PREGNANCY OUTCOME IN CERVICAL INCOMPETENCE: COMPARISON OF OUTCOME BEFORE AND AFTER INTERVENTION.

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ABSTRACT

Context: Cervical incompetence is a major cause of recurrent mid-trimester pregnancy loss and preterm deliveries; it contributes significantly to fetal loss and neonatal morbidity and mortality. Despite its wide use, the effectiveness of cervical cerclage in its management remains unsettled.

Objective: To evaluate the effectiveness of cervical cerclage by comparing the pregnancy outcome before and after its insertion in women with cervical incompetence.

Study design: An observational study [retrospective] of 95 women diagnosed with cervical incompetence that had cervical cerclage inserted from 1st January 2007 to31st December 2010. The pregnancy outcome before and after cervical cerclage were compared, the data was analyzed using SPSS version 18; p value <0.05 was considered significant.

Main outcome measure: The gestational age at the end of pregnancy, the duration of prolongation of the pregnancy after cervical cerclage and the pregnancy outcome.

Results: Of 103 cases of cervical incompetence managed, 95 satisfied the inclusion criteria. The prevalence of cervical incompetence was 8.4/1000 deliveries or 0.85%. There were 85 elective and 10 emergency cerclage with mean gestational age at end of pregnancy of 36.06±3.96 vs. 25.10±3.99 and mean duration of prolongation of pregnancy 20.98±4.71 vs. 4.00±3.37 weeks. After cervical cerclage insertion, there was reduction in miscarriages [P<0.0001] and preterm deliveries [P<0.0001] and increase in term deliveries [P=0.4100] and viable pregnancies [P=0.001]. The child take home rate was 89.4% following elective and 20% after emergency cervical cerclage.

Conclusion: Cervical cerclage resulted in improved pregnancy outcome in women with previous mid-trimester losses or preterm delivery.

Keywords: Cervical cerclage; cervical incompetence; pregnancy outcome; intervention.

INTRODUCTION

Cervical incompetence is the inability of the cervix to maintain pregnancy through to term because of structural or functional defect[1,2]. It is an important cause of recurrent mid-trimester pregnancy loss and preterm delivery[1-2]. The

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incidence varies with different population and mode of diagnosis ranging from 6.7/1000 deliveries in Benin city[3] to 1 in 146 deliveries in Zaria[4], Nigeria or generally 3-12% world wide[5]_.
It may be congenital or acquired; but majority are acquired following trauma to the cervix from complicated deliveries, termination of pregnancy, cone biopsy, cervical amputation during Manchester repair and in-utero exposure to diethylstilbesterol[6]. It presents classically in the second or early third trimester with liquor drainage, rapid, painless, cervical effacement and dilatation with an eventual expulsion of the products of conception.
Cervical cerclage is a common prophylactic intervention performed by Obstetricians in the management of cervical incompetence. However despite its wide use, the effectiveness of cervical cerclage remains controversial due to differences in the result of individual studies and meta-analyses[7]. This result from lack of a well defined population for which there is clear evidence of benefit[7]. The efficacy has been described as uncertain with an estimated beneficial effect of 1 in 25 women from a study in England[8]. Also, there is little consensus on the optimal procedure or technique [e.g. low/high vaginal or abdominal, suture material, endocervical/purse string or timing of insertion i.e. elective, history indicated, ultrasound indicated or pre conception][7]_.
The objective of this study is to compare pregnancy outcome before and after cervical cerclage insertion in women with cervical incompetence.

Subjects, Materials and Methods

The study was an observational study with a retrospective evaluation of the pregnancy outcome in women diagnosed to be having cervical incompetence. Subjects were pregnant women who presented with features of cervical incompetence and had transvaginal cervical cerclage performed as the treatment modality.
The case records of all pregnant women who had cervical cerclage at the University of Ilorin Teaching Hospital [UITH], Ilorin from 1st January 2007 to 31st December 2010 were reviewed.

Inclusion Criteria

- Previous history of mid-trimester/ early third trimester pregnancy loss or preterm delivery characterized by painless cervical effacement and dilatation, drainage of liquor followed by expulsion of the product of conception.
- Ultrasound measured internal Os diameter in pregnancy >15mm before 24weeks gestation.
- cervical dilatation with visible amniotic membrane on speculum examination without uterine contractions.

Exclusion Criteria

Women without a diagnosis of cervical incompetence or presence of uterine contractions.

Procedure:

All participants had transvaginal cervical cerclage insertion performed after establishing the diagnosis. The procedure was performed under regional or general anaesthesia using the McDonald technique, followed by bed rest for at least 48hours and prophylactic antibiotics before discharge. The patients were followed up after the procedure at the antenatal clinic with instructions to report to hospital if there was vaginal bleeding, draining of fluid per vaginam

or uterine contractions. Those who had emergency cerclage had tocolytic using oral Salbutamol 2mg twice daily or Nifedipine 10mg twice daily and bed rest for a minimum of 7days.

