



SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

PERINATAL & MATERNAL OUTCOMES AFTER CERVICAL CERCLAGE FOR CERVICAL INSUFFICIENCY AT ST. PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE AND ITS AFFILIATE CENTRES IN ADDIS ABABA, ETHIOPIA

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Proportion of women who had experienced vaginal bleeding post cerclage

.....figure 1

4. ACRONYMS AND ABBREVIATIONS

OB: Obstetrics GYN: Gynecology

SPHMMC: Saint Paul's Hospital Millennium Medical College

MCH: Maternal and child health

WHO: World health organization

PTB: Preterm birth

PTL: preterm labor

PPROM: Preterm Premature Rupture of Membranes

UK: unknown

gm.: gram

Y12H; Yekatit 12 hospital

RDDH; Ras Desta Damtew hospital

GA; Gestational Age

ANC: Antenatal care

CS: Caesarean section

CL: Cervical length

SVD: Spontaneous vertex delivery

NICU: Neonatal intensive care unit

LEEP: Loop electrosurgical excision procedure

Wks.: weeks

SB: stillbirth

IRB: institutional review board

END: early neonatal death

5. Abstract

BACKGROUND: Cervical insufficiency is an important cause of late miscarriage and extreme preterm labour. Cervical cerclage has been practiced for decades as treatment for cervical insufficiency.

OBJECTIVES; to assess the perinatal outcomes after cerclage done at SPHMCC and its affiliate hospitals.

METHODS; Women with singleton pregnancies for whom cervical cerclage was done at SPHMCC, RDDH, Y12 &DMRH from January 1st 2017 – December 31st 2020 were reviewed.

Results: The mean age of the women was 28 (SD+3.56). The mean gestational age at which cerclage was performed during the index pregnancy was 113days (16wks). Cerclage was done for history indication in 33(81%) of the women and for three (7%) of the women with evidence of physical examination whereas the rest of them it was done for ultrasound findings, 32(78 %) of them had a previous abortion, 9 (22 %) of them never had a miscarriage before.

Conclusion: This analysis has shown that cerclage has favourable outcomes such as prolonging pregnancy, preventing preterm delivery thereby increasing The chance of viable pregnancy.

Key words ... Cervical cerclage, cervical insufficiency, preterm birth

6. CHAPTER ONE: Introduction

A. Background

Cervical cerclage is a well-known surgical procedure carried out during pregnancy. It involves the placement of a suture around the cervix, aiming to give mechanical support and thereby reduce the risk of preterm birth. (1, 2, 3) Cervical insufficiency is often associated with mid trimester pregnancy losses and preterm labour.

It is also possible to improve the perinatal outcome in patients with cervical dilation in the mid-trimester. (3) Cervical cerclage to prevent miscarriage and preterm labour is practiced worldwide. During normal pregnancy the cervix stays tightly closed, allowing the pregnancy to reach full term. Towards the end of pregnancy, the cervix starts to shorten and progressively becomes softer (more favourable sometimes, the cervix starts to shorten and dilates too early, causing either late miscarriage or preterm birth. In the absence of uterine contractions, the cause of this pathological condition is considered to be cervical insufficiency (sometimes also called incompetence) - these changes are physiological preparations for normal labor and delivery. Cervical insufficiency is often associated with mid trimester pregnancy losses and preterm labour. The typical symptoms of cervical insufficiency include a history of recurrent mid-trimester losses or pre-term birth and painless cervical dilatation in the absence of contractions or intrauterine infections. Labor is often short and the premature fetus is born alive. It is reported that the rate of cervical insufficiency is between 0.1% and 2%, and is estimated to account for 15% of the recurrent pregnancy losses between 16 and 28 weeks. Those women with a previous history of second trimester recurrent losses, or presenting with painless cervical dilatation in the absence of contractions and those women whose transvaginal cervical length was found to be benefit from prophylactic or rescue Cerclage. (4,5) Cervical cerclage was initially introduced for two main indications: the prevention of second trimester losses for pregnant patients with painless shortening of the cervix (rescue cerclage) or the treatment of recurrent second trimester late miscarriages and/or preterm deliveries (prophylactic cerclage) (6,7,8) Studies assessing the perinatal outcomes after cervical cerclage are scanty in Ethiopia, the goal of this study was to observe retrospectively and improve service provision for mothers who get their ANC in SPHMMC and affiliate centers.

