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Original Research Article

A retrospective cohort study on the outcome of cervical cerclage in patients with recurrent pregnancy loss

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ABSTRACT

Background: This study aimed to evaluate pregnancy outcomes after cervical cerclage in patient with recurrent pregnancy loss (RPL). Objectives were to estimate the incidence of cervical cerclage done among patients with history of RPL attending Royal hospital over the last 10 years (2013-2022). And to assess the effectiveness of cervical cerclage done among patient with RPL.

Methods: Retrospective cohort study was conducted. The study was carried out from January 1, 2013, to December 31, 2022, at Royal hospital. All booked pregnant women with history of RPL who had cervical cerclage attending antenatal clinic at Royal hospital during the study period were included in the study. A set of prespecified risk factors (internationally well-known risk factors for cervical incompetence) was identified. Patients were grouped according to the presence or absence of risk factors for cervical incompetence. Both groups were followed up till end of pregnancy.

Results: The overall incidence of cervical cerclage done among patient with RPL was 4.5%. Patient with history of RPL and with nil risk factors for cervical incompetence who had cervical cerclage were 11 patients (10.3%) in compared to other group which were 96 patients (89.7%). History of second trimester miscarriage being the most common risk factor for cervical incompetence (72%), and the least common risk factors were fibroid uterus (2.8%), uterine anomalies (2.8%), PCOS (2.8%) in the study. The rate of live birth after cervical cerclage insertion (elective or rescue) in patients with history of RPL in total was 92.5%. The percentage of neonatal morbidity and mortality was 28.6%. Patients with bulging membranes at the time of cervical cerclage insertion who had live birth were 80% (40% term birth, 40% preterm birth) ($p=0.197$). Patients with funneling cervix at the time of cervical cerclage insertion who had live birth were 93.8% (68.8% term birth, 25% preterm birth) ($p=0.589$).

Conclusions: Elective cervical cerclage is recommended in patient with history suggestive of cervical incompetence. As rescue cervical cerclage helped in prolongation of pregnancy till term or late preterm in most of the cases, so cervical assessment is recommended in patients with RPL. Adding progesterone did not show any significant benefit in compared to other group without progesterone, but in view of small sample size further prospective study should be conducted with larger sample size. Screen for genitourinary infections is recommended and to treat accordingly.

Keywords: Recurrent pregnancy loss, Cervical cerclage, Pregnancy outcomes, Retrospective study, Polycystic ovarian syndrome

INTRODUCTION

A pregnancy loss (miscarriage) is defined as the spontaneous demise of a pregnancy before the fetus

reaches viability. The term therefore includes all pregnancy losses from the time of conception until twenty-four weeks of gestation.¹ With the advance of neonatal care even for small babies, therefore the gestational age at

which the neonate can survive differs from one country to others. Miscarriage in general can be divided into early (first trimester) loss or late (second trimester or mid trimester) loss. An early miscarriage is the one when it happens in the first twelve weeks of gestation, whereas a late miscarriage happens after thirteen weeks till viability.³

“RPL is defined as the loss of two or more pregnancies”, not necessary to be consecutive. A pregnancy is diagnosed by urine or serum beta-human chorionic gonadotropin (B-HCG), including those non-visualized pregnancies, i. e., biochemical pregnancy and pregnancy of unknown location (PUL).¹ RPL can be divided into two categories: primary and secondary. Primary RPL describes pregnancy loss in women who have never experienced a live birth, while secondary RPL refers to pregnancy loss in women who have had at least one prior live birth.² Experiencing RPL can profoundly affect the emotional well-being of women and their partners.

The etiology of RPL is generally classified into genetic, anatomic, endocrine, antiphospholipid syndrome (APS), immunological and environmental factors. Aneuploidy (a condition in which there is extra or missing one whole chromosome in some cells or whole-body cells) is the most common genetic cause of RPL. Multiple congenital and acquired uterine abnormalities can risk the women for RPL.⁵ The most common congenital Mullerian duct anomalies are septate uterus. Other acquired uterine abnormalities that can lead to RPL are submucosal myoma, endometrial polyp and Asherman syndrome. Uncontrolled maternal endocrine disorders i. e., diabetes and thyroid dysfunction, can results in RPL. Antiphospholipid syndrome is a multisystemic autoimmune disorder. And the key feature of APS is the presence of antiphospholipid antibodies (APLS) that result in arterial or venous thrombosis and pregnancy loss.⁶ Other immunological factors i. e., inherited thrombophilia can also result in RPL. Cigarette smoking, obesity, alcohol consumption, cocaine use, and increased caffeine consumption (more than three cups of coffee per day) are environmental factors that increase women’s risk for RPL.

