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ORIGINAL

Study on effect of vaginal progesterone to prevent preterm Labour in Women having borderline short cervix detected during tiffa scan

Estudio sobre el efecto de la progesterona vaginal para prevenir el parto prematuro en mujeres con cuello uterino corto borderline detectado durante la gammagrafía tiffa

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ABSTRACT

Worldwide, preterm birth accounts for 9 to 12 percent of all birth-related death and morbidity among infants. Most reliably predicting preterm delivery is the length of the cervical canal in 16 - 24 weeks of pregnancy. A cervical length of 25-35 mm during 16–24 weeks of pregnancy is considered to be borderline. Role of progesterone is quite important during pregnancy in preventing contractions. The purpose of this research is to do a comparison of the efficacy of vaginal progesterone versus no treatment in preventing spontaneous preterm labour when a short cervix is diagnosed by TIFFA scan. 120 antenatal cases at 16 to 24 weeks of gestation were chosen. 60 patients with borderline short cervix were taken, out of which 30 patients who received vaginal progesterone were taken as cases, and 30 others who did not receive were taken as the control. 30 patients with the normal cervix who did not receive progesterone and 30 women who had smaller cervix who received vaginal progesterone were observed for their outcome. It was observed that in case (borderline cervix) group, there was more term deliveries (67 %), in control (borderline cervix) was more early preterm deliveries (57 %), in normal group was 100 % term deliveries and in short cervix group was more early preterm deliveries (43 %). Vaginal delivery was seen in 83 % of patients in the case (borderline cervix),70 % in control (borderline cervix),90 % in the normal cervix, and 90 % in the short cervix group.

Keywords: Cervical Length; Preterm Labor; Short Cervix; Vaginal Progesterone.

RESUMEN

En todo el mundo, el parto prematuro representa entre el 9 y el 12 por ciento de todas las muertes y morbilidad relacionadas con el nacimiento entre los lactantes. La medida más fiable para predecir un parto prematuro es la longitud del canal cervical entre las semanas 16 y 24 de embarazo. Una longitud cervical de 25-35 mm durante las semanas 16-24 de embarazo se considera límite. El papel de la progesterona es muy importante durante el embarazo para prevenir las contracciones. El objetivo de esta investigación es comparar la eficacia de la progesterona vaginal frente a la ausencia de tratamiento en la prevención del parto prematuro espontáneo cuando se diagnostica un cuello uterino corto mediante la exploración TIFFA. Se eligieron 120 casos prenatales de 16 a 24 semanas de gestación. Se tomaron 60 pacientes con cuello uterino corto limítrofe, de las cuales 30 pacientes que recibieron progesterona vaginal se tomaron como casos, y otras 30 que no la recibieron se tomaron como control. Se observaron los resultados de 30 pacientes con cuello uterino normal que no recibieron progesterona y de 30 mujeres con cuello uterino más pequeño que recibieron progesterona vaginal.

Se observó que en el grupo de caso (cuello uterino limítrofe) hubo más partos a término (67 %), en el control (cuello uterino limítrofe) hubo más partos prematuros precoces (57 %), en el grupo normal hubo un 100 % de partos a término y en el grupo de cuello uterino corto hubo más partos prematuros precoces (43 %). El parto vaginal se observó en el 83 % de las pacientes del grupo de casos (cuello uterino limítrofe), el 70 % del grupo de control (cuello uterino limítrofe), el 90 % del grupo de cuello uterino normal y el 90 % del grupo de cuello uterino corto.

Palabras clave: Longitud Cervical; Parto Prematuro; Cuello Uterino Corto; Progesterona Vaginal.

INTRODUCTION

It can be said that nine percent to twelve percent of deliveries throughout the globe are complicated by this condition, making it the major reason for neonatal illness and death.[1] While the precise reason is uncertain, some hypothesised causes include decidual bleeding, cervical incompetence, uterine distension, maternal fever, hormonal abnormalities, and uteroplacental insufficiency. An alarming fact come out which indicates that there has been a significant rise in premature infant deaths due to:[2]

- Fertility-enhancing drugs and procedures which results in multiple births;
- Early induction even in preterms or Caesarean section for pathological pregnancies;
- Increased registration of births near the borderline of viability; and
- Accurate estimation of gestational age by early ultrasound.

Premature infants who make it to their first birthday are more likely to suffer from Long-term effects include cerebral palsy, reduced learning, and chronic illnesses, while short-term effects include respiratory and gastrointestinal infections, central nervous system, hearing and visual disorders.

Using ultrasonography to evaluate the cervical canal is a risk-free, noninvasive, and highly accurate way for predicting the onset of labour. A woman's cervix may alter size and shape, and a USG can detect these changes, allowing for early labour to be predicted.[3] The cervix of a uterus that is not pregnant measures 35 mm to 55 mm in length. Any length between 25 and 35 millimeters at 16 to 24 weeks of pregnancy is considered to be borderline. Premature birth may be predicted with high accuracy by measuring the cervical length between 16 and 24 weeks of pregnancy.[4] Ultrasound imaging of the cervix and the lower uterine area is a reliable diagnostic tool during pregnancy. Women whose cervical lengths measure less than 25 mm have an increased risk of giving delivery before the 24-week mark. At fewer than 14 weeks of gestation, a short cervix may be hard to detect since the lower uterine segment may not have matured.

