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Original Research Article

An audit of the contemporaneous practice of cervical cerclage in a tertiary care hospital in Mumbai

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ABSTRACT

Background: Cervical incompetence refers to the inability of the cervix to support a full-term pregnancy due to functional or structural defect of the cervix.

Methods: Prospective observational study conducted at a tertiary hospital of all consecutive patients who underwent cerclage during 18 months period. The pregnant women were followed-up through their antenatal and immediate postnatal period and perinatal outcomes were assessed.

Results: Of the total 60 patients in the study, 25 patients continued till full term (41.6%). 27 patients (45%) delivered preterm and 8 (13.3%) aborted after cerclage. 40% had conceived with assisted reproductive techniques, 41.6% were primigravida and 35% had history of previous cervical incompetence. 35% patients had multifetal gestations. Mean gestational age at cerclage was 17.4±3.6 weeks. Mean cervical length was 2.8±0.79 cm. Most common reason for opting cerclage was ultrasound indicated. 96% underwent Macdonald's cerclage. The difference in outcomes with use of either Polyester fibre tape and black braided silk was not statistically significant. Ultrasonographic surveillance of cervical length post-cerclage placement did not impact clinical practice. 81% babies went home alive, mean birth weight was 2027±828 gram, 51% required NICU admission. Incompetence related preterm deliveries happened in 46.6% patients in spite of a cerclage. The mean gestational age at delivery in singleton was 34.4±4.6 weeks, while it was much less (30.5±6.5 weeks) in multifetal pregnancies

Conclusions: Cervical cerclage improves pregnancy outcome in carefully selected patients. Outcomes following cerclage could be unfruitful in few, while others may have a complicated antenatal period.

Keywords: Cerclage, Cervical incompetence, Cervix, Preterm

INTRODUCTION

Cervical incompetence refers to the inability of the cervix to support a full-term pregnancy due to functional or structural defect of the cervix. Mechanical support of the cervix by placement of stitch around the perimeter of the cervix (cerclage) has been used as a treatment modality for more than 65 years, when it was first described by Shirodkar and subsequently modified by McDonald.^{1,2}

The vast variations in international guidelines regarding the practice of cervical cerclage in the management of cervical insufficiency reflect the heterogeneity of the literature contributing to these guidelines. There is varied consensus in all the guidelines on the diagnosis of cervical insufficiency, the indications for cerclage and benefits versus risk, optimal cerclage technique and timing of suture placement.

Cerclage continues to remain a commonly performed prophylactic intervention used by most obstetricians as per their own experience despite the absence of a well-defined population for whom there is clear evidence of benefit. Although there are significant benefits of an indicated cerclage, the procedure is not without known complications. Hence, we sought to audit our own practice of the use of cerclage in a teaching tertiary care hospital.

Aims and objectives

Our primary objective was to audit the practice of cerclage by various obstetricians in our tertiary care teaching institute.

METHODS

In this prospective observational study done at Nowrosjee Wadia Maternity Hospital, a tertiary care hospital in Mumbai, we evaluated 60 consecutive patients who underwent cervical cerclage and delivered and consented to be part of the study between March 2019-August 2020. The study was conducted after due approval from the institutional ethics committee. The patients were evaluated on their baseline parameters, the past obstetric history, method of conception, ultrasound findings prior to cerclage and the cervical length, indications for the cerclage, timing of suture placement, suture material used, technique of cerclage, perioperative considerations, complications due to or associated with the cerclage, medications used including use of progesterone, tocolysis, bed rest and pregnancy and immediate neonatal outcomes till discharge. The decision to perform the cerclage, method of performing the cerclage, management of the pregnancy and the medications administered were left to the discretion of the operating clinician.

RESULTS

A total of 60 patients were included in the study, of which 25 (41.6%) patients continued till full term (>37 completed weeks of gestation). 27 (45%) patients delivered preterm (PT) and 8 (13.3%) patients aborted subsequently after cerclage. 42 of 60 (70%) delivered beyond 34 weeks where the neonatal morbidity is expected to be low. 49 pregnancies (81.6%) resulted in a take-home baby.

For the purposes of this study, we have considered patients who aborted subsequent to a cerclage and who delivered due to cervical incompetence-related factors namely premature prelabour rupture of membranes (PPROM) or spontaneous preterm labour as “cervical incompetence-related” and patients who delivered at term or have delivered PT due to factors unrelated to cervical incompetence (such as impending eclampsia or fetal doppler changes) as “cervical incompetence-unrelated”.

