

The outcome of cervical stitch in the prevention of pre-viable and preterm deliveries in Nigerian Tertiary Hospital

Abstract

Background: Cervical incompetence, defined as the inability to sustain a pregnancy to term due to functional and anatomical defects of the cervix is a distressing cause of childlessness in Nigeria. Cervical cerclage, introduced into clinical practice by Shirodkar and McDonald in the 1950s still a time-tested intervention in the prevention of pregnancy wastages from cervical incompetence.

Aim: The purpose of this study was to audit the outcome of the applications of cervical cerclages in the prevention of pregnancy wastages at the Maternity Complex of the Ekiti State University Teaching Hospital and Maternal and Child Specialists' Clinic in Ekiti State, Southwest Nigeria.

Methods: In this prospective observational cohort study, we included all pregnant women who had cervical stitches applied over ten years, (2010-2019). Information on sociodemographic biodata, risk factors, indications, and outcomes were collated. Statistical analysis was performed using the SPSS package, version 22 (SPSS Inc, Chicago, IL). Statistical significance of the categorical variables was tested using the chi-square or Fisher's exact test, confidence level of 95% and P-value of 0.05.

Results: The 134 pregnant women diagnosed with cervical incompetence had cervical stitches applied over the ten years. 15,037 deliveries giving a prevalence rate of 0.89% of cervical incompetence. 75% were multigravida, while 92.5% were of low parity. Risk factors found included recurrent mid-trimester abortions (55%), and prior cervical dilatation (20%). The cervical cerclages were history and physical examination indicated in 22.5% and 75% had ultrasound scanning confirmation. In the majority (82.5%), cervical cerclage was placed at 14-16 weeks using Mersilene tape in 92.5%. Spinal anesthesia and conscious sedation were administered in equal proportion. Majority had McDonald's procedure (96.27%) whereas only 3.73% had Shirodkar's. Placement to removal interval ranged from 10-20 weeks in 53%, while in 12.5% it lasted 4 weeks. The indications for removal included pregnancy carried to term at 72.5%, preterm labor at 7.5%, and vagina bleeding occurred in 7.5% of cases. Vaginal deliveries were achieved in 62.5% while 25% had cesarean delivery. 7.5% expelled pre-viable fetuses. Cervical cerclage placement was successful in 75%, while 25% had failed cerclage. 10% of those who had failed cerclage had live births. We achieved 85% of babies take home. There was no significant association between the overall outcomes of cervical cerclage (inevitable abortion, preterm delivery, term delivery) and certain defined co-variables (age, gravidity, and parity). On multivariate linear regression.

Conclusion: We recommend that timely application of cervical stitches will rescue women from pregnancy wastages associated with cervical incompetence in Ekiti State.

Keywords: cervical insufficiency, cervical cerclage, pre-viable delivery, preterm delivery, Nigeria

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Introduction

The term cervical incompetence was published in The Lancet in 1865.¹ However, it took almost another century for Shirodkar to describe the interval repair of this anatomical cervical abnormality linked with the obstetric history of recurring spontaneous mid-trimester miscarriages and preterm deliveries.^{1,2} Cervical incompetence, also known as cervical insufficiency, cervical weakness, or cervical dysfunction is defined as the inability to sustain a pregnancy to term due to a functional and anatomical defect of the cervix.³⁻⁵ It complicates 0.1-1% of all pregnancies and accounts for roughly 15% of all immature deliveries between 16 and 28 weeks of pregnancy.⁵ The annual preterm births are estimated at 14.8 million worldwide,

with the incidence ranging from 5 to 15%.^{6,7} Cervical incompetence begins with abrupt, painless dilatation of the cervix, generally in the middle of the third trimester, and progresses to prolapse and/or preterm premature rupture of the membranes (PPROM), with preterm and often pre-viable delivery as a result.⁸

