

A Retrospective Analysis of Cervical Cerclage Outcomes in a Low-Income Country

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Abstract

Background: Cervical incompetence (CI) is a common cause of mid-trimester pregnancy loss. Clinical evidence has demonstrated the role of cervical cerclage in reducing preterm births alongside engendering successful maternal and foetal outcomes in carefully selected women with cervical incompetence. This study aimed at determining foetal and maternal outcomes in women with cervical incompetence after elective cervical cerclage. **Methods:** A retrospective analysis of 88 patients who had elective cervical cerclage at the University College Hospital, Ibadan (UCH), Ibadan, Nigeria between January 2015 to December 2017. Data from the case records of these patients were analysed using the Statistical Package for Social Sciences version 22. Descriptive analysis was generated and summarized with the aid of pie chart, bar chart and frequency tables. Chi-square statistic was used in testing for associations between categorical variables. **Results:** The mean age was 32.5 ± 4.2 years. Most of the women (78%) had cervical cerclage performed between 14 -16 weeks' gestation. The most observed complication was pre-term contractions (76.2%). Eighteen women (20.5%) had a miscarriage and 50 women (56.8%) had term deliveries. The mean gestational age (GA) at delivery was 34.1 ± 5.8 weeks. Maternal complications, use of tocolytics and duration of hospital stay had a significant influence on the gestational age at delivery ($p < 0.005$). **Conclusion:** Cervical cerclage is an effective surgical procedure for preventing and delaying preterm births in women with cervical incompetence evidenced by a successful outcome in 56.8% of cases depicted in this study. Its use in a low-income country with high rates of preventable pregnancy wastages cannot be over-emphasized.

Keywords: Cervical Cerclage, Outcomes, Low-income Country.

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INTRODUCTION

Cervical incompetence (CI) is defined as the inability to support a pregnancy to term due to a functional or structural defect of the cervix.¹ It is a clinical diagnosis characterized by acute, painless dilatation of the cervix usually in the mid trimester resulting in the prolapse and or premature rupture of the membranes (PROM) with resultant preterm and often previable delivery [1, 2]. The resultant preterm birth poses a significant economic burden on the families besides the medical burden and further financial burden to the health insurance system with substantial emotional distress to the parents [3].

Cervical incompetence, leading to preterm birth, may be present in up to 1% of the obstetric populations [1, 4-10]. A study in Maiduguri, Nigeria

revealed an incidence of 0.78% [11]. Though the exact aetiology of cervical incompetence is not well understood, factors that affect the structural integrity of the cervix play a role in the development of cervical incompetence [1, 3-5] and this includes previous cervical trauma such as dilatation and curettage, conization, cauterisation or amputation, abnormal cervical development (including exposure in-utero to diethylstilbesterol), connective tissue abnormalities such as Ehlers-Danlos syndrome and uterine anomalies such as unicornuate, bicornuate or septate uterus.

The management of cervical incompetence involves surgical treatment with a cerclage, which reinforces a weak cervix by a purse string suture. Cervical cerclage was introduced by Shirodkar and McDonald in the 1950s and has since become a common obstetric procedure for the secondary

prevention of preterm births [1]. The Transvaginal cerclage (also known as McDonald) is performed using a mersilene tape placed in the body of the cervix near the level of the internal os, followed by continuous suture placement in the body of the cervix in a purse-string fashion to encircle the internal os. As the encirclement is completed, the suture is tightened around the cervical canal sufficiently to reduce the diameter of the canal to 5 to 10mm before knotting. It is quite popular due to the ease of performance compared to the Shirodkar technique.

The high transvaginal cerclage (Shirodkar) involves making a transverse incision in the mucosa overlying the anterior cervix such that the bladder is pushed cephalad. A 5mm mersilene tape on a Mayo needle is passed antero-posteriorly. The tape is then directed posteriorly to anteriorly on the other side of the cervix. The tape is snugly tied anteriorly. The cervical mucosa is then closed with continuous stitches of absorbable suture to bury the anterior knot.

Other procedures include prophylactic transabdominal cerclage where the suture is placed at the uterine isthmus. This is usually deployed when there is a severe cervical anatomical defect or when there has been prior failed transvaginal cerclages. Also, it may be considered in women who have undergone trachelectomy. The placement of the abdominal suture can either be done laparoscopically or by open surgical techniques [7, 8].

