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Pregnancy Outcome of Cervical Cerclage for Divergent Reasons in Dhofar Region, Oman

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ABSTRACT

Background: Cervical insufficiency is one of the causes of preterm birth. The object of the study was to compare maternal and neonatal outcomes with different cerclage indications in Dhofar region, Oman.

Methods: It is a retrospective observational study. Data was collected from the electronic medical records system on standardized Performa in an Excel sheet. All cases of singleton pregnancy that underwent cervical cerclage were studied for the duration of 1/1/2018 – 30/4/2020 (28 months) at Sultan Qaboos Hospital, Salalah, Oman. Statistical analysis was done on SPSS-24. P-value ≤ 0.05 was considered statistically significant.

Results: We had 86 cases with cerclage included in the study, eight of which were lost from follow-up, therefore, analysis of 78 cases was done. Out of 78 cases, 61 were history indicated, 12 were ultrasound indicated and 5 were rescue cerclages. The 3 women had a bicornuate uterus. Maternal age and BMI were comparable in all groups.15 (19%) delivered before 32weeks, 151(19%) cases at 33-36weeks and 48(61.5%) at 37 weeks and more results were not significant in < 32 weeks group. The mode of delivery was vaginal 52(66.7%) and 21(27%) had cesarean section There were five miscarriages, 2 intrauterine fetal deaths (IUFD), and 4 early neonatal deaths (ENND). There were 5 cases of preterm premature rupture of membranes (PPROM), two abruptions and 2 cases had chorioamnionitis with septic shock. Cerclage to delivery interval in most cases was >20 weeks (3-26 weeks). Neonatal survival was comparable in history-indicated and ultrasound-indicated groups 87% and 91.7% respectively. 8 (10%) cases were admitted to the special care baby unit (SCBU) out of which 4 had early neonatal death due to extreme prematurity.

Conclusion: The length of the cervix is reciprocally related to the risk of premature delivery. Therefore, the diagnosis and management of a short cervix is a substantial challenge in obstetrics. Ultrasound-indicated had almost similar outcomes as history indicated. Rescue cerclage is worth attempting to improve fetal outcomes.

Keywords: Cervical cerclage, Cervical Insufficiency, Preterm delivery, Second Trimester Miscarriages, Neonatal survival.

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INTRODUCTION

Cervical cerclage is recommended in cases of singleton pregnancy with a history of second-trimester pregnancy loss, previous preterm delivery, and shortening of cervix <25 mm. The indications for cerclage are dependent on history, examination, and ultrasound. In 2013, 36% of infant deaths were due to preterm-related causes of death. Prematurity also leads to neurodevelopment and cerebral palsy esp if associated with chorioamnionitis[1-2]. The occurrence of cervical incompetence is calculated to be <1% of pregnant women but accounts for 20-25% of second-trimester pregnancy losses.[3] In Denmark from 1980 to 1990, it was analyzed that cervical incompetence was in 4.6 per 1000 women, and 8% with repeated pregnancy loss in the second trimester [4]. Premature birth is most often caused by rupture of the amniotic sac before 37 weeks of pregnancy leading to preterm contractions. Cervical cerclage was first introduced in 1955, to prevent preterm birth in cases where cervical incompetence is thought to be a factor. The purpose of cervical stitch is to strengthen the cervix at the internal orifice, elongating the cervix is another effect of the procedure [5-7]. Cerclage is best placed following first-trimester screening in history indicated at 12-14 weeks of gestation, ultrasound findings of short cervical length (< 2.5 cm) at 16-23 weeks of gestation, and physical examination indicated digital vaginal or per speculum examination at 16-23 weeks (Rescue /Emergency cerclage) [8-12].

There are some contradictions in research relating to management. Recent Cochrane review in the 2017 meta-analysis and 2020 indicates there are very few RCTs and so there is low certainty of evidence. There is evidence that cervical stitch reduces the risk of premature delivery at all gestations of pregnancies with risk factors for premature delivery, hence resulting in reduced risk of perinatal death [13]. Different types of risk factors have been associated depending on previous obstetrical history and the pregnancy itself.

METHODS

This retrospective observational study was conducted at a secondary/tertiary hospital with approximately 6,700 deliveries per year. The data was collected for all cerclages for singleton pregnancies from 1/1/2018 – 30/4/2020 (28 months) at Sultan Qaboos Hospital, Salalah, Dhofar. This study is approved by the Centre of Studies and Research, Oman. Registration no: MOH/CSR/20/24207. Ethical approval was also given by the same committee.

All cases (86) of singleton pregnant women who underwent an elective, ultrasound, and physical examination/Rescue indicated cerclage were identified and included. Inclusion criteria were all patients primi or multi gravida in the reproductive age group of 20-47 years of age, who underwent cervical cerclage for various indications like- elective cases, patients with previous preterm delivery, second-trimester losses or cervical damage or uterine or cervical congenital anomalies or as emergency cases like ultrasound diagnosis of short cervix < 25 mm and rescue cerclage cases for the short and dilated cervix.