Of the 35 patients who delivered before term, incompetence related PT deliveries or abortion happened in 28/60 (46.6%) study group patients in spite of a cerclage.

Demographic characteristics

The mean age of patients at the time of cerclage was 31.88 ± 5.65 years (21-49 years). There was no significant difference between baseline parameters of the patients who had cervical incompetence-related pregnancy outcome vis-à-vis those with incompetence-unrelated pregnancy outcome with regards to gestational age at cerclage and cervical length pre-cerclage (Student t-test, unpaired) (Table 1).

Table 1: Gestational age at cerclage, cervical length pre-cerclage and outcomes.

Parameters	All patients		Cervical incompetence-related outcome		Cervical incompetence unrelated outcome		P value
	Mean	Std. dev.	Mean	Std. dev.	Mean	Std. dev.	
Age in years	31.88	5.65	31.82	6.15	31.93	5.26	0.94
Gestational age at cerclage in weeks	17.4	4.6	16.3	5.2	18.5	4.0	0.06
Cervical length pre-cerclage in cm	2.89	0.79	2.87	0.94	2.96	0.72	0.66

Of the 60 patients included in the study, 25 (41.6%) were primigravida. 21 of the 35 multigravidas (35%) had a past history that could predispose to possibility of cervical incompetence in present pregnancy:

Previous mid-trimester abortion (n-9), previous PT birth before 35 weeks (n-10), previous PPRM before 35 weeks); and/or a cervical cerclage in a previous pregnancy (n-9); three or more dilations and evacuations for first trimester abortion (n-1).

There was no significant difference post-cerclage in the rates of cervical incompetence-related events in patients with history of preterm birth (9/21, 42%) versus the patients with no such history (19/39, 48.7%) (Chi square test, $p=0.66$; >0.05).

Of the 21 patients with a past history of cervical incompetence-related event, 10 had additional ultrasound findings of a short cervix with or without funnelling. There was no statistical difference in the outcome between those with history alone or additional cervical changes. Only

44% (4/9) of those with history of one (n-6), two (n-2) or three (n-1) cerclage in at least one previous pregnancy delivered at term. 2 had a preterm delivery and survived while 3 (33%) aborted.

Method of conception

36 patients in our study had a spontaneous conception (60%), whereas 24 (40%) patients had conceived with various assisted reproductive techniques (ART) including IVF (28%), IUI (10%) and ovulation induction (2%) (Figure 1).

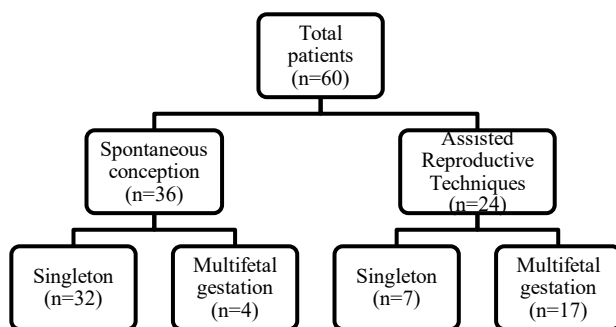


Figure 1: Mode of conception and distribution of singleton and multifetal gestation.

16 of the 36 (44.4%) spontaneously conceived pregnancies continued till term and 29/36 (80%) resulted in a take-home baby. Of the patients who conceived with ART, significant number (17/24) had multifetal gestations. 9 (37.5%) patients continued till term and 20/24 (83%) resulted in a take-home baby.

Outcomes with singleton and multifetal gestation

Of the 39 patients with a singleton pregnancy, 20 delivered at term (51%), with a take-home baby in 34 instances (87%). Of the 19 patients with a PT delivery, 14 delivered due to cervical incompetence-related causes.

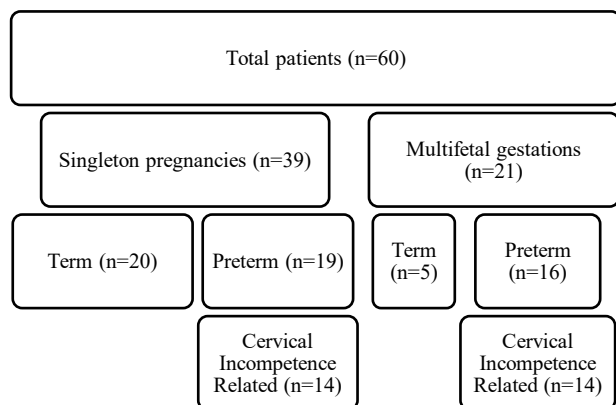


Figure 2: Outcomes in patients with singleton and multifetal gestation.

