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# Maternal and neonatal outcomes of preterm prelabour rupture of membranes in women with and without cervical cerclage: a case control study

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**ABSTRACT**

**Objective.** This study aimed to compare the maternal and neonatal outcome of preterm prelabour rupture of membranes in women with cervical cerclage admitted in a tertiary care unit compared to women without cervical cerclage.
**Materials and Methods.** This is a case control study comparing the maternal and neonatal outcome in Omani women presenting with preterm prelabour rupture of membranes (pPROM) in the presence of cervical cerclage and those with pPROM without cerclage conducted in Sultan Qaboos University hospital from January 2010 to December 2019. The data was collected from the maternal and neonatal register. The Statistical Package for the Social Sciences software was used to analyse data.
**Results.** The mean age of women in the cerclage group was 32.6 ± 5.4 and in no-cerclage group was 28.7 ± 6.2 and the mean parity was 1.7 for both groups. The mean gestational age at the time of ruptured membranes was 28.5 ± 5.4 weeks in the cerclage group and 29.8 ± 5.2 weeks in no-cerclage group with no significant difference. The cerclage was kept *in situ* in women with ruptured membranes for a mean period of 2.6 days. Chorioamnionitis complicated 31% of women in the cerclage group compared to 12% in the no-cerclage ($p = 0.007$) with an OR 3.29 (95%CI 1.35-8.00). Sepsis was significantly more prevalent among newborns born to mothers with cerclage, 25% compared to 6.5% among newborns in the no-cerclage group (OR 5.155, 95%CI 1.95-13.66).
**Conclusions.** Chorioamnionitis and neonatal sepsis was significantly high in the cerclage group with pPROM.

## INTRODUCTION

Preterm prelabour rupture of membranes (pPROM) is defined as rupture of membranes before 37 completed weeks of gestation. pPROM complicates about 3% of pregnancies and is associated with 30-40% of preterm births [1].

There are many causes and risk factors leading to early rupture of membrane including weakening of membranes correlated to programmed cell death (apoptosis), extreme force of uterine contraction which induce shearing force and dissolution of amniochronic matrix [2]. The other common reason for pPROM is intra-amniotic infections. The

main risk factors identified for pPROM includes previous history of pPROM, cervical incompetence, second or third trimester vaginal bleeding, overdistension of the uterus, copper and ascorbic acid deficiency, connective tissue disorders, low socioeconomic status, smoking, drug abuse and surgical procedures like amniocentesis and cervical cerclage [3]. In spite of all these risk factors identified, most often a definite cause may not be found in patients who presents with pPROM.

Diagnosis of spontaneous rupture of the membranes is first made by taking maternal history followed by demonstrating liquor coming out of cervix or pooling of amniotic fluid in the posterior fornix by sterile speculum examination. Nitrazine test, Ferning test or detecting the presence of insulin-like growth factor-binding protein 1 (IGFBP-1) or placental alpha microglobulin-1 (PAMG-1) in vaginal fluid are performed [4]. Once the diagnosis of pPROM is confirmed, antibiotics are given for Group B streptococcus prophylaxis against chorioamnionitis. If the membranes ruptured between 24 and 34 weeks of gestation, steroids were given for foetal lung maturity and magnesium sulphate for foetal neuroprotection from 24-32 weeks if there is impending preterm labour [4].

The most important complication associated with pPROM is preterm delivery. The latency period is inversely related to gestational age at pPROM, where both mean and median latency period of pPROM after 7 days tend to get shortened as gestational age advances [4]. In a study of the length of latency with preterm prelabor rupture of membranes before 32 weeks' gestation, it was found that median latency after pPROM is similar from the period 24 to 28 weeks' gestation, but it shortens with PPROM at and after 29 weeks [5]. The other associated maternal complications include chorioamnionitis, sepsis, placental abruption, antepartum haemorrhage and postpartum haemorrhage.

The neonatal complications associated with pPROM includes sepsis, prematurity, cord compression, cord prolapse, deformations and contractures and pulmonary hypoplasia. Long standing pPROM could lead to deformities similar to what is seen in Potter syndrome [6].

