variable between elective and emergency cases, we found that there is significant difference in the period of pregnancy prolongation. While elective cerclages helped to achieve term gestation in most of the cases, emergency cerclages helped to prolong pregnancy from pre viability to prematurity in most of the cases. Hence, elective cerclages are more effective in prolonging pregnancy compared to rescue cerclages.(p=0.0002).

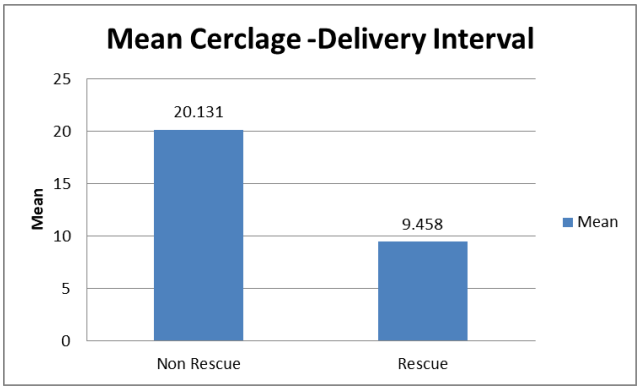

Fig. 4:

6.1.8. Maternal and neonatal complications

No maternal complications were noted in the study. 8 cases (10%) of neonatal death were reported due to cerclage failure. Preterm complications like respiratory distress was found in 12 cases (14%). Low birth weight (<2500 gm) was observed in 23 cases (29%).

Table 6:

	Group	N	Mean	Std. Deviation	P value(Students t test)
Cerclage-delivery interval	Elective	67	**20.131**	**3.7916**	**.0002**
	Rescue	12	9.458	2.73	

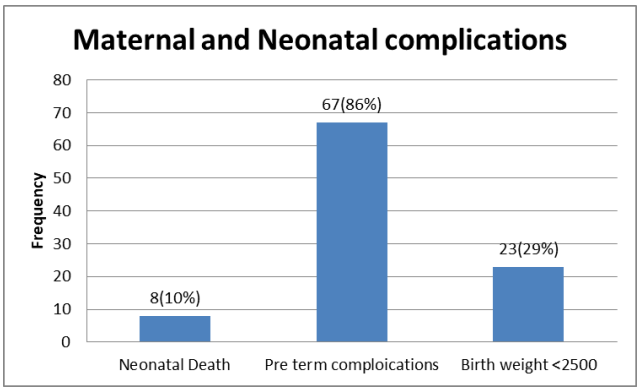

Fig. 5:

6.1.9. Birth weight

Low birth weight (<2500 gm) was observed in 23 cases (29%). 56 cases (71%) had birth weight >2500 gm.

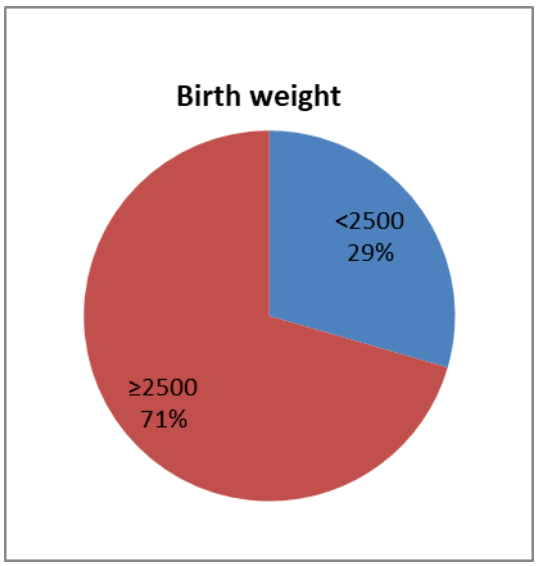

Fig. 6:

7. Discussion

Cervical encerclage is the most frequently performed surgical procedure for cases diagnosed with cervical incompetence. However, the question whether it is really effective in managing incompetence and help to prolong pregnancy till term still remains unanswered. Cerclage was first described in 1950 s. Several studies and randomized trials were carried out in this aspect to find out the significance of this procedure since then.

