International Journal of Reproduction, Contraception, Obstetrics and Gynecology
Thirupathi K et al. Int J Reprod Contracept Obstet Gynecol. 2025 May;14(5):1532-1538
www.ijrcog.org
pISSN 2320-1770 | eISSN 2320-1789

DOI: https://dx.doi.org/10.18203/2320-1770.ijrcog20251237

Original Research Article

A combined efficacy of cervical cerclage and vaginal progesterone use in a pregnant woman with sonographic short cervix and its outcome- an observational study in a tertiary care centre

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Received: 13 March 2025
Revised: 04 April 2025
Accepted: 05 April 2025

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ABSTRACT

Background: Combined use of cervical cerclage procedure and vaginal progesterone administration in a women with sonographic short cervix as a treatment of cervical insufficiency is the most efficacious and safest intervention used to prevent preterm birth and neonatal morbidity/mortality.
Methods: This prospective observational study was conducted in Government Villupuram Medical College and Hospital, Villupuram over a period of June, 2022- July, 2024. This study includes a observational review of 133 patients in a tertiary care centre, who undergone transvaginal cervical cerclage procedures and vaginal progesterone administration over a period of 2 years.
Results: Out of 133 cases, only 100 cases were included in this study, remaining cases were dropped due to incomplete follow up and abortions. Overall efficacy of cervical cerclage and vaginal progesterone combination were expressed in terms of sensitivity as 86% which indicates the reduced incidence of preterm birth by improving latency period in terms of gestational age at the time of delivery as well as by decreasing the incidence of cervical dilatation prior to labour in our study group.
Conclusions: Combination of cervical cerclage and vaginal progesterone administration in a pregnant woman with a sonographic short cervix had a beneficial impact in reducing preterm birth and significant improvement in perinatal outcomes.

Keywords: Cervical cerclage, Cervical incompetence, Neonatal intensive care unit, Preterm birth, Respiratory distress syndrome, Vaginal progesterone

INTRODUCTION

Cervical incompetence can be defined as an inability of cervix to retain intrauterine pregnancy till term as a result of structural and functional defects of cervix. Also it can be described as painless Cervical dilatation which leads to recurrent second trimester pregnancy loss/births. Prematurity and preterm birth (birth before 37 weeks) related risk is higher in cases with cervical incompetence/insufficiency. In cases with second trimester pregnancy loss, 8% incidence was due to cervical incompetence.[1] Cervical cerclage has been proven to enhance the mechanical and functional length of the cervix. Using vaginal progesterone in cervical

incompetence cases who had undergone cervical cerclage procedure ascribed to enhance the relaxant effect of progesterone on myometrial strip. Vaginal progesterone administration in pregnancy maintains higher concentrations of progesterone in bloodstream by regulating metabolism of extracellular matrix and anti-inflammatory effects.[2]

Cervical cerclage procedures can be done by 2 approaches, trans abdominal and transvaginal approach. Transvaginal approach includes McDonalds and Shirodhkar procedures which was widely performed by Obstetricians and both are equally effective. Trans abdominal approach was mainly reserved for patients with repetitive failure of transvaginal procedures which leads to pregnancy loss, cervical anomalies and trachelectomized patients. As per ACOG guidelines,Cervical cerclage procedure was indicated for patients with painless Cervical dilatation in second trimester, transvaginal ultrasound (TVUS) showing cervical length <25mm , in patients with history of preterm birth(<34weeks) in previous pregnancy.[3] The success rate of cervical cerclage and vaginal progesterone combination may be affected by certain patients characteristics and a range of clinical parameters such as BMI, parity, pre cerclage cervical length and previous history of abortions, preterm births.

This observational study was aimed to delineate the combined efficiency of cervical cerclage and vaginal progesterone in cervical incompetence cases in terms of latency period, Gestational age in weeks at the time of delivery, cervical dilatation prior to labour and neonatal outcomes in terms of NICU admission (>2 weeks), APGAR score, (PNMR) Perinatal Mortality Rate, respiratory distress syndrome.