The exclusion criteria were Preterm labor, bleeding, lethal congenital anomalies, infection, PPROM, and age < 20 years (no cases were found). History indicated included one or more previous preterm births less than 30 weeks, mid-trimester pregnancy loss and cervical surgery (e.g., Loop excision for abnormal smear), trauma, or congenital uterine malformations. All asymptomatic patients with a history suggestive of risk factors had cervical sutures as a preventive measure. In those where ultrasound suggested cervical length was <25 mm. Ultrasound findings were confirmed by a senior person before finalizing surgery. In the examination group, the need was identified by a short and dilated cervix with or without bulging membranes and without evidence of pain, bleeding, and leaking. These patients were assessed both physically and by ultrasound for cervical dilatation, a bag of membranes position (intracervical/in the vagina) and cervical length. The information collection tool was as per the Royal College of Obstetrics and Gynaecology, U.K. guideline for preterm birth. Indications of cervical cerclage were determined by past and present risk factors. Most of the cerclages were done under spinal anesthesia with the McDonald technique by a specialist and above, with Mersilene tape. Cervical cerclage removed at around 37 weeks or before if preterm labor/miscarriage.

The data was entered in Excel and analyzed by

using SPSS Version 24. The normality of quantitative variables i.e., maternal age, BMI, gravidity, parity, number of abortions, number of preterm births, No. of Mid-trimester miscarriage, Gestational age at cerclage, Cervical length, Cervical dilatation, Gestational age at delivery, Interval between Cerclage & Delivery, Neonatal birth weight, APGAR score at 1 minute, APGAR score at 5 minutes, and Duration of SCBU stay was assessed by using Shapiro-Wilk test. Normally distributed data was represented by Mean + SD while skewed data was represented by Med [IQR] for history-indicated cerclage, rescue cerclage, and ultrasound -indicated cerclage. The qualitative data i.e. Type of Ultrasound done, Cervical surgery, Type of surgery, Mode of delivery, Type of anesthesia used, PPROM, Chorioamnionitis, Antibiotic used, Septic shock, Preterm delivery, Multi-drug resistance organism, Anti-phospholipid antibodies, Abruption, History of Myomectomy, Bicornuate uterus with ectopic kidney, cervical dilatation, Uterine septum, IUGR(intrauterine growth restriction), IUFD, Neonatal Survival, ENND, Congenital malformation, Admission to SCBU was expressed as frequency and percentages. Pregnancy outcomes and Neonatal outcomes were compared among three cerclage indications by applying the Kruskal-Wallis test followed by Bonferroni post hoc analysis anMann-Whitney U test, for quantitative variables, while Fisher's exact test was applied for qualitative variables. The Pregnancy outcomes and Neonatal outcomes were also compared among three cerclage indications for Gestational age at delivery less than 32 weeks by applying ANOVA & Kruskal-Wallis test followed by Bonferroni post hoc analysis and Mann-Whitney U test, for quantitative variables, while Fisher's exact test was applied for qualitative variables. P-value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 101 cases had cerclage during this period out of which 86 were singleton. Eight cases were lost to follow up therefore 78 cases were included for the statistical analysis. We had a total of 61 histories indicated, 12 ultrasounds indicated, and 5 rescue cerclages. Table 1 represents the descriptive analysis of all the quantitative variables. By applying the Shapiro-Wilk test it was found that except for maternal age and BMI, all the variables were skewed. Demographic details age was in the range of 23-46 years of age with a mean age of 33.49 years, BMI 32.86, Gravida 4.92, and parity of 1.28.

Table 1: Descriptive Statistics of Maternal and neonatal characteristics (n = 78)

Maternal and Neonatal characteristics	Minimum	Maximum	Mean ± SD	Med [IQR]
Maternal age (Years)*	23	46	33.49 ± 4.81	33 [6]
BMI (kg/m^2) *	20	48	32.86 ± 7.061	33 [12]
No. of Gravida**	1	11	4.92 ± 1.946	5 [3]
No. of Para**	0	5	1.28 ± 1.338	1 [2]
No. of Abortions**	0	8	1.06 ± 1.371	1 [2]
No. of Preterm births**	0	3	0.29 ± 0.667	0 [0]
No. of Mid-trimester miscarriage**	0	7	1.63 ± 1.33	2 [1]
Gestational age at cerclage (weeks)**	12	21	15.12 ± 1.396	15 [2]
Cervical length (cm)**	1	4.3	2.8885 ± 0.6507	3 [0.75]
Cervical dilatation (cm)**	0	2	0.0974 ± 0.3553	0 [0]
Gestational age at delivery (weeks)**	18	41	35.01 ± 6.083	37 [5]
Interval between Cerclage & Delivery (weeks)**	3	26	19.85 ± 6.236	22 [5]
Neonatal birth weight (grams)**	254	4305	2534.78 ± 1059.203	2850 [1246]
APGAR score at 1 minute**	0	9	7.5 ± 2.72	9 [1]
APGAR score at 5 minutes**	0	10	8.49 ± 2.94	10 [1]
Duration of SCBU stay (days)**	0	59	1.33 ± 7.164	0 [0]

