Original Article

Comparison of Pregnancy Outcomes of Triangular 3-Bites and McDonald Techniques of Cervical Cerclage in Women with Cervical Insufficiency: A Pilot Study

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Abstract

Background: Cervical cerclage is the procedure of choice for preventing preterm birth due to cervical insufficiency. Despite the simplicity of the McDonald's method of cerclage application, it is still technically difficult to take four bites around the cervix before knotting. There is a need to develop a simpler method of cervical cerclage application with similar or improved pregnancy outcomes. **Aim:** This is to compare the ease/duration of application and pregnancy outcomes of the new triangular three-bite cervical cerclage technique and McDonald's technique in women with cervical insufficiency. **Patients and Methods:** This is a pilot study with 20 participants that met the inclusion criteria. They were randomly grouped into triangular three-bite method (n = 10) and McDonald's method (n = 10). The pregnancy outcomes were compared between the groups with the Chi-square test and student's *t*-test. A *P* value of <.05 was set as level of significance. **Results:** The sociodemographic characteristics of the two groups were similar. There was no statistically significant difference between the two groups regarding the pregnancy outcome (spontaneous miscarriage *P* = 1.00, preterm delivery *P* = 0.61, and neonatal birthweight *P* = 0.96). However, the duration of cerclage application (5.98 ± 1.79 minutes vs. 14.25 ± 7.5 minutes; *P* <.002) and estimated blood loss (29 ± 9.94 mls vs. 48.5 ± 25.82 mls; *P* = .04) were significantly lower in the triangular three-bite arm than in the McDonald's arm. **Conclusion:** The new triangular three-bite technique has similar pregnancy outcomes with the conventional McDonald's technique and has shown a lower duration of procedure and blood loss. Since this is a pilot study, a well-structured randomized control trial to compare the two methods is recommended.

Keywords: *Cervical cerclage, cervical insufficiency, McDonald technique, pregnancy, triangular 3-bites technique*

Introduction

Despite the advances in medicine in the past decades, preterm birth (PTB) and its associated complications remain high and account for a high neonatal mortality burden globally.[1,2] Although

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the mortality rate due to PTB has declined in most advanced countries, its long-term sequelae like chronic lung disease and neurodevelopmental disability in survivors remain high.[3] About one million babies of 15 million delivered prematurely worldwide die due to complications associated with prematurity.[4]

Cervical incompetence or insufficiency (CI) which is painless dilation of the cervix without uterine contractions and subsequent delivery in the second trimester or early third trimester among other causes is one of the major causes of preterm birth.[5,6]

Cervical cerclage which involves putting a suture (stitch) in a purse-string fashion around the neck of the cervix to provide mechanical support to it and to keep it closed during pregnancy is the procedure of choice for CI.[6] McDonald's method which has a similar success rate with other methods and easier to apply is the commonly used method.[7,8] It involves taking 4-6 bites in a purse-string fashion around the cervix as high as possible before the stitch is knotted anteriorly or posteriorly. It is the commonly applied method because of its simplicity.

Despite its simplicity, it is still technically difficult to take up to 4-6 bites on the cervix especially in obese patients and in those with very short cervix before knotting. It is even more difficult, when you factor in the size of the half semi-circle needle [65 mm] on the conventional 5 mm Mersilene tape used for this procedure. This limits the depth the needle can penetrate the cervical tissue, which increases the risk of loosening or slipping of the stitch as stated by Adinma *et al*.[9] in their study. Hence, there is a need to develop a method that will require deeper tissue bites and a reduced number of bites with a similar or improved success rate.

In this study, we compared the first 10 pilot case series of our new prosed triangular three-bite technique with 10 participants that had McDonald's method of cervical cerclage. The ease/duration of performing the procedure, associated complications, and pregnancy outcomes were compared between the two methods. We hypothesized that the rate of PTB, blood loss, and suture slippage with triangular three-bite technique will be less than in the McDonald method, because the bites will be taken deeper through the cervical tissue in the triangular three-bites technique.