The exact mechanism by which cerclage helps to prevent preterm labour is not clearly understood. Cerclage provides mechanical support to a weakened cervix, and enhances the cervical immunological barrier by retention of the mucous plug, and preventing ascending infection by maintaining cervical length. Cerclage may also reduce the extent of stretch at the level of the internal os.

Preterm labor is a condition assosiated with multiple causes. To date, no trial of any predictive tool or intervention has attempted to classify subjects into aetiological subgroups. Use of ultrasound measurements of CL, or biomarkers such as fibronectin, help to define a high risk population,[5,12] but their ability to predict which women would benefit from cerclage is limited. Women should be informed that cerclage may prolong their pregnancy, but there are some associated risks and complications associated with the procedure which should be explained to the patient.[14] Intraoperative complications including bladder damage, cervical lacerations/tear, membrane rupture and bleeding are rare and are reported as occurring in <1% of cases.

Widespread uncertainty about the use of cervical cerclage in clinical practice was observed in studies and trials conducted amongst different study population. Reports from hospitals world over have shown a significant increase in cervical encerclages being performed to prevent preterm birth in cases diagnosed with cervical incompetence over the past few years.

The aim of this study was to evaluate the effectiveness of encerclage in terms of various parameters including cerclage – delivery interval, also evaluating neonatal and maternal outcomes among a population of 79 pregnant patients treated with prophylactic or rescue cervical cerclage.

The incidences of cervical insufficiency among our group of patients were less comparable to published literature (1%).[14–16] (Brown et al., 2013; Romero et al., 2006; Osemwenkha and Osaikhuwuomwan, 2014). Clinical tools are available to improve the selection of candidates for cervical cerclage. Heath et al. showed that the risk of premature delivery was related to the cervical length, as measured by transvaginal ultrasonography.[17] (Heath et al., 1998). The implementation of transvaginal echography in clinical practice led to its inclusion for measurements of cervical length as a useful screening tool for the detection of cervical incompetence[18] (Berghella et al., 2013; Feingold et al., 1984).

Our cohort was carefully selected to include all transvaginal USS indicated cerclages, cerclages inserted secondary to poor obstetric history or to 'rescue' a pregnancy i.e. when the cervix is already dilated with a bulging bag of membranes. The small number of events in the rescue group (12) described here prevented from using statistical analysis to determine the best timing to perform cerclage. Nevertheless, it is observed that early cerclages have better prognosis than late ones.

7.1. Clinical parameters

7.1.1. Age

Maximum number of cerclages carried out in the age group of 21-25 yrs which was 39% of the total. The mean age in our study was 26.506 ± 4.6378 years.

The various maternal ages (mean) quoted by other authors include- median age of women in the study was 27.0 years (mean 27.2 [SD 4.3] years, range 19–40 years) by Gundabattula et al, median maternal age was 32 years (range 18±48 years) in the retrospective study by J R Cook et al, mean age of 31 years in the elective cerclage group in the study by Liddiard et al[19] and a mean age of 27.7 years in the MRC/RCOG study group.

7.1.2. Parity

29 patients (36% in our study group were primigravida and 50 patients (64% were multigravida.

Nulliparity is reportedly associated with delivery before 28 weeks[20] and women with a prior term delivery are significantly more likely to deliver after 35 weeks than women with no prior term delivery.[21]

7.1.3. History

In our study, we included patients with previous history of mid trimester abortions and preterm births. 32 cases (41%) had history of late miscarriages and 7 cases (9%) had history of preterm births.

The identification of patients with a history of late miscarriages is crucial to prevent recurrent pregnancy losses in patients with the potential diagnosis of an incompetent cervix (Romero et al., 2006; Simcox et al., 2007).[12,14] This was confirmed by our observations of a strong correlation between the indication of a cervical cerclage and the history of second trimester miscarriage**.** 49% of all cerclages, in the study, were motivated by a history of late miscarriages or history of preterm labor.

The role of prophylactic cerclage in high-risk patients without a sonographic short cervix for the prevention of preterm delivery/mid-trimester abortion (by history) is unclear.[22–24] Many deliveries before term do not reflect cervical incompetence (Haxton & Bell 1983).[25] Extra information was therefore sought about deliveries before term with the aim of refining the comparison. While the largest trial conducted before the introduction of ultrasound evaluation of the cervix suggested a modest beneficial effect,[7] other trials[24] and systematic reviews[26] before the use of ultrasound have indicated that the evidence of effectiveness is either weak or nonexistent.