Cervical cerclage refers to procedures that use sutures or synthetic tape to reinforce the cervix during pregnancy in women with short cervix. Preterm prelabour rupture of membranes is considered as a complication of cervical cerclage. pPROM occurs in 38% of patients with cervical cerclage [7]. The decision to whether retain or remove the cerclage in pPROM is still controversial. Because retaining the stitch may prolong the latency and enhance delivery at a favourable gestational age. Alternatively, the women will be more prone to infections [8]. A multicentre randomized controlled trial was done to conclude whether retention of cerclage to prolong gestation increased the risk of maternal or foetal infection by Galyean *et al*. [9]. There was no significance difference in primary outcome of prolonging pregnancy by one week between the two groups (P-value = 0.59) or in chorioamnionitis (P-value = 0.25), and composite neonatal outcomes, neonatal death or gestational age at delivery [9].

The outcomes yielded by retention of cervical cerclage after pPROM before 34 weeks of gestation, are clinically comparable with the outcomes of removal of cerclage in terms of latency and perinatal outcome [8].

Additionally, another multicentric retrospective study of 79 women with pPROM and cerclage, in two centres in Toronto and Ontario between 2012-2016, showed increasing odds of latency with cerclage retained compared with removed stitch as well as decline in combined neonatal outcomes, with no variation in clinical chorioamnionitis and sepsis in newborn [10].

Cervical cerclage can prolong the latency period in the presence of pPROM and enhance foetal maturity due to favourable gestational age, although it may have maternal and neonatal complications. So, it is important to know the exact outcome of retaining or removing cerclage with preterm prelabour rupture of membranes. However comparative studies of women with retained cerclage and cerclage removal are far and few. Therefore, this study aimed to compare the maternal and neonatal outcome of preterm prelabour rupture of membranes in women with cervical cerclage and those without cerclage admitted in SQUH from January 2010 to December 2019.

## MATERIALS AND METHODS

The study was conducted at the Obstetrics and Gynecology Department in Sultan Qaboos University Hospital in Muscat, Oman which is a tertiary care centre. It was a case-control study among 142 Omani women who presented with or without, cervical cerclage and preterm prelabour rupture of membranes admitted to SQUH from January

2010 to December 2019. Inclusion criteria were all Omani patients with pPROM with or without cervical cerclage during the study period. Exclusion criteria were women who had iatrogenic preterm delivery due to maternal medical conditions not related to pPROM, women with congenital uterine anomalies and those with gross foetal anomalies.

All women in the cerclage group had a McDonald type of cerclage. When women presented with pPROM with cerclage *in situ*, generally the cerclage was removed if the patient was in labour, or if there was an indication for delivery like evidence of chorioamnionitis, significant vaginal bleeding and non-reassuring foetal status. If none of these indications were present the cerclage was kept *in situ* at least till the patient completed the course of steroids for foetal lung maturity and magnesium sulphate infusion for foetal neuroprotection as per our hospital protocol for pPROM. All women with pPROM underwent genital swab for Group-B streprtococous (GBS) screening. Then they were started on antibiotics Ampicillin for 48 hours till the GBS swab results is reported in addition to erythromycin. Ampicillin was stopped if GBS swab negative or continued for one week if positive. Erythromycin was continued for a week. If all well, patient had twice weekly complete blood count and C-reactive protein to screen for infection. Those who developed clinical evidence of chorioamnionitis were started on a board spectrum antibiotic and delivered vaginally or by caesarean section depending on the obstetrics or other indications.

Approval was obtained from the Medical and Research Ethics Committee (MREC) at the College of Medicine and Health Sciences (COMHS) (MREC #2537).

Data was collected from maternal and neonatal register, admission register in antenatal ward and electronic patient records at SQUH. Demographic data of the patients included age, gravidity, parity, body mass index (BMI), gestational age at cerclage, gestational age at pPROM, latency period of delivery and cervical stitch removal and delivery details including gestational age at delivery, mode of delivery, neonatal APGAR score and birth weight of the baby.

Data was analysed using Statistical package for the social sciences (IBM SPSS software version 27. Chi-square test was used to assess the association of the outcomes with the present of cerclage. Odds ratio was used to express the relationship between the events in both groups. A P-value ≤ 0.05 was considered significant.

### *Patient and public involvement*

The patients will be interested to know the outcome of pregnancies if there is preterm prelabour rupture of membranes in spite of cervical cerclage.