The hormone progesterone plays a crucial role in keeping a pregnancy going. Cervical ripening, cervical dilation, and preterm labour may all be linked to a decrease in its effect.[5] Clinical evidences for the role of progesterone in ripening the cervix throughout the third trimester and at term is provided by the impact of the progesterone receptor antagonist (mifepristone) in doing so.[6] Because of its ability to block oxytocin's effects and slow the creation of gap junctions, progesterone keeps the uterus quiet. Myometrial contraction-related gene expression and the production of stimulating prostaglandins are also downregulated. There has been no evidence of teratogenic consequences from beginning progesterone medication during the second trimester of pregnancy.

Women with a short or inadequate cervix may benefit from progesterone supplementation, since this has been established in a number of randomised studies.[7]

A recent “meta-analysis of five high-quality trials in asymptomatic women with a short cervix (25mm) at mid-trimester found that vaginal progesterone substantially reduced the risk of PTB and neonatal morbidity and mortality”.[8] Preterm labour of fewer than 33 weeks was reduced in women who had a "sonographically short cervix in the middle of their pregnancy, a singleton pregnancy, and a history of spontaneous" PTB when progesterone was administered vaginally (relative risk [RR]:0,62;95 % CI:0,47-0,81; P=0,006).

The risk of premature birth can be reduced by using vaginal progesterone, according to recent studies. This is especially true for women whose cervixes are shorter than 25 mm. The occurrence of a cervix that is too short on sonography is modest, according to previous study.[9] “Women with an initial cervical length of 26 to 29 mm” had a significantly higher rate “of spontaneous preterm birth at 37 weeks gestation than a historical cohort of low-risk women with an initial cervical length >25 mm”.[10]

METHODS

This research was a cross-sectional study that took place over the course of a year at the obstetrics and gynaecology unit at SCB Medical College and Hospital in Cuttack, Odisha, India. (November 2020 to November 2021) after obtaining approval from the Institute’s Ethical Commitee (EIC No.516). The study and control group were picked up from the women attending the Antenatal OPD and Labor room. 120 Antenatal cases

at 16 to 24 weeks of gestation were chosen and those who had a short cervix, borderline short cervix, and normal cervix during TIFFA Scan were taken. Sample size was calculated for each group by using the formula: Z^2*p*q/d^2=2,58^2(0,01) (0,99)/ (0,05) (0,05) =27 where Z at 1 % significant level for two-tailed test=2,58, p=proportion for incompetent cervix =0,01, q=1-p=0,99 and d=error. So, the sample size was taken as 30 in each group. Total sample =4*30= 120.

Inclusion criteria consisted of Singleton pregnancy, Pregnant women at 16 to 24 weeks with a borderline short cervix (2,5 to 3,5 cm), short cervix (less than 2,5 cm), and normal cervix (3,5 to 5 cm) as detected during the TIFFA scan and history of previous preterm birth.

Pregnant women with more than 24 weeks gestation, Women with cervical cerclage in the current pregnancy, Multiple gestations, Pregnant women with medical or surgical illness, Pregnant women with obstetric complications,

Hemodynamically unstable patients and patients with Major uterine malformations were excluded from the study.

Each woman had a TIFFA scan performed to gauge her cervical length. All subjects provided their informed permission before the research began. The patient's history was carefully recorded, and a thorough physical examination was performed. Women who underwent a dating scan and could accurately recall the date of their previous menstrual cycle were the only ones included.60 patients with borderline short cervix were taken, out of which 30 patients received vaginal progesterone and were taken as cases, and 30 others who did not receive were taken as the control. 30 patients with the normal cervix who did not receive attention in the postpartum period and the perinatal outcome of the groups were compared. Data was collected regarding-

- Gestational age at the entry into the study.
- Cervical length at the entry into the study.
- Duration of gestation in completed weeks.
- Mode of delivery.
- Condition of the newborn.

Compliance with Ethical Standards

The authors confirm that they have no financial or personal stakes in the outcomes of this work.

This research was green-lighted by the Institutional Ethics Committee (IEC) with approval number 516. All participants provided their informed consent before taking part.

All observations were subjected to analysis and necessary statistical calculations were made. The interpretation was done by processing the data the IBM Social Science Statistical Software, Version 20. The Chi-square test was used for statistical analysis to compare categorical data. In order to analyse the data from the independent samples (Mean+/-SE), the F-test was used. Important outcomes were “defined as those with a p value of 0,05”, and very important results as those with a p value of 0,001.

RESULT

Table 1 The mean age of subjects in case (borderline cervix) was (20,56 ± 0,47) years, control (borderline cervix) was (20,70 ± 0,44), normal cervix was (21,87 ± 0,44) and in short cervix was (21,63 ± 0,57). The mean age in all groups was more or less similar (p=0,237).