B. Statement of the problem

Cervical insufficiency has been a cause for second and early third trimester fetal loss. Cervical insufficiency is not a categorical but rather a continuous variable, meaning that there are various degrees in the competency of the cervix. Fetal loss is a painful experience. A history of second or early third trimester fetal loss, after painless dilatation of the cervix, prolapse or rupture of the membranes, and expulsion of a live fetus despite minimal uterine activity, is characteristic for cervical insufficiency, In such cases the risk of recurrence is high, and a policy of prophylactic cerclage may be safer than one of serial cervical length measurements followed by cerclage, tocolysis and bed rest in case of cervical shortening or dilatation. (6,9)

It may occur in a single pregnancy or recur in consecutive pregnancies. Furthermore, a certain degree of competency of the cervix can be expressed differently in subsequent pregnancies. Women with risk factors for cervical insufficiency in their gynaecological/obstetric history should be followed by transvaginal ultrasonography.

Structural cervical weakness is the likely cause of many recurrent second-trimester losses, but it probably accounts for only a minor proportion of all second-trimester losses.

The majority of these cases are probably caused by other disorders, such as decidual inflammation/infection, placental bleeding, or uterine overdistension.(10) These other disorders can initiate biochemical changes in the cervix that lead to premature cervical shortening and often a single (i.e., noncurrent) second-trimester loss/birth. The incidence of true cervical insufficiency is estimated at less than 1% of the obstetric population. In Denmark from 1980 to 1990, cervical insufficiency was diagnosed in 4.6 per 1000 women, and it is estimated to occur in 8% of women with recurrent mid-trimester losses (11, 12)

Cervical abnormalities, either congenital or as a result of trauma, are a risk factor for structural cervical weakness and, in turn, recurrent cervical insufficiency. Cervical trauma, which is more common than a congenital abnormality, may result from labor or delivery (spontaneous, forceps or vacuum assisted, caesarean), rapid mechanical cervical dilation before a gynaecologic procedure, or treatment of cervical intraepithelial neoplasia.

Congenital abnormalities that have been associated with structural cervical weakness include genetic disorders affecting collagen (e.g., Ehlers-Danlos syndrome), uterine anomalies, in utero diethylstilbestrol exposure, and biologic variation. (13, 14)

Using transvaginal sonography of the cervix to detect asymptomatic cervical shortening and funnelling has become a common method of evaluation. However, many preterm deliveries occur in women who did not have risk factors and were therefore considered low-risk.

Painless mid-trimester cervical dilation is one of the complications that may occur in low-risk, asymptomatic women, and there is no known method of predicting or preventing this condition.

Despite the inconsistencies that exist in the diagnosis and management of cervical insufficiency, cervical cerclage has become an established treatment for cervical incompetence.

Observational studies show that in classical cases with a severely traumatized or virtually absent cervix, neonatal survival may be up to 93% after effective cerclage as compared to 27% before the cerclage. (7, 15)

Cervical cerclage (emergency and elective) is performed both for treatment and prophylactic purposes in cases of cervical insufficiency.

C. Literature review

A premature birth is one that occurs before the start of the 37th week of pregnancy.

A prematurely delivered baby is at high risk of short and long term complications. Premature babies, especially those born very early, often have complicated medical problems. Globally, neonatal mortality accounts for 38% of all under five mortalities where 75% of the deaths took place during the first week of the neonatal period. (13, 16)

The rate of preterm birth (PTB) is escalating globally and ranges from 5 to 7% in developed countries and significantly higher in the least developed countries. Of the global 135 million live births, 14.9 million (11.1%) babies were born preterm in 2010. More than 60% of preterm births occurred in Sub-Saharan Africa and 9.1 million (12.8%) in south Asia (14, 17). Preterm birth may either be spontaneous or iatrogenic when a woman is electively delivered. Spontaneous Preterm birth can be as a result of maternal or fetal causes or a combination of them both. However, in the majority of spontaneous cases, the cause is unknown or idiopathic. Maternal conditions that may lead to Preterm birth include hypertensive disorders, autoimmune conditions like systemic lupus, diabetes mellitus, smoking, as well as maternal infections such as malaria, urinary tract infections, or intrauterine infection, The incidence of cervical insufficiency in the general obstetric population is reported to vary between approximately 1/100 and 1/2000. (18, 19) Preterm births have different causes and risks of mortality, morbidity, impaired growth, and non-communicable diseases. . More than seventy years ago Shirodkar introduced a new method of treatment for recurrent abortion due to cervical insufficiency, and used catgut for suture material, he changed catgut with Mersleine tape and placed it at the level of the internal cervical so. Until McDonald invented a procedure that doesn't involve dissection of the cervix Shirodkar method was widely practiced. The placement of the suture material by displacing the bladder with the Shirodkar cerclage has resulted in a greater number of patients being delivered by cesarean section because of the difficulty in removing the suture buried under the cervical surface, and required to leave the suture inside .(8 ,19) McDonald's technique involved placing a transvaginal purse-string suture at the cervicovaginal junction without bladder mobilization; after the procedure, women were bedbound for up to 7 days and were followed-up with weekly speculum examinations. (20, 32)

