

A retrospective analysis of Cerclage versus cerclage + progesterone in a tertiary unit over a calendar year

Asena Akdeniz¹ Dr Nicole Moriarty^{1,2} Dr Natalie Suff^{1,2} Dr Manju Chandiraman^{1,2}
¹King's College London, ²Guy's and St Thomas' NHS Foundation Trust

Introduction

- Preterm Birth is defined as delivery before 37 completed gestational weeks.
- 15 Million babies are born prematurely around the world. In the UK, 53,000 babies are born annually before 37 weeks.
- Prematurity is the leading cause of neonatal morbidity and mortality in the first years of life
- Preterm infants have higher rates of admission to hospital and childhood illness in the first 5 years of life.
- Estimated cost of caring for premature neonates is £2.4 billion each year
- Interventions to reduce the risk of preterm birth include specialist preterm birth surveillance clinics, where women who have had previous preterm births, Midtrimester losses, cervical conization or other risk factors for preterm birth can be monitored. Transvaginal cervical length measurements are offered during the second trimester.
- It, and availability of medical and surgical interventions.
- The commonest preventative intervention in the UK is transvaginal cervical cerclage. These are offered for women with a significant history of preterm birth or Midtrimester loss, or who present with a cervical length <25mm on ultrasound. Emergency or rescue cerclages can also be offered for women with asymptomatic cervical dilatation in the absence of signs/symptoms of infection.
- Progesterone is also frequently used to reduce the risk of preterm birth. In the UK this is prescribed as a vaginal pessary in 200mg or 400mg doses up to 34/40.
- The aims of these interventions is to achieve 37 weeks or more gestational age prior to delivery.
- While guidelines recommend a single intervention to reduce the risk of preterm delivery, progesterone and cerclage insertion are used in combination frequently in clinical practice.
- We conducted a retrospective cohort analysis to ascertain whether combination therapy impacts the rate of preterm birth.

Results

970 Women attended the preterm surveillance clinic in GSTT in 2022. Of these, 152 underwent a cerclage for prevention of preterm birth. 16 women were excluded as their records did not show evidence of attendance to the preterm surveillance clinic in the period stated. A further 26 participants were excluded due to placement of a transabdominal cerclage prior to pregnancy. Three women had multiple pregnancies, and so were also excluded from the study. This left 108 women who had a cervical cerclage placed in the year 2022. Unfortunately, delivery data was unavailable for 38 of these participants, and so they were also excluded. Among these 70 women, 28 received vaginal progesterone in addition to cerclage, the remaining 42 were treated with cerclage alone. All women included met the inclusion and exclusion criteria.

Objectives

- Primary Outcomes:**
- Spontaneous preterm birth <37 weeks of gestation (including second trimester loss >14 weeks).
- Secondary Outcomes:**
- Spontaneous preterm birth <30 weeks and <34 weeks of gestation
 - Gestation at delivery
 - Complications of pregnancy including infection (chorioamnionitis), PROM
 - Requirement for emergency cerclage (bulging fetal membranes)
 - Time between intervention and delivery.
 - Adverse perinatal outcome

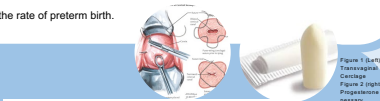


Figure 1 (left) Transvaginal Cerclage
 Figure 2 (right) Progesterone pessary

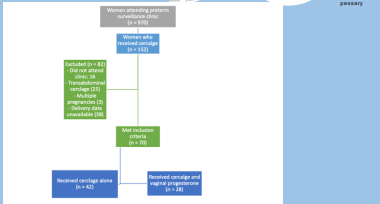


Figure 3 - Number of women included and excluded

Characteristic	Cerclage with vaginal progesterone	Cerclage	Reason for Exclusion	Treatment Group (n)	Control Group (n)
Age (years)	28	42	Age between 16-40	28	42
History Multiple Birth (n)	0	14	Multiple Birth	0	14
Time between Cerclage and Time of Delivery (weeks)	14	14	Time between cerclage and delivery	5	4
Prevalence Midtrimester Loss (n)	19	26	Midtrimester Loss	0	12
Mean Gestational Age at Time of Uterine Cervix (weeks)	16	16	Cervical length	4	23
Emergency Pessary (n)	2	0	Emergency Pessary	1	1
Mean Gestational Age at Time of Emergency Cerclage (weeks)	17	NA	Emergency Cerclage	1	1
Mean Gestational Length at Cerclage (weeks)	23	23	Gestational Length of Pregnancy	2	0
Range of Cervical Length at Cerclage (cm)	6.45	12.45	Midtrimester Fetal Loss (n)	0	0

Table 2 - The number of patients meeting each type of secondary outcome in the treatment group and the control group, and the overall number of patients in each group.