Table 1. Association between different groups of patients and age

Group	Age group (years)			Total	Mean+/standard error	Pvalue
	<20	20-25	26-30		==	
Case (borderline cervix)	13(43 %)	15(50 %)	2(7 %)	30	20,56 ± 0,47	0,237
Control (borderline cervix)	12(40 %)	17(57 %)	1(3 %)	30	20,70 ± 0,44	
Normal cervix	13(43 %)	11(37 %)	6(20 %)	30	21,87 ± 0,67	
Short cervix	11(37 %)	17 (57 %)	2 (6 %)	30	21,63 ± 0,57	
Total	49	60	11	120		

Table 2 evaluates the Association between different groups of patients and Socio-Economic Status using the Modified Kuppuswamy Scale. Lower and upper-lower groups together comprised of a majority of the patients, 90 % in case (borderline cervix),67 % in control (borderline cervix),74 % in the normal cervix, and 73 % in the short cervix group. There were no patients in the upper-class group.

Table 3 evaluates the Association between different groups of patients and gestational age (GA) at delivery in weeks. Each group comprised 30 patients. It was observed that in case (borderline cervix) group, there was more term deliveries (67 %), in control (borderline cervix) was more early preterm deliveries (57 %), in normal

group was 100 % term deliveries and in short cervix group was more early preterm deliveries (43 %). The mean GA of subjects in case (borderline cervix) was (37,42 ± 0,45) weeks, control (borderline cervix) was (33,83 ± 0,44), normal cervix was (39,49 ± 0,13) and in short cervix was (35,54 ± 0,66) weeks.

Table 2. Association between different groups of patients and Socio-Economic Status

Group	Socio Economic Status				Total	x2	P value
	1 (lower)	2 (Upper lower)	3 (Lower middle)	4 (Upper middle)			
Case (borderline cervix)	12 (40 %)	15 (50 %)	3 (10 %)	0(0 %)	30	9,01	0,436
Control (borderline cervix)	8 (27 %)	12 (40 %)	9 (30 %)	1 (3 %)	30		
Normal cervix	11 (37 %)	11 (37 %)	8 (26 %)	0(0 %)	30		
Short cervix	13 (43 %)	9 (30 %)	8 (27 %)	0 (0 %)	30		
Total	44	47	28	1	120		

Table 3. Comparison of Mean value (± Standard Error) of different parameters Between Study group

Group Parameter	Case (borderline cervix)	Control (borderline cervix)	Normal cervix	Short cervix	P- Value
Age (Age)	20,56 ± 0,47	20,70 ± 0,44	21,87 ± 0,67	21,63 ± 0,57	0,237
GA by LMP (weeks) (screening)	21,22 ± 0,37 a	21,02 ± 0,38 ab	20,38 ±0,38 ab	19,69 ± 0,41 b	0,025
GA at USG (weeks) (TIFFA Scan)	20,83 ± 0,39 a	20,36 ± 0,34 ab	19,88 ± 0,028 ab	19,34 ± 0,31 b	0,015
Cervix Length (cm)	2,87 ± 0,06 b	2,92 ± 0,05 b	4,10 ± 0,05 a	2,18 ± 0,03 c	<0,001
GA at Delivery (Weeks)	37,42 ± 0,45 b	33,83 ± 0,44 c	39,49 ± 0,13 a	35,54 ± 0,66 d	<0,001
Birth Weight (Kg)	2,79 ± 0,08 a	2,10 ± 0,15 b	2,48 ± 0,07 ab	2,40 ± 0,10 ab	<0,001