In a study done in six public hospitals in Addis Ababa, two hundred fifty-four (66.1%) were spontaneous preterm births. The minimum and maximum gestational age at birth of preterm births were 24 and 36 weeks respectively with a mean gestational age of 32.45 weeks (± 2.903 SD). (15, 21)

Studies conducted across the world identified risk factors associated with preterm birth such as having a previous preterm birth, having a short cervix, Short interval between pregnancies, certain pregnancy related complications (such as multiple pregnancy, pregnancy induced hypertension vaginal bleeding), lack of antenatal care follow-ups, lifestyle factors (such as low pre-pregnancy weight, and substance use during pregnancy). (16, 17, 18, 22)

Survivors of PTB suffer from either long-term or short-term sequelae, such as breathing difficulties, feeding problems, effects on brain function in later life, cerebral palsy, intellectual and developmental disabilities, visual and hearing impairments, and poor prognosis.(23)

Cervical insufficiency and Preterm birth

A clinically convenient label to describe a complex and poorly understood process of premature cervical ripening and the mid trimester onset of parturition

Cervical insufficiency can be of congenital or acquired causes. (24) In case of acquired cervical incompetence, the causes are: an injury during previous labor, previous abortions (especially in cases when the uterus cervix was dilated more than 10 mm) or conization of the cervix Functional cervical insufficiency is most frequently caused by a multiple pregnancy or influence of relaxing and prostaglandins on cervix tissue. (25, 30) The risk factors for cervical insufficiency are based on epidemiological associations and previous histories. Risk factors include prior cervical destructive surgery (i.e., trachelectomy, loop electrosurgical excision procedure [LEEP], large loop excision of the transformation zone [LLETZ], laser conization, or cold-knife cone biopsy), in utero diethylstilbestrol (DES) exposure, prior induced or spontaneous first- and second-trimester abortions, uterine anomalies, multiple gestations, or even prior spontaneous preterm births. (26, 27)

A transvaginal ultrasound can provide a diagnosis if cervical insufficiency is suspected or can be performed to monitor high-risk situations, such as in women with previous second-trimester pregnancy losses. Ultrasound examines the cervical length, dilation, and displacement of fetal membranes into the cervical area as criteria needed to diagnose cervical insufficiency. (28, 29)

The significance of preterm birth is that it contributes to up to 14.1% of perinatal mortality worldwide.

The diagnosis of cervical insufficiency remains difficult either with clinical history or invasive investigative procedures. The dilemma with the diagnosis of an incompetent cervix has been supported by its description as an obstetric syndrome since many confounding factors influence its occurrence. (20, 30)

In a study done in Benin, an overall success rate in terms of prolongation of pregnancy to term of 74.8% shown in this study further buttresses the argument in favour of cerclage procedures as a measure to reducing pregnancy losses and improving fetal salvage (19). In this study, pregnancy outcome was quite favourable, with an overall fetal salvage of 98 (79.7%) (19, 31)

Furthermore, out of the 111 patients with previous pregnancy loss through miscarriages, 68 (61.3%) had term deliveries and 23 (20.7%) preterm births with an overall fetal salvage of 98 (79.7%) (19).

A prospective study to evaluate the fetal salvage rate, cervical morbidity and caesarean section rate in patients with cervical incompetence using a cerclage procedure was conducted at the Jos University Teaching Hospital, Jos, Nigeria, the fetal salvage rate was 23.7% in pregnancies occurring before and 94.4% after cervical cerclage procedure was performed (20, 32).

A prospective study conducted among 207 pregnant women at Nkana and Wusikili Mine Hospitals in Kitwe, Zambia, during 1989-94 indicated that McDonald's cervical cerclage is effective in the treatment of cervical incompetence (22, 33).

The procedure of cervical cerclage used in the treatment of cervical incompetence was first described in 1955 by Shirodkar et al (23, 34).