Sterile cotton umbilical cord tape [18? x 30?] was used for the procedure due to non-availability of Mersilene tape during the study period in our center and the stitch was removed at 37 weeks gestation in uncomplicated cases.

The primary outcome measure was the gestational age at the end of pregnancy; the secondary outcome measures were the duration of prolongation of pregnancy and pregnancy outcome.

Data retrieved from the case records included age, parity, outcome of previous pregnancies, history of index pregnancies, gestational age at cerclage insertion, timing of the procedure [elective or emergency] pregnancy outcome in terms of gestational age at the end of pregnancy and mode of deliveries after cerclage insertion.

Previous complicated dilatation and curettage was defined as one in which there was repair of genital tract injuries or repeat evacuation.

Previous cervical operations refer to surgical procedures on the cervix e.g. cone biopsy.

Previous complicated delivery was one in which there was repair of genital tract laceration or uterine evacuation following vagina delivery.

The data obtained was analyzed using the Statistical Package for Social Sciences [SPSS version 18] with results represented in tables, percentages and p value <0.05 was statistically significant.

The study was conducted in compliance with institutional guideline with local approval.

Sponsorship of the study was by the researchers and there was no conflict of interest in the conduct of the study.

RESULTS

There were 103 cases of cervical incompetence out of 12,142 deliveries giving a prevalence of 8.4/1000 deliveries or 0.85%; however, eight subjects delivered at other facilities, thus, 95 subjects were used for the subsequent analyses. The age range of participants was 16-40 years with modal age 21-25years representing 32[33.7%]; the parity ranged between para 0 and 4 [modal parity was para 0 with 37(40.0%)]. History of previous complicated vaginal delivery was the risk factor in 49[51.6%] of the women while complicated dilatation and curettage was the risk in 42[44.2%] of which 32[76.2%] were for induced abortion as shown in Table 1.

In Table 2, 85[89.5%] of the women had elective cerclage while 10[10.5%] were emergency; the mean gestational age at insertion [weeks] was 15.08±1.10 for elective and 21.10±0.99 for emergency cerclage. The mean gestational age at the end of pregnancy in weeks was 36.06±3.96 for elective and 25.10±3.99 for emergency procedures. The mean duration of prolongation of pregnancy was 20.98±4.71 and 4.00±3.37 weeks for elective and emergency cerclage respectively. Term deliveries were 73[85.95%] after elective cerclage; miscarriages were 6[7.1%] and 7[70%] after elective and emergency cerclage respectively, the caesarean delivery rate following elective cerclage was17.7% while the child take home rate was 76[89.4%] for elective and 2[20%] for emergency procedures.

In table 3 there were a total of 480 pregnancies before and 95 after cerclage insertion. Miscarriage were 335[69.8%] before and 13[13.7%] after cerclage [P<0.0001], preterm deliveries were 60[12.5%] before and 9[9.5%] after cerclage [P<0.0001], term deliveries were

85[17.7%] before and 73[76.8%] after [P=0.4100] and viable pregnancies were 145[30.2%] before and 80[84.2%] after cerclage [P<0.0001].

DISCUSSION

The principal findings of this research are that the prevalence of cervical incompetence was 8.4/1000 deliveries [0.85%] and it affected mostly women of low parity [87.4% were para 0 to 2] in the prime of their reproductive life [79% were ≤30years]. The major predisposing factors for cervical incompetence were previous complicated vaginal deliveries and complicated dilatation and curettage. There were statistically significant reduction in miscarriages and preterm deliveries and increase in term pregnancies and viable pregnancy rates after cervical cerclage. It also showed the efficacy of umbilical cord tape as an improvised material for cervical cerclage.

The prevalence of cervical incompetence in this series was similar to 6.7/1000 reported by Okpere[3] in Benin City, Nigeria but lower than 1 in 146 deliveries in Zaria, Nigeria [4] and the 3-12% global estimate[5]. This may be due to the variation in the diagnosis of the condition although most clinicians employ history of recurrent pregnancy losses, open cervical Os on pelvic examination or ultrasound evaluation. Cervical integrity remains an important factor in pregnancy outcome as its inability to retain the product of conception till term results in adverse reproductive outcome. This becomes important in developing countries where a high premium is placed on childbirth and pregnancy outcome is a major factor in stability of marriages and cervical incompetence affected majorly women in the prime of their reproductive life and of low parity in this study and 62.5% of cervical incompetence patients being nullipara as reported by Ikimalo et al[9]. The importance of intrapartum care was emphasized as about half of the women developed cervical incontinence following complicated vaginal deliveries. Thus, birth attendants should be proactive in the prevention especially of genital trauma during delivery as well as proper repair of such when they occur. In addition, the effect of induced abortion on the reproductive health of women was demonstrated as 44.2% of participants had previous complicated dilatation and curettage of which 76.2% were for induced abortion similar to a report from Lagos, Nigeria[10]. Thus, more attention should be given to contraception among women of reproductive age to avert unwanted pregnancies and subsequent induced abortions.