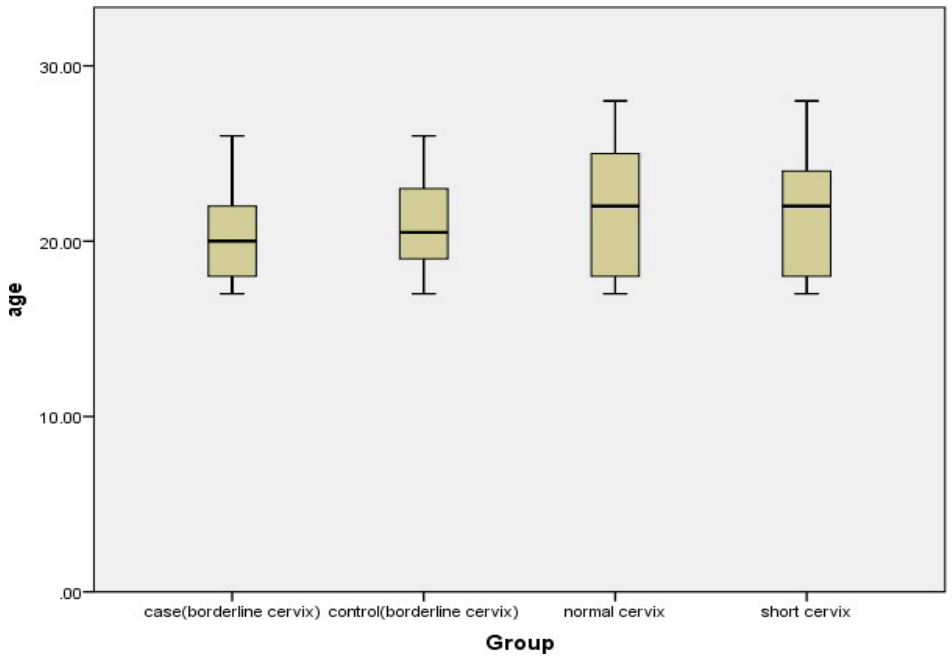

Figure 1A. Box plot of age with outliers

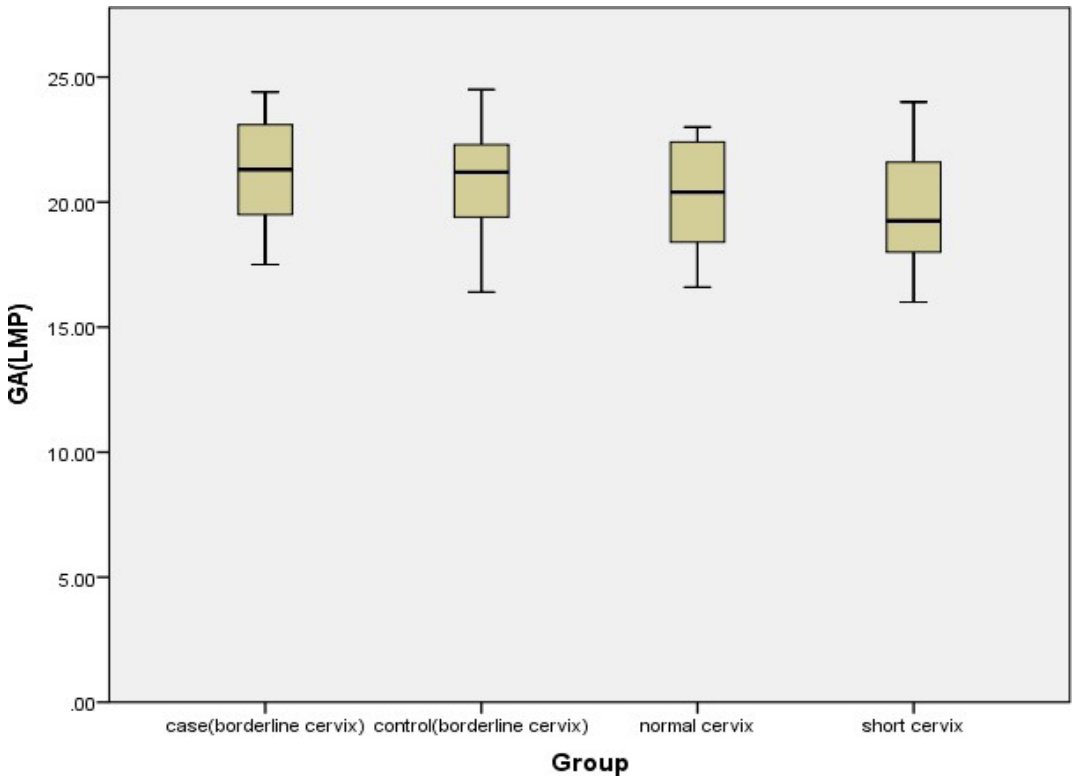

Figure 1B. Box plot of Gestational Age at LMP (weeks) with outlier

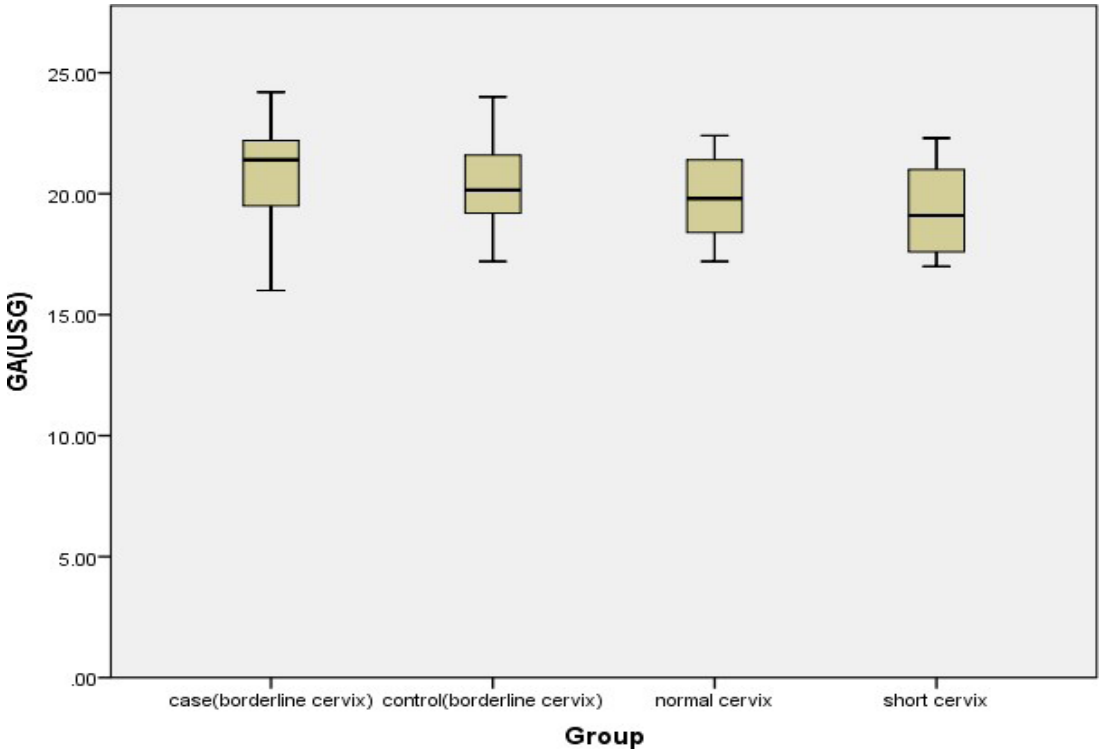

Figure 1C. Box plot of Gestational Age in USG (weeks) with outliers

Table 4 evaluates the Association between different groups of patients and birth weight in kg. Each group comprised 30 patients. It was observed that in the case (borderline cervix) group, birth weight was in the normal range (83 %), in control (borderline cervix) was more low birth weight (57 %), in normal group was 50 % normal birth weight babies and in short cervix group was more low birth weight babies (53 %). The mean birth weight of subjects in case (borderline cervix) was (2,79 ± 0,08) kgs, control (borderline cervix) was (2,10 ± 0,15), normal cervix was (2,48 ± 0,07) and in short cervix was (2,40 ± 0,10) weeks. The association was statistically highly significant (P = 0,001)

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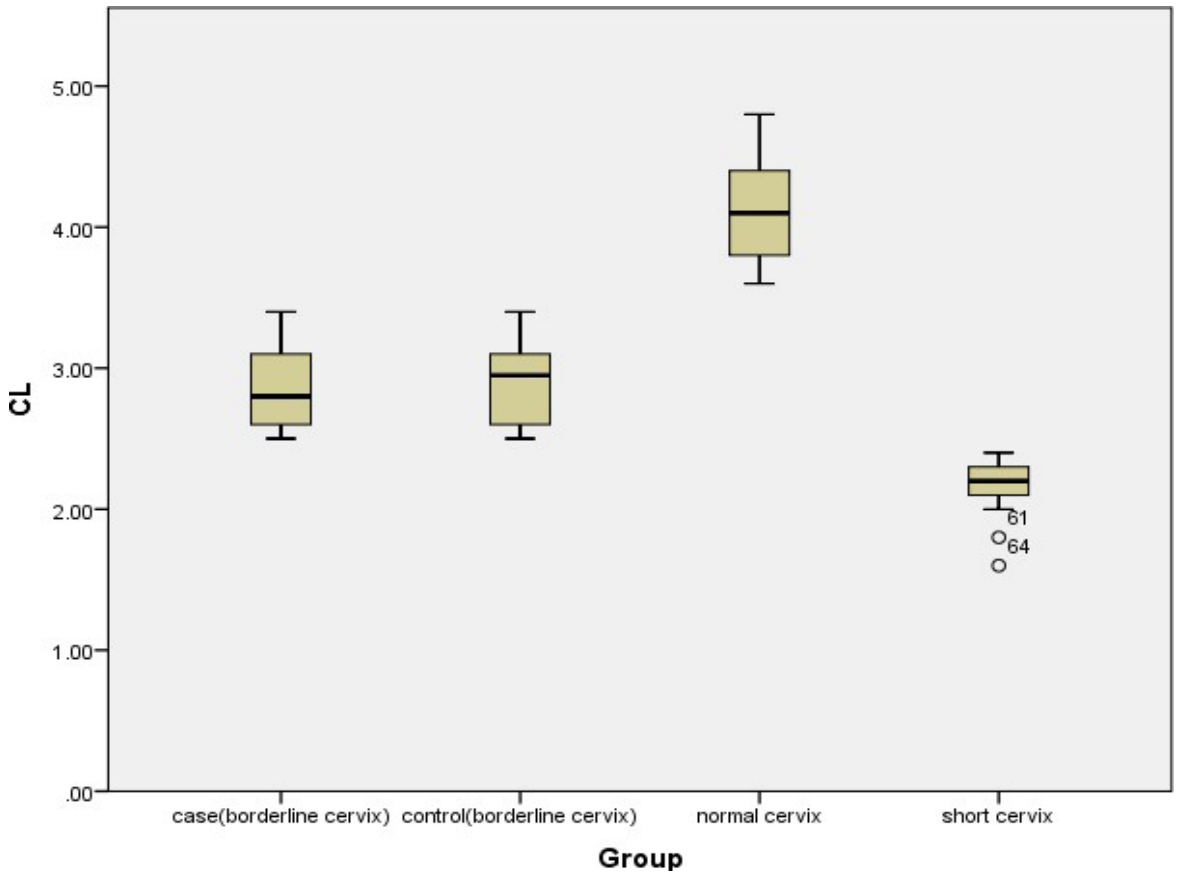