The efficacy of cervical cerclage as a treatment of cervical insufficiency thereby reducing second-trimester miscarriages or PTB has been under scrutiny since a meta-analysis has given no conclusive evidence. (24, 35) The indication for cervical cerclage can be history indicated, Physical examination, or Ultrasound indicated. When a cervical cerclage is performed based on history indication History-indicated cervical cerclage insertion is required when factors in a woman's history could predispose to spontaneous miscarriage or preterm birth. (36)

D. Significance of study

Cerclage has been shown to prolong pregnancy and in turn, have favourable perinatal outcomes. Assessing the perinatal outcomes in our setup helps us to see pitfalls, possible places for improvement. In the future, this study can provide local evidence for counselling mothers prior to the procedure.

This study provides baseline data for future studies and, findings of this undertaking are expected to guide our understanding in providing care for women with mid second trimester pregnancy losses.

7. CHAPTER TWO: Objectives

A. GENERAL OBJECTIVES:

The aim of this study is to assess maternal and fetal outcomes after cervical cerclage for women with cervical insufficiency done at SPHMCC and its affiliate hospitals from January 2017 to December 31st 2020.

B. SPECIFIC OBJECTIVES:

- ✓ To assess maternal outcomes after cerclage was done for diagnosed cervical insufficiency.
- ✓ To assess fetal outcomes after cerclage.

8. CHAPTER THREE: Methodology

A. Study area and period

This study was conducted in St Paul's Hospital Millennium Medical College (SPHMMC) and its two affiliate centers. It is a tertiary hospital serving as a referral centre from all over the country and located in Addis Ababa, Gullele sub city which has an altitude of 2,400 meters (7,800 feet) (41) above sea level. The college was established through a decree of the Council of Ministers in 2010, although the medical school opened in 2007 and the hospital was established in 1968 by the late Emperor Haile Selassie. A medical college was formed in 2007. Obstetrics and Gynecology department is one of the major departments which provide general as well as sub-specialty services.

Obstetrics and Gynecology department is one of the major departments which provide general as well as sub-specialty services. The department is staffed with clinical health professionals and supportive non-clinical staff. Regular antenatal and is being provided by two nurses, five midwives, one medical intern, one general practitioner, five OBGYN residents (from year 1 to year 4) with consulting maternal-fetal medicine specialists or senior obstetrician/gynaecologist. Currently, there are 6 antenatal and 3 postnatal out-patient clinics. Monthly on average, 595 new pregnant mothers are getting services at antenatal clinics. Together with repeat visits, more than 3000 pregnant mothers are visiting the facility monthly. The other study areas are Ras Desta Damtew General Hospital and Yekatit 12 Hospital and Medical College both having a resident in OB/GYN and consultants on job and cerclage is performed on an elective and emergency basis.

These three hospitals were chosen because they have residents and adequate OB/GYN consultants who are equipped with the skills to perform cervical cerclage, follow the women through antenatal care and treat the anticipated complications

B. Study Design

A facility based cross-sectional study.

C. Source of Population

The source population were all pregnant women who visit St Paul hospital millennium medical college, Ras Desta Damtew hospital and Yekatit 12 referral hospital. These three hospitals were chosen because they have residents and adequate OB/GYN consultants who are equipped with the skills to perform cervical cerclage, follow the women through antenatal care and treat the anticipated complications.

D. Study population

Study population: All pregnant women who have undergone cervical cerclage.

E. Inclusion and Exclusion criteria

1. Inclusion Criteria

All women with cervical cerclage done in the study period.

2 . Exclusion criteria

Those women whose records have less than 75% information for analysis was be excluded.

F. Data collection procedure and instrument

A structural questionnaire written English which is a validated tool and customized for this study was used. The data was collected by four trained data collectors from clients' records and by phone follow-up which were retrieved after fulfilling necessary legal procedures from each institutions and the data was coded into the questionnaire by the principal investigator. Completeness and consistency of questionnaires were supervised, monitored and completed by the primary investigator.

The instrument had five sections

- ✓ Socio demographic data,
- ✓ Past obstetric data,
- ✓ Procedure-related data,
- ✓ Antenatal care and delivery related data,
- ✓ Maternal and Neonatal outcome and complication related data's

G. Data processing and Analysis

In preparation for data entry, all questionnaires were numbered consecutively

The data was entered into Epi-info version 3.5.4 after the data entry and cleaning the data was be exported to SPSS version 24 for further analysis in relation to the outcome. Descriptive statistics: frequencies, percentages, cross tabulation, graphs and tables were performed.

H. Data Quality Assurance and Management

To keep the data as accurate as possible, the principal investigator checked the collected data for completeness, accuracy, clarity and constituency through the data collection period and made the necessary corrections daily.