## RESULTS

This study included a total of 142 pregnant women who met the inclusion criteria, among them 42 with cervical cerclage 100 patients without cerclage. Gravidity ranged from (1-15) for both groups. The average gestational age at cerclage was 14.71 weeks. The demographic characteristics of both groups are shown in **Table 1**. There was significant difference in age and BMI between women with and without cerclage. Gestational age at pPROM for cerclage group ranged from 14-36 weeks with a mean of

**Table 1.** *Demographic characteristics of women.*

| | Study group | n | Mean | SD | 95%CI | P-value |
|---|---|---|---|---|---|---|
| Age | Cerclage | 42 | 32.64 | 5.36 | 30.97-34.31 | < 0.001* |
| | Without cerclage | 100 | 28.77 | 6.24 | 27.53-30.01 | |
| Gravida | Cerclage | 42 | 4.62 | 2.50 | 3.84-5.40 | 0.001* |
| | Without cerclage | 100 | 3.13 | 2.47 | 2.64-3.62 | |
| Parity | Cerclage | 42 | 1.62 | 1.71 | 1.09-2.15 | 0.514 |
| | Without cerclage | 100 | 1.41 | 1.74 | 1.06-1.76 | |
| BMI | Cerclage | 39 | 31.39 | 5.26 | 29.69-33.09 | 0.006* |
| | Without cerclage | 82 | 28.31 | 5.88 | 27.02-29.60 | |
| Gestational age at PPROM | Cerclage | 42 | 28.52 | 5.37 | 26.85-30.19 | 0.183 |
| | Without cerclage | 100 | 29.81 | 5.17 | 28.78-30.84 | |

*Statistically significant; test: Independent samples t-test.

**Table 2.** *Comparison of pregnancy outcome between the groups.*

| Parameter | Cerclage group (n = 42) | No-cerclage group (n = 100) | P-value |
|---|---|---|---|
| Mean gestational age at delivery in weeks | 28.83 | 32.82 | 0.001* |
| Vaginal delivery (number) | 20 | 76 | |
| Caesarean section (number) | 18 | 24 | 0.001* |
| Aborted (number) | 4 | | |
| Mean birth weight of babies | 1,482.24 g ± 660 g | 2,009.31 g ± 685 g | 0.221 |
| APGAR score at 1 minute | 5.93 (0-9) | 7.76 (0-9) | 0.007* |
| APGAR score at 5 minutes | 7.48 (0-10) | 9.22 (4-10) | 0.005* |

*Statistically significant.

28.52 ± 5.37 weeks, while in no-cerclage group it was 29.81 ± 5.17 and it was not statistically significant. **Table 2** shows pregnancy outcome in both groups. The mean gestational age at delivery in cerclage group was 28.83 weeks and in the no-cerclage group was 32.82 weeks (p = 0.001). **Table 3** shows the major maternal outcome with significant association between cerclage and chorioamnionitis. Among minor complications noted, the most frequent were acute funisitis, presence of bacterial colonies, abdominal pain and retroplacental hematoma. The mean latency from the onset of rupture of membranes to cerclage removal was 2.62 days.

**Table 3.** *Major maternal outcomes.*

| Maternal outcome | Cerclage group (n = 42) | No-cerclage group (n = 100) | P-value |
|---|---|---|---|
| Chorioamnionitis | 31% (95%CI 17.6-47.1) | 12% (95%CI 6.4-20.0) | 0.007* |
| Other types of sepsis | 31.7% (95%CI 17.6-47.1) | 2% (95%CI 0.2-7.0) | < 0.001* |
| Retro placental haematoma | 7.1% (95%CI 1.5-19.5) | 4% (95%CI 1.1-9.9) | 0.430 |

*Statistically significant.

Neonatal complications are expressed and compared to the cerclage group in **Table 4**. Sepsis was the major difference in the two groups representing 31.7% of all complications in cerclage group and only 8.0% in the no-cerclage group. In contrast, respiratory distress syndrome (RDS), hyperbilirubinemia, hypoglycaemia and neonatal death were not significantly different. Some of the other neonatal complications noted were hypocalcaemia, hypothermia, pseudomonas conjunctivitis, extreme prematurity, severe IUGR, cephalohematoma and polycythaemia.