METHODS

This prospective observational study was conducted in Government Villupuram Medical College and Hospital, Tamil Nadu in 133 cases over a period of June, 2022-July, 2024 after getting approval from Institutional ethical committee. Informed written consent of patients was obtained before cervical cerclage procedures.

Inclusion criteria

ACOG recommendations on indications for cervical cerclage in a singleton gestation was taken as guidelines for our study. For patient with history of cervical insufficiency in previous pregnancy, prophylactic or history based cerclage was applied between 12-16 weeks of gestation after first trimester screening tests. For patients with painless cervical dilatation in second trimester, emergency cerclage was performed. In present pregnancy, for patients with sonographic features of short cervix (TVUS <25 mm). For patients with history of preterm birth in previous pregnancy.

Exclusion criteria

For patients with history of regular uterine contractions, active vaginal bleeding, Multiple gestation- twin gestation, foetal chromosomal anomalies/any foetal infections, chorioamnionitis, dilated cervix >3cm, pregnancies ended before 21 weeks of gestation were excluded from the study.

Interventions

Patients were subjected to detailed history taking, complete clinical examination.

Pre cerclage cervical length was measured by TVUS with empty bladder, mean value was calculated by using 3 measurements.

Degree of cervical dilatation was also measured by TVUS under sterile conditions by using povidone iodine.

McDonalds cerclage procedure was applied to all patients

Prophylactic antibiotics, intramuscular progesterone were given to all patients.

McDonalds cerclage procedure was done by grasping the anterior portion of the cervix with sponge holding forceps/clamp and purse string stitch was taken involving a band of tissue at the upper part of the cervix.

Prolapsed membranes were relocated by placing and inflating a Paediatric Foleys catheter into the cervical canal in those patients with dilated cervix < 2.5cm.

The McDonald's cervical stitch was generally removed around 37 weeks of gestation or earlier if needed.

Postoperative antibiotics and Vaginal progesterone (400mg daily at night from 16 weeks till rupture of membranes or delivery) were given to all patients.

Postoperative complications were defined as massive vaginal bleeding, chorioamnionitis and premature rupture of membranes.

Antenatal corticosteroids (dexamethasone 6mg 4 doses for 48 hrs) were given for all cases before 36 weeks of gestation.

Tocolytics (oral nifidipine 10mg od as prophylactic) was given to all cases at the time of cerclage and before 36 weeks of gestation.

Hospitalization time was defined as the period from cervical cerclage procedure until discharge.

Statistical analysis

Statistical Analysis was performed by using SPSS software. Numerical data were expressed as Mean+/- Standard deviation or Median and Range. Continuous variables were compared using Student's t test when normally distributed and using Mann Whitney U test when did not distributed normally. Chi square test was used for assessment of Qualitative variables. Values of $p<0.05$ were considered to be statistically significant.

RESULTS

In our study, 133 cases of singleton pregnant women who were at high risk of preterm birth, were selected from the outpatient department of Government Villupuram Medical College and Hospital, Villupuram, Tamil Nadu over a period of June,2022-July,2024. All 133 cases in our study group had singleton pregnancy, with gestational age at the first antenatal visit was 12-16 weeks, with history of previous spontaneous preterm birth, had sonographic length of cervix <25mm in mid trimester. Out of 133 cases in our study group, 18 cases were dropped from our study due to incomplete follow up and 15 cases were excluded from the study due to abortions before 21 weeks. The final analysis of the results included only 100 pregnant women who completed the study in this tertiary centre.