Cervical incompetence is one of the most common structural cause for RPL if left untreated. Cervical incompetence is a condition in which the cervix cannot hold the pregnancy till term. Patient usually presents with spontaneous painless cervical dilatation in the second or third trimester.⁷ The etiology of cervical incompetence can be classified into congenital or acquired causes. Congenital causes are uncommon and include Müllerian duct anomalies, conditions associated with abnormal or deficient collagen production such as Ehlers-Danlos syndrome, and in utero exposure to diethylstilbestrol (DES). Whereas, acquired causes are common and include cervical trauma during childbirth especially if instrumental delivery or precipitate labor, cervical conization, loop electrosurgical excision procedures (LEEP), or any other surgical procedure requiring mechanical cervical dilation, including dilation and curettage or hysteroscopy.^{7,8}

Cervical incompetence diagnosis can be done based on history, ultrasound, or clinical presentation of the patient (exam-based diagnosis). Patients with history based diagnosis cervical incompetence are those with a clinical history consistent with cervical incompetence, which includes a history of at least one to three consecutive second-trimester losses or early preterm births and patients with a history of a prior exam-indicated cerclage. Whereas ultrasound-based diagnosis includes patients with a history of at least 1 preterm birth or second-trimester loss AND a shortened cervical length before 24 weeks in the current pregnancy. Finally, exam-based diagnosis, includes patients present with painless dilation in the second or early third trimester in the absence of contractions or other clear pathologies such as bleeding, PPRM, infection, or placental abruption.⁷ Patients with multiple gestation, uterine anomalies or obese women.¹²

Cervical incompetence can be managed with progesterone support, cervical cerclage or both together.¹⁰ Cervical cerclage is a minor surgical procedure done to maintain the structural integrity of the cervix to prolong gestation and improve obstetrical outcomes.¹¹ Cervical cerclage can be done via vaginal or abdominal approaches. The most common used technique is known as McDonald cervical cerclage, it is done via vaginal approach. Cervical cerclage can be done as elective procedure or in emergency sitting when the patient presents with painless cervical dilatation, this type of cerclage is known as rescue cerclage. Cervical McDonald cervical cerclage is removed at thirty-six to thirty-seven weeks of gestation to allow for vaginal delivery or can be removed at the time of cesarean section. Complications of cervical cerclage include infection or sepsis, inadvertent rupture of membranes, lacerations at the surgical site, bladder injury and anesthesia-related complications.^{11,12}

RPL will not only affects the couples psychologically, but other complications of prematurity may be encountered if baby born in late second trimester or early third trimester. These complications include prolonged neonatal intensive care unit (NICU) admission, respiratory distress syndrome (RDS), chronic lung disease (CLD), necrotizing enterocolitis (NEC), retinopathy of prematurity (ROP) and anemia of prematurity. As the gestational age decreases at the time of delivery the more severe the complications are and might end up with neonatal mortality. Neonatal mortality is defined as neonatal death from the time of birth till 28 days of live.¹³⁻¹⁵

There is no national or international study conducted to evaluate the pregnancy outcome after cervical cerclage specifically in patients with RPL. Conducting such study will help in formulating evidence based local guidelines/ protocols in managing patient with RPL, thus preventing further pregnancy losses, preterm birth, neonatal prematurity complications.

This study aimed to estimate the incidence of cervical cerclage done among patients with history of RPL

attending Royal hospital over the last 10 years (2013-2022). And to assess the effectiveness of cervical cerclage done among patient with RPL.

METHODS

Study design

Retrospective cohort study. The study was carried out from January 1, 2013, to December 31, 2022, at Royal hospital.

