Foetal Salvage by Modified McDonal's Method

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Abstract

Background: Cervical cerclage is the main stay of surgical treatment for cervical insufficiency and is reasonable in the following situations. Cerclage can be accomplished either transvaginally or transabdominally.

Aim: To evaluate the effectiveness of cervical cerclage by modified McDonald's method in form of better perinatal, foetal and maternal outcome.

Materials and Methods: This is a prospective cohort study conducted on 100 ANC pregnant women with history of previous spontaneous preterm birth, previous 2nd trimester abortion, previous early and late recurrent foetal loss and women with short cervix in pregnancy at PDZH, Udaipur.

Result: Mean age 25.94 \pm 3.69 years, mean gravida 2.71 \pm 1.27, mean gestational age at time of cervical cerclage 18.1 \pm 3.76 weeks. Mean good APGAR among 93 live births was 94% babies between 7–10. Among 3 neonatal death all babies were <2.5 kg (p < 0.05). Maximum patient reach at term who had cervical cerclage between 14–18 week i.e. 49% (p < 0.05). In short cervix cases total foetal salvage by modified McDonald's method is 84.61%, abortion 7.69%, NICU admission 23.07% and neonatal death is 7.69%.

Conclusion: Cervical cerclage is a simple procedure, require little surgical expertise but has very good results. Advantage of our method over McDonald's method is that it is simpler procedure having less stitches on cervix so that less chances of haemorrhage, at the time of surgery or postsurgery. Round body prolene suture does less trauma to cervix and less

chances of infection to genital tract in comparison to braided silk suture.

Keywords: Cervical cerclage; McDonald's method; Prolene suture.

Introduction

The conception of a baby and giving birth to a new life is a miracle and joyful experience, unique only to the mother to be. It's like opening of a whole new exiting world, but at times the destiny is cruel, it snatches away the opportunity from the women to be a mother.

The rate of foetal wastage in the form of mid trimester abortion and premature delivery is quite high in our country. In about 50% of such cases etiological factor is unknown.

Preterm births are terms used to describe neonates who are born too early. Preterm infants were those delivered before 37 completed weeks. Prematurity is also classified according to gestation age at birth.¹

Near term [34–36 week] Moderate preterm [32–33 week] Severe preterm [28–31 week] Extreme preterm [<28 week]

An estimated worldwide Incidence of preterm deliveries is 10.6% live births in 2014.² Rates ranges

from 5% in some northern European countries to over 15% in some countries in sub-Saharan Africa and Asia.² Patient with prior preterm birth had 2.4% incidence of preterm deliveries compared to women with no history of preterm birth. Moreover incidence increased to 5.2% when the patient had 2 or more previous preterm deliveries. Incidence of preterm deliveries also increasing due to progress in assisted reproductive techniques leading to multifoetal pregnancies. Improved antenatal assessment of high risk pregnancies as well earlier intervention also contribute to iatrogenic prematurity. Therapeutic intervention to treat preterm Labor (secondary prevention) with tocolytic compound has been

disappointing, despite many pharmacological compounds investigated as potential tocolytic.

Whatever the cause of onset of parturition the final common pathway in a cascade of events of preterm birth is cervical shortening and dilation.

Etiopathogenesis of Preterm Labor³

Cervical incompetence as a cause of second trimester abortion is now a well established clinical entity. Role of cervix is to provide mechanical strength and act as a barrier to prevent ascending infection. There are some predictors of preterm Labor.³