Materials and Methods

Study sites

This study was conducted at two private specialist hospitals that offer specialized care in obstetrics and gynecology. Both are referral centers for obstetrics cases from the community and the neighbouring states.

Study design

This is a comparative pilot study to compare the new triangular three-bite technique with the conventional McDonald's technique of cervical cerclage.

Inclusion criteria

Pregnant women between the ages of 18 and 45 years with history-indicated and ultrasound-indicated cervical cerclage who are willing and have signed informed consent were recruited.

Exclusion criteria

Those with contraindications to cervical cerclage (fetal demise, preterm premature rupture of membranes, vaginal bleeding, etc.) were excluded. Those who were not willing to participate and women who presented late after 20 weeks of gestation were also excluded.

Study procedure

Pregnant women who met the inclusion criteria were randomly recruited for this pilot study. The first pregnant woman was randomly allocated to the study group (triangular three-bite technique) and subsequent consenting pregnant women were allotted to the groups alternately till the sample size of 20 was attained. Early transvaginal ultrasound scan or date of last menstrual period was used to determine the gestational age of those who conceived naturally, while the date of embryo transfer and early ultrasound were used for those who conceived through in-vitro fertilization.

Cervical cerclage was inserted for both groups between 14 and 16 weeks of gestational age. It was inserted in the operating room under total intravenous anesthesia with ketamine hydrochloride and face mask oxygen delivery in the lithotomy position. The standard sterile protocol was followed, 5 mm Mersilene tape [Polyester fibre ligature white woven], 30 cm long with 65 mm half semi-circle round body needle at both ends [Ethicon Inc 2007 USA] was used for suture placement in both groups.

In the study group (new triangular three-bite technique), with the patient in a dorsal lithotomy position and under anesthesia, cleaning of the perineum and vagina and application of drapes were done. Two Sim's specula were passed to retract the anterior and posterior vaginal walls respectively and expose the cervix. Then, two pairs of sponge forceps were used to grasp both the anterior and posterior lips of the cervix. A gentle downward traction was applied to expose the full length of the ectocervix, while the assistant retracts the vaginal walls with the two Sim's specula. A triangular suture (taking only three deep bites) was applied around the cervix as high as possible to approximate at the level of the internal Cervical Os [Figure 1]. This is at the junction

of the rugose vagina and smooth cervix. The bites were taken deep through the substance of the cervix, avoiding the vessels at 3 and 9 o'clock positions. The first deep bite (passing through the substance of the cervix) entered at the midpoint between the 11 and 12 o'clock positions and exited at the 8 o'clock position. The second bite entered at the midpoint between the 8 and 7 o'clock positions and exited between the 5 and 4 o'clock positions. The last bite entered at the 4 o'clock position and exited at between the 1 and 12 o'clock positions to complete the triangle. A surgeon's knot was then tied at the 12 o'clock position with three hitches done [double wind for first hitch and single wind for the second and third hitches – 2:1:1 configuration] and the tape was cut leaving about 3 cm length behind [this gives a 3:3:3 principle]. The 12 o'clock position was preferred for tying the knot as it allowed for ease of application and suits the upright orientation of the triangle with the wide base of the triangle posterior where you have more space in the posterior vaginal fornix, while the narrow apex of the triangle is anterior where you have reduced space in the anterior vaginal fornix.

Those in the control group (conventional McDonald technique) had similar preoperative preparation, and four bites like a purse string were taken as high as possible and knotted anteriorly at the 12 o'clock position. The bites in this group were taken as deep into the substance of the cervix as the curvature of the size 65 mm needle will allow [Figure 2]. The first bite entered between the 11 and 12 o'clock positions and exited at the 10 o'clock position. The second bite entered at the midpoint between the 9 and 8 o'clock positions and exited between the 7 and 6 o'clock positions. The third bite entered between 6 and 5 o'clock positions and exited between the 4 and 3 o'clock positions. The fourth bite entered between 3 and 2 o'clock positions and exited at between the 1 and 12 o'clock positions to complete the purse string. A surgeon's knot was then tied at the 12 o'clock position with four hitches done [double wind for first hitch and single wind for the other hitches – 2:1:1:1 configuration] and the tape was cut leaving about 2 cm length behind.