Figure 1D. Box plot of Cervix Length (cm) with outlier

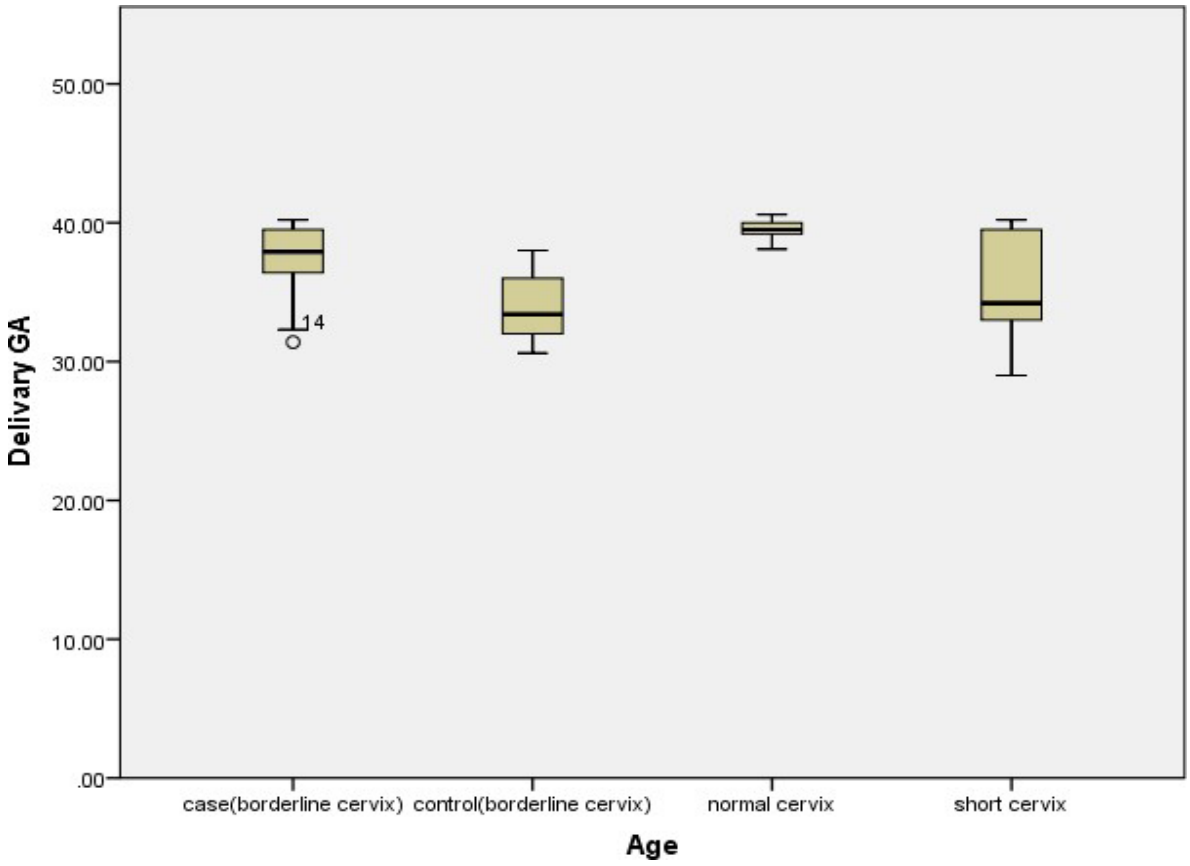

Figure 1E. Box plot of GA (Delivery) with outliers

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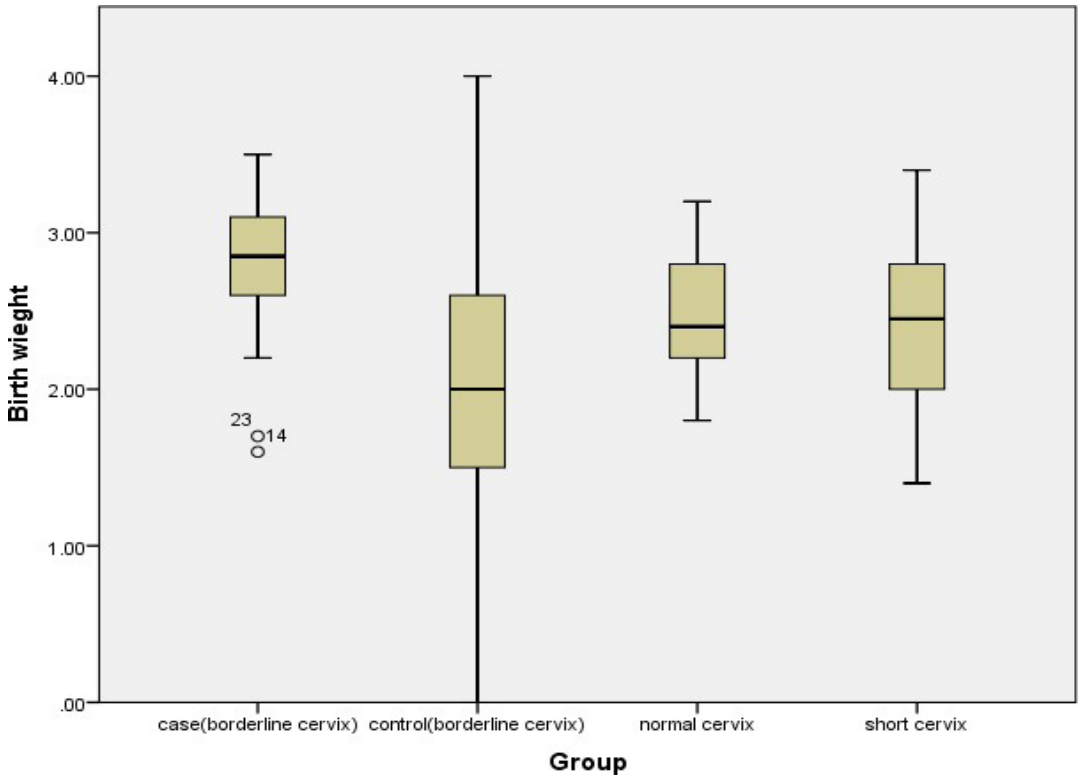