Inclusion and exclusion criteria

All booked pregnant women with history of RPL who had cervical cerclage attending antenatal clinic at Royal hospital during the study period were included in the study. Patients with missing data or who delivered outside royal hospital were excluded from the study. Patient with history of previous cervical cerclage insertion were also excluded from the study.

Sampling

A set of prespecified risk factors (internationally well-known risk factors for cervical incompetence) was identified. These risk factors are second trimester miscarriage, preterm birth, fibroid uterus, PCOS, uterine anomaly, urogenital infections, obesity (BMI more than thirty-five), multiple gestation and previous cervical procedures/ tears. Patients were grouped according to the presence or absence of risk factors for cervical incompetence. Hundred and seven patients were included in the study, all patient with history of RPL and had cervical cerclage, among them ninety-six patients with one or more prespecified risk factors and eleven patients without any of the prespecified risk factors. Both groups were followed up till the end of pregnancy.

Data collection

Data was collected using Al- Shifaa Health Records.

Ethical considerations

Study was approved by scientific research committee (SRC) at Royal hospital in 2023.

Statistical analysis

Collected data was analyzed using IBM SPSS Statistics 29.0. incidence was presented in percentage with 95% confidence interval. For the descriptive purposes, continuous variables were presented with mean and standard deviation or median with interquartile. Categorical variables were presented using frequency and percentages. Categorical factors were compared with cerclage status using chi-square test and continuous variables were compared using independent 't'

test or Mann-Whitney test. The $p < 0.05$ was considered as statistical significance.

RESULTS

Total number of patients included in the study were 107 patients, all these patients had history if RPL and they underwent cervical cerclage insertion. 96 patients account for 89.7%, had one or more of the prespecified risk factors. Whereas 11 patients account for 10.3%, who had no risk factors for cervical incompetence. As shown in Figure 1. The incidence of cervical cerclage among patients with history of RPL was 4.5%.

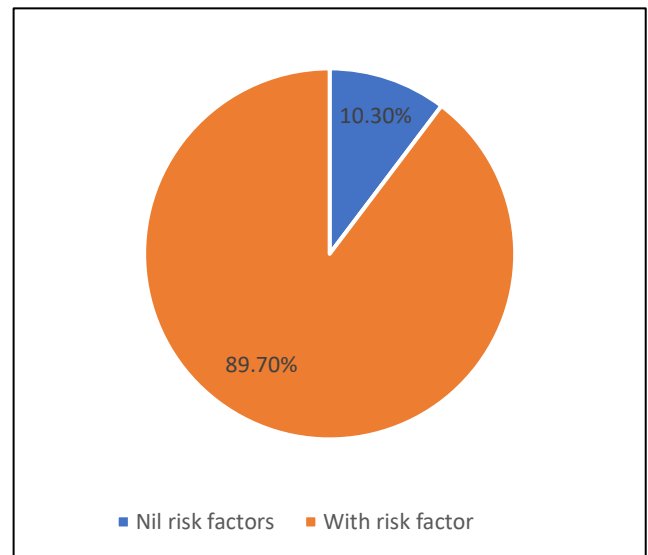


Figure 1: Total number of patients included in the study. This figure showed the percentage of patients in each group.

The study cohort was stratified by maternal age to evaluate baseline characteristics, gestational age at first prenatal visit, pregnancy outcomes, and prevalent comorbidities shown in Table 1. The largest proportion of patients were aged 30-34 years (n=25), followed by 35-39 years (n=20), 25-29 years (n=15), ≥ 40 years (n=10), and < 25 years (n=5). Majority of patients presented for antenatal care during first trimester (5-12 weeks), with subset presenting in late 1st to 2nd trimester (up to 26 weeks). Term deliveries predominated across all age groups, although preterm births were more frequently observed in the advanced maternal age cohort. Common comorbid conditions included hypothyroidism, gestational diabetes mellitus (GDM), obesity, type 2 diabetes mellitus (T2DM), hypertension (HTN), and antiphospholipid syndrome (APLS), with younger patients generally demonstrating fewer medical complications. These data highlight influence of maternal age on pregnancy outcomes and prevalence of associated medical conditions.