Indications for cervical cerclage includes a history-indicated cerclage which is the insertion of a cervical cerclage due to factors in a woman's obstetric or gynaecological history which increases her risk of spontaneous second-trimester loss or preterm delivery. This is usually performed as a prophylactic measure and usually inserted electively between 12-14 weeks of gestation. This is done to provide additional support for the cervix before the foetal weight starts to exert increasing pressure. Ultrasound-indicated cerclage refers to the insertion of a cervical cerclage as a therapeutic measure in cases of cervical length shortening seen at ultrasonography. It is performed on asymptomatic women who do not have exposed foetal membranes in the vagina. Sonographic assessment of the cervix is usually performed between 14 and 24 weeks of gestation. Rescue cervical cerclage on the other hand is the insertion of a cerclage as a salvage measure in cases of premature cervical dilatation with exposed foetal membranes. This may be discovered by ultrasound examination of the cervix or following speculum examination performed for symptoms such as vaginal discharge, bleeding or 'sensation of pressure'.

Complications following cerclage insertion are influenced by whether the cerclage is inserted electively or as an emergency. These complications include sepsis, premature rupture of membranes, premature

labour, cervical dystocia (due to cervical scarring), cervical laceration at delivery and haemorrhage [1, 9].

Cervical cerclage has become the mainstay for the management of cervical incompetence [1, 2]. Although cervical cerclage is a common obstetric procedure, there is still controversy regarding its efficacy and patient selection. The effectiveness of cervical cerclage in reducing incidence of mid-trimester miscarriage or preterm birth has been questioned as a meta-analysis has given no conclusive evidence to this effect.⁷

MATERIALS AND METHODS

This was a retrospective study conducted at the University College Hospital, Ibadan. Patients who had cervical cerclage for cervical incompetence over a three-year period, from January 2015 to December 2017. The case notes of all patients who had cervical cerclage within the study period were retrieved and data obtained from the case notes was entered into a pre-designed proforma. Data obtained included the sociodemographic characteristics of the patients, the past and present obstetric history, indication for cerclage, gestational age at the insertion, technique of cerclage insertion, type of suture material used, complications following the procedure, use of postoperative tocolysis, antibiotics, analgesia, bedrest, and eventual outcome. Neonatal data included APGAR scores and birth weight.

The indication for cerclage insertion was categorized into history indicated (recurrent mid-trimester miscarriages), ultrasound indicated (asymptomatic progressive shortening of the cervix of 25mm or less) and rescue (bulging membranes at 4cm dilatation or less).

The records of complications following the procedure were extracted from patients' case notes and the outcome was categorized as abortion (gestational age of less than 28 weeks), preterm delivery (28 to less than 37 weeks of gestation), and term delivery (37 to 42 completed weeks of gestation).

Data was entered into the computer using Statistical Package for Social Sciences (SPSS) version 22.0. Normally distributed numeric variables were summarized using their means and standard deviations (mean \pm SD). Categorical variables were summarized and presented using frequency tables with proportions and charts as appropriate. The chi square was used to test significance for categorical variables. The level of significance (P value) was set at < 0.05 .

RESULTS

Eighty-eight patients had cervical cerclage during the 3-year period under review. The socio-demographic and obstetric characteristics of the patients

are presented in Table 1: The age range was 21-41 years with a mean age of 32.5 years. Women within the age range of 26-30 years had the highest incidence of cerclage insertion. About 97.7% (86) of the respondents were married with most of the women (89.8%) being of Yoruba extraction. About 84.1% of respondents had tertiary level of education and 92% (81) were of the Christian faith.

The parity ranged from 0-4. Forty-four patients (50%) were nulliparous while 29 (33%) and 15 (17%) were primipara and multipara respectively. The mean number of previous mid-trimester miscarriages was 3 with a range of 1-10. Most of the study population (94.3%) had a previous spontaneous miscarriage with about 72.7% of them having 1-3 previous miscarriages. Furthermore, about 87.5% (77) of the study population had a previous induced abortion, an identifiable risk factor for cervical incompetence.