Figure 1F. Box plot of Birth Weight (kg) with outliers

Table 4. Association between different groups of patients and Pattern of Delivery

Group	Pattern Of Delivery		Total	x2	P-value
	Caesari n Section	Vaginal Delivery			
Case (borderline cervix)	5 (17 %)	25 (83 %)	30		
Control (borderline cervix)	9 (30 %)	21 (70 %)	30		
Normal cervix	3 (10 %)	27 (90 %)	30	5,760	0,124
Short cervix	3 (10 %)	27 (90 %)	30		
Total	20	100	120		

Table 5 evaluates the Association between different groups of patients and the Pattern of Delivery. Vaginal delivery was seen in 83 % of patients in the case (borderline cervix),70 % in control (borderline cervix),90 % in the normal cervix, and 90 % in the short cervix group. Caesarian section was observed 17 % in the case (borderline cervix) group, 30 % in the control (borderline cervix) group, 10 % in the normal cervix group, and 10 % in the short cervix group. The association is not statistically significant (P = 0,124).

Table 5. Association between different groups of patients and SNCU admission

Group	SNCU Admission		Total	x2	P- value
	No	Yes			
Case (borderline cervix)	25 (83 %)	5 (17 %)	30		
Control (borderline cervix)	11 (37 %)	19 (63 %)	30		
normal cervix	25 (83 %)	5 (17 %)	30	25,567	<0,001
short cervix	12 (40 %)	18 (60 %)	30		
Total	73	47	120		

Table 6 evaluates the Association between different groups of patients and SNCU admission. Sncu admission was 17 % in the case (borderline cervix) group,63 % in the control (borderline cervix) group,17 % in the normal

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cervix group, and 60 % inthe short cervix group. The association was observed highly significant (P < 0,01)

Figure 1 A-F evaluate the comparative analysis of the mean of different groups of patients and parameters in which the Age is not statistically significant (P = 0,237); GA at LMP and USG (week) were observed significant (P = 0,025 and 0,015) difference. Other parameters such as Cervix Length (cm), GA at Delivery (Weeks), and Birth Weight (Kg) were observed. The mean GA by LMP during the screening and at USG (TIFFA Scan) was between 19 to 21 weeks and the association was significant. The mean cervical length in case (borderline cervix) was (2,87 ± 0,06) cm, in control (borderline cervix) was (2,92 ± 0,05) cm, in normal cervix was (4,10 ± 0,05) and in the short cervix, it was (2,18±0,03) and the association was found to be significant. The mean GA at delivery in case (borderline cervix) was (37,42 ± 0,45), in control was (33,83 ± 0,44), in normal cervix was (39,49 ± 0,13) and in the short cervix, it was (35,54 ± 0,66) and the association was (p<0,001). The mean birth weight in cases (borderline cervix) was (2,79 ± 0,08), in control (borderline cervix) was (2,10 ± 0,15), in normal cervix was (2,48±0,07) and in short, cervix was (2,40 ± 0,10) and was found to be statistically significant (<0,001).

DISCUSSION

We used TIFFA scans to determine whether or not 120 pregnant women who were seen in the “Department of Obstetrics and Gynecology” at SCB Medical College in Cuttack had a short cervix, a borderline cervix, or a normal cervix.

Oliveira et al.[11] studied the average mother's age when she was identified with the need for a cervical measurement to avoid premature birth was 33,8.

Bortoletto et al.[12] investigated the average cervical length in high-income nations was 40,03 millimetres, whereas in middle- and low-income countries it was 35,33 millimetres.

Gulersen et al.[13] studied that were more likely to give birth prematurely who had 10mm cervical length (at 32 or 34 weeks gestation) as compared to 10 mm (p<0,001).