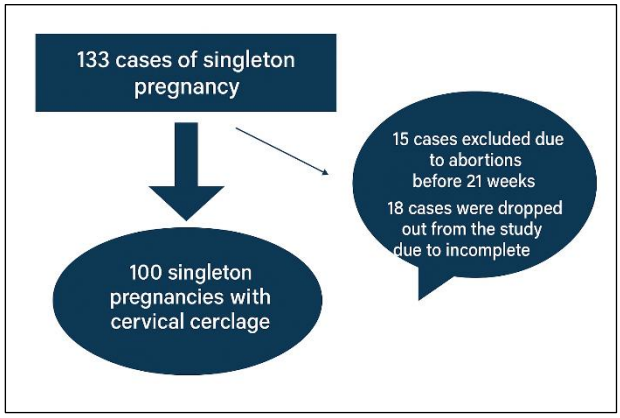

Figure 1: Flow diagram of the study.

In our study group of 100 cases, 37 cases belong to 18-25years of age, 25 cases belong to 25-30years of age, 20 cases belong to 30-35years of age and 18 cases were >35 years of age. Age distribution had no significant association with our results statistically. Our study results show distribution of cases in par with body mass index, parity, type of pregnancy, previous history of abortions/preterm birth and PPROM.

As per our study, 40 cases were distributed in BMI of 25-29.9, 29 cases were in BMI of >30, 25 cases were distributed in BMI of 18.5-24.9 and 5 cases were in BMI of <18.5. As per parity criteria, 37 cases were belonged to Primi parous group and 63 cases belongs to multiparous group. Out of 100 cases, 81 cases had spontaneous conception and 19 cases were conceived by assisted reproductive techniques. Out of 63 cases in multiparous women, 36 cases were presented with previous history of preterm birth/PPROM and remaining 27 cases had previous history of abortions.

Also, these results indicated that there were no statistically significant differences noted according to parity, body mass index, previous history of abortions/preterm birth/PPROM.

Table 1: Patient characteristics and their distribution.

Parameters	Frequency
Age	18-25 yrs-37 cases
	25-30 yrs.-25 cases
	30-35 yrs.-20 cases
	>35 yrs.-18 cases
BMI	<18.5-5 cases
	18.5-24.9-25 cases
	25-29.9-40 cases
	>30-29 cases
Parity	Prim parous-37 cases
	Multiparous-63 cases
Type of pregnancy	Spontaneous conception-81
	ART(OI/IVF)-19 cases
Previous H/o preterm birth/PPROM	36 cases
Previous H/o abortions	27 cases

In our study, TVUS done for all cases to measure pre cerclage cervical length. Out of 100 cases, 69 cases were presented with precerclage cervical length of <2.5cm, 19 cases were presented with precerclage cervical length of <2cm, 8 cases were presented with sonographic features of funnelling and 4 cases were presented with cervical dilatation (<3cm). Prophylactic cerclage (McDonald's cervical) was done for cases presented with precerclage cervical length of <2.5cm (n=69). Emergency cerclage was performed for cases presented with precerclage cervical length of <2cm (n=19), funnelling (n=8) and cervical dilatation (n=4).

Table 2: Sonographic features (TVUS) of cervical incompetence at the time of admission between 12-16 weeks of gestation.

Parameters	Frequency
Pre cerclage cervical length	
<2.5 cm	69
<2cm	19
Funnelling	8
Cervical dilatation (<3cm at the time of admission)	4

Mean hospitalization time for cases in prophylactic cerclage group was 1.13 days and for emergency cerclage group was 5.45 days. Mean gestational age (in weeks) at

the time of cerclage was 13.4 weeks+/- 1.5 days for prophylactic cerclage and 19.2 weeks+/- 2.5 days for emergency cerclage group (p=0.000). Latency period was the period from cervical cerclage to labour in weeks. Mean latency period for prophylactic cerclage group was 18.5 weeks+/- 4.3 days and for emergency cerclage group was 13.5 weeks+/- 3.5 days (p=0.000).

Mean gestational age in weeks at the time of delivery for prophylactic cerclage group was 35.3 weeks+/- 3.5 days and emergency cerclage group was 32.5 weeks+/- 5.3 days (p=0.001).

Table 3: No of cases for cerclage, mean hospitalization time, mean gestational age at cerclage, mean latency period.