** Represents normally distributed data ** represents non-normally distributed data*

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Table 2 shows the descriptive statistics of all quantitative variables for history-indicated cerclage, rescue cerclage, and ultrasound-indicated cerclage individually. The normally distributed variables were represented by Mean + SD while skewed data was represented by Med [IQR]. There was a history of first, and second-trimester miscarriage and preterm birth in 51%, 79%, and 21.7% respectively. Before cervical cerclage, the average length of the cervix in the history and the ultrasound category were 3.14 ± 0.10 and 2.2 ± 0.22 cm, respectively. In the Rescue cerclage the mean cervical length was 1.74 ± 0.93 cm and dilation 1.02 ± 0.71 cm Gestational age at cerclage was 15 (12-17) vs 15.67 (13-18) vs 18.2 (17-21) weeks of gestation in different groups respectively in history, an ultrasound indicated and rescue cerclages

Table 2: Descriptive Analysis by Cerclage Indication (n = 78)

Maternal and Neonatal characteristics	History – indicated Cerclage (n=61)		Rescue Cerclage (n=5)		Ultrasound – indicated Cerclage (n=12)	
	P-value (Shapiro-Wilk)	Mean ± SD / Med [IQR]	P-value (Shapiro-Wilk)	Mean ± SD / Med [IQR]	P-value (Shapiro-Wilk)	Mean ± SD / Med [IQR]
Maternal age (Years)	**0.369***	33.59 ± 4.832	**0.980***	32.80 ± 5.07	**0.347***	33.25 ± 4.993
BMI (kg/m^2)	**0.052***	32.46 ± 7.406	**0.366***	34 ± 6.205	**0.378***	34.42 ± 5.632
No. of Gravida	0.048	5 [2]	**0.787***	3.6 ± 2.408	**0.199***	4.83 ± 1.992
No. of Para	< 0.001	1 [2]	0.033	0 [4]	0.048	1 [2]
No. of Abortions	< 0.001	1 [2]	0.046	0 [2]	0.011	1 [1]
No. of Preterm births	< 0.001	0 [0]	< 0.001	0 [2]	< 0.001	0 [0]
No. of Mid-trimester miscarriage	< 0.001	2 [1]	0.046	0 [2]	0.009	1.5 [2]
Gestational age at cerclage (weeks)	< 0.001	15 [1]	**0.054***	18.2 ± 1.643	**0.245***	15.67 ± 1.435
Cervical length (cm)	**0.091***	3.1459 ± 0.4109	**0.617***	1.74 ± 0.7537	0.019	2.2 [0.6]
Cervical dilatation (cm)	NA	NA	**0.481***	1.02 ± 0.7085	< 0.001	0 [0]
Gestational age at delivery (weeks)	< 0.001	38 [4]	**0.966***	28.4 ± 5.413	0.012	37 [10]
Interval between Cerclage & Delivery (weeks)	< 0.001	23 [4]	**0.293***	10.2 ± 4.55	0.042	21 [9]
Neonatal birth weight (grams)	< 0.001	2885 [1003]	**0.462***	1426 ± 1012.765	0.045	2540 [1846]
APGAR score at 1 minute	< 0.001	9 [1]	**0.429***	5.6 ± 3.782	0.001	8.5 [3]
APGAR score at 5 minutes	< 0.001	10 [1]	**0.236***	6.6 ± 4.099	< 0.001	9.5 [3]
Duration of SCBU stay (days)	< 0.001	0 [0]	< 0.001	1 [31]	NA	NA

** Represents significant p-values.*

Table 3 depicts the descriptive statistics for all the maternal and neonatal outcomes in 3 different cerclage indications. Most women had cerclage before 17 weeks. Cerclage to delivery interval was 3-26 weeks (mostly >20 weeks). The mean gestational age at delivery was 35 weeks.48 (61.5%) women had term deliveries. Mode of delivery was vaginal in 67% and cesarean section in 27%. 5 women had miscarriage, 2 had intrauterine fetal deaths, 5 had PPROM, 2 patients had abruption, 2 cases of chorioamnionitis with 2 cases of septic shock. 2 cases of MDRO noted. 2(40%) of cases in rescue cerclage had PPROM. Most of the Spontaneous Vaginal Deliveries i.e., 42 (68.9%), were observed in history-indicated cerclage. Mean birth weight was 2.5 kg and neonatal survival was 86%. 8 babies were admitted to SCBU with extreme prematurity out of which 4 had early neonatal deaths. One baby with rescue cerclage delivered at 945 gm survived after 59 days of admission.