I. Ethical Considerations

Before conducting the study, an official letter was obtained from the SPHMMC IRB and submitted to the Department of Obstetrics and Gynecology of SPHMMC for ethical review and approval and an official letter was submitted to the affiliated hospitals about the study and for their full corporation in retrieving client's record from record room. During the data collection procedure, the privacy of the client's record was kept to the maximum, furthermore, their names were not indicated on the questionnaire.

J. Study variables

- I. Perinatal outcome
 - ✓ Preterm birth
 - ✓ Spontaneous abortions
 - ✓ Preterm PROM
 - ✓ Birth weight
 - ✓ NICU admission
- II. Past obstetrics related
 - ✓ Parity
 - ✓ Previous Abortion

- ✓ Previous cervical procedures
- ✓ Previous Cerclage
- III. Procedure related factors
 - ✓ Type of cerclage
 - ✓ Suture type
 - ✓ Prophylactic antibiotics use
 - ✓ Indication for cerclage
 - ✓ Evidences for cerclage
 - ✓ Cervical dilatation at insertion
 - ✓ Progesterone administration
 - ✓ Mean duration of hospital stay (days)
- I. **Antenatal care and delivery related factors**
 - ✓ ANC
 - ✓ Mode of delivery
 - ✓ SVD
 - ✓ Cesarean birth
 - ✓ GA at delivery
 - ✓ NICU admission

K. Operational definitions

- ✓ **Elective cerclage:** Cervical cerclage done on non-emergency basis for those pregnant women diagnosed to have cervical insufficiency.
- ✓ **Emergency cerclage:** Cervical cerclage done for women presenting with mid trimester painless cervical dilation and prolapse of membranes.
- ✓ **Preterm birth:** Delivery of a premature infant prior to the GA of 37 and OR premature rupture of membranes prior to the GA of 37.
- ✓ **Failed cerclage:** Preterm delivery defined by spontaneous early PTB prior to 32 weeks gestation.
- ✓ **Maternal outcome:** defined as any maternal morbidity, such as cervical laceration, PPROM, Chorioamnionitis, PTL, operative deliveries.
- ✓ **Fetal outcomes:** this is defined as abortion, premature delivery, NICU admission.

9. CHAPTER FOUR: RESULTS

A. DEMOGRAPHIC AND SOCIO-ECONOMIC CHARACTERISTICS OF STUDY POPULATION

There were a total of 41 patients seen with cervical insufficiency during the period of study, 25(61%) from SPHMMC, 10 (24%) from Yekatit 12 referral hospital and 6(15%) were from RDDH. The mean age of the patients was 28 (SD± 3.56) years with a range of 18 to 35. Approximately 46% of the women were in the age group of 25-29. A total of 24 (59%) women were documented as married and 3 (7%) widowed. Almost half of them (51%) were reported to be a housewife and only 1(2%) was a student. Nearly a quarter of them 26 (63.3%) had completed high school, and only 1(2.4%) were reported to be uneducated.

Table 1 Demographic and socio-economic status of women who had cerclage done from Jan 2017 to December 31st of 2020, in three hospitals.

Characteristics	Frequency (N)	Percentage (%)
Age		
15-19	1	2.4
20-24	6	14.6
25-29	19	46.3
30-34	14	34.1
35-39	1	2.4
Marital status	Frequency	Percent
Married	24	59
Separated	9	22
Unmarried	5	12
Widowed	3	7
Monthly income (ETB)	frequency	Percent
<1000	2	5
1000-3000	2	15
>5000	19	46
3000-5000	14	34
Occupation	Frequency	Percent
House wife	21	51.2
Student	1	2.4
Employed	14	34.1
Unemployed	5	12.2
Educational status	Frequency	Percent
Elementary	5	12.3
High school completed	26	63.4
College graduate	9	22
Uneducated	1	2.3

B. PAST OBSTETRIC PERFORMANCE

In evaluating the past obstetric performance of the forty-one women, we have noted that almost two-thirds of them had a second trimester abortion, whereas 7 (17%) women had treatment for cervical insufficiency. Cerclage was applied in 4(57%) of the women who had treatment for cervical insufficiency and only in two women cerclage was applied more than three times .From the forty one women 32(78 %) of them had a previous abortion, 9 (22 %) of them never had a miscarriage before.

Table2: The following table has tried to show the parity of the women.