Parameters	Prophylactic cerclage	Emergency cerclage	P value
No of cases for cerclage	69 cases	31 cases	
Mean hospitalization time	1.13 days	5.45 days	0.003
Mean gestational age in weeks at the time of cerclage	13.4 weeks+/- 1.5 days	19.2weeks +/- 2.8 days	0.000
Mean latency period (from cerclage to labour in weeks)	18.5 weeks +/- 4.3 days	13.5 weeks +/- 5.3 days	0.000

Mean hospitalization time, mean gestational age at the time of cerclage application were significantly higher whereas mean latency period was significantly shorter.

Table 4: Usage of vaginal progesterone, tocolytics and AN steroid in cerclage cases.

Parameters	No of cerclage cases using drugs up to 34 weeks	No of cerclage cases using drugs for more than 34 weeks
Tocolytics use	64 cases	36 cases
AN steroids use	58 cases	42 cases
Vaginal progesterone use	25 cases	75 cases

In our study, vaginal progesterone was given to all cases (n=100) who had undergone cervical cerclage procedure in our tertiary centre. Out of 100 cases, only 25 cases had taken vaginal progesterone up to 34 weeks, remaining 75 cases had taken vaginal progesterone for more than 34 weeks or till delivery or rupture of membranes. Meanwhile, tocolytics and antenatal steroids were also given for our study groups. In this study, 48 cases were covered with antenatal steroids whose gestational age less than 34 weeks and 52 cases who had gestational age >34 weeks were also covered. Tocolytics (prophylactic dose) were also given for 64 cases whose gestational age less than 34 weeks and also for 36 cases whose gestational age was more than 34 weeks.

In our study group, out of 100 cases 67 cases had undergone caesarean section (LSCS) and 33 cases were delivered vaginally. Of these 33 cases of vaginal deliveries, 29 cases had undergone prophylactic cerclage and 4 cases had emergency cerclage procedure. Out of 67 caesarean cases, 40 cases belongs to prophylactic cerclage group and 27 cases belongs to emergency cerclage group.

Table 5: Mode of delivery in cerclage cases and its Mean Gestational age in weeks at the time of birth.

Cerclage group	No. of cases. Vaginal delivery	No. of cases. Caesarean section	Mean gestational age in weeks @ birth
Prophylactic cerclage	29 cases	40 cases	35.3 weeks±3.5 days
Emergency cerclage	4 cases	27 cases	32.5 weeks±5.3 days

Our study shows that combined use of cervical cerclage and vaginal progesterone administration, significantly increased the rate of caesarean delivery in our study group but without significant differences.

The mean gestational age in weeks at the time of delivery was improved in cerclage and vaginal progesterone used cases by 35.3 weeks±3.5 days in prophylactic cerclage group whereas in emergency cerclage group it was 32.5 weeks±5.3 days. The Mean Gestational age in weeks at the time of delivery was higher in prophylactic cerclage group who had taken vaginal progesterone till delivery, but without significant differences..

In prophylactic cerclage group (n=69), 61 cases were taken vaginal progesterone for more than 34 weeks whereas 8 cases were taken vaginal progesterone for less than 34 weeks of gestation. Out of 31 cases in emergency cerclage group, only 14 cases had taken vaginal progesterone for more than 34 weeks and 17 cases had taken it for a gestational age less than 34 weeks. The sensitivity of using vaginal progesterone in cervical cerclage group was 88% and specificity was 54.8%.

In our study group, transvaginal approach of cervical cerclage (McDonald's cerclage) influences the mode of

delivery significantly. Along with vaginal progesterone use latency period also improved in our study group. The sensitivity of cerclage was 86% and specificity was 21.2% in delivered cases.

Table 6: Sensitivity and specificity of vaginal progesterone use in cervical cerclage groups.