Of the 21 patients with multiple gestations of which 3 were triplets, 5 delivered at term (23%), with a take-home baby in 15 (71%) patients. Of the 16 patients who delivered PT, 14 delivered due to cervical incompetence-related causes (Figure 2). There was a significant difference in cervical incompetence-related pregnancy outcomes in multifetal gestations as compared to singleton pregnancies (Chi square test, $p=0.02$; <0.05).

Timing and cervical length at cerclage

The mean gestational age of the patients who underwent cerclage was 17.4 ± 3.6 weeks. 70% of cerclages were done between 15 to 24 weeks (42/60) whereas another 14 (23%) underwent early cerclage at 10-14 weeks. Of the 4 patients with a rescue cerclage beyond 24 weeks for an open internal os, 3 continued till term with all 4 babies surviving.

Table 2: Cervical Length at time of cerclage.

Cervical length	Frequency	Percentage
0.5-1.5	3	5
1.6-2.5	15	25
2.6-3.5	32	53.33
3.6-4.5	9	15
4.6-5.5	1	1.66
Total	60	100
Cervical length	Frequency	
<2.5 cm	18	Singleton (14) Multiple (4)
>2.5 cm	42	Singleton (25) Multiple (17)

The mean cervical length of the patients undergoing cerclage was 2.88 ± 0.79 cm. 70% (n=42) of cerclages were done in patients with cervical length more than 2.5 cm of which 25 were singleton pregnancy and 17 were twins (Table 2).

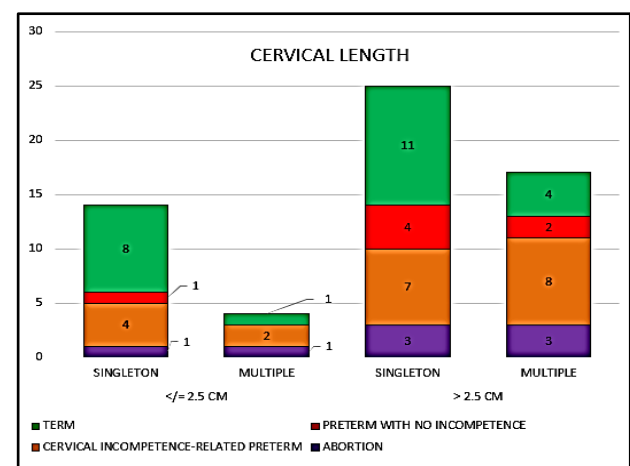


Figure 3: Cervical length and outcomes in singleton and multiple pregnancy.

Out of the 18 patients with cervical length less than 2.5 cm, 9 patients delivered at term (50%). Even among the 42 patients with cervical length greater than 2.5 cm, 21 patients (50%) had a cervical incompetence-related pregnancy outcome (Figure 3).

17 patients in our series had funnelling of the cervix. On comparing the patients with funnelling and those without, there was more incompetence related deliveries in the funnelling group (9/17, 52%) versus non funnelled group (19/43, 44%). However, the difference was not statistically significant (Chi square, $p=0.54$; >0.05).

Indications of cervical cerclage were grouped into following types: history-indicated cerclage (n=11); ultrasound-indicated cerclage, defined as cervical length of <2.5 cm, with or without funnelling of the cervix (n=18); history + ultrasound-indicated (n=10); cerclage for Mullerian abnormality (n=6); cerclage at clinician's discretion, whereby the treating clinician decided to perform a cerclage in absence of any of the above indications (n=15).