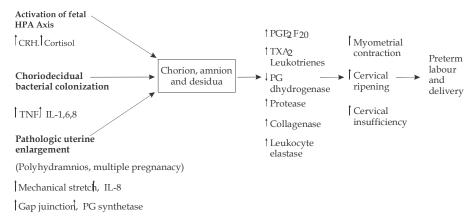


Fig. 1: Etiopathogenesis of Preterm Labour.3

- A. Clinical predictors: (a) Multiple pregnancy
 (b) History of preterm birth (c) Presence of genital tract infection (d) Symptoms of preterm Labor
- B. Biophysical predictors: (1) during pregnancy uterine contractions ≥4/hr. (b) Bishop score ≥4 (c) Cervical length (TVS) ≤25 mm or funnelling of internal os >1 cm. Biophysical predictors -1. during pregnancy, (c) funnelling of internal Os > 1 cm (d) on speculum examination-1. Painless cervical shortening and dilation, 2. Detection of dilation of internal Os with herniation of membranes. (2) Interconceptional period [a] history of cervical incompetence in previous pregnancy [b] passage of number 6-8 hegar dilator beyond internal Os without any resistance and pain, and absence of internal Os snap on its withdrawal specially in premenstrual period [c] funnelling of internal Os in premenstrual hysterocervicography
- C. *Biochemical predictors:* (a) Foetal fibronectin in cervicovaginal discharge (b) IL-6, IL-8, TNF-alpha

Among the known causes of preterm birth cervical incompetency (insufficiency) plays an important role. Cervical incompetence is defined by the American College of Obstetricians and Gynecologists (ACOG) as the inability of the uterine cervix to retain a pregnancy in the second trimester, in the absence of uterine contractions.

The cervix is part of the female reproductive system. Around 2-3 centimetres (0.8-1.2 inch) in length, it is the lower narrower part of the uterus continuous above with the broader upper part or body of the uterus. The lower end of the cervix bulges through the anterior wall of the vagina, and is referred to as the vaginal portion of cervix (or ectocervix) while the rest of the cervix above the vagina is called the supravaginal portion of cervix. A central canal, known as the cervical canal, runs along its length and connects the cavity of the body of the uterus with the lumen of the vagina. The openings are known as the internal os and external orifice of the uterus (or external os) respectively. The mucosa lining the cervical canal is known as the endocervix, and the mucosa covering the ectocervix is known as the exocervix.

The cervical canal varies greatly in length and width between women or over the course of a woman's life, and it can measure 8 mm (0.3 inch) at its widest diameter in premenopausal adults. On average, the ectocervix is 3 cm (1.2 in) long and 2.5 cm (1 in) wide. It is composed of both muscle and fibrous connective tissue, yet the fibrous component is responsible for the tensile strength of the cervix.

The incidence of incompetent os is between 0.1%-1%⁴ and ranges in estimation from 1 in 500 to 1 in 2000 accounting for approximately 20-25% of second trimester losses. It accounts overall for 0.2% of all abortions and about 12% among women with history of habitual abortions.

Cervical insufficiency is thought to be related to a structural defect in tensile strength at the cervicoisthmic junction, but other disorders (e.g. decidual inflammation, intrauterine infection, hemorrhage, uterine over distension) may result in premature cervical shortening, ultimately leading to preterm delivery. Cervical incompetence is part of broader concept of short cervix. Short cervical length should be defined as a cervical length less than 25 mm between 18 and 22 week of gestation.^{5,6} This definition is fully applicable for singleton pregnancies and used in treatment recommendations, but does not entirely apply towards multifetal pregnancies. Pathogenesis of short cervix in both congenital factors (anatomical anomalies) and acquired factors may play an important role. It may occur due to cervical surgery (e.g. cervical biopsy, conisation Menchester repair, LEEP), cervical trauma (e.g. instrumental delivery, dilation and curettage procedure) and systemic disease associated with collagen and elastin disorder (e.g. Ehler's-Danlos syndrome, Marfan's syndrome, osteogenesis imperfecta, epidermolysis bullosa) as well excessive mechanical pressure exerted on cervix like multifoetal pregnancies.