Characteristics	Frequency (N)	Percentage
Last pregnancy		
No pregnancy	10	24
>24months	14	34
6-12months	11	27
12-24months	6	15

Table 3: The following table shows the number of deliveries and other past obstetric performance

Characteristics	Frequency (N)	Percentage
Number of deliveries		
≤ 1	12	55
2-4	8	36
≥ 5	2	9

C. CURRENT PROCEDURE RELATED DATA

In the current pregnancy cerclage was applied at a gestational age of <13, 13-20 and 21-24 weeks in 2(5%), 36(88%) and, 3(7%) of the women respectively. The gestational age at which cerclage was performed during the index pregnancy was at 16 weeks. Cerclage was done for history indication in 33(81%) of the women and for three (7%) of the women with evidence of physical examination whereas the rest of them it was done for ultrasound findings.

Physical examination evidence of cervical dilation and bulging of membranes were found in all three (7%) of the women for whom emergency (rescue) cerclage was done whereas 38(93%) of them received elective cerclage.

Based on ultrasound evidence of short cervical length and funnelling witnessed on ultrasound 5(12%) cerclage was done.

As a standard practice, all women were provided with progesterone after cerclage was performed and preoperative prophylactic antibiotics were administered.

The commonly used suture materials were silk in 33 (81%) of our clients and in 7 (17%) Vicryl were used. All of the women were provided with progesterone and followed with cervical length measurement. The preterm delivery was 4(11 %) in our study. Across all three hospitals McDonald was employed in 41(100%) of the clients.

After cervical cerclage was done the mean duration of hospital stay was 3.54 (SD $\pm$ 1.59days).

Table 4 Cervical cerclage done in three teaching hospitals in Addis Ababa Ethiopia.

Characteristics	Frequency(N	percent%
GA of the current cerclage		
13-20	36	88
21-24	3	7
<13	2	5
Type of the cerclage	Frequency	Percent (%)
Emergency	3	7
Elective	38	93
Indication for the cerclage	Frequency	Percent
History	33	81
PE	3	7
Ultrasound	5	12
Ultrasound evidence	Frequency (N)	Valid percent (%)
Short CL measurement	2	40%
Both short CL &funnelling	3	60%
Suture type	Frequency	Valid percent
Vicryl	7	17
Silk	33	81
prolene	1	2
Duration of hospital stay (days)	Frequency	percent
<5	31	76
6-10	3	7
$\geq$ 11	6	1

D. ANC & Delivery Related factors

The number of women who had ANC visits more than 11 were 5 (13%), the mean number of visits was 8.4(SD±3.48).

The outcome of the cerclage was singleton alive birth in 36(88%) of the cases and 5(12%) of the cases it was inevitable abortion. The mean gestational age of delivery 37± 2 weeks.

Mode of delivery was SVD for 26(72%) and cesarean section was done in 10 (28%) of the women. Across all three hospitals McDonald was employed in 41(100%) of the clients.

In all of the women cerclage was removed, the mean interval from removal to delivery was found to be 11± 6 days.

Table 5 ANC, Delivery and outcome has been shown on the following table

Characteristics	Frequency (N)	Percent (%)
Number of visits		
<5	11	27
6-10	22	54
>11	5	13
Mode of delivery	Frequency(N)	Percent (%)
SVD	26	72
CS	10	28
GA at delivery	Frequency (N)	Percent (%)
28-36W6D	4	11
37W-41W6D	32	89
Outcome	Frequency (N)	Percent (%)
Singleton	36	88
Inevitable abortion	5	12

4.5 Neonatal and Maternal outcome

In our study after cerclage was performed for the 41 women only 7 (17%) of them had Experienced vaginal bleeding. One of the many complications post-cerclage is chorioamnionitis, it has occurred in 4(10%) of the women in this study which was evidenced by leucocytosis 1(25%) and maternal tachycardia and fever 3(75%).

The interval between cerclage and delivery was <2wks in 12(29%) of them, and in 6(16%) of them the interval was above 4weeks.

One of the prenatal outcomes noted in this study was neonatal birth weight, 20(49%) of the neonates delivered had a birth weight of above 2500gm, and 2(5%) of them were less than 1000gm.

There were only six admissions to NICU and all stayed and were discharged less than seven days.