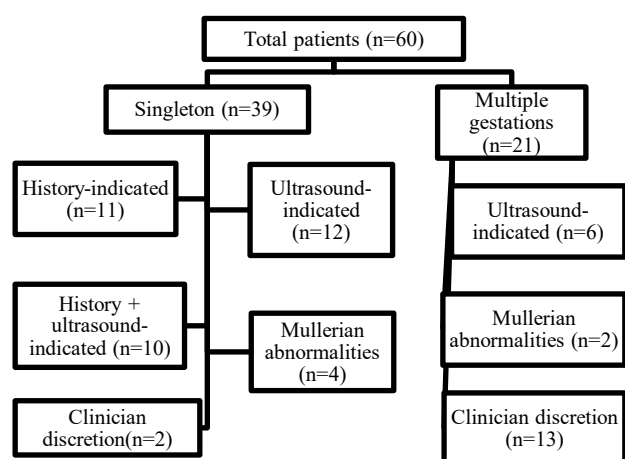


Figure 4: Indication for cerclage.

Significant number of cerclage in multiple pregnancy were done on clinician discretion without a sound indication for cerclage (n=13/21, 62%) (Figure 4). Of the 24 patients with ART conceptions, 12 (50%) underwent cerclage at clinician's discretion. On the other hand, among the 36 patients with spontaneous conceptions, only 3 (8.33%) underwent cerclage at clinician's discretion and all were multifetal gestations.

Technique of cerclage

The preferred method of cerclage was McDonald's technique (96%) in 58 of 60 patients. Shirodkar's cerclage was performed in one patient with a singleton pregnancy with previous two preterm deliveries and one failed McDonald cerclage. The patient subsequently delivered at term. The only abdominal cerclage was performed due to previous three failed McDonald cerclages which ended in previable hysterotomy.

Polyester fibre tape was the preferred material for cerclage in 32 patients, followed by 21 using black braided silk, 5 patients nylon and 2 used linen as the suture material. Comparing the two most used suture materials, the difference in the cervical incompetence-related pregnancy outcomes was not statistically significant (Chi square, $p=0.16$; >0.05).

All the patients received progesterone in some form till 34 weeks or till delivery, whichever was earlier. Tocolysis was also prescribed to all patients (52 patients for short term up to 5 days, 8 for a longer duration).

Outcomes with/without complete bed rest

34 patients (56%) were advised complete bed rest post cerclage whereas the rest were allowed ambulation and avoiding heavy work after 5 days of cerclage. Among the singleton pregnancies, 21 (64%) were advised complete bed rest, whereas 13 (61%) patients with multifetal pregnancies were advised complete bed rest.

Comparing the two groups, the patients in complete bed rest group had slightly higher incidence of cervical incompetence-related delivery outcomes (19/34, 55%) as compared to the patients who were not advised complete bed rest (9/26, 34%). However, this difference is not statistically significant (Chi square test, $p=0.1$; >0.05).

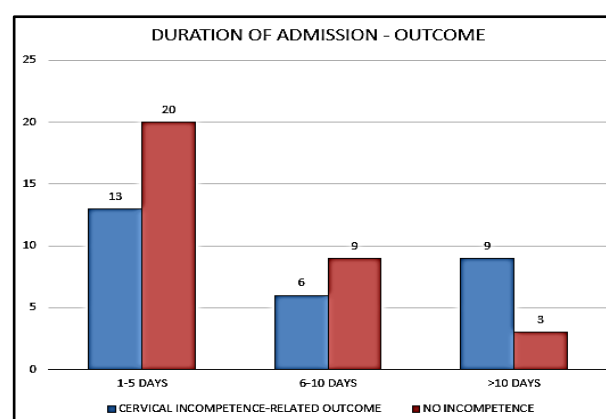


Figure 5: Duration of hospital stay and outcomes.

48 of 60 patients (80%) were discharged post procedure within one to ten days of which 40% had cervical incompetence-related delivery outcome. Among the 12 patients who were kept admitted for a duration of more than 10 days, 9 patients (75%) had a cervical incompetence-related delivery outcome. Contrary results than expected may be due to the fact that these patients on prolonged hospital stay were at significant risk for incompetence (Figure 5).

Cervical length assessment post procedure

The cervical lengths were measured 15 days post-cerclage by an independent assessor who was blinded to the study.

The mean post-cerclage cervical length was similar in patients with cervical incompetence-related pregnancy outcome (2.69 ± 0.77 cm) and patients with no incompetence (2.76 ± 0.70 cm).

The mean difference in the pre- and post-cerclage cervical length in patients with cervical incompetence-related outcome was 0.18 ± 0.47 cm, whereas that in patients without cervical incompetence related outcome was 0.2 ± 0.41 cm. There was no significant difference between the two groups with respect to the post cerclage cervical length or the difference in cervical lengths (Student t-test).