The pathophysiology of cervical incompetence in preterm labor is explained by different primary ideas. The first explanation proposes that cervical incompetence leads to the loss or compromise of the mucus plug, allowing vaginal infection to ascend and cause preterm birth.^{3,8-10} The second proposed model proposes that cervical incompetence is a continuum produced by one or more underlying variables such as infection, local inflammation, hormonal influences,

or genetic susceptibility, which results in premature cervical ripening (in the absence of clinical labor)^{3,8-11} These variables may be piled on a cervix with reduced mechanical integrity, and preterm labor syndrome may result as a result of the inflammatory cascade.^{10,11} Furthermore, Cervical incompetence has been linked with epidemiological and historical variables.^{12,13} Prior cervical surgery, such as cone biopsy, large loop excision of the transformation zone, trachelectomy, in utero exposure to diethylstilbestrol (DES), prior induced or spontaneous first- and second-trimester miscarriages (including cervix dilation and instrumentation), uterine anomalies, multiple gestations, and prior spontaneous preterm births are all examples.^{2,13}

There are many diagnostic criteria for cervical insufficiency during and outside pregnancy that singly or in combination may not be strong enough to predict with a high degree of objectivity the risk of mid-trimester abortion or preterm delivery.³ These diagnostic methods include; a history of recurrent second mid-trimester abortions, ultrasonographic findings of short or opened internal cervical os, internal cervical os admitting without resistance Hegar's or Pratt's dilator size 8 and above, balloon elastance test, and hysterosalpingography.¹⁴

In Nigeria where the assay of interleukin-8 (IL-8) which is a useful biomarker in assessing the inflammatory process in the pathophysiology of cervical insufficiency is not widely available,^{1,3,14} we largely depend on the obstetric history of recurrent mid-trimester abortion, pelvic heaviness in the mid-trimester and ultrasound scanning consistent with the diagnosis of cervical insufficiency. These diagnostic criteria have proven consistent either singly or in combination to effectively diagnose cervical insufficiency in our environment.

In response to the challenges posed by an incompetent cervix on fetal survival, Shirodkar and others invented cervical cerclage, an intervention to forestall his observation that 'some women abort repeatedly between fourth and seventh months in whom no amount of rest and treatment hormones seemed to help them in retaining the products of conception.'^{2,14} The psychological stress of recurrent pregnancy losses is so intense in Africa that women who have no children as a result of recurrent abortions are being tagged as evil-possessed and witches.¹⁵ Assisting women with this challenge is very important to boost their self-esteem. Obstetricians who have a track record of successful cerclage procedures have also continued to enjoy the benefit of the dignity accorded them by women, families, and their communities of practices from saving women from the stress of recurrent abortion and preterm birth with its attendant high perinatal mortality and morbidity.

Vaginal Cerclage was first described half a century ago as prophylactic therapy for patients with a very short cervix as a result of Mullerian abnormalities or cervical surgery.¹⁶ In the 1950s, Shirodkar¹⁷ and McDonald¹⁸ described two significant approaches. By dissecting the vesicocervical before suture placement, the Shirodkar approach entails putting a vaginal cerclage as close to the internal os as possible.¹⁷ The McDonald's procedure is the most common type of vaginal cerclage performed today, and it uses a simple purse-string suture at the cervicovaginal junction.¹⁸ Although there is no indication that one type of vaginal cerclage or suture is preferable to another,¹⁹⁻²¹ the McDonald vaginal cerclage utilizing 5 mm Mersilene polyester tape (Ethicon) is the most commonly reported.

Cervical cerclage remains the therapy of choice for women with cervical insufficiency to prevent the 15-30% incidence of recurrent cervical insufficiency and pregnancy loss, but the best technique and timing for cerclage installation have yet to be determined.²² Elective (prophylactic) cerclage installation at 13-14 weeks of pregnancy is

typically favored over emergency (salvage) cerclage placement at 18-20 weeks of pregnancy once cervical effacement and dilatation have already occurred, but there is limited evidence to back this up.^{23,24}

Hence, this study audits our practice regarding the use of cervical stitch (cerclage) as a foremost intervention in preventing pregnancy wastage and preterm birth in Ekiti State, Southwest Nigeria.