Among 107 patients, 77 patients (72%) had history of second trimester loss and 30 patients (28%) with no prior history if second trimester loss. 25 patients (23.4%) had

history of preterm birth (delivery prior to 37 weeks of gestation), whereas 82 patients (76.6%) with no prior history of preterm birth. 14 patients (13.1%) had history of urogenital infections documented by cultures, and 93 patients (86.9%) with no evidence of urogenital infections. 32 patients (29.9%) had history of previous cervical procedure i. e., LEEP, extensive D and C, whereas 75

patients (70.1%) with no prior history of cervical trauma. 3 patients (2.8%) documented to have uterine anomalies, PCOS and fibroid uterus. 9 patients (8.4%) had BMI of more than 35, and 98 patients (91.6%) had BMI of less than thirty-five. Seven patients (6.5%) had multiple gestation documented by ultrasound, and 100 patients (93.5%) had singleton pregnancy. As shown in Figure 2.

Table 1: Patient demographics.

Age group (in years)	N	Common GA at 1 st visit (weeks)	Common preterm/term outcomes	Common medical conditions
<25	5	5-9	Mostly term	None / occasional GDM
25-29	15	6-10	Term, some preterm	Hypothyroidism, GDM
30-34	25	6-12	Mostly term, some preterm	Hypothyroidism, GDM, obesity, T2DM
35-39	20	6-22	Term, occasional preterm	Hypothyroidism, GDM, HTN, APLS
≥40	10	8-26	Term, some preterm	Hypothyroidism, GDM, T2DM

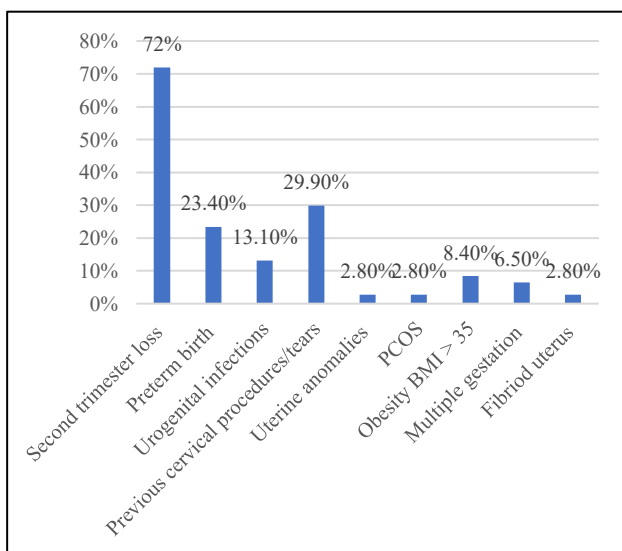


Figure 2: The set of prespecified risk factors for cervical incompetence. This figure shows the percentage of participants with each risk factor.

Figure 3 demonstrates pregnancy outcomes after cervical cerclage in patients with RPL. Among patients (96 patients) with risk factors, 73 patients (76%) completed pregnancy till term, 15 patients (15.6%) had preterm birth and 8 patients (8.3%) had second trimester loss. Among patients (11 patients) without risk factors for cervical incompetence, 9 patients (81.8%) had term birth, 2 patients (18.2%) had preterm birth and none of them had second trimester loss ($p=0.403$).

Neonatal outcomes after cervical cerclage in patients with RPL were also studied, results demonstrated in Figure 4. Among patients (96 patients) with risk factors for cervical incompetence, 78 neonates (81.35%) had no morbidity or mortality, 8 neonates (8.3%) with documented morbidity and NICU admission and 2 neonates (2.1%) who died during neonatal period. Among those patients (11 patients) without risk factors for cervical incompetence, 9 neonates

with no morbidity or mortality, 1 neonate (9.1%) had morbidity and one neonate (9.1%) who died ($p=0.406$).

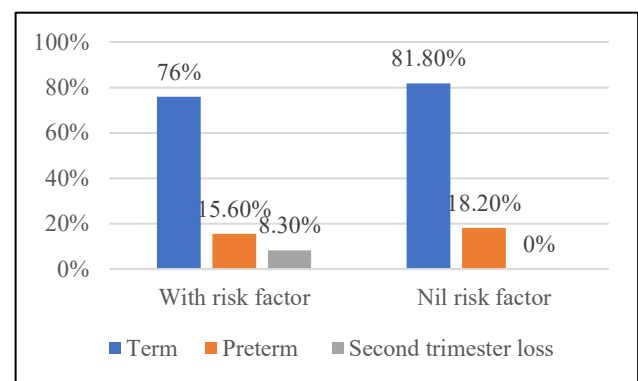


Figure 3: Pregnancy outcomes after cervical cerclage in patient with RPL.