Pregnancy outcome

The mean gestational age at delivery was 33.3 ± 5.5 weeks. 25 of 60 patients had a term delivery (42%). 42 of 60 (70%) had a late preterm or term birth (Figure 6).

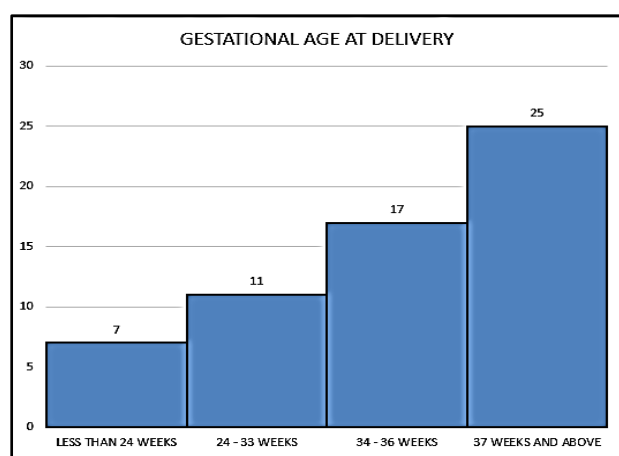


Figure 6: Gestational age at delivery.

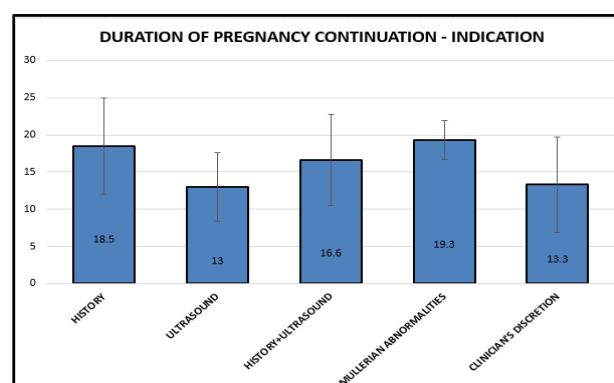


Figure 7: Duration of pregnancy continuation as per indications.

Patients with cervical incompetence-related outcomes had a mean gestational age of 29.5 ± 6.2 weeks while patients with cervical incompetence-unrelated outcomes had a mean gestational age of 36.4 ± 2.6 weeks at delivery. In singleton pregnancies, the mean gestational age at delivery was 34.4 ± 4.6 weeks, whereas it was 30.5 ± 6.5 weeks in multifetal pregnancies.

With respect to the method of conception, the mean gestational age at delivery was 33.4 ± 5.5 weeks for patients who conceived spontaneously, whereas it was 32.5 ± 5.6 weeks for the patients conceived using ART.

The mean duration of pregnancy continuation post-cerclage was 15.5 ± 6.1 weeks. 12 patients had a pregnancy continuation between 1 to 10 weeks post cerclage, 33 patients had between 11 to 20 weeks and 15 patients, the pregnancy continued between 21 to 30 weeks. The durations of pregnancy continuation depending on the indications for cerclage (Figure 7) were not statistically significant.

With respect to the order of pregnancy, the mean duration of pregnancy continuation was 16.4 ± 5.5 weeks in singletons as compared to 13.4 ± 6.4 weeks in multiple pregnancies. There is a significant difference in cervical incompetence-related pregnancy outcomes in multifetal gestations as compared to singleton pregnancies. (Chi square test, $p=0.02$; <0.05). In singleton pregnancies, the mean gestational age at delivery was 34.4 ± 4.6 weeks, whereas it was 30.5 ± 6.5 weeks in multifetal pregnancies.

The mean duration of pregnancy continuation post cerclage in patients who conceived spontaneously was 15.6 ± 6.1 weeks which was similar to patients who conceived post ART (15.2 ± 6.2).

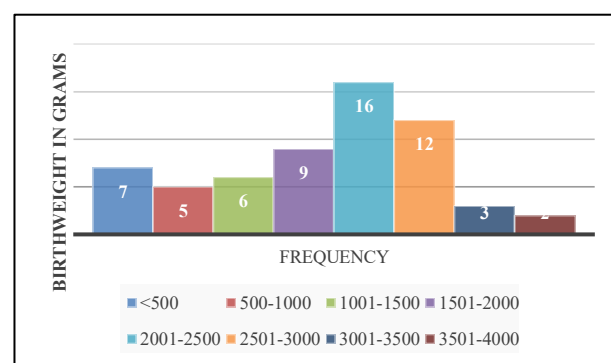


Figure 8: Birth weight of all fetuses.