Methods

Study design

This study was an observational cohort study.

Study location

This study was carried out at the Ekiti State University Teaching Hospital (EKSUTH) and Maternal-Child Specialists' Clinic Ado-Ekiti. The two hospitals were respectively, a topmost state government tertiary hospital and a private clinic with good patient patronage both strategically situated in Ado-Ekiti the capital town of Ekiti State, Southwest Nigeria.

Study subjects

We included all pregnancies in which cervical stitches were applied over ten years (2010-2019). Those excluded were those who carried multiple pregnancies, got pregnant through Assisted Reproduction Techniques (ARTs), and had their cerclages applied elsewhere but came to deliver in our hospitals.

Data collection and storage

A specially designed proforma questionnaire was completed for each client from the date of cervical placement until after the delivery. Information on sociodemographic biodata, risk factors for cervical weakness, indications for cervical stitch placement, and outcomes of cervical cerclage were retrieved in the postpartum period. The data sheets were coded and contained no patient identification information. The data obtained was imputed and kept anonymously in Microsoft Excel Sheet Database.

Ethical consideration

A proposal for this study was submitted for ethical review by the Research and Ethics Committee of Ekiti State University Teaching Hospital, Ado-Ekiti. The approval was conveyed with protocol number EKSUTH/A67/2012/01/09.

Statistical analysis and methods

Statistical analysis was performed using the SPSS package, version 22 (SPSS Inc, Chicago, IL). Statistical significance of the categorical variables was tested using the chi-square or Fisher's exact test, confidence level of 95%, and P-value < 0.05. Data were checked for normality of distribution using a Kolmogorov-Smirnov test. Continuous variables were expressed as means and standard deviations if normally distributed and medians and interquartile ranges (IQRs) if the data were non-normally distributed. For ordinal variables medians and interquartile ranges (IQRs) if data were non-normally distributed. For nominal variables, data were presented using frequency distributions, and 95% confidence for binary proportions was presented.

A multivariate linear regression analysis was used to define the cerclage interval relationship between the groups and defined co-variables (age, gravidity, parity, previous obstetric history, cervical assessment, case assessment, gestational age at insertion, primary surgeon, and suture material used).

Results

One hundred and thirty-four (134) pregnant women were diagnosed with cervical weakness and had cervical stitches applied over ten years at the two centers where this study was carried out. During this same period, there was a total of fifteen thousand and thirty-seven (15,037) deliveries. The prevalence of cervical weakness was therefore approximately 0.89%.

The sociodemographic characteristics of women who had had cervical cerclage for the prevention of pre-viable and preterm labor in Ekiti State, Southwest Nigeria as shown in Table 1. 80% of the women are older gravidas with 48% thirty-five years and above. Approximately 75% had been pregnant four or more times while 92.5% are of low parity. It was important to note that 47 (35%) had no single child alive.

Table 1 Socio-demographic characteristics of women with cervical cerclage in Ekiti State, Nigeria

Variables	Number(n)	Frequency (%)	Mean	STDEV	
Age in years	20 - 24	7	5		
	25 - 29	20	15		
	30 - 34	43	32	10	7.6
	35 - 40	64	48		
	Total	134	100		
Religion	Christianity	117	87.5		
	Islam	17	12.5		
	Total	134	100	20	21.2
Marital status	Married	134	100		
	Total	134	100		
Gravidity	1	4	4.2		
	2	3	2.5		
	3	27	20		
	4	37	27.5	6.7	4.5
	5	30	22.5		
	6 and above	34	25		
	Total	134	100		
Parity	0	47	35		
	1	50	37.5		
	2	27	20	10	5.6
	3	10	7.5		
	Total	134	100		
Ethnicity	Ebira	3	2.5		
	Igbo	17	12.5		
	Yoruba	114	85	13.3	18
	Total	134	100		
Education	Secondary	20	15		
	Tertiary	114	85	20	19.8
	Total	134	100		
Occupation	Employed	60	45		
	Self Employed	3	2.5		
	Unemployed	71	53	13.3	10.8
	Total	134	100		
Husband's Education	Secondary	17	12.5		
	Tertiary	117	87.5	20	21.2
	Total	134	100		
Husband's Occupation	Employed	64	47.5		
	Self Employed	70	52.5	20	1.4
	Total	134	100		