In patients at risk for preterm delivery, serial sonographic examination of the cervix followed by cerclage intervention in those with short cervix detected by ultrasound or physical examination is a reasonable alternative to prophylactic placement of a cerclage based upon uncontrolled studies.[27,28]

Past obstetric history is not a very strong predictor of subsequent early delivery. About 85% of women who have had one previous delivery at 20 to 36 weeks gestation will carry a subsequent pregnancy to term. After two such events, the term delivery rate is about 70% (Bakketeig et al. 1979; Carr Hill & Hall 1985).[29,30]

In a study by J R Cook et al, Thirty-five percent (n = 62) had a history of preterm delivery, 53% (n = 94) had a previous mid trimester losses. Among these women, 26% (n = 36) delivered prior to 34 weeks gestation and 40% (n = 54) delivered before 37 weeks, indicating that this sub-group was at greatest risk of delivering preterm.

7.1.4. Cervical dilatation at time of cerclage

Cervical dilatation at time of cerclage is one of the key factors influencing the success of cerclage. 24 cases in the study had cervical dilatation of approximately 1 cm and 10 cases had cervical dilatation of more than 1 cm at the time of cerclage. Those with advanced dilatation underwent rescue cerclage and those cases in which dilatation of 1 cm or less was found incidentally during vaginal examination in apparently asymptomatic patients underwent therapeutic cerclage. In our study it was found that advanced dilatation of cervix with bulging of membranes in to the vagina, causes failure of cerclage in most of the cases. In cases where cervix is just open (<1 cm), results are better with cerclage and majority of such pregnancies are carried till term.

Several studies have reported that women with rescue cerclage are more likely to deliver before 28 weeks of gestation, more so when cervical dilatation is >2 cm at the time of the procedure with bulging membranes prolapsing beyond the external os.[20,31–33] Other uncontrolled studies have suggested that the presence of membrane prolapse beyond the external os and/or cervical dilatation greater than 4 cm are significant predictors of cerclage failure.[34–36] It is not clear whether this is due to treatment failure or a more advanced underlying process that makes this group of women inherently more likely to deliver.[34]

7.1.4.1. Gestational age at time of cerclage . Mean gestational age at time of cerclage was found to be 18.686 ± 4.0200 weeks in our study group. Majority of cerclages were done during 15-20 weeks (29, 37%). In the study, early cerclage is found to be a positive factor influencing success of cervical cerclages.

However, none of the earlier studies have reported the benefit of early cerclages over late cerclages (>20 weeks) (ACOG Practice Bulletin. Cervical insufficiency, 2003; MRC/RCOG Working Party on Cervical Cerclage, 1993), despite the fact that most studies show better results for early cerclage (ACOG Practice Bulletin. Cervical insufficiency, 2003; Liddiard et al., 2011; Kurup and Goldkrand, 1999; Wu et al., 1996).[7,19,37–39]

Early transvaginal sonography can be helpful to detect short cervix (around 16–17 weeks of gestational age) for patients with a high-risk of late miscarriage or preterm birth, so that early interventions give greater chance of survival of fetus.

The median gestational age at which a suture was inserted in the cerclage group was 15.9 weeks in the study conducted by MRC/RCOG working party group. In the study by Liddiard et al gestational age at cerclage was reported as 14 (6–19) weeks in elective group compared to 23 (17–29) weeks in emergency group. In a study by Althuisius et al cerclages were inserted between 14-27 weeks and preterm delivery <34 weeks have been estimated. Rush et al and Gundabattula et al reported gestational age at time of cerclage to be between 15-21 weeks and 21.9 weeks respectively.[40,41] In a study by A Wafi et al cerclage was performed at a mean gestational age of 14 weeks (range: 10–23) for patients in prophylactic group compared to 16 weeks (range: 11–22) for rescue group.