The effectiveness of the improvised material [umbilical cord tape] in this study corroborated the findings of Pereira et al who reported no difference in spontaneous preterm birth depending on the suture material used after comparing the traditional Mersilene with alternatives like Tevdek and Prolene in their study[11]. The mean prolongation of pregnancy by 4.00±3.37 weeks following emergency cerclage in this study was similar to the average of 4weeks reported by Althuisius[12] and 3-6weeks by Templeman et al[13] with a significant reduction in birth before 34 weeks[12] similar to this study. However, there was no term pregnancy following emergency cervical cerclage in this study contrary to a 66.7% term pregnancy following a report of six cases of emergency cervical cerclage by Egbe et al[5]. Perhaps, the aim in emergency cerclage should be to gain possibly a few weeks in order to improve neonatal

survival and not to achieve term pregnancy.

The caesarean delivery rate was 17.7% following elective cerclage in the study population; this was higher than the 10.3%[14] in this hospital during the same period and is in conformity with reports of Okpere in Nigeria[10] and Waloch in Zambia[15] who reported a higher caesarean delivery rate among women who had cervical cerclage. This high rate may be because recurrent pregnancy loss in itself is a bad obstetric history presenting a low threshold for caesarean delivery. However, no caesarean section was done on the basis of the cerclage procedure alone in this study. The term pregnancy rate of 76.8% following cervical cerclage among all participants in this study was similar to 68.8% by Ikimalo et al[9] and 65.3% by Idrisa et al[16] while the total child take home rate of 78[82.1%] in this study was similar to foetal salvage rate of 85.3% reported by Idrisa et al[16].

This study supported previous reports of improved pregnancy outcome following cervical cerclage by other authors[5,9,16]; however, this does not support reports of meta-analyses[8,17]. Thus this study suggest the usefulness of cervical cerclage in women with previous history of second trimester losses or preterm delivery in carefully selected women similar to the conclusion of Mancuso et al [18] that cervical cerclage may be useful in women with prior early preterm delivery and who have shortened mid-trimester cervical length as well as Althuisius et al [19] who recommend cerclage for women with risk factors and or symptoms of cervical incompetence and shortened cervical length before 27weeks gestation.

CONCLUSION / RECOMMENDATIONS

The outcome of this study suggests an effectiveness of cervical cerclage in prolongation of pregnancy and improvement of pregnancy outcome in cases of cervical incompetence especially in women with previous history of mid trimester pregnancy loss or early preterm delivery. The procedure is therefore recommended for such women.

Table 1: *Maternal characteristics of women with cervical incompetence*

	Frequency	Percentage [%]
Age		
16-20	19	20.0
21-25	32	33.7
26-30	24	25.3
31-35	14	14.7
36-40	6	6.3
Parity		
0	37	40.0
1	27	28.4
2	18	19.0
3	10	10.5
4	3	3.1
Identified risk factor		
Previous complicated vaginal deliveries	49	51.6
Previous dilatation and curettage	42	44.2
Spontaneous abortions	10	23.8
Induced abortions	32	76.2
Previous cervical operations	4	4.2

Table 2: *Details of cerclage insertion and pregnancy outcome*

	Elective n=85 f [%]	Emergency n=10 f [%]
Mean gestational age at cerclage insertion [weeks]	**15.08±1.10**	**21.10±0.99**
Mean gestational age at end of pregnancy [weeks]	**36.06±3.96**	**25.10±3.99**
Mean duration of prolongation of pregnancy [weeks]	**20.98±4.71**	**4.00±3.37**
Pregnancy outcome		
Term delivery	73[85.9]	0
Miscarriage	6[7.1]	7[70]
Preterm delivery	6[7.1]	3[30]
Mode of delivery		
Vaginal delivery	67[78.8]	3[30]
Caesarean delivery	15[17.7]	0
[CPD=10, Foetal distress=3, Cord prolapse=2]		
Child take home rate	76[89.4]	2[20]

CPD: Cephalopelvic disproprtion

TABLE 3: Comparison of pregnancy outcome before and after cervical cerclage

	Before Freq [%]	After Freq [%]	P value
Total Number of pregnancies	480	95	NA
Spontaneous abortions	335[69.8]	13[13.7]	<0.0001
Term deliveries	85[17.7]	73[76.8]	0.4100
Preterm deliveries	60[12.5]	9[9.5]	<0.0001
Viable pregnancies (Term + Preterm deliveries)	145[30.2]	82[86.3]	<0.0001

NA- Not applicable

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