Participants in both groups were admitted to the recovery room for observation and monitoring immediately after the procedure. They were given oral amoxicillin/clavulanic acid 625 mg twice and metronidazole 400 mg thrice daily for 5 days. Also, oral salbutamol 4 mg two times daily for 2 weeks and paracetamol 1,000 mg thrice daily for 2 days. These patients were discharged within 6 hours if they remain stable.

The duration of the cervical cerclage insertion (duration of time starting from the time the first bite on the cervix to cutting the tape after knotting) was assessed in both groups. The lead author performed all the procedures and subjectively assessed and recorded the ease of application of the cervical cerclage using a Five-Likert scale (very easy, easy, neutral, difficult, and very difficult). Immediate complications such as bleeding per vaginam, lower abdominal pain, and membrane rupture were recorded. All the data collected were recorded in the study proforma.

The participants were followed up in the antenatal clinic to the time of delivery by the lead author and two other consultant obstetricians. The gestational age at delivery was recorded for both groups. Incidence of spontaneous miscarriage, preterm delivery, and neonatal birthweight were compared in both groups.

Data and statistical analysis

Analysis was done using the Statistical Package for Social Sciences (SPSS) version 23 (IBM Corp 2015). Data were presented in tables, while continuous data were presented in mean and standard deviation. Categorical variables were analyzed using Chi-square test where appropriate, while continuous data were analyzed using a *t*-test. The statistical significance was inferred at P value ≤ 0.05.

Ethical consideration

Ethical approval was sought and obtained from Ethics committee of Chukwuemeka Odumegwu Ojukwu University Teaching Hospital, Awka, Anambra state, Nigeria, with the approval number – COOUTH/CMAC/ETH.C/Vol. 1/FN: 04/0049.

Results

Of the 25 women who were assessed for eligibility for this pilot study, two declined to participate in the study, while three did not meet the inclusion criteria. Therefore, 20 women who met inclusion criteria for cervical cerclage were recruited and randomly

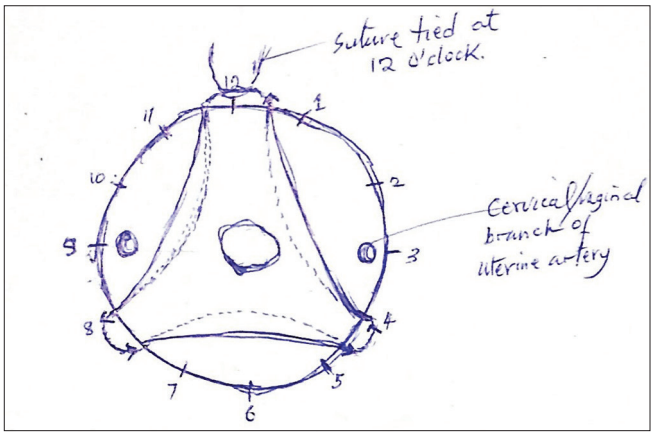

Figure 1: Diagram of the Triangular 3-bites cervical cerclage technique

assigned to the study (triangular three-bite technique) or control (McDonald's technique) group in equal proportion.

Table 1 summarized the sociodemographic characteristics of participants in both groups. The baseline sociodemographic data of the two groups were similar.

The incidence of spontaneous miscarriage in both groups was 10%. Two participants (20%) had preterm delivery in the triangular three-bite group, while three participants (30%) had preterm delivery in the McDonald group (P = 0.61). Both groups had similar mean birthweight; 2.96 ± 0.77 (McDonald method) and 2.95 ± 0.84 (triangular three-bite method) with P value of. 96. This is shown in Table 2.