There is no clear evidence that the gestation at which the cerclage is inserted affects the magnitude of prolongation of pregnancy. In cases presenting before 20 weeks of gestation, insertion of a rescue cerclage is highly likely to result in a preterm delivery before 28 weeks of gestation.[34]

7.1.5. Cerclage –delivery interval

Mean cerclage - delivery interval in the study is 18.510 ± 6.3026 weeks. For prophylactic cerclages mean cerclage –delivery intyerval is 20.131 ± 3.79 weeks and 9.487 ± 2.73 weeks for rescue cerclages. 4 cases of rescue cerclages had less than 1 week cerclage delivery interval and resulted in fetal demise. Cerclage delivery interval is one of the important parameters to assess effectiveness of cerclages.prophylactic cerclages were found to be more effective in prolonging pregnancy compared to rescue encerclages. (p=0.0002).

Other studies published similar results showing evidence that rescue cerclage could prolong pregnancy by 7 to 12 weeks (McDonald, 1957; Liddiardet al., 2011; Kurup and Goldkrand, 1999; Woensdregt et al., 2008).[3,19,38,42] Our present data confirmed these reported observations in terms of the prolongation of pregnancy following rescue cerclage (9 weeks). These results further imply that rescue cerclage is a more favorable approach, which can lead to increased chance for the delivery of a viable infant.

The observed pregnancy prolongations for the patients in this study who had undergone prophylactic cerclage (20 weeks) are consistent with previously reported results (20–22 weeks) (Liddiard et al., 2011; Kurup and Goldkrand, 1999; Khan et al., 2012).[19,38,43] The mean suture to delivery interval in the study by Liddiard et al. in elective cerclage group was 21 weeks with 76% of patients delivering vaginally at an average gestation of 35 weeks compared to 0–14 weeks with a mean of 6 weeks in rescue cerclage group.

According to the available literature, the best results are obtained for prophylactic cerclage (Liddiard et al., 2011; Kurup and Goldkrand, 1999; Wu et al., 1996).[19,39,44] However, the benefits of rescue cerclage, in terms of prolonging pregnancy, appear to be more limited (Kurup and Goldkrand, 1999; Ciancimino et al., 2015; Daskalakis et al., 2006; Gundabattula et al., 2013; Zhu et al., 2015).[41,45,46] However, rescue cerclages helps to prolong pregnancy till viability, if not till term, in most of the cases. An important limiting factor which needs to be highlighted is the presence of a subclinical or overt chorioamnionitis, which remains a predominant issue for patients with cervical dilation, with an incidence of 9%–33% for patients with bulging membranes. In the same study, prophylactic cerclage was associated with a reduced incidence of chorioamnionitis (1%–7.7%) (Harger, 2002).[5]

There has only been one randomized controlled trial by Althusius et al,[47] looking at rescue cervical cerclage and the average suture to delivery interval was 54 days.[48] Other studies by Gupta et al and Daskalakis et al have found mean suture to delivery intervals of 71 days and 8.8 weeks, respectively.[49,50] Gundabattula et al., reported mean prolongation of pregnancy 7.4 weeks with 42.0% women delivering after 28 weeks and 30.4% after 34 weeks. In a study by A Wafi et al., the mean pregnancy prolongation time after cerclage in the prophylactic and rescue groups were 21 weeks and 10 weeks, respectively. Other studies reported cerclage-delivery intervals for emergency cerclages of 7 weeks by Cockwell & Smith, in 2005, 9.1 weeks by Ventolini et al, in 2009 and 7.1 weeks by Vetr & Hejtmanek, in 2005.[32]

7.1.6. Gestational age at delivery

Mean gestational age at delivery in this study is 36.666 ± 5.3354 weeks. In our study 69 cases (87%) of the recorded deliveries following cerclage intervention occurred between 35 and 40 weeks of gestation. Outcomes of patients from the prophylactic group were much better than corresponding results of patients treated with a rescue cerclage, thus confirming observations made by previous publications (Liddiard et al., 2011; Kurup and Goldkrand, 1999; Wu et al., 1996; Harger, 2002).[5,19,38] The number of patients who were able to leave the hospital with a healthy baby was significantly higher after prophylactic intervention than

after rescue cerclage.

