

## Cervical Cerclage For The Prevention of Preterm Delivery: A Randomised Comparative Study

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**OBJECTIVE** – To evaluate the role of cervical cerclage in reduction of preterm delivery in patients with previous preterm delivery. **METHODS** – One hundred and twenty six women with previous preterm delivery were randomised into two groups of prophylactic cerclage (n = 63) and of nonintervention (n = 62), and were followed up till delivery. **RESULTS** – The number of preterm deliveries, low birth weight babies, neonatal admissions and early neonatal deaths in the nonintervention group were significantly higher than in the intervention group. Though the mean gestational age at delivery, mean birth weight, mean total hospital bills and number of pregnancies exceeding 42weeks were higher in the intervention group, it was only in mean gestational age at delivery and in mean birthweight that the differences were statistically significant. **CONCLUSION** – Application of prophylactic cerclage in pregnant women with previous preterm delivery not only reduces preterm delivery rate by 27.6% but at a reasonable cost acceptable to women with no additional risk to the mother and baby.

**Key words:** cervical cerclage, preterm delivery

### Introduction

Preterm delivery is of a major medical, economic and social importance worldwide, more so in developing countries where neonatal services are grossly inadequate<sup>1,2</sup>. Despite the many medical and social advances, the incidence of preterm delivery and its attendant high perinatal morbidity and mortality has remained almost constant<sup>1,2</sup>. It is therefore important to find cost-effective ways of addressing prematurity issues in poor settings and thereby conserving scarce resources currently being spent on the expensive care of preterm babies<sup>1</sup>.

Previous preterm delivery has been shown to be a major risk factor for preterm delivery<sup>1,5</sup>. In a study among pregnant women of Southwestern Nigeria, previous preterm delivery was shown to be the greatest risk factor for preterm delivery<sup>1,2</sup>. History of one previous preterm delivery has been shown to be associated with a recurrence risk of 17 to 40%, the risk increasing with the number of preterm births<sup>2,4,5</sup>.

Attempts to reduce the perinatal morbidity and mortality associated with preterm delivery have led us to embrace prophylactic cerclage for patients with previous preterm

delivery. However, in July 2000 we decided to subject our practice to scientific scrutiny. In this paper, we present the antenatal and labour outcome of the practice of prophylactic cerclage vis-a-vis non-intervention in women with previous preterm deliveries.

### Material and Methods

All women with a history of previous preterm delivery seen at the antenatal booking clinic of our hospital at or before 13 weeks of gestation between July 2000 and October 2003 were recruited into the study. Ethical clearance was obtained from the institution's Ethical Committee before commencement of the study. Ours is a multidisciplinary private hospital located at the foremost economic capital of Nigeria. Its obstetric and neonatal services are supervised by four consultant obstetricians and two neonatologists.

The women recruited into the study were randomised into two groups - the prophylactic cerclage (experimental) group and the non-cerclage (control) group, using computer generated random sampling method after informed consent had been obtained.

Management at the booking and antenatal clinics were according to the departmental protocol with hemoglobin estimation, blood grouping and genotyping, HIV screen, VDRL test, ultrasound scan, and regular visits. The only difference between the two groups was the application of cervical cerclage to the experimental group.

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Table I. Sociodemographic Characteristics of the Patients

Maternal Characteristics	Cerclage Group N=63	Non-intervention Group N=62	T or X2	P Value
Age (years)	24.6 ± 4.4	24.4 ± 4.5	0.75 <sup>a</sup>	0.46
Mean parity	2.9 ± 1.1	2.8 ± 1.0	1.44 <sup>a</sup>	0.16
Mean Bishop score at 14 weeks	4.2 ± 0.4	4.3 ± 0.5	0.56 <sup>a</sup>	0.58
History of previous preterm delivery				
1	24 (63.2)	30 (69.8)		
2	13 (31.6)	9 (20.9)	0.4 <sup>b</sup>	0.53
3	2 (5.3)	4 (9.3)		

a student t test ; b chi square (x2)

Table II. Maternal and Perinatal Outcome in the two Groups

Variables	Cerclage Group N=63 (%)	Control Group N=62 (%)	t <sup>a</sup> or x2 Values	P Value	Odd Ratio	95% Confidence Interval
Preterm delivery	7 (11.1)	24 (38.7)	11.33 <sup>b</sup>	0.001	0.20	0.07 - 0.55
Mean gestational age at delivery	38.6 ± 1.4	35.9 ± 0.6	4.20 <sup>a</sup>	0.014	-	-
Post-term delivery	10 (15.9)	5 (8.1)	1.14% <sup>b</sup>	0.29	2.15	0.62 - 7.81
Mean birth weight (kg)	3.3 ± 0.1	3.0 ± 0.1	6.67	0.003	-	-
Low birth weight	5 (7.9)	18 (29.0)	7.91 <sup>b</sup>	0.001	0.21	0.06 - 0.67
Neonatal admission	3 (4.8)	14 (22.6)	7.00 <sup>b</sup>	0.008	0.17	0.04 - 0.69
Early neonatal death	Nil (0)	5 (8.1)	3.40 <sup>b</sup>	0.03	0.00	0.00 - 1.11
Mean hospital bills (US\$)	846.1 ± 105.4	818.1 ± 221.0	0.32	0.76	-	-

<sup>a</sup> student t test) ; <sup>b</sup> chi square (x2)

#### Prophylactic Cerclage (Intervention) Group

The subjects were seen at the antenatal clinic like other patients until the 14<sup>th</sup> week when they were admitted into the ward for cervical cerclage. On admission, cervical assessment was done to assess the cervix using the modified Bishop's score<sup>6</sup>. Cervical cerclage was performed under general anesthesia

using Macdonald's technique<sup>7</sup>. After surgery they were observed in the ward for two days. Antibiotic prophylaxis with amoxicillin 500 mg 8 hourly and metronidazole 400 mg 8 hourly for 5 days and pentazocine 60 mg 8 hourly for 24 hours were given. After discharge they were seen a week later at the antenatal clinic and during routine antenatal visits thereafter. In absence of complications, the cerclage

stitch was removed at 37 completed weeks. However, the stitch was also removed earlier if there were persistent contractions not amenable to tocolytic drugs or if there was rupture of fetal membranes.