Unfortunately there is no definitive diagnostic test for cervical insufficiency and diagnosis is usually a retrospective one based on a history of recurrent second trimester loss or early preterm delivery following painless cervical dilatation in the absence of other causes of recurrent pregnancy loss, which can present with the following:

- Painless cervical dilatation and bulging fetal membranes upon presentation in the second trimester of pregnancy
- Preterm premature rupture of membranes (PPROM)
- Rapid delivery of a previable infant
- Rare or absent uterine contractions

In women without a history of pregnancy loss, the diagnosis of cervical insufficiency is based on a combination of the following:

- Clinical presentation
- Physical examination
- Ultrasonographic findings

Most patients are asymptomatic, but some may present with any of the following symptoms:

- Pelvic pressure
- Cramping
- Back pain
- Increased vaginal discharge

Although the diagnosis of cervical insufficiency may be based on a history of midtrimester pregnancy loss, the following measures may also be useful:

- Ultrasonographic transvaginal measurement of cervical length: Cervical length has a strong inverse correlation with the risk of spontaneous preterm birth, particularly in women with a history of preterm delivery
- Fetal fibronectin (fFN) testing: Studies have demonstrated the utility of fFN testing in addition to cervical length assessment, with a significant improvement in the prediction of preterm delivery in women with a positive fFN and a cervical length of less than 30 mm

Foetal fibronectin (fFN) protein produced by foetal cells, it is found at the interface of the chorion and deciduas. Foetal fibronectin leaks into the vagina if a preterm delivery is like to occur and can be measured by a screening test.

If fFN test is positive, it is an inconclusive result, a positive test indicate that a women will go into preterm Labor soon, but she may not go into Labor for weeks.

When FN test is negative, the result is a better predictor. A negative result mean that there is a little possibility of preterm Labor within next 7–10 days and the test can be repeated weekly for women who are at high risk. A negative foetal fibronectin test gives a more than 95%, likelihood of remaining undelivered for next 2 weeks. Late Shirodkar⁶ from India, Lash and Lash¹⁵ in United States and Palmer and Lacomme¹⁶ in France were among the pioneer who recognized and treated this condition.

Cervical cerclage is the main stay of surgical treatment for cervical insufficiency and is reasonable in the following situations

- History of second trimester pregnancy loss with painless cervical dilatation
- Prior cerclage placement for cervical insufficiency
- History of spontaneous preterm birth (prior to 34 weeks' gestation) and a short cervical length (i.e. <25 mm) prior to 24 weeks' gestation
- Painless cervical dilatation on physical examination in the second trimester
- Certain lifestyle approaches, such as activity restriction, bed rest, and pelvic rest, have not been shown to be effective and thus, should not be used to treat cervical insufficiency.

Cerclage can be accomplished either transvaginally or transabdominally. The 2 most common transvaginal techniques are as follows:

McDonald's cerclage: McDonald⁵ in 1957 devised a simple procedure by inserting a purse string suture No. 4 mersilene around ectocervix. A non absorbable 5 mm. wide Mersilene tape is placed as a purse string suture as high as possible [level of internal Os] at the junction of the rugose vaginal epithelium and the smooth vaginal part of the cervix below the level of bladder. Bladder mobilization not required. The suture start at the anterior wall of cervix at 12 O' clock position, taking successive bites [4–5 sites], it is carried around the lateral and posterior walls back to anterior wall again where to ends of suture tied and knot placed anteriorly at 12 O' clock position.

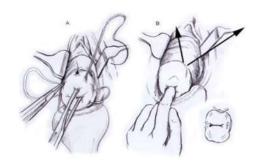


Fig. 2: McDonald's cerclage.

Shirodkar's cerclage: Shirodkar⁶ (1955) performed isthmic cerclage with a strip of homologous fascialata by specially devised half curved aneurysm needle which facilitated placement of suture submucosally high-up at level of internal os. A strip of fascia lata is removed from the outer side of the thigh, quarter of an inch wide and four and a half inches long and each end of this is transfixed

with a linen suture. The cervix is pulled down and a transverse incision is made above the cervix as in anterior colporrhaphy and the bladder is pushed well up above the internal Os.