Table 3 compares the characteristics of the two procedures. The duration of the procedure and estimated blood loss were found to be statistically lower in the triangular three-bite technique than the conventional McDonald's method with P values of <.1 and. 04, respectively. Those in the McDonald's group had more abdominal cramps but this was not statistically different from patients in the triangular three-bites group (P =0.3).

Table 1: Distribution of sociodemographic variables

	Grouping	McDonald *n* (%)	Triangular 3-Bite *n* (%)	Total *n* (%)
Age	18-30 years	4 (40.0)	3 (30.0)	7 (35.0)
	31-40 years	4 (40.0)	6 (60.0)	10 (50.0)
	41-45 years	2 (20.0)	1 (10.0)	3 (15.0)
Parity	Nulliparous	5 (50.0)	8 (80.0)	13 (65.0)
	Prim parous	2 (20.0)	0 (0.0)	2 (10.0)
	Multi parous	3 (30.0)	2 (20.0)	5 (25.0)
Highest level of education	Secondary	3 (30.0)	3 (30.0)	6 (30.0)
	Tertiary	7 (70.0)	7 (70.0)	14 (70.0)
Religion	Christian	10 (100.0)	10 (100.0)	20 (100.0)
Marital status	Married	10 (100.0)	10 (100.0)	20 (100.0)
Occupation	Unemployed	1 (10.0)	2 (20.0)	3 (15.0)
	Business	3 (30.0)	5 (50.0)	8 (40.0)
	Student	1 (10.0)	0 (0.0)	1 (5.0)
	Civil service	3 (30.0)	2 (20.0)	5 (25.0)
	Nurse	1 (10.0)	0 (0.0)	1 (5.0)
	Professional*	2 (20.0)	1 (10.0)	3 (15.0)

*Professional: This has 1 each of Health worker, Lawyer, and Banker

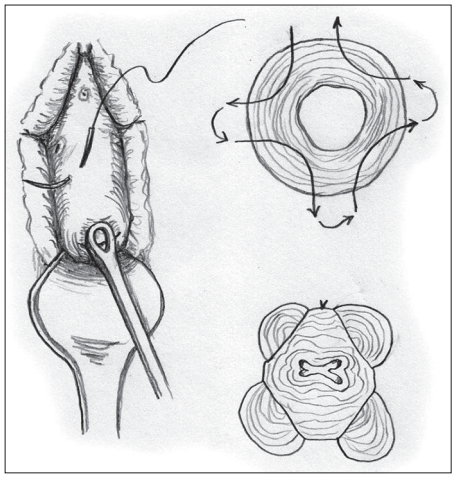

Figure 2: McDonald cervical cerclage method (courtesy of Medscape)

Table 2: Pregnancy outcomes of the groups

Outcome	McDonald *n* (%)	Triangular 3-Bite *n* (%)	Total *n* (%)	RR (CI)	*P*
Miscarriage	1 (10.0)	1 (10.0)	2 (10.0)	1 (0.07-13.86)	1.000
Preterm delivery	3 (30.0)	2 (20.0)	5 (25.0)	1.50 (0.31-7.13)	0.610
	Mean±SD	Mean±SD	Mean±SD	*t*	*P*
Birth weight	2.96±0.77	2.95±0.84	2.97±0.75	-0.04	0.960

Table 3: Characteristics of the procedures

Characteristics	Category	McDonald *n* (%)	Triangular 3-Bite *n* (%)	Total *n* (%)	RR (CI)	*P*
Abdominal cramp	Yes	3 (30)	1 (10)	2 (10)	0.33 (0.04-2.68)	0.3
	No	7 (70)	9 (90)	18 (90)		
Ease of application*	Easy	6 (60)	9 (90)	5 (25)	0.25 (0.03-1.86)	0.17
	Difficult	4 (40)	1 (10)	15 (75)		
		Mean±SD	Mean±SD	Mean±SD	*t*	*P*
Duration (minutes)		14.25±7.5	5.98±1.79	12.23±5.65	3.62	<0.002
Estimated blood loss (ml)		48.5±25.82	29.0±9.94	38.75±21.51	2.22	0.04