More than 75% were delivered by caesarean section, mean birth weight was 2027 ± 828 gram (range from 300-3600 grams) (Figure 8).

In all, there were 11 pregnancy losses, 8 of which resulted in abortions. 3 babies born between 24 and 27 weeks succumbed due to extreme prematurity. The remaining 49 pregnancies (81.6%) resulted in a take-home baby. 51% requiring NICU admission.

DISCUSSION

Global preterm births have increased from 9.8% to 10.6% between 2000 and 2014, accounting for almost 15 million live preterm babies.^{3,4} Cervical shortening, one of the common pathways to preterm births, is defined as less than

25 mm and is quantified by transvaginal sonographic (TVS) examination.⁵ This cut-off has been associated with an increased risk of preterm birth in a variety of screened populations.⁶⁻⁸ We have in our study used this cut off for short cervical length by TVS.

Cerclage remains one of the standard options for prophylactic intervention in the care of women at risk of preterm birth and second trimester fetal loss and is used by most obstetricians, despite difficulties in identifying the population of women who would most benefit. There is a lack of consensus on the optimal cerclage technique, suture used, timing of suture placement and optimal care following insertion. Complications are not well documented and often difficult to separate from risks inherent to the underlying condition.^{5,6,9-11} In our study, the decision to perform cerclage and the subsequent management were based on an intention-to-treat depending upon various factors in the patient's obstetric history and incumbent pregnancy.

Of the 60 patients in our study who underwent cerclage, incompetence related preterm deliveries or abortion happened in 28/60 (46.6%) study group patients in spite of a cerclage.

Both the ACOG and the RCOG recommend cerclage should be performed in patients with three or more previous PT births.^{12,13} However, even a single event of PT birth or a mid-trimester abortion has the potential to cause stress and depressive symptoms which is an independent risk factor for subsequent PT births.^{14,15} Hence, we have considered cerclage in patients with even a single cervical incompetence-related adverse pregnancy outcome as a history indicated cerclage. In our study the durations of pregnancy continuation after cerclage in patients with history of incompetence even in one pregnancy or history along with ultrasound finding was 17.6 ± 5.5 weeks.

Previous terminology (prophylactic, emergency, urgent, rescue) of cervical cerclage can be ambiguous. The RCOG describes nomenclature based on the indications for cerclage as history-indicated, ultrasound-indicated and rescue cerclage, while the ACOG specifies elective cerclage (for previous 3 or more losses) and therapeutic cerclage (for cervical shortening and emergency cerclage). In our study, the indications of cerclage were history-indicated, ultrasound-indicated, history + ultrasound-indicated, Mullerian abnormalities and cerclage at Clinician's discretion. The inclusion of the latter two indications was made as a significant number of patients underwent cerclage solely for these two indications. It is well known that Mullerian abnormalities are a cause for preterm birth.¹⁶ However the guidelines do not recommend routine cerclage for mullerian anomalies.^{12,13}

Pregnancies, both singleton and multifetal, conceived with ART have a higher incidence of preterm birth as compared to spontaneous conceptions.^{17,18} Cervical cerclage has been used in clinical practice in an effort to prevent

preterm birth in twin pregnancy contrary to the evidence in many randomized clinical trials that there is no evidence of benefit for prophylactic cerclage in unselected twin pregnancies. In our study there is a statistically higher incidence of cervical incompetence-related pregnancy outcomes in multifetal gestations as compared to singleton pregnancies in spite of a cerclage in both (Chi square test, $p=0.02$; <0.05).

Method of conception also has a bearing on pregnancy outcomes after cerclage majorly due to the higher incidence of multiple pregnancies in the ART conceived pregnancies. 24 patients who conceived with ART (7 singleton pregnancies and 17 had multifetal gestations), only 9 (37.5%) patients continued till term in spite of a cerclage. Of the 21 patients with multiple gestations, only 5 delivered at term (23%), with a take-home baby in 15 (71%) patients.