The cervix is then pulled forwards, towards the symphysis pubis, and a vertical incision is made in the posterior vaginal wall, again at and above the internal Os, going only through the vaginal wall. Through the right and left corner of the anterior incision an aneurysm needle is passed between the cervix and the vaginal wall till its eye comes out of the posterior incision. Linen attached to each end of the fascia pass through the eye of the aneurysm needle and pull the right end of the fascia retrovaginally forwards, into the anterior incision. Same thing was done from the left side. Two ends of the strip cross each other in the front of the cervix and tighten them so as to close the internal Os. Two ends are stitched together by a number of stitches which take a bite of the muscle fibres of the lowest part of the lower uterine segment using a small curved needle and fine linen. Extra portions of the fascia are cut out and the anterior and posterior incisions are closed with chromic catgut suture number 0.

Number of modification of Shirodkar's circlage procedure appeared further from various authors mainly avoiding the technical difficulty of the original operation. In this Literature we will study the foetal salvage in cervical incompetency by modified McDonald's method done at PDZH, R.N.T. Udaipur, which is simpler modification of McDonald's method by placing purse string suture taking only 2 bites in which 1st bite taken approximately through 4 to 2'O clock position and 2nd bite taken approximately through 10 to 8'O clock position on ectocervix as high as possible at the junction of the rugose vaginal epithelium and the smooth vaginal part of the cervix below the level of bladder.

Aims and Objectives

To evaluate the effectiveness of cervical cerclage by modified McDonald's method in form of better perinatal, foetal and maternal outcome in following cases:

- (a) Pregnant women with previous spontaneous preterm birth and previous 2nd trimester abortion
- (b) Previous early and late recurrent foetal loss
- (c) Pregnant women with short cervix or diameter of internal Os > 1 cm.

Materials and Methods

This is a prospective cohort study conducted on 100 ANC pregnant women with history of previous spontaneous preterm birth, previous 2nd trimester abortion, previous early and late recurrent foetal loss and women with short cervix in pregnancy at Pannadhay Zanana Hospital Udaipur.

Inclusion Criteria

- 1. Age 18 to 40 years
- 2. Gestation age between 14–28 weeks
- 3. History of one or more 2nd trimester abortion
- 4. History of previous one or more preterm
- 5. History of cervical cerclage in previous pregnancy
- 6. Women with cervical length ≤25 mm. or diameter of internal Os > 1 cm in transvaginal ultrasonography.

Exclusion criteria

If there are known case of

- 1. Aneuploidy of foetus
- 2. Congenital anomaly or syndromes or infection of foetus
- 3. Placenta previa
- 4. Abruptio placentae
- 5. Intrauterine foetal death
- 6. Severe oligohydraminos
- 7. Recent history of infection of cervix and vagina
- 8. Premature rupture of membrane, prolapsed membrane, chorioamnionitis, active Labor.

Intervention

Cervical circlage done by modified McDonald's method at gestation age range from 14–28 weeks. In this method cervical Cerclage was done by prolene No. 1 suture material and stitch taken by only 2 bites in which 1st bite was taken approximately through 4 to 2'O clock position and 2nd bite was taken approximately through 10 to 8'O clock position on ectocervix as high as possible at the junction of the rugose vaginal epithelium and the smooth vaginal part of the cervix below the level of bladder. It was knottied at posterior lip of cervix to prevent injury of bladder. Patient was kept in observation for one day. At the time of discharge

Capsule Micronized Progesterone 200 mg once a day till 34 weeks of gestation given and antibiotic prophylaxis by Tablet Cefixime 200 mg twice a day for five days was prescribed to the patient.

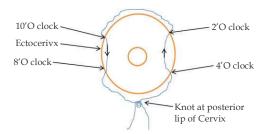


Fig. 3: Cervical Cerclage by Modified McDonald's Method.⁵

Patient advised to come to cut cerclage thread at 37–38 weeks of gestation age. If patient had preterm Labor than it should be cut earlier to prevent complication.

Counselling of patient done regarding alarming sign like pain abdomen, bleeding, dirty vaginal discharge, water leaking per vaginum.

Monthly follow-up was done for foetal and maternal assessment.