All cerclage procedures were carried out using the mersilene tape, with Mc Donald procedure done in 85 (96.6%) patients and the Shirodkar procedure done

in 3 (3.4%) patients. Majority (84.1%) had history-indicated cerclage, with only one respondent having a rescue cerclage, while 13 (14.8%) respondents had an ultrasound-indicated cerclage. The mean cervical dilatation at cerclage insertion was 18.6mm, while 56 (63.6%) patients had cervical length of more than 25mm at cerclage insertion.

27 (30.7%) patients had tocolytics within a range of 5-10 days with a mean duration of 7.52 days (± 1.8) after the procedure, while 61 patients (69.3%) had no tocolytic agents given. 13 (14.8%) of these patients had nifedipine, while 14 (15.9%) had salbutamol. Majority of patients, 77 (87.5%) had parenteral analgesia following the procedure for an average of 36 hours, while all patients had prophylactic antibiotics. The patients remained in the hospital between 6 to 154 days with a mean duration of 22.4 days. Out of the eighty-eight patients who had cerclage, there were no complications observed in 67 (76.1%) patients within the study.

Table 1: Demographic characteristics of patients

Demographic Characteristics	Frequency (n = 88)	Percentage (%)
Age Group (32.5 \pm 4.2)		
21 – 25 years	2	2.3
26 – 30 years	31	35.2
31 – 35 years	29	33.0
36 – 40 years	25	28.4
> 40 years	1	1.1
Marital Status		
Single	2	2.3
Married	86	97.7
Occupation		
Unskilled	6	6.8
Semi-skilled	44	50.0
Skilled	25	28.4
Professional	13	14.8
Ethnicity		
Yoruba	79	89.8
Igbo	6	6.8
Others	3	3.4
Religion		
Christianity	81	92.0
Islam	7	8.0
Educational Status		
Secondary	14	15.9
Tertiary	74	84.1
Parity		
Nulliparous	44	50.0
1	29	33.0
≥ 2	15	17.0
Previous Spontaneous Miscarriage		
None	5	5.7
1 – 3	64	72.7
4 – 6	16	18.2
7 – 10	3	3.4

Figure 1 highlights the observed maternal complications. Of note is that the data presented is not mutually exclusive as some patients presented with more than one complication. Preterm contraction 16 (76.2%) was the most common complication observed in this study, followed closely by premature rupture of membranes (PROM) 15 (71.4%). Majority 17 (81%) of the women had more than one complication.

In this study, cervical cerclage was performed between 13 - 26 weeks' gestation with a mean gestational age at cerclage insertion of 15.4 weeks. (SD ± 2.6). Majority of the patients had cerclage done between 14-16 weeks' gestation (78%), followed closely by gestational age above 16 weeks (16%) and least at below 14 weeks (6%).