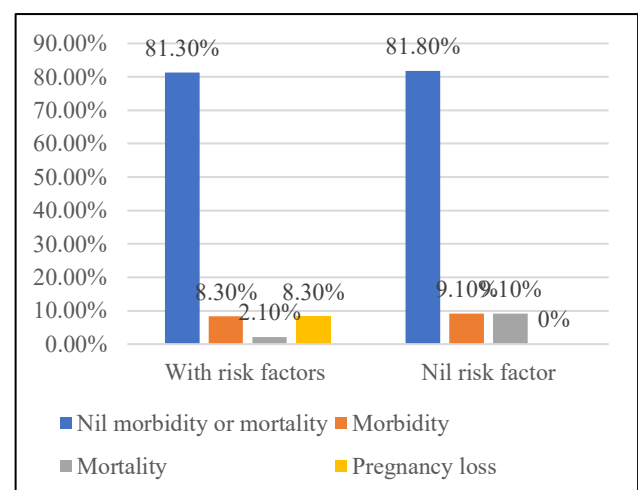


Figure 4: Neonatal outcomes after cervical cerclage in patients with RPL.

Figure 5 demonstrates pregnancy outcomes after cervical cerclage in patients with RPL who had bulging of fetal

membranes at the time of cervical cerclage insertion. 5 patients (4.7%) had bulging membranes at the time of cervical cerclage insertion, among these 5 patients 2 patients (40%) had term birth, 2 patients (40%) had preterm birth and 1 patient (20%) had second trimester miscarriage. Whereas 102 patients (95.3%) with no bulging membrane, among them 80 patients (78.4%) had term birth, 15 patients (14.7%) had preterm birth and 7 patients (6.9%) had second trimester loss ($p=0.197$).

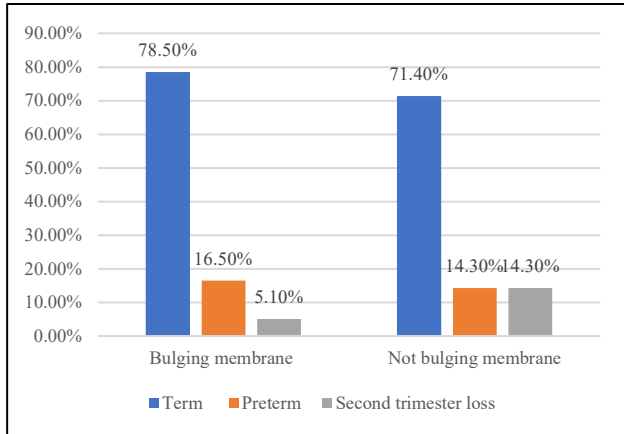


Figure 5: Comparing patients with bulging membranes vs not bulging membranes at the time of cervical cerclage insertion and pregnancy outcomes.

Figure 6 demonstrates pregnancy outcomes after cervical cerclage in patients with RPL who had funneling cervix at the time of cervical cerclage insertion. 16 patients (15%) had funneled of cervix at the time of cervical cerclage insertion, among these 16 patients 11 patients (68.8%) had term birth, 4 patients (25%) had preterm birth and 1 patient (6.3%) had second trimester miscarriage. Whereas 91 patients (85%) with no funneling of cervix, among them 71 patients (78%) had term birth, 13 patients (14.3%) had preterm birth and 7 patients (7.7%) had second trimester loss ($p=0.589$).