## DISCUSSION

Preterm labour contributes to significant neonatal morbidity and mortality. Though there are many causes for preterm labour including advanced maternal age, COVID-19 and periodontal infections *etc*., the focus of this study was on cerclage related pPROM. The mean age of the women in this study was less than 35 in both groups and they did not have any other comorbidities like COVID-19 or periodontal infections [11-13].

Cervical cerclage with pPROM is associated with many maternal and neonatal complication and it is important to know the exact outcomes of retaining cerclage with preterm prelabour rupture of membrane and variation of outcomes rate between removal and keeping cerclage.

As far the most common maternal complications regarding pPROM, it showed that women are most likely to develop chorioamnionitis. In this study it was found that 39% of the 142 patients developed this infection. This is consistent with another study conducted in Oman which indicated that chorioamnionitis complicated around 13-60% of pregnancies [14]. When comparing the two groups in the current study, 31% out of 42 women with cervical cerclage and only 12% out of the 100 patients without cervical cerclage who had chorioamnionitis and this was statistically significant. Recently Kong *et al*. de-

**Table 4.** *Major neonatal outcomes.*

| Neonatal outcome | Cerclage group (n = 42) | No-cerclage group (n = 100) | P-value |
|---|---|---|---|
| Respiratory distress syndrome (RDs) | 43.9% (95% CI 27.7-59.0) | 50% (95% CI 39.8-60.2) | 0.511 |
| Neonatal death | 2.4% (95% CI 0.06-12.6) | 6.0% (95% CI 2.2-12.6) | 0.377 |
| Sepsis | 31.7% (95% CI 17.6-47.1) | 8.0% (95% CI 3.5-15.2) | < 0.001* |
| Hypoglycaemia | 4.9% (95% CI 0.6-16.2) | 11% (95% CI 5.6-18.8) | 0.254 |
| Hyperbilirubinemia | 32.7% (95% CI 19.6-49.6) | 43.0% (95% CI 33.1-53.3) | 0.213 |

*Statistically significant.

fined some cut off values for inflammatory indices in women with preterm prelabour rupture of membranes [15].

The opinion is divided on whether to remove the cerclage or retain it. The retention of cerclage for more than 24 hours after PPROM was significantly associated with increased incidence of maternal chorioamnionitis, 43% with cerclage *versus* 20% without cerclage – odds ratio (OR) 2.90 representing about 3-fold increased risk with exposure to cerclage [7]. However, another study revealed similar rates of clinical chorioamnionitis with the two groups and no significant association [8].

A randomized prospective multicentre trial of 27 hospitals, demonstrated no statistical significance in primary outcome of chorioamnionitis ($p = 0.25$, removed cerclage 8/32, 25.0%, retained cerclage 10/24, 41.7%) [9]. There were no differences regarding infectious process such as placental infections in the two groups according to a retrospective analysis (13/16 – 81.3% cerclage group, 7/11 – 63.6% rest group, P-value 0.391) by Costa *et al*. [16]. The latency from the onset of PPROM and cerclage removal is the most important information to consider. It was about 2.62 days for our patients, and this helped to get steroid administration for foetal lung maturity. In spite of the fact it was much less than a week, chorioamnionitis was still significant in our patients. Colucci *et al*. found at gestation below 32 weeks, an inverse relationship between gestational age at pPROM and the latency to delivery. Median latency after 34 weeks was one day [17].

The gestational age at pRPOM was comparable to groups with and without cerclage, though the women with Cerclage delivered earlier, due to infection. From the result of this study, gestational age at PPROM in the two groups showed no significant difference (28.33 (14-36) with cerclage *versus* 29.81 (16-36) without cerclage, P-value of 0.128) indicating that cerclage was not always responsible for pPROM. However, although results revealed that gestational age at delivery in cerclage group was 28 weeks compared to almost 33 weeks in the non-cerclage group and this was statistically and clinically significant. These findings were similar to a literature review study in 2011, with a total 124 women tested in latency period. Of the 124, 35 of those women were with cerclage and 89 without cerclage, 33 women from 35 (94%) women with cerclage experienced prolongation of pregnancy for 48 hours *versus* 45/89 (51%) in women without cerclage [7]. In another randomized control trial of 56 cases, cerclage was removed in 32 women and retained in 2, but revealed no significant difference in prolongation pregnancy by one week in the two groups [9].