Table 3: Descriptive Statistics for Maternal & Neonatal Outcomes (n=78)

Maternal & Neonatal Outcomes	Total (n=78)	History – indicated Cerclage (n=61)	Rescue Cerclage (n=5)	Ultrasound – indicated Cerclage (n=12)
Type of Ultrasound done TAS TVS NA	13 (16.7%) 63 (80.8%) 2 (2.6%)	12 (19.7%) 48 (78.7%) 1 (1.6%)	0 (0%) 4 (80%) 1 (20%)	1 (8.3%) 11 (91.7%) 0 (0%)
Cervical surgery Tear Shirodkar Nil	2 (2.6%) 1 (1.3%) 75 (96.2%)	2 (3.3%) 1 (1.6%) 58 (95.1%)	0 (0%) 0 (0%) 5 (100%)	0 (0%) 0 (0%) 12 (100%)
Type of surgery Elective Emergency	61 (78.2%) 17 (21.8%)	61 (100%) 0 (0%)	0 (0%) 5 (100%)	0 (0%) 12 (100%)
Mode of delivery LSCS SVD VBAC Abortion	21 (26.9%) 51 (65.4%) 1 (1.3%) 5 (6.4%)	14 (23%) 42 (68.9%) 1 (1.6%) 4 (6.6%)	1 (20%) 3 (60%) 0 (0%) 1 (20%)	6 (50%) 6 (50%) 0 (0%) 0 (0%)
Type of anesthesia General anaesthesia Spinal anaesthesia	17 (21.8%) 61 (78.2%)	14 (23%) 47 (77%)	0 (0%) 5 (100%)	3 (25%) 9 (75%)
PPROM Yes No	5 (6.4%) 73 (93.6%)	3 (4.9%) 58 (95.1%)	2 (40%) 3 (60%)	0 (0%) 12 (100%)
Chorioamnionitis Positive Negative	2 (2.6%) 76 (97.4%)	2 (3.3%) 59 (96.7%)	0 (0%) 5 (100%)	0 (0%) 12 (100%)
Antibiotic used Yes No	3 (3.8%) 75 (96.2%)	2 (3.3%) 59 (96.7%)	1 (20%) 4 (80%)	0 (0%) 12 (100%)
Septic shock Yes No	2 (2.6%) 76 (97.4%)	2 (3.3%) 59 (96.7%)	0 (0%) 5 (100%)	0 (0%) 12 (100%)
Preterm delivery Yes No	30(38.5%) 48(61.5%)	18(29.6%) 43(70.4%)	5(100%) 0(0%)	7(58.3%) 5(41.7%)
Multi-drug resistance organism Present Absent	2 (2.6%) 76 (97.4%)	1 (1.6%) 60 (98.4%)	1 (20%) 4 (80%)	0 (0%) 12 (100%)
Anti-phospholipid antibodies Present Absent	2 (2.6%) 76 (97.4%)	2 (3.3%) 59 (96.7%)	0 (0%) 5 (100%)	0 (0%) 12 (100%)
Abruption Yes No	2 (2.6%) 76 (97.4%)	1 (1.6%) 60 (98.4%)	0 (0%) 5 (100%)	1 (8.3%) 11 (91.7%)
History of Myomectomy Yes No	3 (3.8%) 75 (96.2%)	2 (3.3%) 59 (96.7%)	0 (0%) 5 (100%)	1 (8.3%) 11 (91.7%)
Bicornuate uterus – Yes No	3 (3.8%) 75 (96.2%)	2 (3.3%) 59 (96.7%)	0 (0%) 5 (100%)	1 (8.3%) 11 (91.7%)
Uterine septum Yes No	1 (1.3%) 77 (98.7%)	0 (0%) 61 (100%)	0 (0%) 5 (100%)	1 (8.3%) 11 (91.7%)
IUGR Yes	2 (2.6%)	1 (1.6%)	0 (0%)	1 (8.3%)

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Table-4(a) and Table-4(b) represent the comparison of maternal outcomes among three different cerclage indications. Gestational age at cerclage is statistically significantly different among the three cerclage indications (P-value < 0.001), by multiple comparisons it was found that gestational age at cerclage is significantly different in history-indicated cerclage and rescue cerclage with p-value < 0.001. Cervical length also showed a statistically significant difference among the three cerclage indications (P-value < 0.001). The multiple comparison results represented the considerable difference between history-indicated and ultrasound-indicated cerclage with p-value < 0.001 and history-indicated and rescue cerclage having p-value = 0.001. Cervical dilatation also showed a statistically significant difference between rescue cerclage and ultrasound-indicated cerclage (p-value = 0.019). Gestational age at delivery also showed a statistically significant difference among the three cerclage indications (p-value = 0.014). By pairwise comparison, the statistically significant difference was observed between history-indicated and rescue cerclage with p-value = 0.017. The interval between Cerclage & Delivery is also statistically significantly different among the three cerclage indications having p-value = 0.003. The pairwise comparison showed the statistically significant difference between history-indicated and rescue cerclage (p-value = 0.004). Type of surgery and PPROM were also found to statistically significantly differ among the three cerclage indications with p-value < 0.001 and p-value = 0.035 respectively. The remaining pregnancy outcomes didn't show any statistically significant difference among the three cerclage indications.