Characteristic	Cerclage with vaginal progesterone	Cerclage	Rate
Number of women (n)	28	42	36
Mean Gestational Age at Delivery (weeks)	32.7 (1.0)	35.1 (5.3)	34.6 (3.3)
Range of Gestational Age at Delivery (weeks)	16-40	16-42	16-42
Number of women <30 weeks (n)	15 (54%)	13 (31%)	34 (54%)
Number of women <34 weeks (n)	12 (43%)	20 (48%)	32 (50%)
Number of women <36 weeks (n)	7 (25%)	4 (10%)	11 (17%)
Number of women <37 weeks (n)	2 (7%)	0	2 (3%)
Number of women <38 weeks (n)	1 (4%)	0	1 (2%)

Table 1 - Gestational age at delivery

Methods

A retrospective systematic chart analysis of preterm deliveries between 1st January 2022 and 31st December 2022 at Guy's and St Thomas' NHS Foundation Trust, using electronic maternity records was conducted.
Research Question
 Among women at risk of spontaneous preterm birth, who have undergone a transvaginal cervical cerclage, is the addition of progesterone supplementation following surgery equally as effective at reducing the rates of preterm birth when compared with transvaginal cervical cerclage alone.

Hypothesis:
 We hypothesize that in women who have a transvaginal cervical cerclage in pregnancy, the incidence of sPTB <37 weeks in women who have additional progesterone therapy will be equivalent to those who have a transvaginal cerclage only.

Aim
 In a retrospective cohort study, compare the outcomes of women who have been treated with a preventative cerclage, to those who have also received vaginal progesterone.

- Inclusion:**
- Singleton pregnancy
 - Under care of preterm birth team GSTT
 - Underwent transvaginal cerclage in 2022

- Exclusion:**
- Multiple pregnancy
 - Delivery date unknown
 - Transabdominal Cerclage

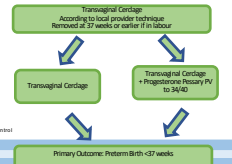


Figure 5 - Treatment group vs control

Results

- The gestational age at which each woman delivered was documented and categorised into whether they were treated with adjunct progesterone, or not. The combined mean gestational age at delivery, was 34 weeks, with a large standard deviation of 6.3. In total, 28 women (40%) had a preterm birth at less than 37 weeks of gestation. There were 22 women (31%) who delivered at less than 34 weeks, and 13 women (19%) who delivered at less than 30 weeks of gestation.
- The median gestational age was 37 weeks, with a range of 16 – 42 weeks. In this population, there were 3 miscarriages < 24 weeks, one termination of pregnancy and 2 neonatal deaths following a livebirth at delivery.
- The primary outcome observed was delivery at a gestational age of less than 37 weeks. Of those women who were treated with cerclage and progesterone, 15 (54%) had a premature birth, 13 women (30%) in the cerclage only group had a preterm birth < 37 weeks. This suggests that the use of vaginal progesterone did not reduce the rate of preterm birth in our cohort. Instead, a trend towards early delivery is visible, although confounders must still be adjusted for.
- Data was stratified for delivery at less than 37 weeks and less than 30 weeks of gestation. This also displayed no positive change following the addition of vaginal progesterone. Frequency of preterm birth at < 34 weeks in the cerclage+progesterone was 43%, this was almost double the frequency of < 34-week deliveries in the control group, which was 23%. Similarly, at < 30 weeks, the frequency of preterm births in the study group was higher than the cerclage only group (25% vs 14%, respectively).

Discussion

- Individually, cerclage and vaginal progesterone have both been shown to significantly prolong pregnancy and reduce the risk of premature delivery. Our results suggest that women who undergo either a history, or ultrasound indicated transvaginal cerclage for the prevention of spontaneous preterm birth do not benefit from the use of adjunct vaginal progesterone.
- Moreover, the study displays a trend towards a reduction in gestational age at delivery in the group who received progesterone. Despite the inability to adjust for confounding variables in this study, it is debatable that this would have a great impact on results, as factors including past obstetric history, gestational age at time of cerclage, and indication for cerclage were similar in both groups studied. Inherent bias must be considered however, as it is likely that those who were at higher risk of delivery, or interventional failure may have been offered dual therapy.
- Whilst the study demonstrated that adjunct vaginal progesterone alongside cerclage did not reduce the incidence of preterm birth compared to cerclage alone, the study does not provide sufficient statistically significant evidence to ask clinicians not to co-prescribe progesterone to at risk women. Current available research offers little definite information to support or oppose our findings, with previous studies displaying inconsistent results. Going forwards, we would recommend a large, randomised control trial to explore this further.

References

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