In the study conducted by MRC/RCOG working party on cervical cerclage, there were fewer deliveries before 33 weeks in the cerclage group (83 (13%) compared with 110 (17%), P=0.03) and this difference reflected deliveries characterised by features of cervical incompetence (painless cervical dilatation and prelabour rupture of the membranes). Liddiard et al reported the mean gestation at delivery between the elective and emergency cerclage groups (35 and 33 weeks, respectively). In a study by J R Cook et al 25% (n = 45) delivered <34 weeks and 36% (n = 65) delivered <37 weeks. In a prospective randomised study, Olatunbosun et al mean gestational age at birth in the rescue cerclage group was 33.0 weeks, which was significantly later than the 28.8 weeks in the bed rest group.[51] Althuisius et al reported mean gestational age at delivery of 29.9 weeks in the rescue cerclage group which was four weeks later than the mean of 25.9 weeks in the bed rest group. This difference was not statistically significant. The prevalence of preterm birth before 34 weeks of gestation was significantly lower in the cerclage group (7/13), while all the women in the bed rest group (10/10) delivered before 34 weeks of gestation. A Wafi et al. reported mean gestational age at delivery for prophylactic group and rescue group as 34 weeks and 29 weeks respectively.

7.1.7. Neonatal survival and preterm complications

71 neonates (90%) survived in this study. 12 cases had complications associated with prematurity, out of which 8 cases resulted in fetal demise. The study population was at moderate risk of early delivery in the index pregnancy as judged by an overall preterm delivery rate of 14%.

Neonatal outcome in this study is not influenced by the procedure as such or by complications like chorioamnionitis, rupture of membranes etc which were not encountered in our present study. It rather depends on the prolongation of pregnancy achieved by the intervention. Pregnancies which were not able to cross the period of viability with help of cerclage, especially in case of rescue cerclages, resulted in poor outcome.

Neonatal survival reported by Liddiard et al. was 93% and 92%, respectively in elective and emergency cerclage group.[19] In the study conducted by MRC/RCOG working party on cervical cerclage, preterm delivery rate was 28%. The difference in the overall rate of miscarriage, stillbirth or neonatal death (55 (9%) compared with 68 (11%)) was less marked and was not statistically significant. Other studies reported different preterm delivery rates including 12 (13%) in cerclage group compared with non cerclage group 10(10%) by Rush et al, 4 (1%) compared to 1 (<1%) by Lazar et al,[25] 6(24%) compared to 5(20%) by Dor et al.[52] Similarly, rates of miscarriage or stillbirth observed was 9 (9%) in both groups by Rush et al,[40] 2 (1%) compared to 1 (<1%) by Lazar et al,[25] 7(28%) compared to 6 (24%) by Dor et al.[52]

A report by Lipitz et al included 32 emergency McDonald cerclages in women with cervical dilatation greater than 1.5 cm and 50% effacement.37 The reported outcomes were infant survival in 15 of 31 (48%) with no comparison group.[53] In 2013, Gundabattula et al. and A Wafi et al reported neonatal survival rate of 50.7% and 78% respectively.

7.1.8. Birth weight

Mean birth weight in the study is 2725.114 ± 810.4 gm. 23 cases resulted in low birth weight (<2500 gm). But low birth weight doesn't seem to influence neonatal outcome to a significant extend since more than half of the low birth weight babies had reached viability and didn't have significant complications associated with prematurity.

In the study conducted by MRC/RCOG working party on cervical cerclage, there was a corresponding difference in very low birth weight deliveries (63 (10%) compared with 86 (13%) between cerclage and non cerclage groups.

7.1.9. Maternal complications

No significant maternal complications were encountered in the study. Cervical cerclages can rarely result in complications like maternal sepsis, lacerations of cervix etc. previous studies with larger study population have encountered such complications which doesn't significantly affect the maternal outcome.[46,54] A much larger study needs to be done to evaluate these complications.

The use of cervical cerclage was associated with increased medical intervention and a doubling of the risk of puerperal pyrexia in the study conducted by MRC/RCOG working group.