Table 2 depicts the risk factors for cervical incompetence among the participants in this study. The commonest risk factor found was the history of recurrent mid-trimester pregnancy losses in 55% of our clients. In 20% of our patients, we obtained a history of prior cervical dilatation for induced abortions. Whereas there were no identifiable factors in 10 of our clients.

The indications for cervical cerclage among our clients were shown in Table 3. The cervical cerclages were history and physical examination indicated in 22.5% of our clients. In 101(75%) cervical incompetence was confirmed with ultrasound scanning. Only 2.5% had a diagnosis made with hysterosalpingography before pregnancy.

Table 2 Risk factors for cervical incompetence in Ekiti State, Nigeria (2)

Variables	Number (n)	Frequency (%)	Mean	STDEV
None	13	10	6.7	7.6
Previous cervical laceration	7	5		
Previous delivery of Macrosomic babies	13	10		
Previous history of recurrent midtrimester abortions.	74	55		
Prior Cervical dilatation for Induced abortion	10	7.5		
Prior cervical dilatation for induced abortion and Previous history of recurrent Midtrimester abortions.	17	12.5		
Total	134	100		

Table 3 Indication for cervical cerclage placement

Variables	Number (n)	Frequency (%)	Mean	STDEV
History of two (2) or more mid-trimester abortions	13	10	8	12.3
Finding uterine funneling	3	2.5		
History of pelvic heaviness in pregnancy	10	7.5		
Speculum finding of the dilated cervix and Herniating membrane	7	5		
Ultrasound scanning of short cervical length	101	75		
Total	134	100		

The majority (82.5%) of our clients had elective cerclage at 14-16 weeks as shown in Table 4. Mersilene tape was used in 92.5% of the patients. Spinal anesthesia and conscious sedation were administered in equal proportion. One hundred and twenty-nine of our patients diagnosed with cervical incompetence in Ekiti State, southwest Nigeria had McDonald's procedure (96.27%) as compared to only five (3.73%) who had Shirodkar's. The duration spent by cervical stitch in situ ranged from 10-20 weeks in 53% of our patients, while in 12.5% of the patients, the stitch was removed within 4 weeks of placement. The indication for removal of the stitch was pregnancy carried to term in 72.5% of cases. Others include preterm labor and vaginal bleeding in 7.5% respectively. We achieved vaginal delivery

in 62.5% of our clients on cervical cerclage and 30% had either elective or emergency cesarean delivery. 10 clients accounting for 7.5% expelled their fetuses before attaining fetal maturity. Cervical cerclage placement was successful in 75% of our clients while in 25% we had failed cerclage. 10% of those who had failed cerclage had live births.

A multivariate linear regression analysis was used to define the relationships between the overall outcomes of cervical cerclage (inevitable abortion, preterm delivery, term delivery) and certain defined co-variables (age, gravidity, and parity) Table 5. There was no statistically significant association between these covariables and overall outcomes of cervical cerclage placement.