During labour our results revealed the need of caesarean section was much higher among cerclage group 45% compared to 24.0% without it, indicating the significant association of caesarean section with presence of cerclage. However, these results were against a retrospective analysis for pregnant women from 2001-2017 with total 30 cases, caesarean section showed no significant association (P-value 0.466) in the presence of cerclage [16].

With respect to neonatal birth weight, this study showed no association of low birth weight with or without cerclage, this was partially in agreement with a previous observational study where they studied the maternal and neonatal outcomes in cerclage and no-cerclage groups with and without previous preterm birth (PTB) and second trimester loss (STL) [18]. Huang *et al*., in 2021 found comparable 1-min/5-min APGAR scores between the two groups and no significant association in contrast to our study which showed relatively lower APGAR in the cerclage group, possibly due to sepsis [18].

Respiratory distress syndrome (RDS) among neonatal outcomes showed no significant relation in the presence of cerclage. However, according to the number of cases of RDS in the two groups, it was more with cerclage removed group; an evidence of increased latency period to delivery by cerclage and thus favourable gestational age and maturity of foetus lungs. This result is in agreement with two previous studies, McElrath *et al*. and Huang *et al*. [8, 18]. Benuzzi *et al*. recommended expectant management of late preterm prelabour rupture of membranes as it improved the neonatal outcome. They concluded each passing week reduced the adverse outcome on babies [19].

There was no significant difference in the number of neonatal deaths, as most of them in the Cerclage group miscarried at 20 weeks or less. Data regarding neonatal death in previous retrospective analysis exhibited foetal death occurred in 9 cases among 18 in the cerclage group *versus* 1 out of 5 in the control group after excluding patients who delivered or miscarried within 2 days of hospital admission and stated that there was no statistical difference between the two groups (P-value = 0.339) [16].

In addition, regarding all the neonatal outcomes which showed no association between the two groups, neonatal sepsis was among the major outcome with a significant statistical difference. This

goes with many previous studies, where they stated that neonatal sepsis was about 2.35-fold higher risk in the presence of cerclage and neonatal mortality from sepsis 13.19 increased risk with the exposure of cerclage [7]. No differences were identified between the two groups for hypoglycaemia and hyperbilirubinemia.

### *Study strengths*

Being from a single centre results in a unified protocol for management like antibiotics and screening for infection. The sample size for the study group is 42 which is on the higher end sample size compared to other published articles in this subject.

### *Study limitations*

The limitations as the results were obtained from a single tertiary health care centre (SQUH), it is a retrospective study and with a small sample size in the cerclage group. The number of women in the cerclage group was too small to compare those who had cerclage removed electively and those who had it removed immediately. There was no comparison of the women in the cerclage group where the stitch was retained or removed. The comparison was between women with and without cerclage.

## CONCLUSIONS

In women with pPROM and cervical cerclage, there was significantly increased risk of chorioamnionitis, maternal and neonatal sepsis compared to women with pPROM without cerclage. This adds to the available body of literature making the physicians inclined towards electively removing the cerclage when women present with pPROM. However, more evidence is required in this regard to provide a more conclusive guidance to the treating physicians of these women.

## COMPLIANCE WITH ETHICAL STANDARDS

### *Authors' contribution*

A.N.: Conceptualization, methodology, data curation, writing – original draft, writing –review & editing. M.Al.S.: Formal analysis, methodology, writing – original draft, writing –review & editing. A.Al.M., T.al.R: Data curation, writing – original draft, formal analysis. V.G.: Data curation, supervision, writing – original draft, writing –review & editing.

### *Funding*

None.

### *Study registration*

N/A.

### *Disclosure of interests*

The authors declare that they have no conflict if interests.

### *Ethical approval*

It was obtained from Medical and Research Ethics Committee of the College of Medicine and Health Sciences, Sultan Qaboos University (MREC 2537).

### *Informed consent*

Not required as this is a retrospective chart review study and no patient identity was shared.

### *Data sharing*

Data are available under reasonable request to the corresponding author.

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