Regular maternal assessment

Examination

General Physical Examinations: Blood Pressure; Weight; Pallor; Breast Examination; Heart and lungs examination.

Obstetrical examinations

Per Abdomen: Detail history to rule out for any sign or symptoms of preterm Labor and premature rupture of membranes, infection of cervix and vagina and chorioamnionitis bleeding.

Biochemical assessment: Proteinuria, CBC, blood group, blood sugar

Outcome variable

A. Fetal

Gestation age at delivery

Preterm birth at <28, 28.1–34, 34.1–36.6, ≥37 week

Foetal weight at birth

B. Maternal

Mode of delivery

- (a) C-section (planned or emergency)
- (b) Vaginal delivery

(c) Instrumental delivery (forceps, vacuum) Postpartum events

Foetal assessment

- Monthly Per abdomen examination till 28 weeks of pregnancy than twice a month in 34 weeks of pregnancy and weekly in >34 weeks of pregnancy done.
- USG for foetal well-being and AFI, daily foetal movement count (DFMC)
- Injection betamethasone 12 mg im 2 doses 24 hours apart will administered to all pregnant women who have crossed 28 week of gestation to promote foetal lung maturity.

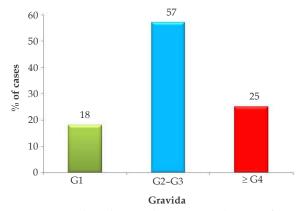
Results and Discussion

Out of 100 cases maximum no of cases were in 20–25 years of age group. Mean age was 25.94 ± 3.69 years which is comparable with study of Ezechi OC et al.¹⁷ which was 24.6 ± 4.4 years. Mean age is higher than my study in Amsavalli et al.,⁹ Jakkia Khan et al.⁸ and Zahra Fardi Azar et al.⁷ (Table 1).

Table 1: Age distribution of patients.

Age (years)	No of cases	Percentage
20-25	49	49
26-30	40	40
31-35	10	10
36-40	1	1
Total	100	100
Total	100	100

Majority (57%) of cases were 2^{nd} and 3^{rd} gravida. 25% cases were multigravida i.e. $\geq G4$. Mean gravida of cases 2.71 ± 1.27 which is comparable to study of Zahra Fardi Azar et al.⁷ i.e. 2.64 ± 1.45 . Mean gravid status is higher in Jakkia Khan et al.⁸ i.e. 5.33 ± 2.36 . (Graph 1).



Graph 1: Cervical Cerclage in relation to Gravida status of cases.

Mean gestation age at cerclage of my study is 18.1 ± 3.76 weeks which is comparable with Zahra Fardi Azar et al.⁷ i.e. 16.62 ± 3.22 weeks and slightly lower in study of Amsavalli et al.⁹ i.e. was 14.3 ± 0.06 weeks (Table 2).

Table 2: Gestational age at time of cervical cerclage.

Gestational Age (in weeks)	No. of cases	Percentage
14-16	46	46
17-20	33	33
21-24	15	15
25-28	6	6

In Jakkia Khan et al.⁸ study total abortion were 17.3%, placental abruption was in 4% cases and chorioamnionitis was in 1.3% cases. In VV Despande et al.¹⁰ abortion were 14% and 3% cases had knot slippage. Vidhyadhar B Bangal et al.¹¹ PPROM/Term PROM were 1.6%, abortion were 4%, uterine irritability was 5% cases, cervical dystocia in 2% cases 62 and chorioamnionitis was 1.6% cases. In Ayflekarahasanglu et al.¹² cases of PPROM/Term PROM were 10%, abortion were 9%, cervical tear 2% and chorioamnionitis was in 1% cases.

In this study cases of PPROM/TERM PROM were 8% which is comparable with Ayflekarahasanglu et al. 12 study. Cases of abortion were 7% which is comparable with Ayflekarahasanglu et al. 12 study and lower than Jakkia Khan et al. 8 and VV Despande et al. 10 study. In this study cervical dystocia was in 1% cases which is lower than Vidhyadhar B Bangal et al. 11 study. In this study cervical tear was in 1% cases which is lower than Ayflekarahasanglu et al. 12 study. In this study no cases of chorioamnionitis, placental abruption and knot slippage (Table 3).