Table 4 (a): Comparison of pregnancy outcomes among different cerclage indications (n=78)

Pregnancy Outcomes	History – indicated Cerclage (n=61)	Rescue Cerclage (n=5)	Ultrasound – indicated Cerclage (n=12)	P-value
Gestational age at cerclage (weeks)	15 [1]	18.2 ± 1.643	15.67 ± 1.435	**< 0.001***
Cervical length (cm)	3.1459 ± 0.4109	1.74 ± 0.7537	2.2 [0.6]	**< 0.001***
Cervical dilatation (cm)	NA	1.02 ± 0.7085	0 [0]	**0.019****
Gestational age at delivery (weeks)	38 [4]	28.4 ± 5.413	37 [10]	**0.014***
Interval between Cerclage & Delivery (weeks)	23 [4]	10.2 ± 4.55	21 [9]	**0.003***
Cervical surgery Tea Shirodkar Nil	 2 (100%) 1 (100%) 58 (77.3%)	 0 (0%) 0 (0%) 5 (6.7%)	 0 (0%) 0 (0%) 12 (16%)	> 0.999***
Type of surgery Elective Emergency	 61 (100%) 0 (0%)	 0 (0%) 5 (29.4%)	 0 (0%) 12 (70.6%)	**< 0.001****
Mode of delivery LSCS SVD VBAC Abortion	 14 (66.7%) 42 (82.4%) 1 (100%) 4 (80%)	 1 (4.8%) 3 (5.9%) 0 (0%) 1 (20%)	 6 (28.6%) 6 (11.8%) 0 (0%) 0 (0%)	0.333***
Type of anesthesia used General anesthesia Spinal anesthesia	 14 (82.4%) 47 (77%)	 0 (0%) 5 (8.2%)	 3 (17.6%) 9 (14.8%)	0.766***
PPROM Yes No	 3 (60%) 58 (79.5%)	 2 (40%) 3 (4.1%)	 0 (0%) 12 (16.4%)	**0.035****
Chorioamnionitis Positive Negative	 2 (100%) 59 (77.6%)	 0 (0%) 5 (6.6%)	 0 (0%) 12 (15.8%)	> 0.999***
Antibiotic used Yes No	 2 (66.7%) 59 (78.7%)	 1 (33.3%) 4 (5.3%)	 0 (0%) 12 (16%)	0.238***
Septic shock Yes No	 2 (100%) 59 (77.6%)	 0 (0%) 5 (6.6%)	 0 (0%) 12 (15.8%)	> 0.999***
Preterm delivery Yes No	 18(29.6%) 43(70.4%)	 5(100%) 0(0%)	 7(58.3%) 5(41.7%)	0.118***
Multi-drug resistance organism Present Absent	 1 (50%) 60 (78.9%)	 1 (50%) 4 (5.3%)	 0 (0%) 12 (15.8%)	0.147***

Anti-phospholipid antibodies Present Absent	 2 (100%) 59 (77.6%)	 0 (0%) 5 (6.6%)	 0 (0%) 12 (15.8%)	> 0.999***
Abruption Yes No	 1 (50%) 60 (78.9%)	 0 (0%) 5 (6.6%)	 1 (50%) 11 (14.5%)	0.391***
History of Myomectomy Yes No	 2 (66.7%) 59 (78.7%)	 0 (0%) 5 (6.7%)	 1 (33.3%) 11 (14.7%)	0.527***
Bicornuate uterus with ectopic kidney Yes	 1 (100%)	 0 (0%)	 0 (0%)	 > 0.999***

** Represents the Kruskal-Wallis test applied. ** represents the Mann-Whitney U test applied. ***represents Fisher's exact test applied. P-values in bold are significant*

Table 4 (b): Pairwise Comparisons

Variables	Results	Cerclage Indications		
		History-indicated & Ultrasound-indicated	History-indicated & Rescue cerclage	Ultrasound-indicated & Rescue cerclage
Gestational age at Cerclage	Test Statistic	-15.526	-39.843	24.317
	Standard Error	6.889	10.147	11.611
	P-value	0.073	**< 0.001***	0.109
Cervical length	Test Statistic	37.738	37.297	0.442
	Standard Error	7.14	10.517	12.034
	P-value	**< 0.001***	**0.001***	> 0.999
Gestational age at Delivery	Test Statistic	9.121	28.746	-19.625
	Standard Error	7.075	10.422	11.925
	P-value	0.592	**0.017***	0.299
Interval between Cerclage & Delivery	Test Statistic	11.984	33.384	-21.4
	Standard Error	7.116	10.482	11.994
	P-value	0.277	**0.004***	0.223

*Bonferroni multiple comparisons test applied. * Represents significant p-values.*

Table-5(a) and Table-5(b) showed the comparison of neonatal outcomes among three different cerclage indications. Neonatal birth weight was found to statistically significantly differ among the three cerclage indications (P-value = 0.032), but the results of multiple pairwise comparisons of all groups were insignificant. Duration of SCBU stay also represents the statistically significant difference between history-indicated and rescue cerclage with p-value = 0.001. Admission to SCBU also showed a statistically significant difference among the three cerclage indications having p-value = 0.006. While the remaining neonatal outcomes didn't show any statistically significant difference among the three cerclage indications.