Vaginal progesterone use in	For GA > 34 weeks (N)	For GA <34 weeks (N)	Percent
Prophylactic cerclage group	61	8	Sensitivity 88%
Emergency cerclage group	14	17	Specificity 54.8%

Table 7: Mode of delivery in cerclage and vaginal progesterone administered cases and its sensitivity and specificity.

Mode of delivery	GA>34 weeks (N)	GA <34 weeks (N)	Percent
Caesarean section	58	9	Sensitivity 86%
Vaginal deliveries	26	7	Specificity 21.2%
Complications	14	11	

Combination of cervical cerclage and vaginal progesterone usage in our study group reduces the incidence of preterm birth as well as cervical dilatation prior to term by improving gestational age in weeks at the time of delivery. Out of 100 cases, only 25 cases had cervical dilatation at the time of delivery of which 19 cases had GA >34 weeks and 6 cases had GA <34 weeks which includes 4 cases of PPROM. The remaining 75 cases were presented without cervical dilatation at the time of delivery. Based on this results, our study had sensitivity of 86% and specificity of 24% in preterm birth prevention.

Table 8: Combined efficacy of cerclage and vaginal progesterone were expressed in terms of cervical dilatation prior to labour and gestational age in weeks at the time of delivery.

Cervical dilatation	GA @ delivery >34 weeks	GA @ delivery <34 weeks	Percent
No of cases without cervical dilatation	65	10	Sensitivity 86%
No of cases presented with cervical dilatation	19	6	Specificity 24%

Perinatal outcomes of our study were expressed in terms of number of live births, birth weight, NICU admission and mean APGAR score. Out of 100 cases delivered, 98 neonates were live births and 2 neonates were died after delivery. Causes of perinatal mortality (PNMR) was extreme preterm (GA <30 weeks) and extremely low birth weight (ELBW<1.5kg). Number of neonates admitted in NICU was 27 cases, of which 14 cases were admitted due to respiratory distress and 11 cases due to neonatal sepsis. Out of 100 neonates, 39 babies had birth weight in range of 2- 2.5kg, 31 babies had birth weight of 2.5-3kg, 17 babies had b.wt >3kg and 13 babies had b.wt of <2kg. According to our study reports, Neonatal birth weight is not statistically significant.

The mean Apgar score was higher in our study group but it is statistically insignificant.

Table 9: Perinatal outcome in terms of birth weight, Apgar score, NICU admission.

Parameters	No. of cases
Total no of live births	98
PNMR	2
NICU admission	
Respiratory distress	14
Neonatal sepsis	11
>2 weeks admission	27
Birth weight in kg	
<1.5	2
1.5-2	11
2-2.5	39
2.5-3	31
>3	17

DISCUSSION

For the successful outcome of cervical cerclage and vaginal progesterone administration was determined by the prevention of preterm birth and its related adverse outcomes.

In our study group, Age and type of pregnancy in case distribution were similar in both prophylactic and emergency cerclage group, but BMI values were significantly higher in emergency cerclage group.

As per Suhag et al study, BMI has no effect on outcomes of cervical cerclage and there was no association between BMI and latency period.[4] High BMI values has been noted to have various adverse Obstetric outcomes. Our study indicated that high BMI values noted to have a negative effect on cerclage efficiency, this should be considered during pre-procedural counselling.

In our study group prophylactic cerclage was done for 69 cases and emergency cerclage was done for 31 cases, whereas vaginal progesterone was given for all cases who had undergone cervical cerclage. Out of 100 cases, only 25 cases had vaginal progesterone usage up to 34 weeks and remaining 75 cases had vaginal progesterone uptake for more than 34 weeks. As per our study, the combined effect of cervical cerclage and vaginal progesterone administration improves the gestational age at the time of birth and lowers the complication rate.

As per ACOG guidelines, cervical cerclage reduces the 20% incidence of preterm labour in cases with previous history of spontaneous preterm birth and short cervical length.[3] It acts mainly by providing mechanical support and promotes Cervical mucus plug formation which guards against ascending infections.