Table 4 Outcome of cervical cerclage placement

Variables	Number (n)	Frequency (%)	Mean	STDEV
Cervical cerclage procedure	MacDonald's			
	Shirodkar's			
	Others			
	Total			
Type of cervical	Elective	111	82.5	
	Emergency	23	17.5	20
	Total	134	100	18.3
Gestational age at placement of cervical cerclage	14 - 16 weeks	111	82.5	
	17 - 19 weeks	13	10	13.3
	20 weeks and above	10	7.5	17
	Total	134	100	
Nature of suture	Mersilene Tape	124	92.5	
	Silk (Double braided)	10	7.5	20
	Total	134	100	24
Anesthesia	Conscious sedation	67	50	
	Spinal anesthesia	67	50	20
	Total	134	100	0
Placement to removal interval (weeks)	Less than 1 week	3	2.5	
	1-4 weeks	13	10	
	5-9weeks	7	5	6.7
	10-14weeks	13	10	6.4
	15-20week	58	43	
	Total	134	100	

Table 4 Continued...

Variables		Number (n)	Frequency (%)	Mean	STDEV
Indications for removal	Bleeding per vaginal	10	7.5	10	12.7
	Onset of labor	10	7.5		
	Rupture of membrane	17	12.5		
	Term pregnancy	97	72.5		
	Total	134	100		
Removal to delivery/ expulsion interval	1 - 2 weeks	47	35	8	5.1
	2 - 7 days	40	30		
	3 - 4 weeks	13	10		
	5 weeks and above	7	5		
	less than 24 hours	27	20		
Mode of delivery	Total	134	100	10	9.5
	Elective caesarean section	27	20		
	Emergency Caesarean section	13	10		
	Expulsion before viability	10	7.5		
	Spontaneous vaginal delivery	84	62.5		
Fetal outcome	Total	134	100	20	16.9
	Alive	107	80		
	Death	27	20		
	Total	134	100		
	1.4 or less	27	20		
Fetal weight	1.5-1.9kg	7	5	5.7	3.8
	2.0-2.4kg	7	5		
	2.5-2.9 kg	16	12.5		
	3.0-3.4 kg	40	30		
	3.5-3.9kg	27	20		
	4kg and above	10	7.5		
	Total	134	100		
	<5	27	20		
Average Apgar scores (1 minute)	6	7	5	8	5.2
	7	30	22.5		
	8	54	40		
	9	16	12.5		
	Total	134	100		
Average Apgar scores (5 minutes)	<5	27	20	10	8.2
	8	13	10		
	9	20	15		
	10	74	55		
	Total	134	100		
Overall outcome of cervical cerclage	Pre-viable delivery	10	7.5	13.3	12.7
	Preterm delivery	23	17.5		
	Term delivery	101	75		
	Total	134	100		

Table 5 Comparison of the demographic characteristics of women with cervical cerclage versus the delivery outcome

Characteristics	Failed	Preterm delivery	Term delivery	Total FREQ	p-value
Age <30	0(0%)	0(0%)	27(28.7%)	27(20.1)	0.48
30-34	10(58.8%)	10(43%)	23(24.5%)	43(32.1)	
35-40	7(41.2%)	13(57%)	44(46.8%)	64(47.8)	
Total	17(12.5%)	23(17.5%)	94(70%)	134	
Gravidity I	0(0%)	0(0%)	4(4.2%)	4(2.99)	0.589
5-Feb	14(82%)	13(57%)	70(74.4%)	97(72.3)	
6 and above	3(18%)	10(43%)	20(21.2%)	33(24.6)	
Total	17(12.5%)	23(17.5%)	94(70%)	134	
Parity 0	10(58.8%)	7(30.4%)	30(31.9%)	47(35)	0.578
1	7(41.2%)	13(56.5%)	30(31.9%)	50(37.3)	
2	0(0%)	3(13%)	24(25.5%)	27(20.1)	
3	0(0%)	0(0%)	10(10.6%)	10(7.4)	
Total	17(12.5%)	23(17.5%)	94(70%)	134	