*There were zero responses for other categories of Very easy, Neutral, and Very difficult

Discussion

The principal findings of this pilot study are statistically significant lower duration of application of cervical cerclage and reduced blood loss that favours the triangular three-bites group compared to the conventional McDonald's group. The ease of application, abdominal cramps, birthweight, miscarriage, and preterm delivery rate outcomes were similar between the two groups.

The new triangular three-bites cervical cerclage technique has a similar pregnancy outcome to the McDonald's method. The 10% miscarriage rate recorded in the two groups is similar to miscarriage rates from previous studies on elective McDonald's cervical cerclage.[10-12] The preterm birth rate in both groups (20% for triangular three-bite vs. 30% for McDonald) is also similar to our finding of 23.3% on a 10-year review of McDonald cervical cerclage in the study centers.[12] Buttressing the importance of cervical cerclage in preventing preterm delivery, Berghella *et al*.[13] in their meta-analysis on 'Cerclage for short cervix on ultrasonography in women with singleton gestations and previous preterm birth' concluded that in women with previous spontaneous preterm birth, singleton gestation, and cervical length less than 25 mm, cerclage significantly prevented preterm birth and composite perinatal mortality and morbidity. Similarly, Owen *et al*.[14] in a multicenter randomized trial of cerclage for preterm birth prevention in high-risk women with shortened mid-trimester cervical length concluded that in women with a prior spontaneous preterm birth less than 34 weeks and cervical length less than 25 mm, cerclage reduced previable birth and perinatal mortality but did not prevent birth less than 35 weeks, unless cervical length was less than 15 mm.

Interestingly, there is a statistically significant difference in the duration of time for application of the triangular three-bite technique as compared to the conventional McDonald's method (P <.1). This is because only three bites are taken against the four bites in the McDonald's method. Also, it is technically easier to take three deep bites around the cervix with a 65-mm semicircle needle on the 5-mm Mersilene tape than to take four bites of the McDonald's method. This shorter duration of the procedure will reduce the duration of exposure to anesthesia and its associated complications. The 5.98 ± 1.79 minutes estimated procedure duration in the triangular three-bites cervical cerclage technique is less than both 30.4 and 19.8 minutes reported by Başbuğ A *et al*.[15] for rescue and elective cervical cerclage.

There is significantly higher estimated blood loss in the McDonald's group than the triangular three-bite group. It is expected that an increase in the number of bites like in the McDonald's will increase the number of needle puncture which will likely increase the risk of inadvertent injury to blood vessels. Also, the needle bites of the three-bite techniques are fashioned in such a way that the major blood vessels at the 3 and 9 o'clock positions of the cervix are far away from the bites. This reduced blood loss will allay the anxiety that usually follows cervical cerclage when patients notice continued spotting *per vaginam* after cerclage application.

We also found that the ease of application of triangular three-bites technique was better than the McDonald's method. McDonald's method has been the most frequent method of cervical cerclage application due to its simplicity and ease of application. However, this practice may change to the triangular three-bite technique if this result of an easier way of application is validated in future randomized controlled studies.

The strength of this study is that it is prospective in nature and the participants were randomly assigned into the two groups. The cervical cerclage procedures were performed by three experienced gynecologists at the study hospitals thereby enhancing the uniformity of the data analyzed. The main limitation of this study is that it is a pilot study and the limited sample size will not support a general application of the findings.

Conclusion

The duration of application was shorter; ease of application was better and estimated blood loss was less in the triangular three-bite technique compared to the McDonald's technique. However, both techniques have similar pregnancy outcomes. A well-structured randomized controlled trial is further recommended.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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