Our study results were similar to the study conducted by Naim et al, which stated that cerclage and vaginal progesterone combination ensured greater reduction of preterm labour (80% cases delivered at term) whereas in our study group 86% reduction in preterm birth was reported due to combined effect of cervical cerclage and vaginal progesterone administration.[5]

As per Berghella and Mackeen et al, meta-analysis from 4 RCT trials, patients with previous history of cervical insufficiency can be followed by serial TVUS cervical length measurements which excludes unnecessary interventions and cerclage related complications.[6] A retrospective study of Brown et al revealed that 50% patients with history of cervical insufficiency did not require cervical cerclage while followed by serial TVUS measurements.[7]

As per Liddiard et al, comparison of obstetric outcome of patients between prophylactic and emergency cerclage group in terms of gestational weeks, birth weight, live birth rate, NICU admission proved that complication rate was higher in emergency cerclage group than prophylactic cerclage group.[8]

As per RCOG and ACOG guidelines, there was 20% recognised reduction of preterm birth in a women with previous history of spontaneous PTB/short cervix by cervical cerclage. It acts through delivering mechanical support to a weakened cervix together with supporting the cervical mucosal plug guarding against ascending infection.[9]

Our study results were similar to Simsek et al in view of significant difference in hospitalization time between prophylactic and emergency cerclage group.[1] In prophylactic cerclage group, mean gestational weeks at the time of birth, mean birth weight was significantly higher, whereas complication rate and delivery under 34 weeks of gestation were significantly higher in emergency cerclage group.

Our study results were akin to Alfirevic et al, which proved that equal effectiveness noted in both vaginal progesterone and cerclage for women with singleton pregnancy, short cervical length in transvaginal ultrasound and at least one prior preterm birth.[10]

As per O Brien et al study conducted for 2 years on patients with history of 2 abortions or preterm deliveries, 73.7% of cerclage patients reached term, 12% had preterm delivery, 7% had abortions.[11] The study conducted by Celen et al revealed that after cerclage 76% delivered at term, 12% had preterm, 10% had abortions.[12] Our study results were consistent with this study since 84% of cerclage patients reached term and 16% had preterm birth.

The study of Romero et al found that vaginal progesterone improves the outcome by reducing the preterm birth, foetal death in singleton pregnancy and midtrimester cervical length </= 25 mm.[13] The meta analysis of OPPTIMUM study proved that vaginal progesterone had significantly reduced the preterm birth risk than foetal death risk.[14] The PROGRESS study assessed that vaginal progesterone effectively prevent the preterm birth.[15]

According to Jarde et al, vaginal progesterone suppositories had significant positive results in women with previous preterm birth than vaginal gel and pessaries.[16]

Limitations

The study population size itself was small when compared to the incidence of cervical incompetency which further reduced due to incomplete follow up and abortion outcome. The small subgroup analyses makes less reliable statistical comparisons. Our study excludes multiple pregnancy, Shirodhkar cerclage procedure and hence it's impact on outcome was not evaluated. The impact of neutrophil lymphocyte ratio on obstetrical outcome was not evaluated.

CONCLUSION

The final outcome of our study implicates that cervical cerclage and vaginal progesterone had significant beneficial outcome in prevention of preterm birth and improvise perinatal outcome in patients with history of preterm birth and short cervix length in transvaginal ultrasound. The effect of cervical cerclage assumed to be somewhat superior in comparison with vaginal progesterone. The vaginal progesterone usage also has some assuring results. The neutrophil lymphocyte ratio also found to be raised in cerclage group.

Further clinical trials needed to relate vaginal progesterone heterogeneity to reduce neonatal death. The combination of both cervical cerclage and vaginal progesterone therapy effect on perinatal outcome might need large level randomized controlled trials.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Thirupathi K, Nathan JM. A combined efficacy of cervical cerclage and vaginal progesterone use in a pregnant woman with sonographic short cervix and its outcome- an observational study in a tertiary care centre. Int J Reprod Contracept Obstet Gynecol 2025;14:1532-8.