Table 5 (a): Comparison of Neonatal Outcomes among different Cerclage Indications (n=78)

Neonatal Outcomes	History – indicated Cerclage (n=61)	Rescue Cerclage (n=5)	Ultrasound – indicated Cerclage (n=12)	p-value
Neonatal birth weight (grams)	2885 [1003]	1426 ± 1012.765	2540 [1846]	**0.032***
APGAR score at 1 minute	9 [1]	5.6 ± 3.782	8.5 [3]	0.285*
APGAR score at 5 minutes	10 [1]	6.6 ± 4.099	9.5 [3]	0.251*
Duration of SCBU stay (days)	0 [0]	1 [31]	NA	**0.001****
IUGR Yes No	 1 (50%) 60 (78.9%)	 0 (0%) 5 (6.6%)	 1 (50%) 11 (14.5%)	0.391***
Intra Uterine Fetal Death Yes No	 1 (50%) 60 (78.9%)	 0 (0%) 5 (6.6%)	 1 (50%) 11 (14.5%)	0.391***

** Represents the Kruskal-Wallis test applied. ** represents the Mann-Whitney U test applied. ***represents Fisher's exact test applied. p-values in bold are significant.*

Neonatal Survival				
Yes	53 (79.1%)	3 (4.5%)	11 (16.4%)	0.198***
No	8 (72.7%)	2 (18.2%)	1 (9.1%)	
Early neonatal death				
Yes	3 (75%)	1 (25%)	0 (0%)	0.331***
No	58 (78.4%)	4 (5.4%)	12 (16.2%)	
Congenital malformation				
Yes	2 (66.7%)	0 (0%)	1 (33.3%)	0.527***
No	59 (78.7%)	5 (6.7%)	11 (14.7%)	
Admission to SCBU				
Yes	5 (62.5%)	3 (37.5%)	0 (0%)	**0.006*** **
No	56 (80%)	2 (2.9%)	12 (17.1%)	

Table – 5 (b): Pairwise Comparison of Neonatal Birth Weight

Cerclage Indications		Test Statistic	Standard Error	p-value
History-indicated	Ultrasound-indicated	10.472	7.155	0.430
History-indicated	Rescue cerclage	24.480	10.540	0.061
Ultrasound-indicated	Rescue cerclage	-14.008	12.061	0.736

Bonferroni multiple comparisons test applied.

Table-6(a) and Table-6(b) depict the comparison of maternal outcomes among three different cerclage indications for gestational age at delivery < 32 weeks. Gestational age at cerclage is statistically significantly different among the three cerclage indications (P-value = 0.020), by multiple comparisons it was found that gestational age at cerclage is significantly different in history-indicated cerclage and rescue cerclage with p-value = 0.015. Cervical length also showed a statistically significant difference among the three cerclage indications (P-value < 0.001). The multiple comparison results represented the considerable difference between history-indicated and rescue cerclage with p-value < 0.001, and history-indicated and ultrasound-indicated cerclage with p-value = 0.002. Type of surgery was also found statistically significantly different among the three cerclage indications with p-value < 0.001. The remaining pregnancy outcomes for gestational age at delivery < 32 weeks, didn't show any statistically significant difference among the three cerclage indications.

Table 6 (a): Comparison of pregnancy outcomes among different cerclage indications for gestational age at delivery less than 32 weeks (n=15)

Pregnancy Outcomes	History – indicated Cerclage (n=9)	Rescue Cerclage (n=3)	Ultrasound – indicated Cerclage (n=3)	p-value
Gestational age at cerclage (weeks)	15 [2]	17	15 ± 1	**0.020***
Cervical length (cm)	3.0889 ± 0.3480	1.2667 ± 0.3055	2 ± 0.4359	**< 0.001****
Cervical dilatation (cm)	NA	1	NA	**-**
Gestational age at delivery (weeks)	22.44 ± 3.941	25 ± 3.606	26 ± 1	0.288**
Interval between Cerclage & Delivery (weeks)	8.22 ± 4.265	7.67 ± 4.163	11 ± 1	0.518**
Cervical surgery Tear				
Shirodkar	0 (0%)	0 (0%)	0 (0%)	NA
Nil	0 (0%)	0 (0%)	0 (0%)	
	9 (60%)	3 (20%)	3 (20%)	
Type of surgery				
Elective	9 (100%)	0 (0%)	0 (0%)	**< 0.001*****
Emergency	0 (0%)	3 (50%)	3 (50%)	
Mode of delivery				
LSCS	0 (0%)	1 (50%)	1 (50%)	
SVD	5 (62.5%)	1 (12.5%)	2 (25%)	0.273***
VBAC	0 (0%)	0 (0%)	0 (0%)	
Abortion	4 (80%)	1 (20%)	0 (0%)	