#### *Non-intervention (No Cerclage) Group*

Cervical assessment was conducted at the 14<sup>th</sup> week of gestation. The patients were also placed on prophylactic amoxicillin and metronidazole for five days. This is to exclude some infection as a cause of preterm delivery and to exert some control for the practice in the intervention group. Routine antenatal visits were then continued unless otherwise indicated.

In both the groups, obstetric complications were managed according to departmental protocol. At the post-natal clinic, all the women were asked to comment on their preference for cerclage with the possibility of reduced risk of preterm delivery and its cost implications vis-a-vis non intervention strategy with reduced hospital bills and increased risk of preterm delivery and its sequelae.

Data on gestational age at delivery, birthweight, neonatal admission rate, indication and outcome, hospital stay and cumulative hospital bill from booking till discharge at postnatal clinic were collected and analyzed statistically using Chi square test with Yates correction, Fischer exact test and t-tests as appropriate. The odd ratios and 95% confidence interval were calculated where appropriate. A 'p' value less than 0.05 was considered significant.

#### **Results**

One hundred and twenty six women with a history of previous preterm delivery who booked at a gestational age of 13 weeks or below were recruited into the study and randomised into two groups of experimental (64) and non-experimental groups (62). However one woman in the experimental group opted out of the study because of financial involvement. Analysis was thus done in one hundred and twenty five patients (experimental – 63 and controls – 62).

The characteristics of the women in the two groups were comparable as shown in Table I.

The maternal and perinatal outcomes evaluated are shown in Table II. The numbers of preterm deliveries, low birth weight babies and neonatal admissions, and early neonatal deaths in the nonintervention group were significantly higher than those in the intervention group. Though the mean gestational age at delivery, mean birth weight, mean total hospital bills and number of pregnancies exceeding 42 weeks were higher in the

intervention group, it was only in the mean gestational age at delivery and mean birthweight that the differences were statistically significant. While the lowest gestational age at delivery among the mothers that had preterm delivery in the intervention group was 33 weeks, the majority (74.6%; 46/63) delivered at 36 weeks or beyond. The two women that delivered at gestational age less than 36 weeks delivered at 33 and 35 weeks. This is in contrast to the nonintervention group in which the lowest gestational age at delivery was 24 weeks, with 41.7% or 10 of the 24 preterm deliveries occurring at 36 weeks or beyond. Six (25.0%) women delivered below 30 weeks, five (20.8%) between 30 and 34 weeks and the remaining three (12.5%) between 34 and 36 weeks. The five (8.1%) perinatal deaths were all early neonatal deaths and were in the nonintervention group as a result of prematurity (gestational ages between 24 and 28 weeks). These differences were statistically significant (Table II).

Majority of the women (77.6%) preferred to have the prophylactic cerclage and its associated extra billing rather than gamble between choosing an insignificant extra bill and increased chance of preterm delivery and its associated morbidity and even mortality. And interestingly, 93.5% (29/31) of the women who had preterm delivery in the current pregnancy, opted for a cerclage in their next pregnancy. Of the 25 patients who would prefer to take their chance in the next pregnancy, all except four were in the non-intervention group who did not have preterm deliveries.

#### **Discussion**

This randomised comparative study shows that insertion of prophylactic cerclage by MacDonald method in pregnant women with previous preterm delivery reduces preterm delivery by at least 27.6% compared to the non-intervention group. The maternal and neonatal outcome was also better in the prophylactic cerclage group except for the larger hospital bills, where the average cost for the intervention group (US \$ 846.07) was higher compared to that for the non intervention group (US \$ 818.11). However, the difference was not statistically significant ( $t=0.32$ ;  $p=0.76$ ). These are important findings in that preterm deliveries are a major contributor to unacceptably high perinatal morbidity and mortality in our environment<sup>1,2</sup>. The usefulness of this procedure in women with history of previous preterm delivery was further demonstrated in this study in which the controls recorded worse perinatal outcome using specific neonatal indices of low birthweight, neonatal admission rate and perinatal death as a result of higher number of preterm births.

The additional hospital billing, as a result of the intervention may be seen as a major drawback especially

in a low resource environment like ours, but majority (77.6%) of the women preferred to have prophylactic cerclage with its associated extra cost rather than choosing an insignificantly lower bill with increased chance of preterm delivery and its associated morbidity and mortality. Interestingly 84.0% (21/25) patients who opted not to have cerclage in their next pregnancy were among the controls without preterm delivery. This was not unexpected since without intervention they did not have preterm delivery and did not see any rational reason for paying extra bills and risk surgery.

Application of prophylactic cerclage in pregnant women with previous preterm delivery has been shown to confer an advantage by reducing preterm delivery rate by 27.6% at a reasonable cost acceptable to women with no additional risk to the mother and baby. Embracing this strategy may reduce the social, economic and emotional stress associated with preterm delivery especially in resource poor countries.

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