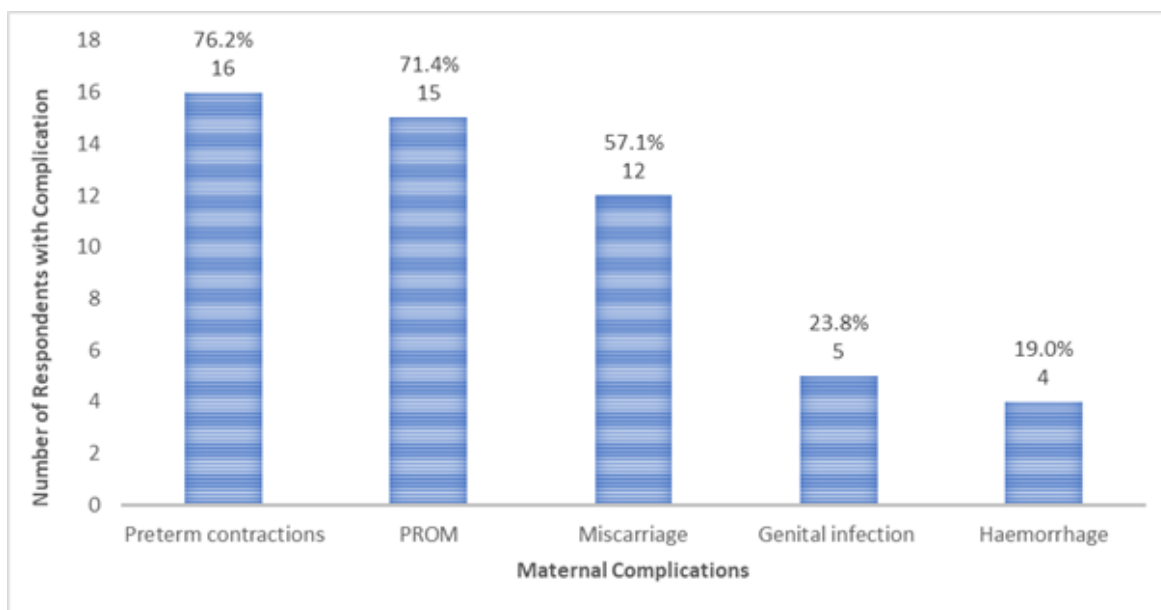


Figure 1: Observed Maternal Complications

Table 2: Cerclage Outcomes with Labour and Foetal Characteristics

Variables	Frequency (n = 88)	Percentage (%)
Indications for Removal of Cerclage		
Term (CS Inclusive)	50	56.8
Preterm Contractions	16	18.2
Preterm Labour	19	21.6
Foetal Distress	3	3.4
Duration from Removal of Cerclage till Labour Onset		
≤ 24 hours	8	22.9
2 – 6 days	20	57.1
1 – 2 weeks	7	20.0
GA at Delivery (Weeks)		
< 28 weeks	18	20.5
28 – 36 weeks	20	22.7
≥ 37 weeks	50	56.8
Type of Labour (n = 70)		
Spontaneous	32	45.7
Induced	3	4.3
No labour (Caesarean Section)	35	50.0
Mode of Delivery (n = 70)		
Caesarean Section	35	50.0
SVD	35	50.0

Fifty (56.8%) had the cerclage removed at term (inclusive of 15 patients that had removal at elective caesarean section), 16 (18.2%) and 19 (21.6%) had removal due to preterm contractions and preterm labour respectively, while 3 patients had removal on

account of foetal distress (Table 2). Among parturient planned for vaginal delivery, Majority 20 (57.1%) had a cerclage removal to onset of labour interval of 2-6 days. The mean gestational age at delivery was 34.1 weeks \pm 5.8.

In this study, 18 (20.5%) respondents had a spontaneous miscarriage and 70 (79.5%) delivered beyond the age of viability. Out of the 70 patients that delivered beyond viability, there were 50 (56.8%) term deliveries and 20 (22.7%) preterm deliveries. For the cases that delivered beyond viability, half 35 (50%) had a vaginal delivery, while the remaining half had a caesarean section. Therefore, 50 (56.8%) patients within this study group had a successful cerclage.

Thirty-two patients had a spontaneous onset of labour at term, 3 patients had induction of labour on account of post-date pregnancy, while 35 patients had caesarean section, with majority, 18 (51.4%) performed at term.

Out of 70 deliveries beyond foetal viability, there were 64 (91.4%) live births and 6 (8.6%) stillbirths, while 10 (14.2%) of the babies had birth asphyxia. The mean birth weight was $2.5\text{kg} \pm 1.1$.

Table 3: Cerclage Outcomes with Patient Characteristics

	GA at Delivery (Weeks)			χ^2 (p-value)
	< 28 weeks (n = 18)	28 – 36 weeks (n = 20)	\geq 37 weeks (n = 50)	
Age Group				
21 – 30 years	7 (21.2%)	7 (21.2%)	19 (57.6%)	0.642
31 – 35 years	8 (27.6%)	7 (24.1%)	14 (48.3%)	
> 36 – 40 years	3 (11.5%)	6 (23.1%)	17 (65.4%)	
Parity				
Nulliparous	9 (20.5%)	11 (25.0%)	24 (54.5%)	0.869
Parous (1 – 6 children)	9 (20.5%)	9 (20.5%)	26 (59.1%)	
Indication for Cervical Cerclage				
History	14 (18.9%)	15 (20.3%)	45 (60.8%)	0.215
Rescue/Ultrasound indicated	4 (28.6%)	5 (35.7%)	5 (35.7%)	
Cervical Length				
\leq 20 mm	9 (39.1%)	6 (26.1%)	8 (34.8%)	0.071
21 – 25 mm	1 (10%)	3 (30%)	6 (60%)	
> 25 mm	8 (14.5%)	11 (20%)	36 (65.5%)	
Maternal Complication				
No	2 (3%)	17 (25.4%)	48 (71.6%)	< 0.001
Yes	16 (76.2%)	3 (14.3%)	2 (9.5%)	

In this study, a statistically significant association was found between maternal complication and the gestational age at delivery, ($p < 0.001$); noteworthy was that, most of those who had no complication (about 72%) had a term delivery, a few of them had a pre-term delivery (25%), while only 3% had a miscarriage (Table 3). Conversely, among those with at least one maternal complication, 76% had a miscarriage, 14% had a preterm delivery, while only about 10% had a term delivery.