Romero et al.[14] investigated 974 women with cervixes shorter than 25 millimetres. Researchers found a substantial (P=0,0006) a decrease in the probability of having a baby too soon Vaginal progesterone users reached 33 weeks of pregnancy on average. Preterm birth (under 33 weeks), respiratory distress syndrome, severe illness at birth, and the need for admission to a newborn intensive care unit were all significantly reduced.

Einerson et al.[15] discovered that universal transvaginal cervical length screening for women without a history of spontaneous preterm delivery, followed by vaginal progesterone therapy for those with a cervical length 20 mm, was more cost-effective than risk-based screening or no screening.

Werner et al.[16] reevaluated the practice of providing vaginal progesterone to all pregnant women with a singleton pregnancy, no history of preterm delivery, and a cervical length of 20 mm or greater in 2015. Despite the model's modest cervical length 20 mm incidence (0,83 %), this technique was cost-effective.

Abdel-aleem et al.[17] investigated that between 18 and 22 weeks of pregnancy, a neck circumference of less than 25 mm was reported in a randomized controlled experiment. In contrast, the use of the pessary in pregnant women significantly decreased the rate of spontaneous premature birth at or below 37 weeks.

Conde-Agudelo et al.[18] found that giving women vaginal progesterone who had a sonographically short cervix reduced the risk of preterm delivery and neonatal morbidity and death without increasing the risk to the mother or the baby.

We found that the substantial differences in GA at LMP and USG (week) were statistically significant (P=0,025 and 0,015, respectively), which is in line with the findings of other research. There were also very significant differences (P=0,001) in other characteristics, including the length of the cervix in centimeters, the gestational age at delivery in weeks, and the birth weight in kilograms. In addition, the current investigation found a very significant (P=0,001) correlation between certain patient subgroups and admission to the SNCU.

Study Limitations

1. Non-probability sampling method was adopted.
2. Maximum patients coming to government hospitals are financially poor. For them, it is difficult to use progesterone as its cost is high.
3. Single-center study.
4. Single-dose as 200 mg.

CONCLUSION

The present study “the effect of vaginal progesterone to prevent preterm labor in patients having borderline short cervix detected during TIFFA Scan” took place from November 2020 to November 2021 at the S.C.B. Medical College and Hospital's Obstetrics and Gynecology Department in Cuttack. Twelve-hundred mothers who were expecting a single baby were included subjected to TIFFA Scan for cervical length estimation 16 to 24

weeks of gestation after excluding high-risk pregnancies. Vaginal progesterone was given to 30 women having borderline short cervix and 30 women having short cervix. Vaginal progesterone was not given to 30 women having borderline short cervix and 30 women having normal cervix. Mean GA by LMP during the screening was between 19 to 21 weeks and mean GA at USG (TIFFA Scan) was between 19 to 20 weeks and the association was observed to be statistically significant (p=0,025 and 0,015). Mean cervical length in case (borderline cervix) was (2,87±0,06) cm, in control (borderline cervix) was(2,92±0,05), in normal cervix group was (4,10±0,05) and in short cervix group was (2,18±0,03) and the association was statistically high (p<0,001). Mean GA at delivery in cases (borderline cervix) was (37,42±0,45) weeks, in control (borderline cervix) was (33,83±0,13) weeks, in normal cervix group was (39,49±0,13) and in short cervix was (35,54±0,66) weeks and the association was observed to be highly significant (p<0,001). Average weight of babies born in cases (borderline cervix) was (2,79±0,08) kgs, in control (borderline cervix) was (2,10±0,15) kgs, in normal cervix group was(2,48±0,07) kgs and in short cervix group was (2,40±0,10) kgs. The association was observed to be highly significant (p<0,001). The association between different groups of patients and pattern of delivery was not statistically significant (p=0,124). There was more vaginal delivery seen in all the groups. SNCU admission was observed more in the control (borderline cervix) group (63 %) and in the short cervix group (60 %). Case (borderline cervix) group and normal cervix group had only (17 %) SNCU admission. So, the association was observed to be highly significant (p<0,001).

"Vaginal progesterone treatment" in women with a borderline short cervix raised mean GA from (33,83±0,13) weeks to (37,42±0,45) weeks, increased mean birth weight from (2,10±0,55) kgs to (2,79±0,08) kgs, and decreased SNCU admission (17 % in case vs. 63 % in control).

Preterm birth is the leading cause of perinatal illness and death in low-income nations. Sonography of the cervical canal is one of the most accurate preterm birth prediction tests. In situations of preterm labour, alterations to the cervix occur slowly and gradually. Preterm labour may be avoided if cervical changes are detected early by ultrasonography.

The favourable safety profile of vaginal progesterone may be attributed to its anti-inflammatory and cervix ripening-regulating actions. Preterm delivery and neonatal morbidity were substantially reduced in this trial when women with a borderline short cervix identified between 16 and 24 weeks of GA were treated with vaginal progesterone. This means that mid-trimester women who are borderline for a short cervix (CL2.5cm) should also be encouraged to use vaginal progesterone.

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