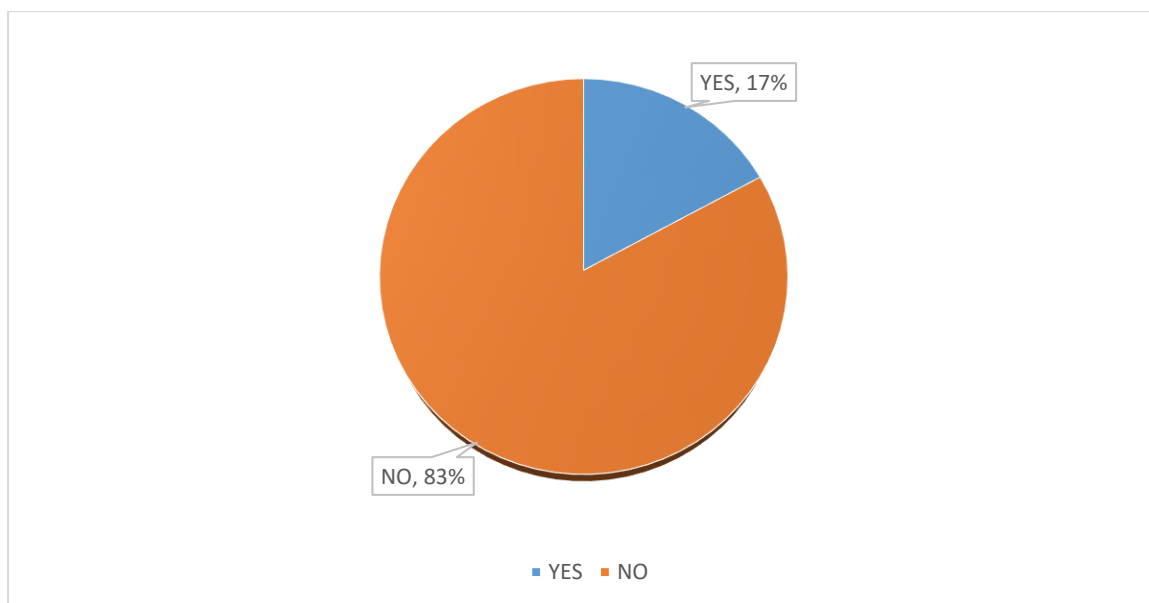


Figure 1. Proportion of women who had vaginal bleeding after cerclage was applied in all three hospitals, from Jan 2017 to Dec 2020

Table 6 the following table shows the morbidities associated with cerclage insertion

Complication	Frequency (N)	Percentage (%)
Chorioamnionitis	4	10
PPROM	12	29
Inevitable abortion	5	12
Preterm delivery	4	10
Vaginal bleeding	2	5
No complications	14	34
Total	41	100%

Table 7 the perinatal outcome, after cerclage was performed in RDDH, SPHMCC, and Y12 HOSPITAL from JAN 2017 to DEC 2020

Characteristics	frequency	percent
Interval between cerclage and delivery	Number	Percent
<2wks	19	53%
2-4wks	11	31%
>4wks	6	16%
Cerclage removal for PPRM	Frequency	percent
Yes	12	29%
NO	29	71%

GA cerclage was removed for PPROM	Frequency (N)	Percent (%)
13-20wks	4	33%
21-28wks	2	17%
29-34wks	6	50%
Treatment of Chorioamnionitis	Frequency (N)	Percent (%)
Yes	4	10
NO	37	90
Evidence of Chorioamnionitis	Frequency	percent
Leucocytosis	1	25
Maternal fever and tachycardia	3	75

10. CHAPTER FIVE: DISCUSSION

Cervical cerclage is performed both for treatment and prophylactic purposes in cases of cervical insufficiency, it has been embedded in the treatment of second trimester painless miscarriage since Shirodkar and McDonald brought it to practice. (32, 8) This descriptive study has analyzed the socio-demographic, past obstetric and also current cerclage data among other things of women who had cerclage done in SPHMMC, RDDH & Y12RH in Addis Ababa Ethiopia from January 2017 to December 2020. It attempts in analysing the basic procedural data's of the procedure which can be used for reflecting and stepping stone for future endeavours.

Across all three hospitals in this study McDonald was employed in 41(100%) of the clients and removed in all of them.

Beginning from the time when cerclage was used for the treatment of cervical insufficiency non-absorbable sutures such as catgut, nylon and silk have been used rigorously. There are few randomized studies that compared the suture type in cerclage. Non-absorbable sutures such as Mersleine, Silk, Nylon are used commonly during cervical cerclage, in our study, it was noted silk, Vicryl, prolene were used in 33(81%), 7(17%), 1(2%) respectively. A study comparing the use of Mersilene and non-Mersilene sutures for cerclage at St. Louis University School of Medicine, Saint Louis, MO university has shown that indication for cerclage placement and gestational age influences the type of suture used which is not the case in our study where the length of hospital stay, indication for cerclage or morbidities associated with cerclage were all similar for all the three types of suture materials. There were no differences in outcomes between Mersilene and non-Mersilene sutures. (34)