Type of anesthesia used General anesthesia Spinal anesthesia	 1 (50%) 8 (61.5%)	 0 (0%) 3 (23.1%)	 1 (50%) 2 (15.4%)	 0.657***
PPROM Yes No	 2 (66.7%) 7 (58.3%)	 1 (33.3%) 2 (16.7%)	 0 (0%) 3 (25%)	 > 0.999***
Chorioamnionitis Positive Negative	 2 (100%) 7 (53.8%)	 0 (0%) 3 (23.1%)	 0 (0%) 3 (23.1%)	 > 0.999***
Antibiotic used Yes No	 1 (50%) 8 (61.5%)	 1 (50%) 2 (15.4%)	 0 (0%) 3 (23.1%)	 0.657***
Septic shock Yes No	 2 (100%) 7 (53.8%)	 0 (0%) 3 (23.1%)	 0 (0%) 3 (23.1%)	 > 0.999***
Preterm delivery Yes No	 0 (0%) 9 (69.2%)	 0 (0%) 3 (23.1%)	 2 (100%) 1 (7.7%)	 0.057***
Multi-drug resistance organism Present Absent	 1 (50%) 8 (61.5%)	 1 (50%) 2 (15.4%)	 0 (0%) 3 (23.1%)	
Anti-phospholipid antibodies Present Absent	 2 (100%) 7 (53.8%)	 0 (0%) 3 (23.1%)	 0 (0%) 3 (23.1%)	 > 0.999***
Abruption Yes No	 0 (0%) 9 (64.3%)	 0 (0%) 3 (21.4%)	 1 (100%) 2 (14.3%)	 0.400***
History of Myomectomy Yes No	 0 (0%) 9 (60%)	 0 (0%) 3 (20%)	 0 (0%) 3 (20%)	 NA
Bicornuate uterus Yes No	 0 (0%) 9 (60%)	 0 (0%) 3 (20%)	 0 (0%) 3 (20%)	 NA

** Represents the Kruskal-Wallis test applied. ** represents the ANOVA test applied. *** represents Fisher's exact test applied. P-values in bold are significant*

Table – 6 (b): Pairwise Comparisons

Variables	Results	Cerclage Indications		
		History-indicated & Rescue cerclage	History-indicated & Ultrasound-indicated	Rescue cerclage & Ultrasound-indicated
Gestational age at Cerclage	Test Statistic	-8.056	-2.222	5.833
	Standard Error	2.873	2.873	3.519
	p-value	**0.015***	> 0.999	0.292
Cervical length	Mean difference	1.8222	1.0889	-0.7333
	Standard Error	0.2385	0.2385	0.2921
	p-value	**< 0.001***	**0.002***	0.082

*Bonferroni multiple comparisons test applied. * represents significant p-values.*

Table 7 represents the comparison of Neonatal Outcomes among three different Cerclage Indications for Gestational age at delivery less than 32 weeks but all the neonatal outcomes showed insignificant differences among the three groups.

Table 7: Comparison of Neonatal Outcomes among different Cerclage Indications for Gestational age at delivery less than 32 weeks (n=15)

Neonatal Outcomes	History – indicated Cerclage (n=61)	Rescue Cerclage (n=5)	Ultrasound – indicated Cerclage (n=12)	p-value
Neonatal birth weight (grams)	593.11 ± 336.115	728.33 ± 289.151	776.67 ± 127.115	0.609*
APGAR score at 1 minute	0 [6]	3.33 ± 3.055	4.67 ± 4.163	0.560**
APGAR score at 5 minutes	0 [7]	4.33 ± 3.786	5.33 ± 4.726	0.588**
Duration of SCBU stay (days)	0 [10]	1	NA	0.489***

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IUGR Yes No	0 (0%) 9 (60%)	0 (0%) 3 (20%)	0 (0%) 3 (20%)	NA
Intra Uterine Fetal Death Yes No	1 (50%) 8 (61.5%)	0 (0%) 3 (23.1%)	1 (50%) 2 (15.4%)	0.657♣
Neonatal Survival Yes No	1 (25%) 8 (72.7%)	1 (25%) 2 (18.2%)	2 (50%) 1 (9.1%)	0.143♣
Early neonatal death Yes No	3 (75%) 6 (54.5%)	1 (25%) 2 (18.2%)	0 (0%) 3 (27.3%)	0.763♣
Congenital malformation Yes No	0 (0%) 9 (60%)	0 (0%) 3 (20%)	0 (0%) 3 (20%)	NA
Admission to SCBU Yes No	4 (66.7%) 5 (55.6%)	2 (33.3%) 1 (11.1%)	0 (0%) 3 (33.3%)	0.471♣

** Represents ANOVA test applied. ** represents the Kruskal-Wallis test applied. *** represents the Mann-Whitney U test applied. ♣ represents Fisher's exact test applied.*

DISCUSSION

This study revealed that pregnancy outcomes were similar in the history and ultrasound cerclage group. There was no statistical difference between gestational age at birth, live birth rate, mean birth weight, APGAR score, and neonatal unit admission. Perioperative complications at history-indicated cerclage are uncommon [14]. The physical examination group had a higher incidence of preterm births and complications, but cerclage improved the pregnancy outcome. The frequency of complications is higher with increasing gestational age and cervical dilatation. The complications related to cervical cerclage such as bleeding, preterm rupture of membranes, infection, and chorioamnionitis, may cause premature birth. The complications are assumed to be low for the elective cerclage gestation. It was seen that cervical cerclage indicated by physical examination had higher complications of preterm premature rupture of membranes (40%) compared with none for cervical sutures recommended by ultrasound.