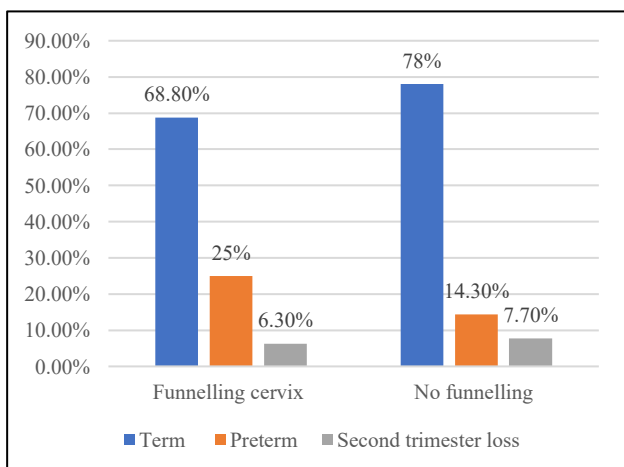


Figure 6: Comparing patients with funneled cervix vs no funneling at the time of cervical cerclage insertion and pregnancy outcomes.

Total of 79 patients (73.8%) of patients who had additional progesterone support along with cervical cerclage insertion, among 79 patients 62 patients (78.5%) had term birth, 13 patients (16.5%) preterm birth and 4 patients (5.1%) had second trimester loss. Remaining 28 patients (26.2%) had no additional progesterone support, among these 28 patients 20 patients (71.4%) had term birth, 4 patients (14.3%) had preterm birth and 4 patients (14.3%) had second trimester loss ($p=0.323$). as shown in Figure 7.

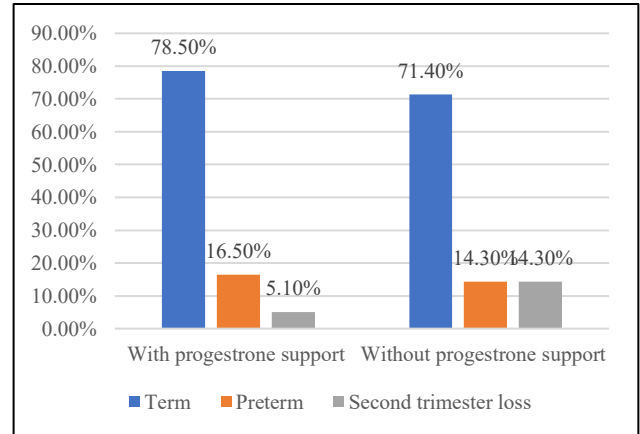


Figure 7: Adding progesterone support to cervical cerclage and pregnancy outcomes.

DISCUSSION

The overall incidence of cervical cerclage done among patient with RPL was 4.5%. Patient with history of RPL and with nil risk factors for cervical incompetence who had cervical cerclage were 11 patients (10.3%). In compared to other group which were 96 patients (89.7%). History of second trimester miscarriage being the most common risk factor for cervical incompetence (72%), and the least common risk factors were fibroid uterus (2.8%), uterine anomalies (2.8 %), PCOS (2.8 %) in the study.

The rate of live birth after cervical cerclage insertion (elective or rescue) in patients with history of RPL in total was 92.5%. With one or more of prespecified risk factors: 76% term birth, 15.6% preterm birth. With nil risk factors: 81.8% term birth, 18.2% preterm ($p=0.403$).

The percentage of neonatal morbidity and mortality was 28.6 %. With one or more of prespecified risk factors: 9.1% neonatal morbidity, 15.6% neonatal mortality. With nil risk factors: 8.3% neonatal morbidity, 2.1% neonatal mortality ($p=0.406$).

Patients with bulging membranes at the time of cervical cerclage insertion who had live birth were 80% (40% term birth, 40% preterm birth) ($p=0.197$).

Patients with funnelling cervix at the time of cervical cerclage insertion who had live birth were 93.8 % (68.8% term birth, 25% preterm birth) ($p=0.589$).

Cervical cerclage, a surgical intervention aimed at preventing preterm birth, is most utilized in pregnancies complicated by cervical insufficiency. The timing of the procedure significantly influences maternal and neonatal outcomes, with elective cerclage generally yielding more favorable results compared to emergency placements.