Silk is a natural, non-absorbable suture material which has been in practice for more than a century and is known for its ease to handle and tie. Silk works by eliciting inflammatory reactions. A randomized control trial study comparing silk with nylon at Bharati Vidyapeeth Deemed University Medical College, Pune, and Maharashtra, India concluded that the average time taken for the procedure was lesser with silk sutures while significant fibrosis was associated with nylon sutures. Both the suture materials were comparable in terms of operability, complication rate and ease of removal and outcome. (34) Vicryl is a lubricated, braided synthetic suture material, with properties such as excellent handling and smooth tie-down properties. It has a significant tensile strength for three to four weeks. It has decreased tissue reactivity compared with catgut as well as improved tensile strength and knot strength, a study done on the use of absorbable suture for the treatment of cervical insufficiency has concluded that absorbable suture material might be a reasonable alternative because of the added benefit of spontaneous degradation instead of surgical removal. (34, 33, 35)

The mean GA at which cerclage was applied in our study was one hundred thirteen days (16weeks) , which is comparable to the mean GA of a study done in North-eastern Nigeria in a teaching hospital .(31) There was no difference between the mean GA based on indication or suture material used even if that was not the case in other studies .Progesterone supplementation appears to reduce the rate of spontaneous singleton preterm birth in women who have had a previous spontaneous preterm singleton birth and in women with a short cervix on ultrasound examination in the current pregnancy. Neonatal morbidity and neonatal mortality are also reduced. All of our patients received progesterone after cerclage was done, yet there are few randomised control studies to show the benefits of combined progesterone treatment after cerclage was done, One small retrospective study observed that combination therapy (cerclage and hydroxyprogesterone caproate) was more effective than cerclage alone for preventing delivery <24 weeks but not <28 or <37 weeks in history indicated cerclage. (28) Almost seventy years ago when cervical cerclage was introduced one of the goals was reducing preterm birth a common complication of cervical insufficiency among others (Table 6), rate of preterm birth was 8(11%) of all the women who reached the age of viability

36(88%) lower than what has been shown by Bukar and colleagues of 5 year review of pregnancy outcome and interval to delivery after cervical cerclage in north-eastern Nigeria to be 33%. This might be explained by our national MOH definition of preterm birth beginning at a gestational age of 28 instead of 24. (10, 15, 31, 29),

The fetal salvage rate was 88 % this may be due to the progression of the pregnancies to term and the lower rate of preterm delivery, the fetal salvage rate was 94.4% in a prospective study to evaluate the fetal salvage rate, cervical morbidity and cesarean section rate in patients with cervical incompetence using a cerclage procedure was at the Jos University Teaching Hospital, Jos, Nigeria showing the benefit of cerclage in pushing pregnancy to the age of viability .(31) The lower fetal salvage rate noted in this study in comparison to the prospective study could be due to the higher sample size of 71 .(31) Fetal salvage is highly dependent on the availability of optimum neonatal care , the rate of preterm delivery .(31) There were no fetal losses, and the mean birth weight of the neonates born were 2660 ± 870 gm. The failure rate of cerclage in this study was recognized to be 5 (12%) which was analogous to a retrospective observational study on 26 women in Daka, Bangladesh where the miscarriage rate was 11.53%. (9) In all of the women cerclage was removed, the mean interval from removal to delivery was found to be 11 ± 6 days but it was 9.3 days. (31) In our study emergency cerclage was only 3(7%) of the cases which was lower in contrast to another study done in South-eastern Nigeria Aba over a course of five year review on 38 women for whom emergency cerclage was done in 10.7% of the women

The limitation of this study was the small sample size, this might be explained by the pandemic due to COVID to decrease the number of cases seen in our ANC and the inherent limitations of retrospective research .The strengths of the study are, being the first for institution can be used as baseline for future studies.

11. CHAPTER SIX: CONCLUSION

We have identified that most pregnancies have progressed to term, with a favourable fetal salvage rate of 88% and an acceptable neonatal birth weight. Despite having a small sample size, this study can be used to advocate for women diagnosed with cervical insufficiency with an acceptable time frame of removal to delivery time (11days) women with recurrent second trimester losses can be advocated on the benefit of long interval cerclage removal to delivery (11 days) and presented.

12. **DECLARATION**

I, the undersigned declare that this thesis is my original work in partial fulfilment of the requirement for the postgraduate study in OBGYN. I also declare that it has never been presented in this or another university and that all resources and materials used in the thesis have been duly acknowledged.

Resident's Name: Dr Kidist Gebretsadik

Signature:

Date of submission:

This thesis has been submitted for examination with my approval as an advisor.

Advisor Name: Dr.Ferid Abas

Signature:  _____

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