Observation from the cross tabulation revealed that 60% of those who had never lost a pregnancy delivered at term, while 40% of them had a preterm delivery. For those who had previously lost a pregnancy, 22% of them had a miscarriage, another 22% had pre-term delivery, while 56% had term delivery.

Bivariate analysis revealed that use of tocolytics, duration of bed rest, and internal os diameter were statistically significant factors that determines term delivery (Table 4). Patients who had tocolytics were less likely (OR = 0.38) to deliver at term, as compared to those who never used tocolytic. Women who had a bed rest between 2 to 4 weeks were less likely (OR = 0.29) to deliver at term, as compared to those who had a bed rest within two weeks or less; women who had bed rest lasting for more than 4 weeks were also less likely (OR = 0.09) to deliver at term, as compared to those who had a bed rest within two weeks or less. Lastly, women with internal OS diameter between 1 – 19 mm were less likely ($p = 0.08$) to deliver at term, in comparison with those who had a closed internal OS diameter.

Table 4: Logistic Regression showing Significant Determinants of Term Delivery among Viable Cases

	OR (95% CI)	p-value
Use of Tocolytics		
No	<i>Ref</i>	
Yes	0.38 (0.12 – 1.16)	0.089
Duration of Bed Rest		
≤ 14 days	<i>Ref</i>	
15 – 28 days	0.29 (0.08 – 0.99)	0.049
≥ 29 days	0.09 (0.02 – 0.45)	0.088
Internal OS Diameter		
0 mm (closed)	<i>Ref</i>	
1 – 19 mm	0.08 (0.01 – 0.81)	0.032

The bivariate analysis revealed that the cervical length and maternal complications were statistically significant factors that determined the experience of miscarriage.

It showed that women with cervical length ranging from 21 – 25 mm were less likely (OR = 0.17) to experience miscarriage, as compared to those with 20

mm or less; while those with cervical length greater than 25 mm were also less likely (OR = 0.27) to experience a miscarriage, when compared to those with 20 mm or less. Lastly, women who had a maternal complication were over a hundred times more likely (OR = 104) to experience miscarriage, in comparison with those who had no complication (Table 5).

Table 5: Logistic Regression showing Significant Determinants of Miscarriage Cases

	OR (95% CI)	p-value
Cervical Length		
≤ 20 mm	<i>Ref</i>	
21 – 25 mm	0.17 (0.02 – 1.61)	0.123
> 25 mm	0.27 (0.09 – 0.82)	0.020
Maternal Complications		
No complication	<i>Ref</i>	
Had complication(s)	104.00 (18.46 – 585.83)	< 0.001

DISCUSSION

Cervical incompetence is a major cause of pre-term births. Preterm births accounts for over 70% of all perinatal mortality [10]. Historical background of a previous miscarriage remains crucial to the diagnosis of cervical incompetence as was observed in this study where half of the patients were nulliparous with a history of previous spontaneous miscarriages. Furthermore, a significant proportion had a history of previous cervical cerclage. A prior history of cerclage has been reported as the main stay of diagnosis [11]. In this situation, use of prophylactic cerclage becomes important to improve pregnancy outcome. Congruent with previous literature [10], history indicated cerclage procedures were more, compared with ultrasound indicated and rescue cerclage respectively. One of the most important pointers towards cervical incompetence is a previous history of recurrent mid-trimester miscarriages. Furthermore, an overall success rate evidenced by prolongation of pregnancy to term demonstrated in this study, further buttresses the argument in favour of cervical cerclage as a measure aimed at reducing pregnancy losses and improving foetal salvage.