Table 3: Indication of cervical cerclage.

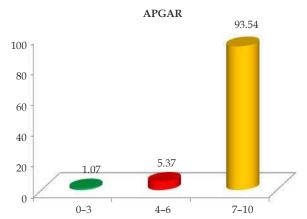
Indication	No. of cases	Percentage
Previous preterm birth or previous 2 nd trimester abortion	74	74
Short cervix	26	26

Jakkia Khan et al.⁸ showed good Apgar was 76%, in our study good Apgar was 94%, which is very high than comparative study (Graph 2). In my study 80% of cases delivered at term at i.e. ≥37 weeks of gestation. 13% cases delivered preterm and 7% cases had pregnancy loss as abortion (Table 4).

Table 4: Outcome of pregnancy by cervical cerclage.

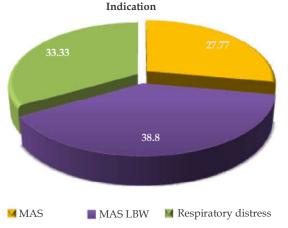
Outcome	No. of cases	Percentage
Abortion (≥20 week)	7	7
Preterm (20-36.6 week)	13	13
Term (≥ 37 week)	80	80

P-value = 0.0097



Graph 2: APGAR at birth (N = 93) (Excluding abortion).

In Michelle N. Han et al.¹³ NICU admission was 62.7% and in present study NICU admission is 20% which is much lower than comparative study showing good perinatal outcome (Graph 3).



Graph 3: Indication of NICU admission.

In Michelle N. Han et al.¹³ perinatal death was 1.6% and in present study perinatal death is nil. All new born survive in perinatal period (Table 5).

Table 5: Foetal morbidity and mortality.

Outcome	No. of cases	Percentage
Normal	90	90
Abortion	7	7
Death in perinatal period	3	3

In Vincenzo Bergella et al.¹⁴ neonatal death was 9% and in present study neonatal death is 7.69% which is comparable with comparative study (Table 6).

Table 6: Correlation of Gestation Age at Delivery with Gestation Age at Cervical Cerclage.

Gestation age at	Gestation age at delivery (weeks)			eeks)
Cerclage (week)	≤20	20.1-28	28.1-36.6	≥37
14-18	6	2	4	49
18.1-24.6	1	0	4	29
25-28	0	0	2	3
Total	7	2	10	81

In Vincenzo Bergella et al.¹⁴ total foetal salvage was 91% and in my study total foetal salvage in short cervix cases is 84.61% (Table 7).

Table 7: Pregnancy outcome in cases of short cervix.

Outcome	No. of cases	Percentage
Abortion	1	7.69
Preterm	3	23.07
Term	9	69.23
NICU admission	3	23.07
Neonatal death	1	7.69

Conclusion

Cervical cerclage is a simple procedure required little surgical expertise but has very good results. Its timely application in women with previous spontaneous preterm birth, previous 2nd trimester abortion and women with short cervices can be very effective in preventing preterm Labor and prolonging the gestation and greater birth weight, thereby improving neonatal survival and reducing the neonatal morbidity associated with prematurity.

Advantage of our method over McDonald's method is that it is simpler procedure having less stitches on cervix so that less chances of haemorrhage, at the time of surgery or postsurgery. Round body prolene suture does less trauma to cervix and less chances of infection to genital tract in comparison to braided silk suture. Preoperative preparation is require to make Braided silk suture which is not require with prolene suture. No cases of chorioamnionitis, placental abruption and knot slippage was not seen in my study, which were reported in studies which is done by McDonald's method of cerclage. Posterior knot give advantage to prevent injury to bladder, less irritation to bladder, preventing urinary tract infection.

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