Discussion

The sociodemographic characteristics found in this study are similar to other studies done in the same and other regions of Nigeria with a mean age of 33.3yr \pm 3.9yr.²⁵⁻²⁷ The prevalence of cervical incompetence in this study was about 0.89%. This prevalence is similar to 0.85% reported from the central part of Nigeria.²⁵ On the contrary, in the southern part of Nigeria, a five times lower prevalence was reported (0.17%).²⁶ This study showed that 75% of our participants had been pregnant more than four times and 68% of them had repeated and consecutive pregnancy losses to cervical incompetence. This study also found that 47(35%) had no child alive justifying the importance of this study. The history of recurrent mid-trimester pregnancy losses was the leading risk factor for cervical incompetence and indication for cervical stitch placement (22.5%) in this study. Though, this is less than 59.4% found in Port-Harcourt, southeast Nigeria.²⁷ Both studies agreed with the American College of Obstetricians and Gynecology (ACOG) guidelines that state that history or ultrasound scanning findings as well as rescue cerclage are recommended reasons for cervical cerclage insertion.²² However, the ultrasound scanning indicated was the highest reason for cervical cerclage in our study accounting for 75%. This may be due to the policies in the hospital that all suspected cervical incompetence should be backed up with an ultrasound scanning diagnosis. The majority (82.5%) of our clients had elective cerclage at 14-16 weeks, traditionally this is the time most obstetrician wants to do this procedure to allow for abortion of chromosomally abnormal fetuses.²⁸ This period has shown to be optimal as regards the outcome of the procedure. Mersilene tape was used in 92.5% of the patients. Mersilene tape is the suture of choice in most studies on cervical cerclage.²⁰ One hundred and twenty-nine of our patients diagnosed with cervical incompetence in Ekiti State, southwest Nigeria had McDonald's procedure (96.27%) as compared to only five (3.73%) who had Shirodkar's. The former is the preferred choice in other studies reviewed.^{20,27,29} However, a study by Feyi-Waboso PA, in Aba, south-eastern Nigeria reported higher use of the Shirodkar technique.³⁰

Relaxation of the patients and adequate exposure of the vagina are important to successfully apply the tape. Spinal anesthesia and conscious sedation were administered in equal proportion in this study like in other studies.²⁷⁻³⁰ The duration spent by cervical stitch in situ ranged from 10-20 weeks in 53% of our patients. This is relatively similar to findings in previous studies in Nigeria.^{25,27} This prolongation may be due to the early insertion of the stitch in this study. The indication for removal of our stitches was pregnancy carried to term in 72.5% of cases. This is in sharp contrast to a study where only 31.7% of their patient carried pregnancy to term.²⁹ Pre-viable and preterm delivery rates in this study were 7.5% and 17.5% respectively, However, an earlier study in Lagos southwest Nigeria found a lower pre-viable delivery rate of 5.6% but a higher preterm birth rate of 30%.³¹ In our study, 75% of our clients sustained their pregnancies till term hence the increased incidence of spontaneous vaginal delivery in 62.5% of our clients on cervical cerclage while only 30% had either elective or emergency cesarean delivery. Cervical cerclage placement was successful in 75% of our clients while in 25% we had failed cerclage. 10% of those who had failed cerclage had live births. The overall outlook of this study showed an increase in the overall outcome of cervical cerclage with about 85% of babies with good Apgar scores at 5mins. The finding here revealed an overall increased fetal survival rate following cervical cerclage application among our women with cervical insufficiency in Southwest Nigeria.

Conclusion

Although the superiority of cervical cerclage over conservative therapy in the management of cervical insufficiency is not clear cut. Even though the fate of the pregnancies in this series could not have been ascertained had cervical stitch not been applied. The success rate of 75/100 of cervical cerclage compared with other studies from this center and the baby take-home rate of 85/100 indicates that our women with indication for cervical cerclage still benefit significantly from the procedure and this practice is strongly recommended in our environment.

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Conflicts of interest

The authors declare that there is no conflicts of interest.

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