The clinical value of cervical cerclage has been subject of many observational and randomized clinical trials[17,18,27,47,48,55–58] and the studies have been subject to several systematic reviews.[59–61] The evidence suggests that cerclage is effective in prolonging pregnancies and success of the procedure depends various confounding factors. At the same time other causes of preterm birth are studied in detail, which can give an alternative to the surgical approach and to find out whether patients could benefit from conservative management alone.[62,63]

A meta-analysis has been performed of the randomised controlled trials and systematic reviews discussed to clarify the role of cervical cerclage in the prevention of preterm delivery.[51,64–73] The conclusion of this meta-analysis was that 'the effectiveness of prophylactic cerclage in preventing preterm delivery in women at low or medium risk for second trimester pregnancy loss has not been proven. The role of cervical cerclage in women whose ultrasound reveals a short cervix remains uncertain'. Hence, there is scope for further studies to clarify the benefit of cerclage in clinical practice, to find out patients who can benefit from the procedure and

to develop reliable criteria for cervical cerclage.[74]

8. Limitations of the Study

1. Relatively less incidence of cervical insufficiency in the study popoulation restrict evaluation of outcomes and effectiveness.
2. Complication rates observed were less as compared to other studies, probably because of the smaller sample size.
3. A comparison with a group of pregnant women with cervical insufficiency who were managed expectantly would have been ideal. But ethically, we could not withhold cerclage given its benefits, unless the woman refused to have the procedure. This limited our ability to design a randomized trial.
4. Given the present limited state of our knowledge about the pathophysiology of cervical insufficiency, much more research must be conducted.
5. Further studies are required to determine the need for and the use of antibiotics, progesterones and tocolytics prior to the procedure so that universal guidelines can be derived.

9. Summery

This ambispective cohort study was carried out in the Department of Obstetrics and Gynecology, Amala Institute Of Medical Sciences, Thrissur. Seventy nine cases requiring cervical cerclage for cervical incompetence were included in the study.

Both prophylactic and rescue encerclages were included in the study and aim is to find out the effectiveness of cerclage in prolonging pregnancy and to assess neonatal and maternal outcome.

1. Incidence of cervical insufficiency in the study group is less compared to that suggested by existing literature.
2. Mean age group of patients in the study is 26.506 ± 4.6378 years.
3. 29 (36%) Cases were primigravida women and 50 (64%) cases were multigravida in the study group.
4. Mean gestational age at the time of cerclage is 18.686 ± 4.0200 weeks. Better prognosis is seen with early cerclage compared to late cerclages (>20 weeks).
5. Mean cerclage to delivery interval is 18.510 ± 6.3026 weeks. Cerclage delivery interval in prophylactic cases is 20.131 ± 3.79 weeks and in rescue cerclages it is 9.487 ± 2.73 weeks. These results are comparable with previous studies and trials. Prophylactic cerclage is more effective in prolonging pregnancy than rescue cerclages.(p=0.0002)
6. Mean gestational age at delivery is 36.666 ± 5.3354 weeks. Prophylactic cerclages has helped majority of the cases to reach term and rescue cerclages helped most of cases to reach viability.
7. Mean birth weight is 2725.114 ± 810.4 gms. 23 cases (29%) had low birth weight babies (<2500 gm).
8. No significant maternal complications were noted in the study
9. 12 cases (14%) showed preterm complications. 8 cases (10%) resulted in failure of procedure and resulted in fetal demise.

10. Conclusion

Based on this study we conclude that cerclage intervention is beneficial in prolonging pregnancy till term, especially in case of prophylactic cerclages. In rescue cerclages, significant pregnancy prolongation is seen in only few cases, which is less compared to elective procedures. However, it is observed that the pregnancy extended from previability to prematurity in most of them. Cases with advanced dilatation tends to have little benefit with intervention. On the other hand elective cases had better results with good neonatal outcome. Since no significant maternal complications were encountered in the study, maternal outcome cannot be commended. Elective cervical cerclage appear to have low complication rates and high live-birth rates.

Our findings are consistent with the existing literature. Our results support the use of cerclage interventions to prolong pregnancy with a consequent reduction of fetal losses and neonatal deaths. Therefore, cerclage remains probably the best option for patients with cervical insufficiency.

11. Source of Funding

None.

12. Conflict of Interest

The authors declare no conflict of interest.

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