Majority of the women undergoing cerclage in this study population fell within the third decade of life,

which is in keeping with studies from other parts of Nigeria [10, 12]. Women in this environment tend to wait till the third decade of life before starting a family at which time they would have completed their tertiary education as observed in this study. Most cerclages are inserted after the first trimester when it is expected that miscarriages from other causes would have occurred. However, occasionally emergency or rescue cerclage is inserted later in pregnancy following cervical shortening, dilation or bulging membranes. In this study, one patient had a rescue cerclage and she however, had spontaneous miscarriage at 22 weeks. Gestational age of less than 22 weeks and presence of membranes prolapsing beyond the external cervical os have been found to be associated with a decreased success rate of emergency or rescue cerclage [13]. The failed cerclage in this case may have been attributable to the presence of the membranes within the vagina.

The McDonald's cervical stitch was the method utilized in majority of the patients in this study because it is the most deployed method in the West African sub-region [14], the reason being that it is easier to perform compared to the Shirodkar procedure. This was also the case in studies conducted in many centres in Nigeria [10, 11, 15]. In studies conducted at the University of Maiduguri Teaching Hospital

(UMTH) and Federal Medical Centres in Yola and Nguru respectively, all situated in the North-Eastern part of Nigeria, preterm births accounted for 18.4% of the complications following cerclage insertion.¹² This was slightly lower than what was recorded in our study. The higher incidence of preterm births in our study may have been attributed to the fact that majority of patients who had complications following the procedure, had preterm contractions, and were not placed on tocolytics, thereby increasing the risk of preterm labour and eventually preterm birth. The foetal salvage in this study was 91.4% and comparable to studies from other parts of Nigeria where figures range between 92% to 94% [16, 17]. Generally, foetal salvage depends on the success of the cerclage, frequency of preterm delivery and availability of neonatal care services [16].

The mean interval from elective removal of cerclage at term to delivery in this study was 4.6 days, with majority (57.1%) of the patients delivering within 1 week of its removal. This time interval is, however, lower than the 14 days reported by Bisulli and colleagues [18], with only 11% of the patients delivering within 48 hours of cerclage removal. The sample size of this study was small (n=35) in comparison to the 141 cases observed by Bisulli and may not be sufficient to draw conclusion on the mean interval to delivery after elective removal of cervical cerclage.

A wide range of successful pregnancy outcomes have been reported from previous studies, ranging from 63% in North-Eastern Nigeria, 63.4% in Edo, 71.9% in Abuja to 76.8% in Ilorin [10-12, 19]. These outcomes were higher than the 56.8% observed in this study. This may be attributed to the higher number of miscarriages observed following the procedure in this study compared to other studies. The outcome of cerclage procedure in this study was not influenced by factors such as age, parity, gestational age at cerclage placement or indication; although, an association was observed between successful outcome and tocolytic use, maternal complications and duration of hospital stay following the procedure. In this study, bed rest was advised for a mean duration of 22.4 days post-cerclage. The percentage of women who had vaginal delivery in this study was the same as those who had abdominal delivery. The main indications for abdominal delivery were poor obstetric history and preterm labour. In a comprehensive review of cervical cerclage, Drakeley and his colleagues noted an increase in caesarean deliveries in their cervical cerclage group [20]. They postulated that pregnancies were “medicalised” once a stitch was inserted, hence, an increased anxiety to expedite delivery. This was highlighted in this study, with about 65.7% of the indications for caesarean delivery being a history of infertility, advanced maternal age or a bad obstetric history with no living children.

Although cerclage is considered a relatively simple and safe surgical procedure, it is not without complications. In this study, 76.2% of patients amongst those that had complications had preterm contractions. None had cervical laceration or chorioamnionitis following the procedure. This is in contrast with findings by other studies in Nigeria, where PROM and vulvovaginitis were reported as the commonest complications [11, 12]. The use of prophylactic antibiotics postoperatively in this centre may have influenced these findings, as these antibiotics are likely to prevent the occurrence of infections, thus reducing the occurrence of vulvovaginitis.

CONCLUSION

Cervical cerclage deployed in the management of cervical incompetence is associated with a potential for considerable prolongation of pregnancy and good foetal outcome. Our study demonstrated favourable foeto-maternal outcomes. Therefore, it can be posited that cervical cerclage may have a significant beneficial effect in carefully selected cases of cervical incompetence especially in a developing country like Nigeria. However, more robust randomized studies are needed to compare foeto-maternal outcomes in cerclage and control groups.

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