The choice of cerclage techniques in our study was McDonald in 58 of our 60 patients probably because it is an easier technique with minimal dissection and manipulation. There is no data to indicate superiority of one technique over the other.

Emergency cerclage as a salvage measure in the case of premature cervical dilatation up to 27+6 weeks gestation may benefit in appropriately selected patients as suggested by ACOG, RCOG and NICE guidelines.^{9,12,13} However it needs to be explained to the patient that it aims to delay the birth, and so increase the likelihood of the baby surviving and of reducing serious neonatal morbidity but the risks of the procedure including cervical laceration, intraoperative rupture of membranes, and sepsis and potential of extreme prematurity needs to be addressed. In our subset of patient there were 4 such patients all of which survived. Hence there is potential of placing cerclage in already dilated cervix at advanced gestation.

The choice of suture material as per the NICE guideline may be left on the discretion of the surgeon.⁹ In our cases the two most used suture materials were polyester fibre tape (32, 53%) and black braided silk (21, 35%), the difference in the cervical incompetence-related pregnancy outcomes was not statistically significant. (Chi square, $p=0.16$; >0.05).

In our group of patients all received progesterone, tocolytics, antibiotics and bed rest in the perioperative time although current NICE guidelines, ACOG and RCOG guidelines do not advise the above following cervical cerclage.^{9,13,14} Most clinicians are comfortable using progesterone as it is a known immunological modulator and promotes uterine quiescence.¹⁹

Certain nonsurgical approaches, including activity restriction and bed rest have not been proven to be effective for the treatment of cervical insufficiency and their use is discouraged.^{9,12,13} However bed rest or at least restricted activity has been used frequently by most

clinicians in our study. The patients in the complete bed rest group had a slightly higher incidence of cervical incompetence-related delivery outcomes as compared to the patients who were not advised complete bed rest. This contrary result may be due to the fact that the patients who had a past history of a cervical incompetence-related event and a short cervix on ultrasound were more likely to be advised complete bed rest than the ones offered cerclage on clinicians discretion where probably cerclage was not indicated.

There is a lack of evidence regarding ultrasonographic surveillance of cervical length after cerclage placement. In our subset of patients the mean post-cerclage cervical length was similar in both groups. Hence this practice of assessing cervical length post cerclage cannot be recommended.

The mean duration of pregnancy continuation post-cerclage was 15.5 ± 6.1 weeks. The duration of pregnancy continuation post cerclage depending on the indications for cerclage or the mode of conception was not statistically significant. However, the mean duration of pregnancy continuation was more in singleton as compared to multifetal pregnancies (16.4 ± 5.5 weeks versus 13.4 ± 6.4 weeks) suggesting that cerclage may be less effective in multiple pregnancy.

49/60 (81.6%) patients had a take-home baby. This is due in part to the prolongation of the pregnancy by 11 to 30 weeks as well as improved neonatal outcomes in preterm deliveries due to improved healthcare.

The present study was conducted with a relatively small sample size and hence warrants a need for study with a substantially larger sample size.

CONCLUSION

Cervical cerclage improves the pregnancy outcome in carefully selected patients. 42 of 60 (70%) delivered beyond 34 weeks and 49 pregnancies (81.6%) resulted in a take-home baby. The choice of cerclage technique and suture material should be left to the operating surgeon and may be individualized. Ultrasonographic surveillance of cervical length after cerclage placement does not impact clinical practice.

Effectiveness of the cerclage and incompetence-related pregnancy outcome is not impacted by history of preterm birth versus no such history, indications for cerclage or the mode of conception, gestational age at cerclage, cervical length pre-cerclage or presence of funnelling.

Cerclage may not be as effective in multiple pregnancy as compared to singleton. Cervical incompetence-related pregnancy outcomes were higher in multifetal gestations as compared to singleton pregnancies in spite of a cerclage in both.

Mean gestational age at delivery was 34.4 ± 4.6 weeks in singleton pregnancies; whereas, it was 30.5 ± 6.5 weeks in multifetal pregnancies. The mean duration of pregnancy continuation was more in singleton as compared to multifetal pregnancies (16.4 ± 5.5 weeks versus 13.4 ± 6.4 weeks).

There is potential of placing cerclage in already dilated cervix at advanced gestation beyond 24 weeks. Maternal and operative complications including cervical laceration, intraoperative rupture of membranes, and sepsis need to be explained prior to procedure.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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