Emergency cerclage, typically performed during the second trimester once cervical dilation or membrane prolapse is observed, has been shown to improve pregnancy outcomes compared to expectant management. Meta-analyses and observational studies report that emergency cerclage can extend gestation by several weeks and reduce the risk of extremely preterm birth. For example, one study demonstrated a 43% increase in overall survival, along with notable reductions in delivery before 28 weeks.¹⁶ Another investigation revealed an average delay of 52 days in delivery following emergency cerclage, with a neonatal survival rate exceeding 80%.¹⁷

In contrast, elective cerclage, usually performed between 12 and 14 weeks of gestation in high-risk women, is associated with superior outcomes. These include a higher gestational age at delivery, greater birth weight, and reduced rates of complications such as premature rupture of membranes (PROM), neonatal sepsis, and composite neonatal morbidity.^{18,19}

In summary, while both elective and emergency cerclage can be beneficial in managing cervical insufficiency, proactive intervention tends to result in more favorable obstetric and neonatal outcomes. Clinical decisions regarding cerclage placement should consider individual risk profiles and symptom presentation to optimize effectiveness.

The outcomes of this study are consistent with international research evaluating the effectiveness of cervical cerclage in preventing RPL and preterm birth. Our overall live-birth rate of 92.5% is comparable to findings from a Danish national cohort, which reported take-home baby rates of 73% after vaginal cerclage and 95% after abdominal cerclage.²⁵ Similarly, a study from Lyon demonstrated a significant improvement in live-birth outcomes from 23% prior to cerclage to 86% after cervico-isthmus cerclage, mirroring the high term-delivery rate observed in our population. Evidence from a large registry study also supports the benefit of prophylactic cerclage, showing reduced recurrence of second-trimester miscarriage and extreme preterm birth, particularly in women with a well-defined history of cervical insufficiency.^{26,27} Rescue cerclage outcomes in our study, although slightly less favorable than elective cerclage, align with multicenter analyses demonstrating that emergency cerclage remains effective in prolonging pregnancy, even in the presence of cervical dilation or bulging membranes.²³ Notably, most existing studies focus exclusively on cervical insufficiency; however, the comparable success observed in our cohort of women with RPL suggests that selected RPL patients may similarly

benefit from cerclage. Despite differences in study populations and the absence of a non-cerclage control group in our design, the consistency of our findings with global data supports the role of cerclage-particularly elective placement-in improving pregnancy outcomes in high-risk groups.

Strengths and limitations

The study was done in a tertiary hospital, in which all patients referred from different parts of Oman. Even though the sample size was small, but the study was done over ten years duration. Need control group without cervical cerclage to ensure the effectiveness of cervical cerclage. As any other retrospective research, selection bias and medical records with errors, missing data, or inadequate documentation may affect research accuracy and comprehensiveness.

CONCLUSION

This retrospective cohort study demonstrated that cervical cerclage plays a significant role in improving pregnancy outcomes among women with a history of RPL, particularly in those with risk factors suggestive of cervical incompetence. The overall live birth rate following cerclage was high (92.5%), with the majority of patients achieving term delivery. Although rescue cerclage was associated with slightly higher rates of preterm birth, it still contributed to prolonging gestation and reducing the incidence of second-trimester pregnancy losses.

The study findings support the recommendation of performing elective cerclage in women with a strong obstetric history suggestive of cervical insufficiency, accompanied by serial cervical assessment through transvaginal ultrasound. While the addition of progesterone therapy did not show a statistically significant improvement in outcomes, this may be attributed to the limited sample size.

Further prospective studies with larger cohorts are warranted to confirm these findings and refine management protocols for RPL patients. Screening and timely management of genitourinary infections are also advised to minimize preventable adverse pregnancy outcomes. In summary, cervical cerclage-particularly when performed electively-remains an effective intervention for improving gestational outcomes in women with recurrent pregnancy loss and risk factors for cervical incompetence.

Recommendations

Elective cervical cerclage is recommended in patient with history suggestive of cervical incompetence. Serial cervical assessment using transvaginal ultrasound is recommended starting from twelve weeks of gestations. As rescue cervical cerclage helped in prolongation of pregnancy till term or late preterm in most of the cases, so

cervical assessment is recommended in patients with RPL. Adding progesterone did not show any significant benefit in compared to other group without progesterone, but in view of small sample size further prospective study should be conducted with larger sample size. Screen for genitourinary infections is recommended and to treat accordingly.

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Conflict of interest: None declared

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

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