In cervical cerclage advisable by ultrasound the interval between suture placements to delivery interval was more and comparable to history indicated compared to those having rescue cerclage. However, physical examination indicated cerclage influenced prolongation of pregnancy and this group delivered at a much earlier gestation. All 4 early neonatal deaths were less than 28 weeks (extreme prematurity), 3 in history and one in the physical examination indicated group[15].

There are very few studies in the literature regarding clear indications of cervical cerclage. In studies by Andrea et al and Groom et al, no notable differences were found in the pregnancy outcome in the elective, ultrasound-indicated, and rescue cervical cerclage group. The study also highlighted that delivery gestational age (35 and 33 weeks), and live birth rate (93% and 92%) had no significant deviation between planned and non-planned cervical cerclage[15,16]. Despite the poor prognosis in rescue cerclage could be placed as occasionally it could be fruitful[11]. A recent study by J. Mullin, et al. compared planned and ultrasound-assessed patients requiring cervical sutures. This study showed the majority of women undergoing ultrasound surveillance did not require a cerclage[17]. The mean gestational age of delivery was similar between women with elective cerclage and those who had ultrasound surveillance, but preterm birth rates were twice as high in the ultrasound group. Khan et al. study showed planned cerclages had a better outcome compared to emergency cerclage[18]. Our study concluded similar results with gestational age at delivery 35.67 ± 1.53 and 34.42 ± 3.41, and fetal survival rate 53(87%) & 11 (91.6%) both with history and ultrasound advocated cerclage. It is medically accepted to have cervical cerclage in ultrasound detected short cervix as compared to history indicated to improve the outcome of pregnancy resulting in a better prognosis for the newborns. This will further reduce surgical procedures which have their risks. The cervix would shorten and dilate leading to early pregnancy loss or preterm delivery in patients in whom the prime opportunity for either history or ultrasound recommended suture is missed. The cervical mucus plug efficacy is reduced when the cervix is dilated. The cervical mucus has physical and immunological properties to prevent vaginal infection resulting in premature labor [19].

Abu et al. selected 40 articles to analyze after separating the abstracts of 141 articles. The analysis disclosed that pregnancy may be prolonged on average by four to five weeks by rescue cervical cerclage, hence reduction by two-fold likelihood of

premature delivery for less than 34 weeks[20]. In our data, the interval between cervical suture and delivery was 3-14 weeks. In rescue cerclage the fetal survival rate was 60%, indicating pregnancy outcome may be improved with emergency cerclage [21,22]. In our study, we did not find any correlation with BMI. This may be because most of our cases were in the high BMI group. In a study by Poggi et al., it was disclosed that obese women had a higher chance of preterm delivery <35 weeks in comparison to average weight [23]. On the other hand, Farinelli et al. in the randomized trial found that in those at high risk of recurrent preterm birth, BMI was not associated with cervical length and gestation[24]. Suhag et al also reported length of the cervix or duration of pregnancy at birth in ultrasound-assessed cerclage was not associated with BMI[25]. Namouz et al. studied thirty-four studies and concluded that symptoms presentation, chorioamnionitis, systemic infection, cervical dilation > 3 cm, cervical cerclage after 22 weeks, and prolapsed membranes were poor outcome predictors[26]. The previous preterm deliveries as well as second-trimester pregnancy loss were independent risk factors according to our study. The use of antibiotics could enhance the cervicovaginal environment resulting in better pregnancy outcomes in ultrasound-indicated and rescue cerclage.

The weakness of our study was that it was retrospective having fewer patients. It will be beneficial to have a randomized trial in the future though it will be difficult because of ethical issues. The outcome of pregnancy was identical with both history and ultrasound groups in our study. Serial cervical ultrasound scans as surveillance in women in whom history is suggestive of cervical incompetence and cerclages can be advantageous.

In pregnancies with previous premature birth and a history of second-trimester loss in ultrasound -indicated cerclage, both play a vital part in anticipating birth less than 28 weeks of pregnancy. However, women should be properly counseled before cervical cerclage, discussing benefits, risks, complications, and any alternative management. It is considered beneficial if cervical length surveillance is done by ultrasound.[15]. It was also observed in some studies there was no advantage of cervical cerclage when the cervical length was 15–25 mm and without any risk factors for premature birth.[10]. we need a good randomized controlled trial in patients undergoing ultrasound surveillance for cervical length with other options like progesterone. This study has helped us make standard protocols and guidelines for the local population to offer better healthcare services to the community. The cervical cerclage when applied with proper indication will reduce surgical risk, preterm labor, perinatal morbidity & mortality. Proper counseling plays an important role in management.

CONCLUSION

It has been observed that there an increase in live birth rates in elective and ultrasound-indicated cervical cerclage with few complications which makes cervical length surveillance is a good option. It is hard to predict who would need rescue cervical cerclage. The rescue cerclage seems to have an advantage of prolonging the pregnancy though it may be associated with high pregnancy loss and increased complication rate due to other risk factors.

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CONFLICT OF INTEREST

None.

ETHICAL APPROVAL

This study is approved by the Centre of Studies and Research, Oman. Registration no: MOH/CSR/20/24207.

AUTHORS CONTRIBUTION

All authors contributed equally.

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